OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE
**SF 424 (R&R)**

| 3. DATE RECEIVED BY STATE | State Application Identifier |
|---|---|
| | |

**1. TYPE OF SUBMISSION***

❍ Pre-application ❍ Application ● Changed/Corrected Application

**4.a. Federal Identifier**
MH104073

**b. Agency Routing Number**

| 2. DATE SUBMITTED | Application Identifier |
|---|---|
| | |

**c. Previous Grants.gov Tracking Number**

**5. APPLICANT INFORMATION** **Organizational DUNS*:** 063690705

Legal Name*: University of Alabama at Birmingham
Department: Office of Sponsored Programs
Division:
Street1*: 1720 2nd Avenue South
Street2: AB 1170
City*: Birmingham
County: Jefferson
State*: AL: Alabama
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 352940111

Person to be contacted on matters involving this application
Prefix: First Name*: Keamonnee Middle Name: Last Name*: Hollingsworth Suffix:
Position/Title: Sponsored Programs Officer
Street1*: 1720 2nd Avenue South
Street2: AB 1170
City*: Birmingham
County: Jefferson
State*: AL: Alabama
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 352940111
Phone Number*: 2059345266 Fax Number: 2059755977 Email: knh777@uab.edu

**6. EMPLOYER IDENTIFICATION NUMBER** *(EIN) or (TIN)** 1636005396A6

**7. TYPE OF APPLICANT*** H: Public/State Controlled Institution of Higher Education

Other (Specify):
**Small Business Organization Type** ❍ Women Owned ❍ Socially and Economically Disadvantaged

**8. TYPE OF APPLICATION***

❍ New ● Resubmission
❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).
❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)* :

**Is this application being submitted to other agencies?*** ❍Yes ●No What other Agencies?

**9. NAME OF FEDERAL AGENCY***
National Institutes of Health

**10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER**
TITLE:

**11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT***
Development of a Behavioral Intervention for Chronic Pain in Individuals with HIV

**12. PROPOSED PROJECT**

| Start Date* | Ending Date* |
|---|---|
| 12/01/2014 | 11/30/2018 |

**13. CONGRESSIONAL DISTRICTS OF APPLICANT**
AL-007

# SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE



**14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION**

Prefix: First Name*: Jessica Middle Name: Last Name*: Merlin Suffix: M.D.
Position/Title: Assistant Professor
Organization Name*: University of Alabama at Birmingham
Department: Infectious Diseases
Division: School of Medicine
Street1*: 1720 2nd Avenue South
Street2: BBRB 220
City*: Birmingham
County: Jefferson
State*: AL: Alabama
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 352942170
Phone Number*: 2158061888 Fax Number: 2059345600 Email*: jmerlin@uab.edu

**15. ESTIMATED PROJECT FUNDING**

a. Total Federal Funds Requested*
b. Total Non-Federal Funds* $0.00
c. Total Federal & Non-Federal Funds*
d. Estimated Program Income* $0.00

**16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?***

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:
b. NO ○ PROGRAM IS NOT COVERED BY E.O. 12372; OR
● PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

**17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)**

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

**18. SFLLL or OTHER EXPLANATORY DOCUMENTATION** File Name:

**19. AUTHORIZED REPRESENTATIVE**

Prefix: First Name*: Lynn Middle Name: W. Last Name*: Stedman Suffix: MBA
Position/Title*: Director, Office of Sponsored Programs
Organization Name*: University of Alabama at Birmingham
Department: Office of Sponsored Programs
Division:
Street1*: 1720 2nd Avenue South
Street2: AB 1170
City*: Birmingham
County: Jefferson
State*: AL: Alabama
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 352940111
Phone Number*: 2059345266 Fax Number: 2059755977 Email*: osp@uab.edu

**Signature of Authorized Representative***
Keamonnee Hollingsworth

**Date Signed***
04/24/2014

**20. PRE-APPLICATION** File Name:

**21. COVER LETTER ATTACHMENT** File Name:1235-Cover_Letter_Final.pdf

# 424 R&R and PHS-398 Specific
# Table Of Contents

OMB Number: 4040-0010
Expiration Date: 06/30/2016

# Project/Performance Site Location(s)

**Project/Performance Site Primary Location**

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

| | |
|---|---|
| Organization Name: | University of Alabama at Birmingham |
| Duns Number: | 0636907050000 |
| Street1*: | 1720 2nd Avenue South |
| Street2: | AB 1170 |
| City*: | Birmingham |
| County: | Jefferson |
| State*: | AL: Alabama |
| Province: | |
| Country*: | USA: UNITED STATES |
| Zip / Postal Code*: | 352940111 |
| Project/Performance Site Congressional District*: | AL-007 |

File Name

**Additional Location(s)**





Funding Opportunity Number: PA-14-049. Received Date: 2014-04-24T11:32:34.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

# RESEARCH & RELATED Other Project Information

**1. Are Human Subjects Involved?*** ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ● **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number 00005960

**2. Are Vertebrate Animals Used?*** ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

**3. Is proprietary/privileged information included in the application?*** ❍ **Yes** ● **No**

**4.a. Does this project have an actual or potential impact - positive or negative - on the environment?*** ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

**5. Is the research performance site designated, or eligible to be designated, as a historic place?*** ❍ **Yes** ● **No**

5.a. If yes, please explain:

**6. Does this project involve activities outside the United States or partnership with international collaborators?*** ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

| | Filename |
|---|---|
| **7. Project Summary/Abstract*** | 1236-Project_Summary_Final.pdf |
| **8. Project Narrative*** | 1237-Project_Narrative_Final.pdf |
| **9. Bibliography & References Cited** | 1238-Refs_Cited_Final.pdf |
| **10.Facilities & Other Resources** | 1239-Facilities_Final.pdf |
| **11.Equipment** | 1240-EQUIPMENT_final.pdf |
| **12. Other Attachments** | 1241-Referees_Final.pdf |





Funding Opportunity Number: PA-14-049. Received Date: 2014-04-24T11:32:34.000-04:00

**Project Summary**
The overall goal of this 4-year K23 proposal is to support Jessica Merlin, MD, MBA to become an independent investigator in the field of HIV and chronic pain, with a focus on health psychology/mental health and chronic pain behavioral intervention development and testing. Chronic pain is a chronic condition with a unique neurobiologic basis, which has a substantial impact on physical and emotional function. Chronic pain in HIV-infected patients is common, and associated with serious health consequences, including up to 10 times greater odds of impaired physical function. Many pharmacologic therapies, including opioids, often do not lead to improved pain and function, and carry significant risk. Evidence-based behavioral interventions are among the most effective and safe non-pharmacologic chronic pain treatments investigated in the general medical population. Therefore, behavioral interventions to improve pain, physical, and emotional function in HIV-infected patients are needed. There is much to be learned from existing interventions. However, the success of a behavioral intervention is heavily influenced by how well it is tailored to the target population's biological, psychological, and social environment. Therefore, the **Specific Aims** of this proposal are: Aim 1: Use intervention mapping to systematically develop and pre-test a tailored behavioral intervention for chronic pain in HIV-infected patients. Aim 2: Conduct a two-arm pilot randomized controlled trial of the behavioral intervention compared to routine HIV and pain care, to determine feasibility, acceptability, and preliminary impact. Based on preliminary studies, our proposed intervention targets include depression/anxiety, substance use, and use of prescription opioids for pain management; new targets may emerge during the intervention mapping process. The proposed research represents the first study to address chronic pain as a chronic disease in HIV-infected patients, and to develop and test a behavioral intervention specifically tailored to this population. At the completion of the pilot trial in Aim 2, the intervention will be ready to be tested in an R01 to evaluate its efficacy. This proposal represents a 4-year comprehensive mentoring, training, and research plan to transition the candidate, Dr. Merlin, to a career as a successful independent investigator. By the end of the award period, Dr. Merlin will have contributed substantially to the field of HIV and chronic pain behavioral research. Already an expert on biomedical approaches to chronic pain in HIV-infected individuals, she will be positioned to become a leader in developing and testing behavioral interventions in this area, including conducting behavioral clinical trials.

**Project Narrative**

Due to its specific pathophysiology and impact on health outcomes, the Institute of Medicine has described chronic pain as a complex chronic disease and a “national public health crisis.” The unique neurobiological basis and psychosocial context of chronic pain in HIV-infected patients underscores the importance of developing a behavioral intervention specifically tailored to this population. The project described in this application will develop and pilot test such an intervention, which can then be further tested in an R01-supported randomized controlled trial.

## References


1. Merlin JS, Cen L, Praestgaard A, Turner M, Obando A, Alpert C, Woolston S, Casarett D, Kostman J, Gross R, Frank I. Pain and physical and psychological symptoms in ambulatory HIV patients in the current treatment era. *J Pain Symptom Manage.* 2012;43:638-45. PMCID: PMC3786171.
2. Perry BA, Westfall AO, Molony E, Tucker R, Ritchie C, Saag MS, Mugavero MJ, Merlin JS. Characteristics of an Ambulatory Palliative Care Clinic for HIV-Infected Patients. *J Palliat Med.* 2013;16:934-37. PMCID: PMC3727562.
3. Merlin JS, Westfall AO, Raper JL, Zinski A, Norton WE, Willig JH, Gross R, Ritchie C, Saag MS, Mugavero MJ. Chronic Pain, Psychiatric, and Substance abuse Comorbidities: Implications for Adherence to HIV Care, ART, and Virologic Suppression. International Workshop on HIV Observational Databases; March, 2012: Athens, Greece.
4. Merlin JS, Westfall AO, Raper JL, Zinski A, Norton WE, Willig JH, Gross R, Ritchie CS, Saag MS, Mugavero MJ. Pain, Mood, and Substance Abuse in HIV: Implications for Clinic Visit Utilization, ART Adherence, and Virologic Failure. *J Acquir Immune Defic Syndr.* 2012;61:164-70. PMCID: PMC3459261.
5. Merlin JS, Westfall AO, Chamot E, Overton T, Willig JH, Ritchie C, Saag M, Mugavero MJ. The Relationship of Pain to Physical Function in Patients with HIV: An Underappreciated Phenomenon. Infectious Diseases Society of America; October, 2012: San Diego, CA.
6. Merlin JS, Westfall AO, Chamot E, Overton ET, Willig JH, Ritchie C, Saag MS, Mugavero MJ. Pain is Independently Associated with Impaired Physical Function in HIV-Infected Patients. *Pain Med.* 2013; 14(12):1985-93. PMCID: PMC3886835.
7. Merlin JS, Walcott MM, Herbey I, Chamot E, Ritchie C, Saag MS, Kertesz S. Qualitative Investigation of a Brief Chronic Pain Screening Tool in HIV-Infected Patients. *AIDS Patient Care STDS.* 2014; 28(4): 176-82. Pub Med Journal: In Process.
8. Merlin JS, Zinski A, Norton WE, Ritchie CS, Saag MS, Mugavero MJ, Treisman G, Hooten WM. A Conceptual Framework for Understanding Chronic Pain in Patients with HIV. Pain Pract 2013; 14(3): 207-16. Pub Med Journal – In Process.
9. Institute of Medicine. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington, DC: The National Academies Press; 2011.
10. Vervest AC, Schimmel GH. Taxonomy of pain of the IASP. *Pain.* 1988;34:318-21.
11. Turk DC, Rudy TE. IASP taxonomy of chronic pain syndromes: preliminary assessment of reliability. *Pain.* 1987;30:177-89.
12. Fishbain DA. Approaches to treatment decisions for psychiatric comorbidity in the management of the chronic pain patient. *Med Clin North Am.* 1999;83:737-60, vii.
13. Bair MJ, Robinson RL, Katon W, Kroenke K. Depression and pain comorbidity: a literature review. *Arch Intern Med.* 2003;163:2433-45.
14. Morasco BJ, Gritzner S, Lewis L, Oldham R, Turk DC, Dobscha SK. Systematic review of prevalence, correlates, and treatment outcomes for chronic non-cancer pain in patients with comorbid substance use disorder. *Pain.* 2011;152:488-97.
15. Manchikanti L, Cash KA, Damron KS, Manchukonda R, Pampati V, McManus CD. Controlled substance abuse and illicit drug use in chronic pain patients: An evaluation of multiple variables. *Pain Physician.* 2006;9:215-25.
16. Dominick CH, Blyth FM, Nicholas MK. Unpacking the burden: understanding the relationships between chronic pain and comorbidity in the general population. *Pain.* 2012;153:293-304.
17. Newshan G, Bennett J, Holman S. Pain and other symptoms in ambulatory HIV patients in the age of highly active antiretroviral therapy. *J Assoc Nurses AIDS Care.* 2002;13:78-83.
18. Harding R, Lampe FC, Norwood S, Date HL, Clucas C, Fisher M, Johnson M, Edwards S, Anderson J, Sherr L. Symptoms are highly prevalent among HIV outpatients and associated with poor adherence and unprotected sexual intercourse. *Sex Transm Infect.* 2010;86:520-4.
19. Silverberg MJ, Jacobson LP, French AL, Witt MD, Gange SJ. Age and racial/ethnic differences in the prevalence of reported symptoms in human immunodeficiency virus-infected persons on antiretroviral therapy. *J Pain Symptom Manage.* 2009;38:197-207.
20. Silverberg MJ, Gore ME, French AL, Gandhi M, Glesby MJ, Kovacs A, Wilson TE, Young MA, Gange SJ. Prevalence of clinical symptoms associated with highly active antiretroviral therapy in the Women's Interagency HIV Study. *Clin Infect Dis.* 2004;39:717-24.

21. Cervia LD, McGowan JP, Weseley AJ. Clinical and demographic variables related to pain in HIV-infected individuals treated with effective, combination antiretroviral therapy (cART). *Pain Med.* 2010;11:498-503.
22. Lee KA, Gay C, Portillo CJ, Coggins T, Davis H, Pullinger CR, Aouizerat BE. Symptom experience in HIV-infected adults: a function of demographic and clinical characteristics. *J Pain Symptom Manage.* 2009;38:882-93.
23. Miaskowski C, Penko JM, Guzman D, Mattson JE, Bangsberg DR, Kushel MB. Occurrence and characteristics of chronic pain in a community-based cohort of indigent adults living with HIV infection. *J Pain.* 2011;12:1004-16.
24. Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite JA, Jensen MP, Kerns RD, Ader DN, Brandenburg N, Burke LB, Cella D, Chandler J, Cowan P, Dimitrova R, Dionne R, Hertz S, Jadad AR, Katz NP, Kehlet H, Kramer LD, Manning DC, McCormick C, McDermott MP, McQuay HJ, Patel S, Porter L, Quessy S, Rappaport BA, Rauschkolb C, Revicki DA, Rothman M, Schmader KE, Stacey BR, Stauffer JW, von Stein T, White RE, Witter J, Zavisic S. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. *J Pain.* 2008;9:105-21.
25. Noble M, Treadwell JR, Tregear SJ, Coates VH, Wiffen PJ, Akafomo C, Schoelles KM. Long-term opioid management for chronic noncancer pain. *Cochrane Database Syst Rev.* 2010:CD006605.
26. Chou R, Fanciullo GJ, Fine PG, Adler JA, Ballantyne JC, Davies P, Donovan MI, Fishbain DA, Foley KM, Fudin J, Gilson AM, Kelter A, Mauskop A, O'Connor PG, Passik SD, Pasternak GW, Portenoy RK, Rich BA, Roberts RG, Todd KH, Miaskowski C, Panel APS-AAoPMOG. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain.* 2009;10:113-30.
27. Koeppe J, Armon C, Lyda K, Nielsen C, Johnson S. Ongoing pain despite aggressive opioid pain management among persons with HIV. *Clin J Pain.* 2010;26:190-8.
28. Gudin J. Opioid therapies and cytochrome p450 interactions. *J Pain Symptom Manage.* 2012;44:S4-14.
29. Brady TJ. Measures of self-efficacy: Arthritis Self-Efficacy Scale (ASES), Arthritis Self-Efficacy Scale-8 Item (ASES-8), Children's Arthritis Self-Efficacy Scale (CASE), Chronic Disease Self-Efficacy Scale (CDSES), Parent's Arthritis Self-Efficacy Scale (PASE), and Rheumatoid Arthritis Self-Efficacy Scale (RASE). *Arthritis Care Res (Hoboken).* 2011;63 Suppl 11:S473-85.
30. Somers TJ, Shelby RA, Keefe FJ, Godiwala N, Lumley MA, Mosley-Williams A, Rice JR, Caldwell D. Disease severity and domain-specific arthritis self-efficacy: relationships to pain and functioning in patients with rheumatoid arthritis. *Arthritis Care Res (Hoboken).* 2010;62:848-56.
31. Knittle KP, De Gucht V, Hurkmans EJ, Vlieland TP, Peeters AJ, Ronday HK, Maes S. Effect of self-efficacy and physical activity goal achievement on arthritis pain and quality of life in patients with rheumatoid arthritis. *Arthritis Care Res (Hoboken).* 2011;63:1613-9.
32. Bartholomew LK, Parcel GS, Kok G, Gottleib NH, Fernandez ME. *Planning Health Promotion Programs: An Intervention Mapping Approach.* San Francisco, CA: Jossey-Bass; 2011.
33. van Oostrom SH, Anema JR, Terluin B, Venema A, de Vet HC, van Mechelen W. Development of a workplace intervention for sick-listed employees with stress-related mental disorders: Intervention Mapping as a useful tool. *BMC Health Serv Res.* 2007;7:127.
34. Crane HM, Lober W, Webster E, Harrington RD, Crane PK, Davis TE, Kitahata MM. Routine collection of patient-reported outcomes in an HIV clinic setting: the first 100 patients. *Curr HIV Res.* 2007;5:109-18.
35. Kozak MS, Mugavero MJ, Ye J, Aban I, Lawrence ST, Nevin CR, Raper JL, McCullumsmith C, Schumacher JE, Crane HM, Kitahata MM, Saag MS, Willig JH. Patient reported outcomes in routine care: advancing data capture for HIV cohort research. *Clin Infect Dis.* 2012;54:141-7.
36. Lawrence ST, Willig JH, Crane HM, Ye J, Aban I, Lober W, Nevin CR, Batey DS, Mugavero MJ, McCullumsmith C, Wright C, Kitahata M, Raper JL, Saag MS, Schumacher JE. Routine, self-administered, touch-screen, computer-based suicidal ideation assessment linked to automated response team notification in an HIV primary care setting. *Clin Infect Dis.* 2010;50:1165-73.
37. *American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders*. 4th ed; 2000.
38. Meeus M, Vervisch S, De Clerck LS, Moorkens G, Hans G, Nijs J. Central sensitization in patients with rheumatoid arthritis: a systematic literature review. *Semin Arthritis Rheum.* 2012;41:556-67.
39. Meeus M, Nijs J. Central sensitization: a biopsychosocial explanation for chronic widespread pain in patients with fibromyalgia and chronic fatigue syndrome. *Clin Rheumatol.* 2007;26:465-73.
40. Griffis CA. Neuroimmune activation and chronic pain. *AANA J.* 2011;79:31-7.

41. Hardt J, Jacobsen C, Goldberg J, Nickel R, Buchwald D. Prevalence of chronic pain in a representative sample in the United States. *Pain Med.* 2008;9:803-12.
42. Verhaak PF, Kerssens JJ, Dekker J, Sorbi MJ, Bensing JM. Prevalence of chronic benign pain disorder among adults: a review of the literature. *Pain.* 1998;77:231-9.
43. Johannes CB, Le TK, Zhou X, Johnston JA, Dworkin RH. The prevalence of chronic pain in United States adults: results of an Internet-based survey. *J Pain.* 2010;11:1230-9.
44. Turk DC, Wilson HD, Cahana A. Treatment of chronic non-cancer pain. *Lancet.* 2011;377:2226-35.
45. Robinson-Papp J, Simpson DM. Neuromuscular diseases associated with HIV-1 infection. *Muscle Nerve.* 2009;40:1043-53.
46. Mazzotta E, Agostinone A, Rosso R, Di Biagio A, De Socio GV, Cappelletti A, Zicolella R, Polilli E, Bonfanti P, Di Matteo L, Manzoli L, Parruti G. Osteonecrosis in human immunodeficiency virus (HIV)-infected patients: a multicentric case-control study. *J Bone Miner Metab.* 2011;29:383-8.
47. Johnson A, Condon KD, Mapas-Dimaya AC, Schrager J, Grossberg R, Gonzalez R, O'Mahony S. Report of an HIV clinic-based pain management program and utilization of health status and health service by HIV patients. *J Opioid Manag.* 2012;8:17-27.
48. Rizzuto N, Cavallaro T, Monaco S, Morbin M, Bonetti B, Ferrari S, Galiazzo-Rizzuto S, Zanette G, Bertolasi L. Role of HIV in the pathogenesis of distal symmetrical peripheral neuropathy. *Acta Neuropathol.* 1995;90:244-50.
49. Bradley WG, Shapshak P, Delgado S, Nagano I, Stewart R, Rocha B. Morphometric analysis of the peripheral neuropathy of AIDS. *Muscle Nerve.* 1998;21:1188-95.
50. Yoshioka M, Bradley WG, Shapshak P, Nagano I, Stewart RV, Xin KQ, Srivastava AK, Nakamura S. Role of immune activation and cytokine expression in HIV-1-associated neurologic diseases. *Adv Neuroimmunol.* 1995;5:335-58.
51. Keswani SC, Polley M, Pardo CA, Griffin JW, McArthur JC, Hoke A. Schwann cell chemokine receptors mediate HIV-1 gp120 toxicity to sensory neurons. *Ann Neurol.* 2003;54:287-96.
52. Shi Y, Shu J, Gelman BB, Lisinicchia JG, Tang SJ. Wnt Signaling in the Pathogenesis of Human HIV-Associated Pain Syndromes. *J Neuroimmune Pharmacol.* 2013;8:956-64.
53. Shi Y, Gelman BB, Lisinicchia JG, Tang SJ. Chronic-pain-associated astrocytic reaction in the spinal cord dorsal horn of human immunodeficiency virus-infected patients. *J Neurosci.* 2012;32:10833-40.
54. Remien RH, Mellins CA. Long-term psychosocial challenges for people living with HIV: let's not forget the individual in our global response to the pandemic. *AIDS.* 2007;21 Suppl 5:S55-63.
55. Bravo P, Edwards A, Rollnick S, Elwyn G. Tough decisions faced by people living with HIV: a literature review of psychosocial problems. *AIDS Rev.* 2010;12:76-88.
56. Adler RH. Engel's biopsychosocial model is still relevant today. *J Psychosom Res.* 2009;67:607-11.
57. Gatchel RJ. Comorbidity of chronic pain and mental health disorders: the biopsychosocial perspective. *Am Psychol.* 2004;59:795-805.
58. Gatchel RJ, Peng YB, Peters ML, Fuchs PN, Turk DC. The biopsychosocial approach to chronic pain: scientific advances and future directions. *Psychol Bull.* 2007;133:581-624.
59. Singh JA, Lewallen DG. Medical and psychological comorbidity predicts poor pain outcomes after total knee arthroplasty. *Rheumatology (Oxford).* 2013;52:916-23.
60. Leong IY, Farrell MJ, Helme RD, Gibson SJ. The relationship between medical comorbidity and self-rated pain, mood disturbance, and function in older people with chronic pain. *J Gerontol A Biol Sci Med Sci.* 2007;62:550-5.
61. Hasse B, Ledergerber B, Furrer H, Battegay M, Hirschel B, Cavassini M, Bertisch B, Bernasconi E, Weber R, Study SHC. Morbidity and aging in HIV-infected persons: the Swiss HIV cohort study. *Clin Infect Dis.* 2011;53:1130-9.
62. Pence BW, Miller WC, Whetten K, Eron JJ, Gaynes BN. Prevalence of DSM-IV-defined mood, anxiety, and substance use disorders in an HIV clinic in the Southeastern United States. *J Acquir Immune Defic Syndr.* 2006;42:298-306.
63. Bing EG, Burnam MA, Longshore D, Fleishman JA, Sherbourne CD, London AS, Turner BJ, Eggan F, Beckman R, Vitiello B, Morton SC, Orlando M, Bozzette SA, Ortiz-Barron L, Shapiro M. Psychiatric disorders and drug use among human immunodeficiency virus-infected adults in the United States. *Arch Gen Psychiatry.* 2001;58:721-8.
64. Ribeiro CM, Gurgel WS, Luna JR, Matos KJ, Souza FG. Is bipolar disorder a risk factor for HIV infection? *J Affect Disord.* 2013;146:66-70.

65. Nurutdinova D, Chrusciel T, Zeringue A, Scherrer JF, Al-Aly Z, McDonald JR, Overton ET. Mental health disorders and the risk of AIDS-defining illness and death in HIV-infected veterans. *AIDS.* 2012;26:229-34.
66. Edelman EJ, Gordon K, Becker WC, Goulet JL, Skanderson M, Gaither JR, Brennan Braden J, Gordon AJ, Kerns RD, Justice AC, Fiellin DA. Receipt of opioid analgesics by HIV-infected and uninfected patients. *J Gen Intern Med.* 2013;28:82-90.
67. Gaynes BN, Pence BW, Eron JJ, Miller WC. Prevalence and comorbidity of psychiatric diagnoses based on reference standard in an HIV+ patient population. *Psychosom Med.* 2008;70:505-11.
68. Orlando M, Burnam MA, Beckman R, Morton SC, London AS, Bing EG, Fleishman JA. Re-estimating the prevalence of psychiatric disorders in a nationally representative sample of persons receiving care for HIV: results from the HIV Cost and Services Utilization Study. *Int J Methods Psychiatr Res.* 2002;11:75-82.
69. Galvan FH, Burnam MA, Bing EG. Co-occurring psychiatric symptoms and drug dependence or heavy drinking among HIV-positive people. *J Psychoactive Drugs.* 2003;35 Suppl 1:153-60.
70. Morasco BJ, Corson K, Turk DC, Dobscha SK. Association between substance use disorder status and pain-related function following 12 months of treatment in primary care patients with musculoskeletal pain. *J Pain.* 2011;12:352-9.
71. Earnshaw VA, Chaudoir SR. From conceptualizing to measuring HIV stigma: a review of HIV stigma mechanism measures. *AIDS Behav.* 2009;13:1160-77.
72. Slade SC, Molloy E, Keating JL. Stigma experienced by people with nonspecific chronic low back pain: a qualitative study. *Pain Med.* 2009;10:143-54.
73. Leserman J, Whetten K, Lowe K, Stangl D, Swartz MS, Thielman NM. How trauma, recent stressful events, and PTSD affect functional health status and health utilization in HIV-infected patients in the south. *Psychosom Med.* 2005;67:500-7.
74. Reif S, Mugavero M, Raper J, Thielman N, Leserman J, Whetten K, Pence BW. Highly stressed: stressful and traumatic experiences among individuals with HIV/AIDS in the Deep South. *AIDS Care.* 2011;23:152-62.
75. Morasco BJ, Lovejoy TI, Lu M, Turk DC, Lewis L, Dobscha SK. The relationship between PTSD and chronic pain: mediating role of coping strategies and depression. *Pain.* 2013;154:609-16.
76. Otis JD, Keane TM, Kerns RD. An examination of the relationship between chronic pain and post-traumatic stress disorder. *J Rehabil Res Dev.* 2003;40:397-405.
77. Pence BW, Raper JL, Reif S, Thielman NM, Leserman J, Mugavero MJ. Incident stressful and traumatic life events and human immunodeficiency virus sexual transmission risk behaviors in a longitudinal, multisite cohort study. *Psychosom Med.* 2010;72:720-6.
78. Hwang SW, Wilkins E, Chambers C, Estrabillo E, Berends J, MacDonald A. Chronic pain among homeless persons: characteristics, treatment, and barriers to management. *BMC Fam Pract.* 2011;12:73.
79. Leaver CA, Bargh G, Dunn JR, Hwang SW. The effects of housing status on health-related outcomes in people living with HIV: a systematic review of the literature. *AIDS Behav.* 2007;11:85-100.
80. Rueda S, Raboud J, Plankey M, Ostrow D, Mustard C, Rourke SB, Jacobson LP, Bekele T, Bayoumi A, Lavis J, Detels R, Silvestre AJ. Labor force participation and health-related quality of life in HIV-positive men who have sex with men: the Multicenter AIDS Cohort Study. *AIDS Behav.* 2012;16:2350-60.
81. Rueda S, Raboud J, Mustard C, Bayoumi A, Lavis JN, Rourke SB. Employment status is associated with both physical and mental health quality of life in people living with HIV. *AIDS Care.* 2011;23:435-43.
82. Jackson T, Iezzi A, Lafreniere K. The impact of psychosocial features of employment status on emotional distress in chronic pain and healthy comparison samples. *J Behav Med.* 1997;20:241-56.
83. Jackson T, Iezzi A, Lafreniere K, Narduzzi K. Relations of employment status to emotional distress among chronic pain patients: a path analysis. *Clin J Pain.* 1998;14:55-60.
84. De Souza L, Frank AO. Patients' experiences of the impact of chronic back pain on family life and work. *Disabil Rehabil.* 2011;33:310-8.
85. Leonard MT, Cano A. Pain affects spouses too: personal experience with pain and catastrophizing as correlates of spouse distress. *Pain.* 2006;126:139-46.
86. Mavandadi S, Zanjani F, Ten Have TR, Oslin DW. Psychological well-being among individuals aging with HIV: the value of social relationships. *J Acquir Immune Defic Syndr.* 2009;51:91-8.
87. Chesney MA, Chambers DB, Taylor JM, Johnson LM. Social support, distress, and well-being in older men living with HIV infection. *J Acquir Immune Defic Syndr.* 2003;33 Suppl 2:S185-93.

88. Kuehn BM. Opioid prescriptions soar: increase in legitimate use as well as abuse. *JAMA.* 2007;297:249-51.
89. Silverberg MJ, Ray GT, Saunders K, Rutter CM, Campbell CI, Merrill JO, Sullivan MD, Banta-Green CJ, Von Korff M, Weisner C. Prescription long-term opioid use in HIV-infected patients. *Clin J Pain.* 2012;28:39-46.
90. Solomon DH, Rassen JA, Glynn RJ, Garneau K, Levin R, Lee J, Schneeweiss S. The comparative safety of opioids for nonmalignant pain in older adults. *Arch Intern Med.* 2010;170:1979-86.
91. Li L, Setoguchi S, Cabral H, Jick S. Opioid use for noncancer pain and risk of myocardial infarction amongst adults. *J Intern Med.* 2013;273:511-26.
92. Li L, Setoguchi S, Cabral H, Jick S. Opioid Use for Noncancer Pain and Risk of Fracture in Adults: A Nested Case-Control Study Using the General Practice Research Database. *Am J Epidemiol.* 2013;178:559-69.
93. Reddy RG, Aung T, Karavitaki N, Wass JA. Opioid induced hypogonadism. *BMJ.* 2010;341:c4462.
94. Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, Weisner CM, Silverberg MJ, Campbell CI, Psaty BM, Von Korff M. Opioid prescriptions for chronic pain and overdose: a cohort study. *Ann Intern Med.* 2010;152:85-92.
95. Morasco BJ, Dobscha SK. Prescription medication misuse and substance use disorder in VA primary care patients with chronic pain. *Gen Hosp Psychiatry.* 2008;30:93-9.
96. Chun LJ, Tong MJ, Busuttil RW, Hiatt JR. Acetaminophen hepatotoxicity and acute liver failure. *J Clin Gastroenterol.* 2009;43:342-9.
97. Lee C, Straus WL, Balshaw R, Barlas S, Vogel S, Schnitzer TJ. A comparison of the efficacy and safety of nonsteroidal antiinflammatory agents versus acetaminophen in the treatment of osteoarthritis: a meta-analysis. *Arthritis Rheum.* 2004;51:746-54.
98. Fendrick AM, Greenberg BP. A review of the benefits and risks of nonsteroidal anti-inflammatory drugs in the management of mild-to-moderate osteoarthritis. *Osteopath Med Prim Care.* 2009;3:1.
99. Evans JM, McGregor E, McMahon AD, McGilchrist MM, Jones MC, White G, McDevitt DG, MacDonald TM. Non-steroidal anti-inflammatory drugs and hospitalization for acute renal failure. *QJM.* 1995;88:551-7.
100. Hippisley-Cox J, Coupland C, Logan R. Risk of adverse gastrointestinal outcomes in patients taking cyclo-oxygenase-2 inhibitors or conventional non-steroidal anti-inflammatory drugs: population based nested case-control analysis. *BMJ.* 2005;331:1310-6.
101. Antman EM, Bennett JS, Daugherty A, Furberg C, Roberts H, Taubert KA, Association AH. Use of nonsteroidal antiinflammatory drugs: an update for clinicians: a scientific statement from the American Heart Association. *Circulation.* 2007;115:1634-42.
102. Hahn K, Arendt G, Braun JS, von Giesen HJ, Husstedt IW, Maschke M, Straube ME, Schielke E, Group GN-AW. A placebo-controlled trial of gabapentin for painful HIV-associated sensory neuropathies. *J Neurol.* 2004;251:1260-6.
103. Skljarevski V, Zhang S, Iyengar S, D'Souza D, Alaka K, Chappell A, Wernicke J. Efficacy of Duloxetine in Patients with Chronic Pain Conditions. *Curr Drug ther.* 2011;6:296-303.
104. Moore RA, Cai N, Skljarevski V, Tölle TR. Duloxetine use in chronic painful conditions - individual patient data responder analysis. *Eur J Pain.* 2013.
105. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain.* 2000;85:317-32.
106. Buer N, Linton SJ. Fear-avoidance beliefs and catastrophizing: occurrence and risk factor in back pain and ADL in the general population. *Pain.* 2002;99:485-91.
107. Turk D, Meichenbaum D, Genest M. *Pain and Behavioral Medicine: A Cognitive Behavioral Perspective*. New York: The Guilford Press; 1983.
108. Bandura A, Alumni and Friends Memorial Book Fund. *Social foundations of thought and action : a social cognitive theory*. Englewood Cliffs, N.J.: Prentice-Hall; 1986.
109. Turk DC, Dworkin RH, Allen RR, Bellamy N, Brandenburg N, Carr DB, Cleeland C, Dionne R, Farrar JT, Galer BS, Hewitt DJ, Jadad AR, Katz NP, Kramer LD, Manning DC, McCormick CG, McDermott MP, McGrath P, Quessy S, Rappaport BA, Robinson JP, Royal MA, Simon L, Stauffer JW, Stein W, Tollett J, Witter J. Core outcome domains for chronic pain clinical trials: IMMPACT recommendations. *Pain.* 2003;106:337-45.
110. Lorig KR, Stewart A, Ritter PL, Gonzalez V, Laurent DD, Lynch J. *Outcome measures for health education and other health care interventions.* Thousand Oaks, Calif: SAGE; 1996.

111. Lorig KR, Ritter PL, Laurent DD, Plant K. The internet-based arthritis self-management program: a one-year randomized trial for patients with arthritis or fibromyalgia. *Arthritis Rheum.* 2008;59:1009-17.
112. Kerns RD, Sellinger J, Goodin BR. Psychological treatment of chronic pain. *Annu Rev Clin Psychol.* 2011;7:411-34.
113. Eccleston C, Williams AC, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. *Cochrane Database Syst Rev.* 2009:CD007407.
114. Beck AT, Dozois DJ. Cognitive therapy: current status and future directions. *Annu Rev Med.* 2011;62:397-409.
115. Turk DC, Gatchel RJ. *Psychological approaches to pain management : a practitioner's handbook*. 2nd ed. New York: Guilford Press; 2002.
116. Kim JE, Dodd M, West C, Paul S, Facione N, Schumacher K, Tripathy D, Koo P, Miaskowski C. The PRO-SELF pain control program improves patients' knowledge of cancer pain management. *Oncol Nurs Forum.* 2004;31:1137-43.
117. Von Korff M, Moore JE, Lorig K, Cherkin DC, Saunders K, González VM, Laurent D, Rutter C, Comite F. A randomized trial of a lay person-led self-management group intervention for back pain patients in primary care. *Spine (Phila Pa 1976).* 1998;23:2608-15.
118. Warsi A, LaValley MP, Wang PS, Avorn J, Solomon DH. Arthritis self-management education programs: a meta-analysis of the effect on pain and disability. *Arthritis Rheum.* 2003;48:2207-13.
119. Trafton JA, Sorrell JT, Holodniy M, Pierson H, Link P, Combs A, Israelski D. Outcomes associated with a cognitive-behavioral chronic pain management program implemented in three public HIV primary care clinics. *J Behav Health Serv Res.* 2012;39:158-73.
120. Evans S, Fishman B, Spielman L, Haley A. Randomized trial of cognitive behavior therapy versus supportive psychotherapy for HIV-related peripheral neuropathic pain. *Psychosomatics.* 2003;44:44-50.
121. Kroenke K, Bair M, Damush T, Hoke S, Nicholas G, Kempf C, Huffman M, Wu J, Sutherland J. Stepped Care for Affective Disorders and Musculoskeletal Pain (SCAMP) study: design and practical implications of an intervention for comorbid pain and depression. *Gen Hosp Psychiatry.* 2007;29:506-17.
122. Kroenke K, Wu J, Bair MJ, Krebs EE, Damush TM, Tu W. Reciprocal relationship between pain and depression: a 12-month longitudinal analysis in primary care. *J Pain.* 2011;12:964-73.
123. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med.* 2001;16:606-13.
124. Newcombe DA, Humeniuk RE, Ali R. Validation of the World Health Organization Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): report of results from the Australian site. *Drug Alcohol Rev.* 2005;24:217-26.
125. Merlin JS, Turan JM, Herbey I, Westfall AO, Starrels JL, Kertesz SG, Saag MS, Ritchie CS. Provider Documentation of Aberrant Drug-Related Behaviors (ADRBs) in Patients Referred to an HIV/Chronic Pain Clinic. Association for Medical Education and Research in Substance Abuse; November 2013: Bethesda, MD.
126. Merlin JS, Walcott M, Ritchie CS, Herbey I, Kertesz SG, Chamot EC, Saag M, Turan JM. Patient perspectives on psychological aspects of chronic pain while living with HIV. Accepted at the International Association of Providers of AIDS Care Conference; June 2014: Miami, FL.
127. Edlund MJ, Martin BC, Devries A, Fan MY, Braden JB, Sullivan MD. Trends in use of opioids for chronic noncancer pain among individuals with mental health and substance use disorders: the TROUP study. *Clin J Pain.* 2010;26:1-8.
128. Mathews WC, May S. EuroQol (EQ-5D) measure of quality of life predicts mortality, emergency department utilization, and hospital discharge rates in HIV-infected adults under care. *Health Qual Life Outcomes.* 2007;5:5.
129. Merlin JS, Westfall AO, Saag S, Chamot EC, Walcott M, Ritchie C, Kertesz S. Validity Testing of a New Brief Chronic Pain Screening tool in HIV-infected Patients. Accepted at the International Association of Providers of AIDS Care Conference; June 2014: Miami, FL.
130. Quality Metric Inc. *User's Manual for the SF-36v2 Health Survey*. 2nd edition ed. Lincoln, NE; 2009.
131. Li KK, Harris K, Hadi S, Chow E. What should be the optimal cut points for mild, moderate, and severe pain? *J Palliat Med.* 2007;10:1338-46.
132. Strauss AL, Corbin JM. *Basics of qualitative research : techniques and procedures for developing grounded theory*. 2nd ed. Thousand Oaks: Sage Publications; 1998.
133. Creswell JW. *Research design : qualitative, quantitative, and mixed methods approaches*. 4th ed. Thousand Oaks: SAGE Publications; 2014.

134. Delbecq AL, VandeVen AH, Gustafson DH. *Group techniques for program planning : a guide to nominal group and Delphi processes*. Glenview, Illinois: Scott Foresman and Company; 1975.
135. Gallagher M, Hares T, Spencer J, Bradshaw C, Webb I. The nominal group technique: a research tool for general practice? *Fam Pract.* 1993;10:76-81.
136. Spitzer RL, Williams JB, Gibbon M, First MB. The Structured Clinical Interview for DSM-III-R (SCID). I: History, rationale, and description. *Arch Gen Psychiatry.* 1992;49:624-9.
137. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med.* 2006;166:1092-7.
138. Burkholder GA, Tamhane AR, Salinas JL, Mugavero MJ, Raper JL, Westfall AO, Saag MS, Willig JH. Underutilization of aspirin for primary prevention of cardiovascular disease among HIV-infected patients. *Clin Infect Dis.* 2012;55:1550-7.
139. Rigler SK, Studenski S, Wallace D, Reker DM, Duncan PW. Co-morbidity adjustment for functional outcomes in community-dwelling older adults. *Clin Rehabil.* 2002;16:420-8.
140. Kitahata MM, Rodriguez B, Haubrich R, Boswell S, Mathews WC, Lederman MM, Lober WB, Van Rompaey SE, Crane HM, Moore RD, Bertram M, Kahn JO, Saag MS. Cohort profile: the Centers for AIDS Research Network of Integrated Clinical Systems. *Int J Epidemiol.* 2008;37:948-55.
141. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. *Arch Intern Med.* 1998;158:1789-95.
142. Rao D, Feldman BJ, Fredericksen RJ, Crane PK, Simoni JM, Kitahata MM, Crane HM. A structural equation model of HIV-related stigma, depressive symptoms, and medication adherence. *AIDS Behav.* 2012;16:711-6.
143. Rao D, Choi SW, Victorson D, Bode R, Peterman A, Heinemann A, Cella D. Measuring stigma across neurological conditions: the development of the stigma scale for chronic illness (SSCI). *Qual Life Res.* 2009;18:585-95.
144. Leserman J, Ironson G, O'Cleirigh C, Fordiani JM, Balbin E. Stressful life events and adherence in HIV. *AIDS Patient Care STDS.* 2008;22:403-11.
145. *Medical Outcomes Study: 36-Item Short Form Survey Scoring Instructions.* RandHealth. (Accessed April 18, 2014, at http://www.rand.org/health/surveys_tools/mos/mos_core_36item_scoring.html%20.)
146. Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. *Ann Acad Med Singapore.* 1994;23:129-38.
147. Aberg JA, Kaplan JE, Libman H, Emmanuel P, Anderson JR, Stone VE, Oleske JM, Currier JS, Gallant JE, America HMAotIDSo. Primary care guidelines for the management of persons infected with human immunodeficiency virus: 2009 update by the HIV medicine Association of the Infectious Diseases Society of America. *Clin Infect Dis.* 2009;49:651-81.
148. *Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents.* (Accessed April 18, 2014, at http://aidsinfo.nih.gov/Guidelines/HTML/1/adult-and-adolescent-treatment-guidelines/.)
149. Chesney MA, Ickovics JR, Chambers DB, Gifford AL, Neidig J, Zwickl B, Wu AW. Self-reported adherence to antiretroviral medications among participants in HIV clinical trials: the AACTG adherence instruments. Patient Care Committee & Adherence Working Group of the Outcomes Committee of the Adult AIDS Clinical Trials Group (AACTG). *AIDS Care.* 2000;12:255-66.
150. Mugavero MJ, Lin HY, Willig JH, Westfall AO, Ulett KB, Routman JS, Abroms S, Raper JL, Saag MS, Allison JJ. Missed visits and mortality among patients establishing initial outpatient HIV treatment. *Clin Infect Dis.* 2009;48:248-56.
151. Horberg M, Hurley L, Klein D. Early missed visits post-HIV diagnosis and Mortality in a Large Healthcare System. Poster presentation, Conference on Retroviruses and Opportunistic Infections 2012, Seattle, WA.
152. Zhang Y, Dou Z, Sun K, Ma Y, Chen RY, Bulterys M, Zhao Y, Zhu H, Liu Z, Zhang F. Association between missed early visits and mortality among patients of china national free antiretroviral treatment cohort. *J Acquir Immune Defic Syndr.* 2012;60:59-67.
153. Mugavero MJ, Davila JA, Nevin CR, Giordano TP. From access to engagement: measuring retention in outpatient HIV clinical care. *AIDS Patient Care STDS.* 2010;24:607-13.
154. Denzin NK, Lincoln YS. Handbook of Qualitative Reserch. Thousand Oaks, CA: Sage, 2000. In.
155. Tran BX, Ohinmaa A, Nguyen LT. Quality of life profile and psychometric properties of the EQ-5D-5L in HIV/AIDS patients. *Health Qual Life Outcomes.* 2012;10:132.

156. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res.* 2011;45:626-9.
157. Mimiaga MJ, Reisner SL, Grasso C, Crane HM, Safren SA, Kitahata MM, Schumacher JE, Mathews WC, Mayer KH. Substance Use Among HIV-Infected Patients Engaged in Primary Care in the United States: Findings From the Centers for AIDS Research Network of Integrated Clinical Systems Cohort. *Am J Public Health.* 2013;103:1457-67.

## FACILITIES AND OTHER RESOURCES

### Overview

The University of Alabama at Birmingham (UAB) is located in Birmingham, Alabama, in the heart of the southeastern United States. UAB is a publicly funded institution encompassing 13 schools and spanning 60 city blocks in downtown Birmingham. Founded in 1969, UAB is an urban university with a strong medical center, which has an annual economic impact exceeding $5 billion. As of Fall 2012, 17,999 students were enrolled in 142 degree programs, with 63% in undergraduate programs, 23% in graduate programs, and 14% in doctoral programs. *Forbes* lists UAB among the top 20% of all US undergraduate institutions. *The Princeton Review* has ranked the university among the top 10 nationally for student diversity for three consecutive years.

UAB has grown rapidly from its beginnings only 44 years ago. This growth has been due, in large part, to a strong commitment to research. UAB is ranked 21st nationally in funding from the National Institutes of Health and 32nd in total federal research funding. UAB is currently listed by the Carnegie Foundation in both the highest research tier and in the "community engagement" classification, an indication of how quickly UAB translates basic research discoveries to benefit the community. *US News & World Report* ranks a number of graduate programs at UAB among the nation's top 10, including healthcare management, primary care, and nursing service administration. **The HIV program in the UAB School of Medicine is ranked 8th.**

UAB is an ideal environment for my development as an independent investigator in HIV and chronic pain. The following is a summary of Facilities and Other Resources at UAB that will directly contribute to my research and career development.

### UAB Department of Medicine (Seth Landefeld, Chairman)

The UAB School of Medicine is one of the leading public medical schools in the US. It ranks 7th among public medical schools and 18th among all US medical schools in NIH funding. The Department of Medicine, in which I am faculty, is the largest department within the UAB School of Medicine. It encompasses 11 divisions and over 400 faculty members. The Department had total research funding of over $106 million in 2012. Of the over $250 million awarded to UAB by the NIH in FY 2012, 25%, went to investigators in the Department of Medicine. In addition to attending on the inpatient medicine service for the Department two weeks per year, I teach research ethics to the medical residents as part of their longitudinal ethics curriculum (see Responsible Conduct of Research).

### UAB Division of Infectious Diseases (Edward Hook, Director)

My primary appointment at UAB is within the Department of Medicine's Division of Infectious Diseases. The Division of Infectious Diseases is comprised of more than 100 support staff (including office assistants, lab technicians, and data analysts) and 40 full-time faculty members. The faculty are active in teaching, patient care, and research. The Division provides clinical care for a statewide catchment area and consultative services for the University of Alabama at Birmingham Hospital and the Birmingham Veteran's Administration (VA) Hospital. Major clinical trials units within the division include: 1) the AIDS Clinical Trials Group (Dr. Michael Saag, PI); 2) the STD Clinical Research Center (Dr. Edward Hook III, PI); 3) the AIDS Vaccine Research Center (Dr. Paul Goepfert, PI); and 4) the Mycosis Study Group (Dr. Peter Pappas, PI). In addition, there are three weekly Infectious Diseases conferences which I regularly attend: a Case Conference to discuss interesting cases seen on the wards and in outpatient clinics; an Infectious Diseases Grand Rounds that typically features a lecture on various infectious disease topics given by faculty, guests, or fellows; and a Journal Club for faculty and fellows.

This well-supported academic environment has been an ideal place for me to begin my career in HIV clinical research. In addition, through the Department and the Division, I have received $20,000 per year of start-up funding for my first three years on faculty, ending August 2014. This funding is carried forward if not spent (see Institutional Commitment letter), and may be used for research-associated costs and travel to attend conferences or meet with mentors/collaborators.

### UAB Center for AIDS Research (CFAR-Michael Saag, Director)

The UAB CFAR is one of the seven original Centers established by NIAID in 1988, and one of 20 CFARs in the US. It has benefited from institutional leadership that has supported HIV research to an extraordinary level, based on the belief that UAB investigators should play a leading role in combating this global epidemic. This is exemplified by the provision of outstanding institutional support: over $7.3M to the CFAR since Dr. Michael Saag, my primary mentor, assumed leadership of the Center in 2004. The mission of the UAB CFAR is to support UAB investigators to conduct multidisciplinary, cutting-edge research in HIV prevention, pathogenesis, clinical care, psychosocial manifestations, and therapeutics. The UAB CFAR accomplishes its mission by stimulating interdisciplinary research interactions, nurturing the development of young investigators, and providing research design and statistical analysis support for CFAR investigators conducting clinical, epidemiologic, behavioral, community, and translational research. The UAB CFAR also

includes the 1917 Clinic Cohort, and is a site of the national CFAR Network of Integrated Clinical Systems (CNICS) (see below). This provides additional opportunities for longitudinal data collection and analysis. Dr. Saag, my primary mentor, founded CNICS and serves as the national PI.

As a CFAR investigator, I am able to take advantage of all the resources the CFAR has to offer. I have collaborated with Mr. Andrew Westfall, the CFAR Statistician, on all of my projects. The CFAR provides me with numerous opportunities to collaborate with other CFAR investigators on areas of mutual interest, including monthly seminars which I attend. I receive partial salary support from the CFAR, which has allowed me to spend more time on my research than the 75% provided by my institutional K12 career development award. I am also part of the CFAR Behavioral and Community Science Core Leadership, through which I interact regularly with senior behavioral researchers at UAB*. The UAB CFAR has been continuously funded for the past 25 years, and we were recently notified that funding for an additional 5 years has been approved.*

**UAB 1917 Clinic**

The 1917 Clinic was founded in 1988 to provide outpatient services to patients with HIV disease in the state of Alabama and surrounding states. The goals of the clinic are to provide primary, continuity patient care, social service support and case management, education to health care providers regarding the care of HIV-infected patients, and community outreach. Over 8000 patients have been evaluated since the clinic opened; over 2000 of those are currently active patients.

**UAB 1917 Clinic Cohort (Michael Mugavero, Director)**

The UAB 1917 Clinic Cohort is a prospective, observational HIV clinical cohort established in 1992 as a component of the UAB CFAR. The Cohort includes patients engaged in medical care at the UAB 1917 Clinic. Detailed demographic and clinical data are available for patients treated at the UAB 1917 Clinic since 1988 (>8000 overall, 2186 active). A system of 100% quality control allows for a high-quality database that contributes to numerous HIV cohort collaborations including the CFAR Network of Integrated Clinical Systems (CNICS) (see below). Since its inception, the UAB 1917 Clinic Cohort has produced over 75 peer-reviewed manuscripts, with another 35 manuscripts published through multi-site HIV cohort collaborations. All of my research at UAB to date has been conducted within the 1917 Clinic Cohort. I lead the Cohort's twice monthly research meetings, in which investigators including behavioral scientists and epidemiologists from all over campus gather to discuss potential collaborations and works in progress.

**CFAR Network of Integrated Clinical Systems (CNICS – Michael Saag, National PI; Michael Mugavero, Site PI)**

CNICS was founded by my mentor, Dr. Michael Saag, and successfully re-funded in 2011 as an R24 research platform. CNICS is a national 8-site research network that allows for the collection of pre-set clinical and Patient Reported Outcome (PRO) data on a wide variety of topics every 6 months (e.g., depression, anxiety, and substance use). In addition, CNICS also provides the infrastructure for individual investigators to collect project-specific PRO data (e.g., the Brief Chronic Pain screening tool and SF-36 that I will collect in my K23 project). PRO data is collected using electronic touch screen computers at the point of care.

The UAB 1917 Clinic Cohort serves as the UAB CNICS site. Access to existing 1917 Clinic Cohort CNICS data has allowed me to conduct preliminary investigations (Section C1, Preliminary Studies). Additionally, CNICS, and particularly the UAB site, has proven to be an excellent cohort for the development and testing of behavioral interventions. This is due to the coupling of rich CNICS clinical and PRO data with additional prospective recruitment and qualitative data collection infrastructure (see RISC, below). In my K23, I will leverage our local 1917 Clinic Cohort/CNICS infrastructure to develop and test a behavioral intervention for chronic pain in HIV-infected patients. This will lead to an R01-supported national CNICS-wide randomized controlled trial of the intervention.

**HIV Research and Informatics Service Center (RISC – Michael Mugavero, Director)**

The UAB HIV Research and Informatics Service Center (RISC) provides a collaborative infrastructure to conduct HIV clinical and behavioral research through a combination of research and informatics expertise. Research core services include study coordination, recruitment and tracking, consultation on study design, logistics, and implementation. Informatics core services include software development, database design and management, study eligibility queries, generation of analysis-ready datasets via integration and queries of multiple data sources, desktop support, graphic design, and health informatics consultation. RISC leadership includes Michael Mugavero, MD MHSc (Research Director). The RISC team includes 2 data analysts, 2 programmers, 1 information systems specialist, 2 quality assurance technicians, 3 research coordinators, 2 research assistants, 1 research specialist, 4 research technicians, 4 interventionists and a grants management specialist. Several of these staff have expertise in qualitative data collection, including in-depth interviews and focus groups, and data management. On average, the RISC provides informatics and/or research core services to >75 unique users supported by >40 extramural grants and contracts annually, including over 250

unique data queries for a wide range of investigators from across the UAB campus and around the world. The RISC also provides these services to the UAB 1917 Clinic Cohort/CNICS site.

I am one of five Infectious Diseases and CFAR faculty within the RISC. As a RISC faculty member, I have direct access to the resources of the RISC to support my research efforts. Specifically, I will use RISC services (e.g., programming of project-specific PROs, recruitment of participants, qualitative interviewing, data management) to carry out the research I propose in this K23. In addition, I receive dedicated administrative assistance and grants management support from Ms. Sandra Roberts, the RISC Administrator. My office is within the RISC, down the hall from Dr. Mugavero and Ms. Roberts' offices, and adjacent to the CFAR office suite, to facilitate collaboration and interaction. I have both a desktop and laptop computer supported by the RISC Informatics Core, which run SAS and NVivo 10.0.

**UAB HIV/Chronic Pain Interdisciplinary Subspecialty Clinic**

The UAB HIV/Chronic Pain clinic was started in 2004 to provide pain management services to HIV-infected individuals at the 1917 clinic. I assumed leadership of the clinic when I came to UAB in August 2011. *Since then, I have worked to expand the clinic's interdisciplinary team to include a dedicated Nurse Practitioner, Registered Nurse, Social Worker, and Physical Therapist.* In addition, we provide training to 2-4 palliative care fellows annually who rotate with me in the clinic. Together, we evaluate patients one half-day per week. From 2011-2013, our team evaluated 99 unique patients, most of whom we co-manage longitudinally in close collaboration with their HIV primary care providers. This clinic has substantial clinical and administrative support due to the dedication of team members throughout the week.

This clinic is physically located within the 1917 Clinic. *Given the complex behavioral and mental health needs of my patients, I collaborate closely with 1917 clinic-based psychology, psychiatry, and counseling colleagues, including an addiction counselor. We have begun to have regular interdisciplinary team meetings which include my advisor, Dr. Burel Goodin, a pain psychologist who completed his clinical psychology internship with my mentor Dr. Robert Kerns. This clinic will serve as the site where Dr. Goodin will provide me with clinical supervision (one 4-hour session/month - see Candidate's Plan for Career Development/Training Activities During the Award Period).*

***UAB-Highlands Pain Treatment Clinic***

*The UAB-Highlands Pain Treatment Clinic is located five blocks from the main UAB hospital campus, in the Highlands Hospital building. This practice consists of nine fellowship-trained anesthesiologists, two licensed clinical psychologists, and three nurse practitioners. This clinic provides consultative services related to chronic pain treatment with an emphasis on medical management, procedural therapies, and cognitive-behavioral interventions. I have established collaborative relationships with the two clinical psychologists at the Pain Treatment Clinic, and specifically plan to work closely with Dr. Burel Goodin, who will be an advisor on my K23. This clinic will provide shadowing opportunities for me (1 session/week for 3 months/year - see Candidate's Plan for Career Development/Training Activities During the Award Period).*

**UAB Center for Clinical and Translational Science (CCTS)**

The UAB CCTS was officially approved by the University of Alabama Board of Trustees on February 3, 2006 and funded by the NIH on May 19, 2008. The Center works with investigators to accelerate the translation of research into improved human health. The mission of the Center is to connect researchers by providing them with access to resources and services, train the next generation of researchers and research teams, and make the community a partner in clinical and translational research. The CCTS's focus covers every phase of translation: from idea formation (T0); to the first testing of the idea in a cell, animal, or person (T1); to large scale clinical trials (T2); to moving a proven idea into health practice (T3); and encouraging its adoption as a standard approach (T4).

The CCTS provides several services developed for junior faculty in which I participate. The Nascent Project Panel is a standing panel of investigators who can help review projects that are in the developmental and conceptualization stage. I presented my K23 Aims to the Nascent Project Panel in March 2013. I also attend monthly biostatistics seminars and meetings of junior faculty who are writing Career Development Awards, receive one-on-one grant feedback from dedicated staff, and participate in continuing education in the Responsible Conduct of Research (see Responsible Conduct of Research). In 2012, I received a CCTS pilot grant, which was co-sponsored by the UAB CFAR (The Role of Chronic Pain and Age in HIV Outcomes, 5/12-4/13).

**UAB School of Public Health (SOPH), including the Department of Health Behavior**

With 60 primary faculty members, the SOPH ranks 2nd in extramural support among the 10 UAB schools, and 11th in schools of public health across the country. The SOPH has 22 programs of study and is comprised of the following five departments: Biostatistics, Environmental Health Sciences, Epidemiology, Health Behavior, and Health Care Organization and Policy. The SOPH has a strong track record of working closely with the CFAR and the 1917 Clinic Cohort. I will take courses for my Master of Science in Public Health (MSPH) in Health Behavior within the UAB SOPH. The UAB SOPH is located 2 blocks from my office. Dr. Susan Davies, my intervention mapping advisor, is core faculty in the Department of Health Behavior. She teaches the SOPH course in intervention development that I will take during Year 1 of my K23.

***UAB Department of Psychology, Medical Clinical Psychology Program***

*UAB's Medical Clinical Psychology program is jointly sponsored by UAB's School of Medicine and the College of Arts and Sciences. This is an American Psychological Association (APA)-accredited clinical psychology doctoral training program with an emphasis in medical psychology. The program has particular strengths in medically-relevant areas including health psychology and behavioral medicine. I will take classes in this program as part of my didactic training in health psychology/mental health. Notably, my mentor Dr. Mallory Johnson received his PhD in clinical medical psychology from this program in 1998.*

**Center for Outcomes and Effectiveness Research and Education (COERE)**

I am an investigator in the COERE, a UAB university-wide center led by Dr. Kenneth Saag, the PI of my institutional K12 career development award. Training and mentoring of junior faculty in outcomes research and methods is central to the COERE's mission. I participate in numerous informal training opportunities through the COERE, including works in progress and research methods seminars. Additionally, my K12, which is administered through the COERE, includes additional seminars specifically for K12 awardees focused on the transition from junior faculty to independent investigator.

**Center for Palliative and Supportive Care (CPSC)**

UAB's CPSC is recognized nationally by the Center to Advance Palliative Care as one of the leading programs in palliative care in the US. Within the center, I co-founded and co-direct the Palliative Care Center Scholars Program, which brings pain and palliative care researchers from across campus together monthly to discuss collaborations and works in progress. I also attend on the inpatient palliative care service 2 weeks per year, to maintain my professional ties to this field. This allows me to consult on patients with chronic pain in the inpatient setting.

**Center of Excellence in Pain Education (CoEPE)**

In 2012, UAB was named one of 11 NIH National CoEPEs. The purpose of the CoEPE is to translate research findings in pain management to fill identified gaps in medical school pain curricula. As one of the CoEPE core faculty, I have written an HIV and chronic pain module, which will be used as a teaching tool for medical students nationwide.

**Summary of Facilities and Other Resources**

UAB has an outstanding and well-established clinical and research infrastructure, with unique strengths in my areas of focus. The ongoing research and career development support I receive from the resources described here will ensure a high likelihood of success of the proposed research aims, and help me successfully transition to being an independent investigator *and obtain R01 funding by the end of my K23.*

## EQUIPMENT

There are no major items of equipment necessary for this proposal.

**List of Referees**

My letters of reference are from:

Nathan Goldstein, MD
Associate Professor of Geriatrics and Medicine
Mt. Sinai School of Medicine

Robert Gross, MD, MSCE
Associate Professor of Medicine and Epidemiology
University of Pennsylvania

Michael Mugavero, MD, MHSC
Associate Professor of Medicine
University of Alabama at Birmingham

Kenneth Saag, MD
Professor of Medicine and Epidemiology
University of Alabama at Birmingham

OMB Number: 4040-0001
Expiration Date: 06/30/2016

# RESEARCH & RELATED Senior/Key Person Profile (Expanded)

**PROFILE - Project Director/Principal Investigator**

Prefix: First Name*: Jessica Middle Name Last Name*: Merlin Suffix: M.D.

| | |
|---|---|
| Position/Title*: | Assistant Professor |
| Organization Name*: | University of Alabama at Birmingham |
| Department: | Infectious Diseases |
| Division: | School of Medicine |
| Street1*: | 1720 2nd Avenue South |
| Street2: | BBRB 220 |
| City*: | Birmingham |
| County: | Jefferson |
| State*: | AL: Alabama |
| Province: | |
| Country*: | USA: UNITED STATES |
| Zip / Postal Code*: | 352942170 |

Phone Number*: 2158061888 Fax Number: 2059345600 E-Mail*: jmerlin@uab.edu

Credential, e.g., agency login: jmerlin

Project Role*: PD/PI Other Project Role Category:

Degree Type: MD MBA Degree Year: 2005

| | File Name |
|---|---|
| **Attach Biographical Sketch*:** | 1257-Merlin_Bio_Final.pdf |
| **Attach Current & Pending Support:** | |

**PROFILE - Senior/Key Person**

Prefix: First Name*: Michael Middle Name S Last Name*: Saag Suffix: M.D.

| | |
|---|---|
| Position/Title*: | Professor |
| Organization Name*: | University of Alabama at Birmingham School of Medicine |
| Department: | Infectious Diseases |
| Division: | Medicine |
| Street1*: | 1720 2nd Avenue South |
| Street2: | BBRB 256D |
| City*: | Birmingham |
| County: | Jefferson |
| State*: | AL: Alabama |
| Province: | |
| Country*: | USA: UNITED STATES |
| Zip / Postal Code*: | 352942170 |

Phone Number*: 2059347349 Fax Number: E-Mail*: msaag@uab.edu

Credential, e.g., agency login: msaag

Project Role*: Other (Specify) Other Project Role Category: Mentor

Degree Type: MD Degree Year: 1981

| | File Name |
|---|---|
| **Attach Biographical Sketch*:** | 1258-Saag_Bio_Final2.pdf |
| **Attach Current & Pending Support:** | 1259-Saag_Support_Final.pdf |



Tracking Number: GRANT11635420 Funding Opportunity Number: PA-14-049 . Received Date: 2014-04-24T11:32:34.000-04:00

**PROFILE - Senior/Key Person**

Prefix: First Name*: Mallory Middle Name O Last Name*: Johnson Suffix: Ph.D

Position/Title*: Professor
Organization Name*: University of California, San Francisco
Department: Medicine
Division:
Street1*: 50 Beale Street
Street2: Suite 1300
City*: San Francisco
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 941051823

Phone Number*: 4155979374 Fax Number: 4155979213 E-Mail*: Mallory.Johnson@ucsf.edu

Credential, e.g., agency login: MalloryJ

Project Role*: Other (Specify) Other Project Role Category: Co-Mentor

Degree Type: Ph.D. Degree Year: 1998

| | File Name |
|---|---|
| **Attach Biographical Sketch*:** | 1260-Johnson_Bio_Final.pdf |
| **Attach Current & Pending Support:** | 1261-Johnson_Support_Final.pdf |

**PROFILE - Senior/Key Person**

Prefix: First Name*: Robert Middle Name D Last Name*: Kerns Suffix: Ph.D

Position/Title*: Professor of Psychiatry, Neurology, Psycholog
Organization Name*: Yale University and VA Connecticut Healthcare System
Department: Medicine
Division:
Street1*: 950 Campbell Avenue
Street2: PRIME Center / 11ACSLG
City*: West Haven
County:
State*: CT: Connecticut
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 065162770

Phone Number*: 2039373841 Fax Number: 2034798126 E-Mail*: Robert.Kerns@va.gov

Credential, e.g., agency login: ROBERTKERNS

Project Role*: Other (Specify) Other Project Role Category: Co-Mentor

Degree Type: PhD Degree Year: 1980

| | File Name |
|---|---|
| **Attach Biographical Sketch*:** | 1262-Kerns_Bio_Final.pdf |
| **Attach Current & Pending Support:** | 1263-Kerns_Support_Final.pdf |

**BIOGRAPHICAL SKETCH**

Provide the following information for the Key Personnel in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

| NAME<br>Jessica S. Merlin | POSITION TITLE<br>Assistant Professor, Division of Infectious Diseases, Division of Gerontology, Geriatrics, and Palliative Care |
|---|---|
| eRA COMMONS USER NAME<br>jmerlin | |

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Carnegie Mellon University, Pittsburgh, PA | BS | 06/00 | Biology |
| University of Pennsylvania, Philadelphia, PA | MD | 05/05 | Medicine |
| University of Pennsylvania, Wharton School, Philadelphia, PA | MBA | 05/05 | Health Care Management |
| Hospital of the University of Pennsylvania, Philadelphia, PA | Residency | 07/05-06/08 | Internal Medicine |
| Hospital of the University of Pennsylvania, Philadelphia, PA | Fellowship | 07/08-06/10 | Infectious Diseases |
| Mt. Sinai School of Medicine, NY, NY | Fellowship | 7/10-6/11 | Palliative Care |
| Board Certified, Internal Medicine | | 08/08 | |
| Board Certified, Infectious Diseases | | 10/10 | |
| Board Certified, Palliative Care | | 10/12 | |

**Personal Statement**

I am an Assistant Professor of Medicine at the University of Alabama at Birmingham (UAB) and the Principal Investigator of this Career Development Award. The focus of my K23 is to develop and test a behavioral intervention for chronic pain in HIV-infected patients. My long-term goal is to become a successful independent investigator focusing on improving pain, physical, and emotional function in HIV-infected patients with chronic pain, and to develop and test behavioral interventions in this area, including conducting behavioral clinical trials. This is an important emerging field in which there is limited knowledge.

I have completed a Center for Clinical and Translational Science pilot grant, and 18 months of a two year institutional K12 Patient-Centered Outcomes Research Career Development Award. During this time, I have investigated the relationship of pain and outcomes in HIV-infected patients, adapted and tested a Brief Chronic Pain Screening Tool in HIV-infected patients, and conducted qualitative interviews to understand the chronic pain experience in HIV-infected patients. I have also received targeted mentorship in psychometrics and qualitative research, and taken corresponding courses at the UAB School of Public Health, in addition to the core quantitative coursework series that I am currently completing.

My pilot grant and K12 have provided me with the opportunity to receive initial research training, conduct investigations that will serve as the foundation for the work I propose in my K23 application, and write first author manuscripts that have been accepted by peer-reviewed journals. I have also achieved national recognition in my field. I received an American Academy of Hospice and Palliative Medicine Young Investigator Award; developed a module on HIV and chronic pain for the NIH Pain Consortium Center of Excellence in Pain Education; serve on the Infectious Diseases Society of America's HIV and Pain Guidelines Panel; and am a Core Faculty member of the IAS-USA, in which I lecture on HIV and chronic pain. However, in order to complete the project described here, achieve my long-term career goals, and become an independent investigator, I need additional training in health psychology/mental health and chronic pain behavioral intervention development and testing. I have selected an excellent mentorship team, led by Dr. Michael Saag, with co-mentors Drs. Mallory Johnson and Robert Kerns. My mentors have extensive and complementary areas of expertise in health psychology/mental health (Johnson), chronic pain behavioral intervention development and testing (Kerns), and behavioral clinical trials within cohorts such as CNICS (Saag), plus a strong track record of mentoring junior investigators.

In sum, the proposed career development award will provide critical support for my transition to a career as an independent physician-investigator, focusing on developing and testing behavioral interventions for chronic pain in HIV-infected patients.

**Research and/or Professional Experience**

**Employment**

2005-2008 Resident in Internal Medicine, Hospital of the University of Pennsylvania, Philadelphia, PA
2008-2010 Fellow in Infectious Diseases, Hospital of the University of Pennsylvania, Philadelphia, PA
2010-2011 Fellow in Palliative Medicine, Mt. Sinai School of Medicine, NY, NY
August 2011- Assistant Professor, Department of Medicine, Divisions of Infectious Diseases and Gerontology, Geriatrics, and Palliative Care, University of Alabama at Birmingham, Birmingham, AL

**Honors**

2000 Phi Beta Kappa
2001 Phi Kappa Phi Graduate Fellowship
2003 Norman V. Weschler Fellowship for MBA Studies
2008 College of Palliative Care Scholarship Award
Mary E. Groff Fellowship in Clinical Research Methods, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania
Penn Pearls Teaching Award, University of Pennsylvania School of Medicine
2010 Infectious Diseases Society of America Conference Travel Grant
2010 Certificate in Clinical Epidemiology, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania
2011 American Academy of Hospice and Palliative Medicine Young Investigator Award
2011 International Association of Hospice and Palliative Care Travel grant for travel to Vietnam
2011 American Academy of Hospice and Palliative Medicine Mentorship Program award
2011 Advanced Illness and Multimorbidity (AIM) Scholar, University of Alabama at Birmingham
2013 American Academy of Hospice and Palliative Medicine Research Scholar
2014 Tinsley Harrison Teaching Scholar
2014 Research Supplement Award based on the UAB Department of Medicine Research Metrics Survey (includes grant funding, publications, and external lectures given)
2014 Faculty participant, Chief Resident Immersion Training Program in Addiction Medicine, Boston University

**Professional Societies and Committees**

2010-present Infectious Diseases Society of America
2010-present Infectious Diseases Society of America HIV and Pain Guidelines Panel
2008-present American Academy of Hospice and Palliative Medicine
2010-2011 International Association of Hospice and Palliative Care
2010-2013 American Academy of Hospice and Palliative Medicine HIV Special Interest Group founding Chair
2010-present Reviewer, Journal of General Internal Medicine
2011-present Reviewer, Journal of AIDS and Clinical Research
2011-present Reviewer, Journal of Pain and Symptom Management
2011-present Reviewer, Journal of Palliative Medicine
2012-present Reviewer, Pharmacoepidemiology and Drug Safety
2012-present Reviewer, BMC Infectious Diseases
2012-present Associate Editor, Pain Medicine
6/13-present Reviewer, Substance Abuse
2/14-present Reviewer, Pain
3/14-present Reviewer, Journal of the American Medical Association
4/14-present Reviewer, AIDS and Behavior

**Peer-reviewed Publications**

1. Merlin JS, Walcott M, Herbey I, Chamot E, Ritchie CS, Saag MS, Kertesz S. Qualitative Investigation of a Brief Chronic Pain Screening Tool in HIV-Infected Patients. AIDS Pt Care STDs 2014; 28(4):176-82. Pub Med Journal – In Process.

2. Merlin JS, Westfall AO, Chamot E, Overton ET, Willig JH, Ritchie C, Saag MS, Mugavero MJ. Pain is independently associated with impaired physical function in HIV-infected patients. Pain Med 2013; 14 (12): 1985-93. PMCID: PMC3886835.

3. Molony E, Westfall AO, Perry BA, Tucker R, Ritchie C, Saag M, Mugavero M, Sullivan JC, Merlin JS. Low back pain and associated imaging findings among HIV-infected patients referred to an HIV/palliative care clinic. Pain Med 2014; 15(3): 418-24. PMCID: PMC3949151.

4. Perry BA, Westfall AO, Molony E, Tucker R, Ritchie C, Saag MS, Mugavero MJ, Merlin JS. Characteristics of an Ambulatory Palliative Care Clinic for HIV-Infected Patients. J Palliat Med 2013; 16(8): 934-7. PMCID: PMC3727562.

5. Merlin JS, Zinski A, Norton WE, Ritchie CS, Saag MS, Mugavero MJ, Treisman G, Hooten WM. A Conceptual Framework for Understanding Chronic Pain in Patients with HIV. Pain Pract 2013; 14(3): 207-16. Pub Med Journal – In Process.

6. Merlin JS, Childers J, Arnold RM. Chronic pain in the outpatient palliative care clinic. Am J Hosp Palliat Care 2013; 30(2):197-203. PMID: 22556285.

7. Merlin JS, Tucker RO, Saag MS, Selwyn PA. The role of palliative care in the current HIV treatment era in developed countries. Top Antivir Med 2013; 21(1):20-6. PMID: 23596275.

8. Merlin JS, Westfall AO, Raper JL, Zinski A, Norton WE, Willig JH, Gross R, Ritchie CS, Saag MS, Mugavero MJ. Pain, mood, and substance abuse in HIV: implications for clinic visit utilization, antiretroviral therapy adherence, and virologic failure. J Acquir Immune Defic Syndr 2012; 61(2):164-70. PMCID: PMC3459261.

9. Merlin JS, Cen L, Praestgaard A, Turner M, Obando A, Alpert C, Woolston S, Casarett D, Kostman J, Gross R, Frank I. Pain and physical and psychological symptoms in ambulatory HIV patients in the current treatment era. J Pain Symptom Manage 2012; 43(3):638-45. PMID: 22115794. Pub Med Journal – In Process.

10. Merlin JS, Morrison G, Gluckman S, Lipschik G, Linkin DR, Lyon S, O'Grady E, Calvert H, Friedman H. Medical students in developing countries. J Gen Intern Med 2011; 26(8):833. PMCID: PMC3138993.

11. Merlin J, Morrison G, Gluckman S, Lipschik G, Linkin DR, Lyon S, O'Grady E, Calvert H, Friedman H. Blood and body fluid exposures among US medical students in Botswana. J Gen Intern Med 2011; 26(5):561-4. PMCID: PMC3077487.

**Scientific Abstracts**

1. Merlin JS, Westfall AO, Saag S, Chamot EC, Walcott M, Ritchie C, Kertesz S. Validity Testing of a New Brief Chronic Pain Screening tool in HIV-infected Patients. Accepted as poster presentation, International Association of Providers of AIDS Care Conference, Miami, FL, 2014.

2. Merlin JS, Walcott M, Ritchie CS, Herbey I, Kertesz SG, Chamot EC, Saag M, Turan JM. Patient perspectives on psychological aspects of chronic pain while living with HIV. Accepted as poster presentation, International Association of Providers of AIDS Care Conference, Miami, FL, 2014.

3. Mgbemena O, Westfall AO, Ritchie C, Hicks J, Raper J, Overton, ET, Norton WE, Merlin JS. Preliminary Outcomes of a Pilot Physical Therapy Program for HIV-infected Patients with Chronic Pain. Poster presentation, American Pain Society, Tampa, FL, 2014.

4. Merlin JS, Walcott M, Herbey I, Chamot E, Ritchie C, Saag MS, Kertesz S. Qualitative Investigation of a Brief Chronic Pain Screening Tool in HIV-Infected Patients. Poster Presentation, American Pain Society, Tampa, FL, 2014.

5. Merlin JS, Turan JM, Herbey I, Westfall AO, Starrels JL, Kertesz SG, Saag MS, Ritchie CS. Provider Documentation of Aberrant Drug-Related Behaviors (ADRBs) in Patients Referred to an HIV/Chronic Pain Clinic. Oral presentation, Association for Medical Education and Research in Substance Abuse, Bethesda, MD, 2013.

6. Merlin JS, Westfall AO, Chamot E, Overton T, Willig JH, Ritchie C, Saag MS, Mugavero MJ. The Relationship of Pain to Physical Function in Patients With HIV: An Underappreciated Phenomenon. Poster presentation, ID Week, San Diego, CA, 2012; Association for Medical Education and Research in Substance Abuse, Bethesda, MD, 2012. Oral presentation, American Academy of Hospice and Palliative Medicine, New Orleans, LA, 2013.

7. Merlin JS, Westfall AO, Raper JL, Zinski A, Norton WE, Willig JH, Gross R, Ritchie C, Saag MS, Mugavero MJ. Pain, Psychiatric Illness, and Substance Abuse in HIV: Implications for Clinic Visit Utilization, ART Adherence, and Virologic Failure. Poster presentation, International Workshop of HIV Observational Databases, Athens, Greece, 2012.

8. Merlin JS, Cen L, Praestgaard A, Turner M, Obando A, Alpert C, Woolston S, Casarett D, Kostman J, Gross R, Frank I. Pain and Physical/Psychological Symptoms in Ambulatory Patients with HIV. Poster presentation, ID Week, Vancouver, BC, 2010; Oral presentation, American Academy of Hospice and Palliative Medicine, Vancouver, BC, 2011.

9. Merlin JS, Morrison G, Gluckman S, Lipshcik G, Linkin D, Lyon S, O'Grady S, Calvert H, Friedman H. Blood and Body Fluid Exposures Among US Medical Students in Botswana. Oral presentation, International Meeting on Simulation in Healthcare, New Orleans, LA, 2011.

**Research Support**

UL1 TR00165-05 Kimberly (PI) /Merlin (pilot awardee) 5/1/2012-4/30/2013
The Role of Chronic Pain and Age in HIV Outcomes
The goal of this pilot study is to evaluate the association between chronic pain and age, alone and in the context of psychiatric illness and substance abuse, on health behaviors and clinical outcomes in patients with HIV.
Role: PI

K12 HS019465-01 Saag (PI)/Merlin (K12 scholar) 9/1/2012-8/31/2014
Screening for and Understanding Chronic Pain in HIV-infected patients.
The goal of this career development award is to support Dr. Jessica Merlin in Patient-Centered Outcomes Research and Career Development in HIV and chronic pain. The focus of this project is to adapt, pilot test, and validate a Brief Chronic Pain Screening tool in HIV-infected patients, and learn more about the chronic pain experience in this population.
Role: Scholar

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order

| NAME<br>Saag, Michael Switow | POSITION TITLE<br>Professor of Medicine<br>Director, UAB Center for AIDS Research |
|---|---|
| eRA COMMONS USER NAME (credential, e.g., agency login) msaag | |

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Tulane University, New Orleans, LA | BS | 05/1977 | Chemistry |
| University of Louisville, Louisville, KY | MD | 06/1981 | Medicine |
| University of Alabama at Birmingham | Postdoc | 06/1987 | Virology & Mol Biology |

**A. Personal Statement**

I am the Director of the UAB Center For AIDS Research (CFAR) and a Professor of Medicine in the Division of Infectious Diseases. I am also the principal investigator of the CFAR Network of Integrated Clinical Systems (CNICS), a NIAID-funded National Network of 8 CFAR centers that are merged for the purposes of Behavioral and Clinical Outcomes Research. As the CNICS National PI, I have expertise in the conduct of clinical trials, including behavioral interventions. I am the founding director of the UAB 1917 HIV Clinic, which has pioneered treatment programs based on real world clinical trials and studies focused on quality improvement in the area of HIV. I serve as Co-PI of the NA-ACCORD, an international collaboration of more than 30 sites that merge data for comparative effectiveness research, and serve on the Executive Steering Committee of the ART-CC, an international cohort research group. I have been on the Board of Directors of the American Board of Internal Medicine (and as Chair of the Infectious Disease Subspecialty Board) and the NIH Office of AIDS Research Advisory Council. I am the past President of the HIV Medicine Association and a member of the HHS Guidelines Panel on Antiretroviral Therapy. I was listed as one of the top ten cited HIV researchers by *Science* (1996) and received two Argus Awards for Best Lectures to the 1st year medical students at UAB (2009 and 2010). I have had over 15 trainees who have gone on to successful academic careers and I am currently mentoring 3 young investigators, including Dr. Merlin, who are working in Health Related Outcomes Research.

The goal of this K23 application is to provide Dr. Jessica Merlin with mentored career development as she grows into an independent investigator in the field of HIV and chronic pain behavioral research. The proposed study will develop and test a behavioral intervention for chronic pain in HIV-infected patients. My research background and professional experiences mentoring faculty in HIV research make me well suited to serve as Dr. Merlin's primary mentor, along with co-mentors Drs. Mallory Johnson and Robert Kerns, on the project described in this application. In addition to providing general oversight for Dr. Merlin's project, I will contribute specific expertise regarding the conduct of clinical trials, including behavioral clinical trials, within cohorts such as CNICS. This expertise will be important as Dr. Merlin conducts a pilot randomized controlled trial (RCT) during Aim 2, and submits an R01 during Year 4 to conduct a national CNICS-wide RCT of the intervention.

**B. Positions and Honors**

1981-1982 Intern, Department of Medicine, The University of Alabama at Birmingham (UAB), B'ham, AL
1982-1984 Resident, Department of Medicine, The University of Alabama at Birmingham, Birmingham, AL
1984-1985 Chief Resident and Instructor, Department of Medicine, UAB, Birmingham, AL
1985-1987 Post-Doctoral Fellow, Division of Infectious Diseases, Department of Medicine, UAB, B'ham, AL
1987-1992 Assistant Chief, Medical Service, Birmingham Veterans Affairs Medical Center, Birmingham, AL
1987-1992 Assist Professor/Medicine, Division/Infectious Diseases, Department/Medicine, UAB, B'ham, AL
1988-1999 Associate Director, General Clinical Research Center, UAB, Birmingham, AL
1988-2004 Assoc Director, Clinical Care & Therapeutics, Center for AIDS Research, UAB, Birmingham, AL
1988-2007 Director, UAB AIDS Outpatient Clinic, The University of Alabama at Birmingham, B'ham, AL
1992-1997 Associate Professor/Medicine, Division/Inf Diseases, Department/Medicine, UAB, B'ham, AL
1997-Present Professor/Medicine, Infectious Diseases Division, Department of Medicine, UAB, B'ham, AL
2004-Present Director, University of Alabama at Birmingham Center for AIDS Research, Birmingham, AL
2007- 2010 Director, University of Alabama at Birmingham, Division of Infectious Diseases, Birmingham, AL

**Honors and Awards**

1980 Alpha Omega Alpha
1981 Presley Martin Memorial Award for Excellence in Clinical Medicine
1984 Aesculapian Award for Excellence in the Clinical Practice of Medicine
1986-1987 The Walter B. Frommeyer Fellowship Award in Investigative Medicine
1996 Myrtle Wreath Award, Hadassah
2001 Odessa Woolfolk Community Service Award
2005 Live the Dream Award, Birmingham Regional Chamber of Commerce, Birmingham, AL
2006 Leonard Tow Humanism in Medicine Award, The Arnold P. Gold Foundation
2007 Hettie Butler Terry Community Service Award, UAB Medical Alumni Association
2007 UAB Center for AIDS Research, Gold winner in the Non-Profit category of the 2007 Excellence in Information Integrity Award; presented by the Information Integrity Coalition
2009/2010 Recipient: Best Patient, Doctor, and Society Lecturer; and Nominated, Best Fundamentals II Lecturer; UAB School of Medicine Annual Argus Society Awards, presented by the UAB Medical Alumni Association
2010 The UAB President's Medal of Honor

**Professional Memberships**

1988-Present Member, Executive Committee, UAB Center for AIDS Research, Birmingham, AL
1993-1996 Chairperson, Therapeutics Subcommittee, AIDS Research Advisory Committee, NIAID
1994-97; 2000-03 Member, Adult ACTG Executive Committee, NIH/NIAID
2000-2004 Member, Subspecialty Board on Infectious Diseases, American Board of Internal Medicine
2004-2008 Chair, Subspecialty Board on Infectious Diseases, American Board of Internal Medicine
2004-2011 Member, Board of Directors IDSA; HIV Medicine Association; President, HIVMA (2010)
2005-2008 Member, NIH Office of AIDS Research Advisory Council
2008-present Member, DHHS Antiretroviral Therapy Guidelines Committee

**C. Selected Peer-reviewed Publications (from 199 peer-reviewed publications)**


1. **Saag MS**, Hahn BH, Gibbons J, Li Y, Parks S, Parks WP, Shaw GM. Extensive variation of human immunodeficiency virus type-1 *in vivo*. *Nature* 334(6181):440-444,1988.
2. **Saag MS**, Powderly WG, Cloud GA, et al for the NIAID Mycoses Study Group, and the AIDS Clinical Trials Group. Comparison of amphotericin B with fluconazole in the treatment of acute AIDS-associated cryptococcal meningitis. *N Engl J Med* 326(2):83-89,1992.
3. Piatak Jr M, **Saag MS**, Yang LC, Clark SJ, Kappes JC, Luk K-C, Hahn BH, Shaw GM, Lifson JD. High levels of HIV-1 plasma during all stages of infection determined by competitive PCR. Science 259:1749-1754,1993.
4. **Saag MS**, Emini EA, Laskin OL, et al. A short term clinical evaluation of L-697,661, a nonnucleoside inhibitor of HIV-1 reverse transcriptase. N Engl J Med 329:1065-1072,1993.
5. Wei X, Ghosh SK, Taylor ME, Johnson VA, Emini E, Deutsch P, Lifson JD, Bonhoeffer S, Nowak MA, Hahn BH, **Saag MS**, Shaw GM. Viral dynamics in human immunodeficiency virus type 1 infection. Nature 373:117, 1995
6. **Saag MS**, Holodniy M, Kuritzkes DR, et al,. HIV viral load markers in clinical practice. *Nature Med* 2:625, 1996.
7. **Saag MS**, Cahn P, Raffi F, Wolff M, et al, for the FTC-301 Study Team. Efficacy and safety of emtricitabine vs stavudine in combination therapy in antiretroviral-naïve patients – A randomized trial. *JAMA* 292(2):180-190,2004.
8. Chen RY, Accortt NA, Westfall AO, Mugavero MJ, Raper JL, Cloud GA, Stone BK, Carter J, Call S, Pisu M, Allison J, **Saag MS**. Distribution of health care expenditures for HIV-infected pts. *CID* 42:1003-10, 2006.
9. Stringer JSA, Zulu I, Levy J, Stringer EM, Mwango A, Chi BH, Mtonga V, Reid S, Cantrell RA, Bulterys M, **Saag MS** Rapid scale-up of antiretroviral therapy at primary care sites in Zambia - Feasibility and Early Outcomes. *JAMA* 296(7):782-793, 2006.
10. Willig JH, Abroms S, Westfall AO, Routman J, Adusumilli S, Varshney M, Allison J, Chatham A, Raper JL, Kaslow RA, **Saag MS**, Mugavero MJ. Increased regimen durability in the era of once daily fixed-dose combination antiretroviral therapy. *AIDS* 22:1951-1960, 2008. PMCID: PMC2828871
11. Kitahata MM, Gange SJ, Abraham A, Merriman B, **Saag MS**, et al, for The NA-ACCORD. Effect of early versus deferred antiretroviral therapy for HIV on survival. *NEJM*, 360(18):1815-26, 2009. PMCID: PMC2854555
12. Mugavero MJ, Lin HY, Allison JJ, Giordano TP, Willig JW, Raper JL, Wray NP, Cole SR, Schumacher JE, Davies S. **Saag MS**. Racial disparities in HIV virologic failure: do missed visits matter? *JAIDS* 50(1):100108, 2009. PMCID: PMC2766510

13. Cole SR, Napravnik S, Mugavero MJ, Lau B, Eron JJ, **Saag MS**. Copy-years Viremia as a Measure of Cumulative HIV Viral Burden. *Am J Epidemiology* 2010;171:198-205. PMCID: PMC2878100
14. Merlin JS, Zinski A, Norton WE, Ritchie CS, **Saag MS**, Mugavero MJ, Treisman G, Hooten WM. A Conceptual Framework for Understanding Chronic Pain in Patients with HIV. Pain Pract. 2013 Apr 1; PMID: 23551857.
15. Merlin JS, Westfall AO, Raper JL, Zinski A, Norton WE, Willig JH, Gross R, Ritchie CS, **Saag MS**, Mugavero MJ. Pain, mood, and substance abuse in HIV: implications for clinic visit utilization, antiretroviral therapy adherence, and virologic failure. J Acquir Immune Defic Syndr. 2012 Oct 1;61(2):164-70. PMCID: PMC3459261.

**D. Research Support**

**ACTIVE**

**5 P30 AI027767 (Saag, PI)** **06/19/09-05/31/14**

NIH/NIAID

*UAB Center for AIDS Research*

This CFAR is organized as a partnership between The University of Alabama at Birmingham and the Southern Research Institute. The primary purpose of this partnership is to generate interdisciplinary AIDS research efforts. This Center is responsible for the planning, evaluating, managing and documenting a broad array of research activities within the two institutions. Particular emphasis is placed upon linking clinical and basic science studies through the use of shared facilities and to translate as quickly as possible fundamental knowledge about AIDS and its related disorders into clinical treatment and prevention programs.

**1 U01 AI069452 (Saag, PI)** **12/01/13-11/30/20**

NIH/NIAID

*Alabama-Clinical Trials Unit*

The Alabama HIV/AIDS CTU is designed to provide an administrative infrastructure that brings Network investigators at UAB together to facilitate the conduct of high capacity, quality-assured, safety-driven clinical trials through provision of administrative support, financial support, communications, staff training, oversight, regulatory support, pharmacy services, synchronization of scientific effort, community relations, and CAB support, and coordination of study personnel in order to achieve maximal efficiency of available staff effort.

**1 R24 AI067039 (Saag, PI)** **09/01/11-08/31/16**

PHS/NIH/NIAID

*Unsolicited R24 for the CFAR-Network of Integrated Clinical Sciences, CNICS*

The CFAR Network of Integrated Clinical Systems (CNICS) project is a multi-site, electronic medical records resource network that can substantially contribute to the contemporary HIV research agenda. As a clinic-based research network, CNICS directly reflects the outcomes of clinical decisions and management options used daily in the care of HIV infected individuals.

**5 U01 AI069918-06 (R Moore, PI; M Saag, Co-PI)** **07/01/11-06/30/16**

NIH /NIAID

*Johns Hopkins Subcontract- North American AIDS Cohort Collaboration on Research Design-NA-ACCORD*

The NA-ACCORD is a regional collaboration of single-site and multi-site cohorts representing over 50 sites with greater than 60,000 patients from the United States and Canada. It is funded by the NIH as part of the International Epidemiologic Databases to Evaluate AIDS (IeDEA) initiative that is supporting similar collaboration through-out the world. The NA-ACCORD provides a mechanism to combine previously collected data from classical epidemiologic and clinical HIV cohorts to address scientific questions that cannot be addressed in the individual cohorts because of limited sample sizes.

**1 U01 AI103401-01 (Saag, PI)** **01/01/13-12/31/18**

NIH/NIAID

*UAB-MISS WIHS Cohort*

The Women's Interagency HIV Study (WIHS) is a multicenter longitudinal study funded by the National Institute of Allergy and Infectious Diseases (NIAID), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institute of Drug Abuse (NIDA), and the National Cancer Institute (NCI) to investigate the impact and progression of HIV disease in women.

**P30 AI027767 Supplement (Saag, PI)** **06/01/11-05/31/14 (NCE)**

NIH

*Creative and Novel Ideas in HIV Research (CNIHR)*

A funding mechanism to attract and mentor international and domestic young investigators from outside the field of HIV/AIDS research to bring promising ideas to this field of study.

**1 U01 AR057954-01 (Saag, PI)** **09/30/09-07/31/14**
*Patient-reported outcomes in routine clinical care of patients infected with HIV (PROMIS)*
The proposal is designed to improve medical care and patient outcomes in clinical care as well as to assess the validity of key PROMIS domains most relevant for clinical care among HIV-infected individuals.

**CLINICAL TRIALS**

**Tobira 652-2-202 (Saag PI)** Tobira 08/23/11–08/22/14
A Phase 2b Randomized, Double-Blind, Double-Dummy Trial of 100 or 200 mg Once-Daily Doses of Cenicriviroc (CVC, TBR-652)or Once-Daily EFV, Each With Open-Label FTC/TDF, in HIV-1-Infected, Antiretroviral Treatment-Naïve, Adult Patients With Only CCR5-Tropic Virus

**GSK ING111762 (Saag PI)** Glaxo-Smith-Kline 12/06/10- Present
A Phase III Randomized, Double-blind Study of the Safety and Efficacy of GSK1349572 50 mg Once Daily Versus Raltegravir 400 mg Twice Daily, Both Administered with an Investigator selected Background Regimen Over 48 Weeks in HIV-1 Infected, Integrase Inhibitor-Naïve, Antiretroviral Therapy-Experienced Adult

**GS-US-264-0106 (Saag PI)** Gilead 02/03/11- Present
A Phase 3 Randomized, Open-Label Study to Evaluate Switching from Regimens Consisting of a Ritonavir-boosted Protease Inhibitor and Two Nucleoside Reverse Transcriptase Inhibitors to Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate (FTC/RPV/TDF) Fixed-dose Regimen in Virologically-Suppressed, HIV-1 Infected Patients

**BI 1220.47 (201335) (Saag PI)** Boehringer-Ingelheim Pharma 05/18/11-05/17/14
A phase III, randomised, double-blind and placebo-controlled study of once daily BI 201335 120 mg for 24 weeks and BI201335 240 mg for 12 weeks in combination with pegylated interferon-α and ribavirin in treatment-naive patients with genotype 1 chronic hepatitis C infection

**GS-US-264-0110 (Saag PI)** Gilead 05/10/11-05/09/14
A Phase 3B, Randomized, Open-label Study to Evaluate the Safety and Efficacy of a Single Tablet Regimen of Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate Compared with a Single Tablet Regimen of Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults

**A4001095 (Saag PI)** Pfizer 09/07/11-09/06/15
A Multicenter, Randomized, Double-Blind, Comparative Trial of Maraviroc + Darunavir/Ritonavir Versus Emtricitabine/Tenofovir+Darunavir/Ritonavir for the Treatment of Antiretroviral-Naïve HIV-Infected Patients with CCR5-Tropic HIV-1

**AI444-043-016 (Saag PI)** BristolMyersSquibb 02/10/12-01/09/16
A Phase 3, Open Label Study of Safety and Efficacy with BMS-790052 plus Peg-Interferon Alfa 2a and Ribavirin in Previously Untreated HCV Patients Coinfected with Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)

**GS-US-334-0107 (Saag PI)** Gilead 04/12/12-04/11/16
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of GS-7977 + Ribavirin for 12 Weeks in Subjects with Chronic Genotype 2 or 3 HCV Infection who are Interferon Intolerant, Interferon Ineligible or Unwilling to Take Interferon

**GS-US-334-0109 (Saag PI)** Gilead 05/29/12-05/28/14
An Open-Label Study to Evaluate the Safety of GS-7977+ Ribavirin for 12 Weeks in Subjects with Chronic HCV Infection Who Participated in a Gilead or Pharmasset Sponsored Clinical Study of GS-7977 (PSI-7977)

**GS-US-334-0110 (Saag PI)** Gilead 05/18/12-05/17/14
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of GS-7977 +Ribavirin for 12 Weeks in Treatment-Naïve Subjects with Chronic Genotype 1, 4, 5 or 6 HCV Infection

**LAI 116482 (Saag PI)** Glaxo-Smith-Kline 09/12/12-09/11/16
A Phase IIb, Dose Ranging Study of Oral GSK1265744 in combination with Nucleoside Reverse Transcriptase Inhibitors for Induction of HIV-1 Virologic Suppression followed by an Evaluation of Maintenance of Virologic Suppression when Oral GSK1265744 is Combined with Oral Rilpivirine in HIV-1 Infected, Antiretroviral Therapy-Naive Adult Subjects

**Gilead GS-US-337-0102** Gilead 10/04/12-10/03/16
This clinical trial is for HCV Treatment-naïve patients

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

| NAME<br>Mallory O. Johnson | POSITION TITLE<br>Professor of Medicine |
|---|---|
| eRA COMMONS USER NAME (credential, e.g., agency login) MalloryJ | |

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Rhodes College, Memphis, Tennessee | B.A. | 06/91 | Psychology |
| University of Alabama at Birmingham, AL | M.A. | 05/96 | Clinical Medical Psychology |
| University of Alabama at Birmingham, AL | Ph.D. | 06/98 | Clinical Medical Psychology |
| University of California, San Francisco | Intern | 06/98 | Clinical Psychology |
| University of California, San Francisco | Fellow | 06/99 | Behavioral Medicine |

A. Personal Statement

I am a licensed psychologist with a PhD in clinical medical psychology emphasizing the intersection of mental and physical health. After my PhD, I completed an APA accredited internship at UCSF focused on mental health assessment and intervention. I have experience developing, testing, implementing, and evaluating theory-based behavioral interventions in HIV-infected patients that address mental health co-morbidities, including depression and anxiety. I will serve as a co-mentor on Dr. Jessica Merlin's K23 Career Development Award, alongside primary mentor Dr. Michael Saag and co-mentor Dr. Robert Kerns, as Dr. Merlin works to develop a tailored behavioral intervention for individuals with HIV and chronic pain. I will provide expertise on health psychology/mental health, and specifically the incorporation of mental health factors such as depression and anxiety into the intervention. These are important areas of focus for Dr. Merlin's research approach and career development.

My experiences uniquely suit me to be Dr. Merlin's co-mentor. In addition to my scientific expertise as described above, I have developed a behavioral intervention for self-management of symptoms in HIV-infected patients, a topic closely related to that of Dr. Merlin's proposed aims. I have a strong funding track record, including roles as investigator and mentor. I have been the PI of a K08 award, four R01s (one of which has been renewed for five additional years), an R21, a K24 mid-career mentorship award, and a K24 renewal pending from NIDA. I have served as primary mentor for six faculty on K awards, one fellow on an F32, and I am faculty on four T32 training programs. Importantly, my role as co-mentor on this K23 is consistent with the objectives of my pending K24 application to NIDA, which was assigned an impact score of 10. For the pending K24, my mentoring will be expanded to include mentees from new sources (such as UAB, an institution with which I have several ongoing collaborations, including via CNICS and WIHS) and the establishment of online mentoring pods for team-based and distance mentoring, which are particularly useful in geographically diverse teams such as Dr. Merlin's. Of note is that I received my doctorate from UAB and I have several active collaborations that bring me to UAB at least once annually, which will facilitate my role as a member of Dr. Merlin's mentoring team.

B. Positions and Honors

**Positions and Employment**

2003-2007 Assistant Professor of Medicine, UCSF, San Francisco, CA
2007-2012 Associate Professor of Medicine, UCSF, San Francisco, CA
2012- Professor, Department of Medicine, UCSF School of Medicine
2012- Professor, Department of Community Health Systems, UCSF School of Nursing (joint)
2012- Professor, Department of Clinical Pharmacy, UCSF School of Pharmacy (joint)
2010- Director of Academic Affairs, Center for AIDS Prevention Studies, UCSF, San Francisco, CA

**Other Experience and Professional Memberships**

2000- Ad hoc reviewer for multiple NIH study sections
2009- Member, Behavioral and Social Consequences of HIV/AIDS (BSCH) NIH study section
2013-Present Member, Cross-Network Behavioral Science Advisory Group (BSAG) for the Office of HIV/AIDS Network Coordination (HANC).

**Honors**

2007 APA's Emerging Leader in Psychology and AIDS
2008-2012 Nominated for the AIDS Research Institute's Outstanding Mentoring Award
2011 UCSF Distinction in Mentoring Award
2011 Distinguished Alumni Scholar, University of Alabama at Birmingham

C. Selected Peer-reviewed Publications (Selected from over 100 peer-reviewed publications)

**Most relevant to the current application**


1. Strauss, SE, **Johnson, M.O.,** Marquez, C., Feldman, M. (2013). Characteristics of successful and failed mentoring relationships: qualitative study across 2 institutions. *Academic Medicine, 88(1), 82-9*. PMID:23165266[PubMed - in process] .
2. Soto T, Komaie G, Neilands T.B., **Johnson M.O.** (2013) Exposure to crime and trauma among HIV-infected men who have sex with men: associations with HIV stigma and treatment engagement. *J Assoc Nurses AIDS Care*, *24(4),* 299-307.
3. Duncan L.G., Moskowitz J.T., Neilands T.B., Dilworth S.E., Hecht F.M., **Johnson, M.O.** (2012). Mindfulness-based stress reduction for HIV treatment side effects: a randomized, wait-list controlled trial. *J Pain Symptom Manage, 43(2),* 161-171. PMCID #3252947
4. **Johnson, M.O.**, Dilworth, S.E., Stephens, E., Lum, P.J., & Neilands, T.B. (2011). Expectancy and readiness-based predictors of treatment uptake among the urban poor living with HIV. *Journal of AIDS and Human Retrovirology, 58(5), 469-71.*
5. Zhao, L., Holzemer, W., Tulsky, J., **Johnson M.O.,** and Dawson Rose, C. (2011). HIV Infection as a Predictor of Methadone Maintenance Outcomes in Chinese Injection Drug Users. *AIDS Care, 24(2),* 195-203.
6. **Johnson, M.O.**, Dilworth, S.E., Taylor, J., & Neilands, T.B. (2011). Improving coping skills for self-management of treatment side effects can reduce antiretroviral medication nonadherence among people living with HIV. *Annals of Behavioral Medicine, 41(1),* 83-91. PMCID: 303747.
7. **Johnson, M.O.**, Dilworth, S.E., & Neilands, T.B. (2011). Partner reports of patients' HIV treatment adherence. *Journal of AIDS and Human Retrovirology, 56(4), e117-e118.* NIHMS: 265946.
8. **Johnson, M.O.**, Subak, L., Brown, J.S., Lee, K., and Feldman, M. (2010). An Innovative Program to Train Health Sciences Researchers to be Effective Clinical and Translational-Research Mentors. *Academic Medicine, 85(3),* 484-489. PMCID #2856696.
9. Rotheram-Borus, M.J., Desmond, D., Comulada, S., Arnold, E., **Johnson, M.O.** (2009). Reducing Sexual and Drug Acts among Marginally-Housed HIV+ Adults. *American Journal of Public Health, 99(6), 1100-1107.* PMCID #2679793.
10. Wrubel, J., Stumbo, S. & **Johnson, M.O.** (2008). Antiretroviral medication support practices among partners of men who have sex with men: A qualitative study. *AIDS Patient Care and STDs, 22(11),* 851-858*.* PMCID: 2929154.
11. Wong F.L., Rotheram-Borus M.J., Lightfoot M, Pequegnat W, Comulada W.S., Cumberland W, Weinhardt L.S., Remien R.H., Chesney M, **Johnson M.O.** (2008). Effects of behavioral intervention on substance use among people living with HIV: the Healthy Living Project randomized controlled study. *Addiction, 103(7),* 1206-14. PMCID #2665995.
12. Carrico, A.W., **Johnson, M.O.**, Moskowitz, J.T., Neilands, T.B., Morin, S.F., Charlebois, E.D., Steward, W.T., Remien, R.H., Wong, L.F., Rotheram-Borus, M.J., Lightfoot, M.A., Chesney, M.A., & the NIMH Healthy Living Project Team (2007). Affect regulation, stimulant use, and viral load among HIV-Positive Persons on Anti-Retroviral Therapy. *Psychosomatic Medicine, 69(8)*, 785-792. PMID # 17942835.
13. **Johnson M.O.**, Neilands TB, Dilworth S, Morin SF, Remien RH, Chesney MA.(2007). The Role of Self-Efficacy in HIV Treatment Adherence: Validation of the HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES). *Journal of Behavioral Medicine, 30,* 359-370. PMCID: 2423379.
14. **Johnson M.O.**, Charlebois E, Morin S.F., Remien R.H., Chesney M.A.; National Institute of Mental Health Healthy Living Project team. (2007) Effects of a behavioral intervention on antiretroviral medication

adherence among people living with HIV; the healthy living project randomized controlled study. *J Acquir Immune Defic Syndr, 15:46(5)*, 574-80. PMCID #2442469.
15. **Johnson M.O.,** Catz S.L., Remien R.H., Rotheram-Borus M.J., Morin S.F., Charlebois E, Gore-Felton C, Boldsten RB, Wolfe H, Lightfood M, Chesney M.A.; NIMH Healthy Living Project Team. Theory-guided, empirically supported avenues for intervention on HIV medication non-adherence: findings from the Healthy Living Project. (2003) *AIDS Patient Care STDs*, *17(12);* 645-56.

**D. Research Support**

**Ongoing Research Support**

K24 MH087220 Johnson (PI) 7/1/09-6/30/14
Dyadic processes in the patient-provider relationship.
The purpose of this K24 is to request the necessary funding to (1) provide expanded mentoring of early career clinician-researchers in patient-oriented research (POR), and (2) extend his current research program to the study of patient-provider relationships.
Role: PI

R01 NR010187 Johnson (PI) 8/15/06-5/30/15
Relationship Factors and HIV Treatment Adherence
The purpose of the study is to investigate, through qualitative and quantitative methods, the relationship factors that are associated with adherence to ART. The objective of the study is to identify relationship factors that serve as barriers and facilitators to ART adherence among HIV+ seroconcordant and serodiscordant couples.
Role: PI

R01 MH102198 Johnson & Christopoulos (MPI) 9/1/13-8/30/18
Development and Validation of a Multidimensional Index of Engagement in HIV Care
Framed by a model of Health Care Empowerment, we will develop an Index of Engagement in HIV Care through an iterative process of obtaining input from patients, providers, and research experts. We will then operationalize the index and validate it in a multi-site network of HIV clinical care sites (the CFAR Network of Integrated Clinical Systems) to predict retention in care and virologic suppression.
Role: Co-PI

R01 MH086346 Darbes (PI) 02/01/10-03/30/15
Couples in Context: An RCT of a couples-based HIV prevention intervention in South Africa.
The purpose of this randomized controlled trial is to determine whether participation in a couples-based counseling intervention increases uptake of couples-based HIV testing among couples in South Africa.
Role: Co-I

2U01AI034989-20 Greenblatt (PI) 12/1/97-12/31/17
The Connie Wofsy Women's HIV Study (WIHS)
The WIHS is the largest and longest-duration cohort study of HIV infection in women in the U.S. The study addresses key issues concerning processes and conditions associated with excess morbidity in HIV+ women in the current treatment era.
Role: Co-I

R24MH094274 Gandhi (PI) 7/11/11-6/30/14 (NCE)
The CFAR [Center for AIDS Research] Network of Integrated Clinical Systems (CNICS) group proposes to develop and implement a new comprehensive mentoring program to facilitate successful growth and development of the next generation of HIV investigators with diverse backgrounds to support multidisciplinary HIV research.
Role: Co-I

K23MH097649 Saberi (PI) 6/15/12-4/30/17
Technology-based adaptive treatment strategies for antiretroviral adherence
Role: Mentor

K01 MH093205 Camlin (PI) 1/1/11-12/31/16
Identifying Opportunities for HIV Prevention among Female Migrants in Kenya.
Role: Mentor

K23 MH092220 Christopoulos (PI) 9/1/10-8/30/15
Optimizing Rapid and Full Engagement in Care for Persons with Newly Diagnosed HIV.
Role: Mentor

K23 MH087218 Cocohoba (PI) 4/1/10-3/31/13
Beyond Pill-Counting: Effect of Pharmacist Counseling on Antiretroviral Adherence
Role: Mentor

K08 MH085566 Sevelius (PI) 12/1/08-11/30/13
Culturally relevant interventions for high risk women
Role: Mentor

K01AA021671 Woolf-King (PI) 9/1/13-8/30/18
Alcohol use and high-risk behavior among HIV-positive men
Role: Mentor

**Recently Completed Research Support**

R01 MH079700 Johnson (PI) 7/1/07-5/30/13
Preparing Patients to Start Antiretroviral Therapy: A Randomized Controlled Trial
The primary specific aim is to evaluate the effect of a theory-driven intervention on ART uptake (rates of initiation of ART and time to initiation of ART). The secondary aims are: 1) To examine the effect of the intervention on relevant treatment-related outcomes including CD4 and viral load, and medication adherence among those who initiate ART, and 2)To explore differences in health status and morbidity between the two experimental arms.
Role: PI

R01 MH084723 Moskowitz (PI) 7/18/08-5/31/13
A Positive Affect Intervention for those Recently Diagnosed with HIV
This research builds on these observational findings to determine whether a 5-session theory- and evidence-based intervention designed to teach skills for increasing the frequency and intensity of daily positive affect does so, and whether this intervention has beneficial effects on subsequent psychological well being, health behaviors, and physical health up to 15 months after diagnosis with HIV.
Role: Co-I

R01 MH68208 Johnson (PI) 4/1/04-2/28/10
RCT of an HIV treatment side effects coping intervention.
The specific aims of the study were to 1) Test the effect of a theory-based, cognitive behavioral side effects management intervention on quality of life (QOL) among HIV+ adults taking antiretroviral medications; and 2) To evaluate the impact of the intervention on rates of medication adherence.
Role: PI

F32 MH086323 Saberi (PI) 7/1/09-6/30/12
Quality of sleep in HIV infection: Associations with treatment and adherence.
Role: Sponsor

**Pending Research Support**

K24DA037034 Johnson (PI) 7/1/14-6/30/19
Mentoring and Empowerment in the Context of HIV Care for At-Risk Populations
Role: PI
Application scored 10—pending

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

| NAME<br>Robert D. Kerns, Ph.D. | POSITION TITLE<br>Nat'l Advisor for Pain Research, VACO;<br>Prof. Psychiatry, Neurology, Psychology, Yale;<br>Dir., PRIME Ctr, VA Connecticut HCS |
|---|---|
| eRA COMMONS USER NAME (credential, e.g., agency login) ROBERTKERNS | |

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| West Virginia University, Morgantown WV | B.A. | 05/1974 | Psychology |
| Southern Illinois University, Carbondale, IL | M.A. | 08/1977 | Bioclinical Psychology |
| Southern Illinois University, Carbondale, IL | Ph.D. | 05/1980 | Bioclinical Psychology |
| VA Connecticut Healthcare System, West Haven, CT | Predoctoral Intern | 06/1979 | |

A. Personal Statement

I am a Professor of Psychiatry, Neurology, and Psychology at Yale University, the National Advisor for Pain Research for the Veterans Health Administration, and the Director of the Pain Research, Informatics, Multimorbidities, and Education (PRIME) Center at the VA Connecticut Healthcare System. I am a clinical health psychologist, and am recognized as a national and international leader in the area of theory-based chronic pain behavioral intervention development and testing. Among my most important contributions to the field of pain management, and those most directly relevant to the proposed project, are those related to developing and testing cognitive behavioral interventions for chronic pain in special populations, and development of a conceptual and measurement model for understanding persons' readiness to adopt a self-management approach to chronic pain. These projects include the use of Social Cognitive Theory to develop and understand the mechanism for cognitive behavioral interventions, such as the self-management intervention Dr. Merlin proposes. I have 30+ years of experience in this area, during which I have been continuously funded by the VA and NIH. Additionally, I have significant expertise in the use of prescription opioids for pain management, and currently Chair the Department of Health and Human Services National Action Plan for Prevention of Opioid-Related Adverse Drug Events.

My role in Dr. Merlin's Career Development Award will be to work with her primary mentor Dr. Michael Saag and co-mentor Dr. Mallory Johnson to provide specific, step-by-step expertise and guidance in chronic pain behavioral intervention development and testing. I have a strong mentorship track record, and have served as primary or co-mentor to six individuals during career development awards including three current awardees. All past awardees have gone on to careers as independent investigators. In addition, I will ensure that Dr. Merlin has the opportunity to participate in highly relevant training opportunities at the PRIME center, including shadowing in our interdisciplinary Integrated Pain Clinic and Opioid Reassessment clinic.

B. Positions and Honors

Positions and Employment

1980-1987 Chief, Counseling/Health Psychology Section, VA Medical Center, West Haven, CT
1982-1988 Assistant Clinical Professor of Psychology, Department of Psychiatry, Yale University
1988-1990 Lecturer, Department of Psychology, Yale University, New Haven, CT
1997-2000 Psychologist, Yale Center for Pain Management, Department of Anesthesiology, Yale University School of Medicine, New Haven, CT
1988-2003 Associate Professor, Departments of Psychiatry and Neurology, Yale University School of Medicine
1990-2003 Associate Professor, Department of Psychology, Yale University, New Haven, CT
1987-2008 Chief, Psychology Service, VA Connecticut Healthcare System, West Haven, CT
2005-2013 National Program Director for Pain Management, VA Central Office
2003-present Professor, Departments of Psychiatry and Neurology, Yale University School of Medicine
2003-present Professor, Department of Psychology, Yale University

2008–present Director, Pain Research, Informatics, Multimorbidities, and Education (PRIME) Center, VA Connecticut Healthcare System
2013-present National Advisor for Pain Research, VA Central Office

**Other Experience and Professional Memberships**
Member (or Fellow): American Academy of Pain Medicine, American Pain Society, American Psychological Association, International Association for the Study of Pain, Society of Behavioral Medicine.
Member, Professional Advisory Board, American Chronic Pain Association
Member, Editorial Boards: Annals of Behavioral Medicine, Clinical Journal of Pain, Health Psychology, Journal of Cancer Pain and Palliative Care, Pain Medicine, Psychological Services
Member, Polytrauma/Blast-related Injury QuERI Executive Committee, Veterans Health Administration

**Honors**
Elected Fellow, Society of Behavioral Medicine (1994); Recognized for Outstanding Contributions to Public Service Psychology, American Psychological Association (APA; 1995); Elected Fellow, APA (1996); Recognized by the VHA Employee Education System for Outstanding Contributions to the VHA National Pain Management Strategy (2000), Awarded Extended Educational Leave (Sabbatical) by the VA Connecticut Healthcare System and Yale University (2001); Acknowledged for Outstanding Service to Health Psychology, APA (2001); Honorary Master's Degree, Yale University (2003); Leadership Award, Association of VA Psychologist Leaders (2006); David M. Worthen Award for Academic Excellence, VHA (2006); Mark Wolcott Award for Clinical Leadership, VHA (2006); Patient Advocacy Award, American Academy of Pain Medicine (2008); John and Emma Bonica Public Service Award, American Pain Society (2010); Member, Institute of Medicine Committee on Advancing Pain Research, Care and Education (2010-2011).

C. Selected Peer-reviewed Publications (Selected from 200 peer-reviewed publications)

**Most relevant to the current application**


1. Marcus KS, **Kerns RD**, Rosenfeld B, Breitbart W (2000). HIV/AIDS –related pain as a chronic pain condition: implications of a biopsychosocial model for comprehensive assessment and effective management. *Pain Med*, *1(3):* 260-73.
2. **Kerns, R.D.**, Sellinger, J.J., & Goodin, B. (2011). Psychological treatment of chronic pain. A*nnual Review of Clinical Psychology, 7,* 411-434.
3. Edelman EJ, Gordon K, Becker WC, Goulet JL, Skanderson M, Gaither JR, Brennan Braden J, Gordon AJ, **Kerns RD**, Justice AC, Fiellin DA. (2013). Receipt of opioid analgesics by HIV-infected and uninfected patients. Journal of General Internal Medicine, 28(1), 82-90
4. **Kerns, R.D.**, Burns, J.W., Shulman, M., Jensen, M.P., Nielson, W.R., Czlapinski, R., Dallas, M., Chatkoff, D., Sellinger, J., Heapy, A., & Rosenberger, P. 2013. Can we improve cognitive-behavioral therapy for chronic back pain engagement and adherence? A controlled trial of tailored versus standard therapy? *Health Psychology.* [Epub ahead of print]
5. Burns, J.W., Nielson, W.R., Jensen, M.P., Heapy, A., Czlapinski, R., & **Kerns, R.D.** (in press). Specific and general therapeutic mechanisms in cognitive-behavioral treatment for chronic pain. *Journal of Consulting and Clinical Psychology.*


**Additional recent publications (in chronological order):**


1. Midboe AM, Lewis ET, Cronkite RC, Chambers D, Goldstein MK, **Kerns RD**, Trafton JA (2011). Behavioral medicine perspectives on the design of health information technology to improve decision-making, guideline adherence, and care coordination in chronic pain management. *Translational Behavioral Medi2cine,1(1):*35-44.
2. Goulet JL, Brandt C, Crystal S, Fiellin DA, Gibert C, Gordon AJ, **Kerns RD**, Maisto S, Justice AC. (2013). Agreement between electronic medical record-based and self-administered pain numeric rating scale: clinical and research implications. *Medical Care, 51(3*), 245-50
3. Becker WC, Fraenkel L, Edelman EJ, Holt SR, Glover J, **Kerns RD**, Fiellin DA. (2013). Instruments to assess patient-reported safety, efficacy, or misuse of current opioid therapy for chronic pain: a systematic review. *Pain, 154(6),*905-16.
4. Dorflinger L, **Kerns RD**, Auerbach SM. (2013). Providers' roles in enhancing patients' adherence to pain self management. *Translational Behavioral Medicine, 3(1)*, 39-46
5. Finan PH Burns JW, Jensen MP, Nielson WR, **Kerns** RD (2012). Pain coping but not readiness to change is associated with pretreatment pain-related functioning.*Clinical Journal of Pain, 28(8): 687-92.*

6. Lincoln, L.E., Pellico, L., **Kerns, R.D.,** & Anderson, D. (2013). Barriers and facilitators to chronic non-cancer pain management in primary care: A qualitative analysis of primary care providers' experiences and attitudes. *Journal of Palliative Care and Medicine, S3,* 001.
7. Burgess DJ, Gravely AA, Nelson DB, van Ryn M, Bair MJ, **Kerns RD**, Higgins DM, Partin MR. (2013). A national study of racial differences in pain screening rates in the VA health care system. *Clinical Journal of Pain, 29(2*),118-23
8. Higgins DM, **Kerns RD,** Brandt CA, Haskell SG, Bathulapalli H, Gilliam W, Goulet JL. (2014). Persistent Pain and Comorbidity Among Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn Veterans. *Pain Medicine* [Epub ahead of print]
9. Burgess DJ, Nelson DB, Gravely AA, Bair MJ, **Kerns RD**, Higgins DM, van Ryn M, Farmer M, Partin MR.(2014). Racial differences in prescription of opioid analgesics for chronic non-cancer pain in a national sample of veterans*. Journal of Pain,* [Epub ahead of print]
10. Dorflinger, L.M., Gilliam, W.P., Lee, A.W. & **Kerns, R.D.** (in press). Development and application of an electronic health record information extraction tool to assess quality of pain management in primary care. *Translational Behavioral Medicine.*

D. Research Support

**Ongoing Research Support**

VA HSR&D COIN (CIN 13-407) 10/13-09/18
Pain Research, Informatics, Multimorbidities, and Education (PRIME) Center, West Haven VAMC
The PRIME Center will enhance local and national capacities for a broad research and education agenda focused on pain and pain management, and is designed to serve as a key resource in support of the VHA's National Pain Management Strategy. Its primary research focus is to improve our understanding of the complex interactions between pain and associated chronic disease and behavioral health factors and to develop efficacious interventions that can reduce unnecessary pain and suffering and overall disease burden.
Role: Director

Donaghue Foundation/Mayday Fund Program for Research Leadership 7/10-6/14
Implementing a VA Stepped Care Model of Pain Management
The project examines the implementation of the Stepped Care Model of Pain Management (SCM-PM) at VA Connecticut Healthcare System (VACHS) with goals of improving pain care services and aiding national implementation efforts.
Role: PI

VA HSR&D Merit (IIR 09-058-2) Heapy (PI) 7/10-6/14
IVR-based Cognitive Behavior Therapy for Chronic Low Back Pain
The primary purpose of this study is to test the efficacy of an innovative method, interactive voice response (IVR), for delivering an empirically validated psychological (cognitive behavior therapy [CBT]) treatment for chronic pain in order to improve access and sustainability of this intervention.
Role: Co-I

VA Patient Safety Center of Inquiry Midboe/Trafton Co-PIs 10/12-9/14
Promoting Patient Safety through improved Tools for Opioid Prescribing
The purpose of this project is to implement and evaluate the effectiveness of (1) a dashboard of metrics to assess facility-level adherence to recommended care practices in the VA/DOD Clinical Practice Guideline for Opioid Therapy for Chronic pain, and (2) ATHENA-OT, a computerized decision support system, to facilitate and guide use of these recommended care practices for reducing opioid-related adverse events.
Role: Co-I

VA QUERI RRP (HX001023-01) Lewis, PI 1/13-12/14
Adherence to Practice Recommendations for Veterans with SUDs Receiving Opioids
This project will examine relationships between receipt of guideline-recommended practice for opioid therapy and adverse event and pain management outcomes in patients with SUDs.
Role: Co-I

VA RR&D Pilot Merit Award Weiner (PI) 1/13-12/14

Low back pain in older veterans: Preparing for personalized care
This pilot study will gather data to prepare for a randomized controlled clinical trial that will determine, in older veterans with low back pain (LBP) who receive a lumbar MRI, the functional benefits of personalized pain care administered in a Geriatric Evaluation and Management-Pain (GEM-Pain) clinic as compared to usual care.
Role: Co-I

VA HSR&D CREATE Project (CRE 12-030) Lorenz (PI) 1/13-12/15
Effective Screening for Pain (ESP) Study
Provide an evaluation of a highly scalable, efficient strategy for improving the assessment and documentation of pain (currently missing from many important specialty settings), and provide insight into an implementation strategy to guide that dissemination.
Role: Co-I

VA HSR&D CREATE Project (CRE12-012) Kerns/Brandt/Goulet (Co-PIs) 1/13-12/16
Musculoskeletal Diagnosis (MSD) Cohort: Examining pain and pain care in the VA
The study will identify and characterize Veterans with MSD receiving VA primary care, and examine variation in pain treatment, outcomes, and costs by patient and facility characteristics, using VA administrative data
Role: Co-PI

VA RR&D Merit Award Higgins/Kerns, Co-PIs 7/13-6/15
Development of an Internet-based Behavioral Pain Management Intervention
This pilot study will develop an Internet-based behavioral intervention for chronic low back pain and examine preliminary efficacy, usability, and satisfaction of this intervention.
Role: Co-PI

NIH SBIR 1 R43 TR 000362-01A1 Johnson (PI) 09/13-06/14
Evidence-Based Pain Intervention for Veterans: Leveraging Mobile & Social Media
The primary objective is to develop Sx3: Self Management of Pain, Sleep and Stress Management – a theoretically-grounded, mobile-optimized, Internet-based, interactive pain self-management program.
Role: Site PI

VA HSR&D IHX000911A Hwang (PI) 10/13-09/17
Analgesic Safety and Effectiveness in Older Veterans with Arthritis
This study is designed to determine long-term safety of commonly used analgesic medications in older veterans diagnosed with arthritis, the effectiveness of analgesic medications in older veterans diagnosed with arthritis, and factors that predict positive and negative treatment outcomes.
Role: Co-I

**Completed Research Support**

NCCAM 3R01AT005896-02S1 Goulet, (PI) 10/12-9/13
Integrative Care for Chronic Musculoskeletal Pain in VA Hospitals and Clinics
This project focuses on understanding clinically meaningful outcomes associated with the use of integrative medical services (acupuncture and chiropractic care) for the treatment of chronic pain within everyday practice.
Role: Co-I

VA HSR&D REAP (REA 08-266) 10/08-9/13
Pain Research, Informatics, Medical comorbidities, and Education (PRIME) Center.
This Research Enhancement Award Program (REAP) Center will develop local and national capacity for health services research in the area of pain and pain management
Role: Director

VA RR&D Merit Review B6044R (Kerns) 4/10-3/13
Cognitive-Behavior Therapy for Diabetic Peripheral Neuropathic Pain
This study is the first randomized controlled trial of cognitive-behavior therapy for painful diabetic peripheral neuropathic pain.
Role: PI

## CURRENT AND PENDING SUPPORT

**SAAG, MICHAEL S.**

ACTIVE SUPPORT

5 P30 AI027767 (Saag) $ DC 06/19/09-05/31/14
NIH/NIAID
UAB Center for AIDS Research
Major Goals: The primary purpose of this center is to support interdisciplinary AIDS research efforts. This Center is responsible for the planning, evaluating, managing and documenting a broad array of research activities within the two institutions. The purpose of this project is linking clinical and basic science studies through the use of shared facilities and to translate as quickly as possible fundamental knowledge about AIDS and its related disorders into clinical treatment and prevention programs.

1 U01 AI103401-01 (Saag) $ DC year two 01/01/13-12/31/18
NIH/NIAID
UAB-MISS WIHS Cohort
Major Goals: The Women's Interagency HIV Study (WIHS) is a multicenter longitudinal study funded by the National Institute of Allergy and Infectious Diseases (NIAID), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institute of Drug Abuse (NIDA), and the National Cancer Institute (NCI) to investigate the impact and progression of HIV disease in women.

P30 AI027767 (Saag) $ DC 06/01/11-05/31/14
NIH
Creative and Novel Ideas in HIV Research (CNIHR)
Major Goals: A funding mechanism to attract and mentor international and domestic young investigators from outside the field of HIV/AIDS research to bring promising ideas to this field of study.

1 U01 AI069452 (Saag) $ DC year one 12/01/13-11/30/20
NIH/NIAID
Alabama-Clinical Trials Unit
Major Goals: The Alabama HIV/AIDS CTU is designed to provide an administrative infrastructure that brings Network investigators at UAB together to facilitate the conduct of high capacity, quality-assured, safety-driven clinical trials through provision of administrative support, financial support, communications, staff training, oversight, regulatory support, pharmacy services, synchronization of scientific effort, community relations, and CAB support, and coordination of study personnel in order to achieve maximal efficiency of available staff effort.

1 R24 AG044325 (K High, Wake Forest, PI) $ DC Year one 09/01/13-05/31/18
NIH/NIA
Developing Research at the Interface of HIV and Aging
Role: Co-Investigator
Major Goals: This program identifies pilot projects to forward the work being done in HIV and aging.

1 R24 AI067039 (Saag) $ 09/01/11-08/31/16
PHS/NIH/NIAID
Unsolicited R24 for the CFAR-Network of Integrated Clinical Sciences, CNICS
Major Goals: The CFAR Network of Integrated Clinical Systems (CNICS) project is a multi-site, electronic medical records resource network that can substantially contribute to the contemporary HIV research agenda. As a clinic-based research network, CNICS directly reflects the outcomes of clinical decisions and management options used daily in the care of HIV infected individuals.

1 U01 AA020802 (Saag) $ DC year three 09/10/11-08/31/16
NIH/NIAAA
Integration of Evidence Based Alcohol Interventions into HIV Care
Major Goals: This program seeks to develop a tailored Computer Based Intervention (CBI) that addresses alcohol risks specific to HIV-infected patients.

1 R01 MH097670 (Mugavero) $ DC 04/01/12-3/31/17
NIH/NIMH
Integrating ENGagement and Adherence Goals upon Entry iENGAGE to Control HIV
Major Goals: The main goal is to facilitate patient adjustment to a new diagnosis of HIV infection and to develop the necessary patient motivation and skills for optimal adherence to HIV care and ART.

2 U01 AI069918-06 (R Moore) $ DC 07/01/11-06/30/16
NIH-Johns Hopkins University
Johns Hopkins Subcontract- North American AIDS Cohort Collaboration on Research Design-NA-ACCORD
Major Goals: The NA-ACCORD is a regional collaboration of single-site and multi-site cohorts representing over 50 sites with greater than 60,000 patients from the United States and Canada. It is funded by the NIH as part of the International Epidemiologic Databases to Evaluate AIDS (IeDEA) initiative that is supporting similar collaboration through-out the world. The NA-ACCORD provides a mechanism to combine previously collected data from classical epidemiologic and clinical HIV cohorts to address scientific questions that cannot be addressed in the individual cohorts because of limited sample sizes.

1 U01 AR057954-01 (Crane) $ DC Year five 9/30/2009-7/31/14 (in NCE) NIH/ NIAMS
Patient-reported outcomes in routine clinical care of patients infected with HIV
Major Goals: The proposal is designed to improve medical care and patient outcomes in clinical care as well as to assess the validity of key PROMIS domains most relevant for clinical care among HIV-infected individuals. CNICS has already developed extensive infrastructure for the collection of patient-based measures at multiple clinic sites which will be leveraged by this proposal.

CLINICAL TRIALS

Tobira 652-2-202 (Saag) Tobira 08/23/11 – 08/22/14
A Phase 2b Randomized, Double-Blind, Double-Dummy Trial of 100 or 200 mg Once-Daily Doses of Cenicriviroc (CVC, TBR-652)or Once-Daily EFV, Each With Open-Label FTC/TDF, in HIV-1-
Infected, Antiretroviral Treatment-Naïve, Adult Patients With Only CCR5-Tropic Virus

GSK ING111762 (Saag) Glaxo-Smith-Kline 12/06/10- Present
A Phase III Randomized, Double-blind Study of the Safety and Efficacy of GSK1349572 50 mg Once Daily Versus Raltegravir 400 mg Twice Daily, Both Administered with an Investigator selected Background Regimen Over 48 Weeks in HIV-1 Infected, Integrase Inhibitor-Naïve, Antiretroviral Therapy-Experienced Adult

GS-US-264-0106 (Saag) Gilead 02/03/11- Present
A Phase 3 Randomized, Open-Label Study to Evaluate Switching from Regimens Consisting of a Ritonavir-boosted Protease Inhibitor and Two Nucleoside Reverse Transcriptase Inhibitors to Emtricitabine/Rilpivirine/ Tenofovir Disoproxil Fumarate (FTC/RPV/TDF) Fixed-dose Regimen in Virologically-Suppressed, HIV-1 Infected Patients

BI 1220.47 (201335) (Saag) Boehringer-Ingelheim Pharma 05/18/11-05/17/14
A phase III, randomised, double-blind and placebo-controlled study of once daily BI 201335 120 mg for 24 weeks and BI201335 240 mg for 12 weeks in combination with pegylated interferon-α and ribavirin in treatment-naive patients with genotype 1 chronic hepatitis C infection

GS-US-264-0110 (Saag) Gilead 05/10/11-05/09/14
A Phase 3B, Randomized, Open-label Study to Evaluate the Safety and Efficacy of a Single Tablet Regimen of Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate Compared with a Single Tablet Regimen of Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults

A4001095 (Saag) Pfizer 09/07/11-09/06/15

A Multicenter, Randomized, Double-Blind, Comparative Trial of Maraviroc + Darunavir/Ritonavir Versus Emtricitabine/Tenofovir+Darunavir/Ritonavir for the Treatment of Antiretroviral-Naïve HIV-Infected Patients with CCR5-Tropic HIV-1

AI444-043-016 (Saag) BristolMyersSquibb 02/10/12-01/09/16
A Phase 3, Open Label Study of Safety and Efficacy with BMS-790052 plus Peg-Interferon Alfa 2a and Ribavirin in Previously Untreated HCV Patients Coinfected with Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)

GS-US-334-0107 (Saag) Gilead 04/12/12-04/11/16
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of GS-7977 + Ribavirin for 12 Weeks in Subjects with Chronic Genotype 2 or 3 HCV Infection who are Interferon Intolerant, Interferon Ineligible or Unwilling to Take Interferon

GS-US-334-0109 (Saag) Gilead 05/29/12-05/28/14
An Open-Label Study to Evaluate the Safety of GS-7977+ Ribavirin for 12 Weeks in Subjects with Chronic HCV Infection Who Participated in a Gilead or Pharmasset Sponsored Clinical Study of GS-7977 (PSI-7977)

GS-US-334-0110 (Saag) Gilead 05/18/15-05/17/14
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of GS-7977 +Ribavirin for 12 Weeks in Treatment-Naïve Subjects with Chronic Genotype 1, 4, 5 or 6 HCV Infection

LAI 116482 (Saag) Glaxo-Smith-Kline 09/12/12-09/11/16
A Phase IIb, Dose Ranging Study of Oral GSK1265744 in combination with Nucleoside Reverse Transcriptase Inhibitors for Induction of HIV-1 Virologic Suppression followed by an Evaluation of Maintenance of Virologic Suppression when Oral GSK1265744 is Combined with Oral Rilpivirine in HIV-1 Infected, Antiretroviral Therapy-Naive Adult Subjects

Gilead GS-US-337-0102 (Saag) Gilead 10/04/12-10/03/16
This clinical trial is for HCV Treatment-naïve patients & is currently under review at WIRB

Gilead GS-US-311-1089 (Saag) Gilead 10/04/12-10/03/16
This clinical trial is for HCV Treatment-naïve patients & is currently under review at WIRB

## CURRENT AND PENDING SUPPORT

**JOHNSON, MALLORY**

ACTIVE:

R01MH102198 (Johnson [Contact], Christopoulos) $ 08/14/13-06/30/18
NIH/NIMH
Development and Validation of a Multidimensional Index of Engagement in HIV Care
Major Goals: The purpose of this project is to develop and validate a patient-centered metric of engagement in HIV care.

R01MH086346 (Darbes) $ 03/01/10-02/28/15
NIH/NIMH
Couples in Context: An RCT of a couples-based HIV prevention intervention
Major Goals: The purpose of the proposed study is to compare a couples-based intervention comprised of 2 group sessions and 4 couples' counseling sessions to a single group session comparison group on rates of testing for HIV and reduction of sexual risk behavior among heterosexual couples living in Soweto, South Africa.

P30MH062246 (Morin) $ 09/01/11-08/31/16
NIH/NIMH
Center for AIDS Prevention Studies (CAPS) – Administrative Core
Major Goals: This NIMH Center grant is devoted to supporting rigorous theory-based research that will have the maximum impact in the theory, practice and policy of HIV prevention.

R34MH102109-01A1 (Sevelius) $ 01/01/14-12/31/16
NIH/NIMH
Major Goals: SHEROES: Culturally relevant sexual risk reduction among high-risk women
To conduct a pilot randomized controlled trial of a theory-driven, culturally grounded HIV prevention, testing, and treatment intervention for high-risk transgender women. *Effort will be provided as needed.*

PENDING:

K24DA037034-01 (Johnson) $ 07/01/14-06/30/19
NIH/NIDA
Mentoring and Empowerment in the Context of HIV Care for At-Risk Populations
Major Goals: The purpose of this K24 application is to support the continuation and proposed expansions of Dr. Mallory Johnson's programs of mentoring and patient-oriented research (POR) in social and behavioral approaches to optimizing engagement in HIV care among drug-using populations.

## CURRENT AND PENDING SUPPORT

**Kerns, Robert**

ACTIVE

CIN 13-407 (Kerns) $ 10/2013-09/2018
VA HSR&D
Pain Research, Informatics, Multimorbidities, and Education (PRIME) Center, West Haven VAMC
Major Goals: The PRIME Center will enhance local and national capacities for a broadly conceived research and education agenda focused on pain and pain management, and is designed to serve as a key resource in support of the VHA's National Pain Management Strategy. The primary research focus of the PRIME Center will be to improve our understanding of the complex interactions between pain and associated chronic disease and behavioral health factors and to develop efficacious interventions that can reduce unnecessary pain and suffering and overall disease burden.
Role: Director

(Kerns) $ 07/2010-06/2014 Donaghue Foundation/Mayday Fund
Implementing a VA Stepped Care Model of Pain Management
Major Goals: The project will examine the implementation of the Stepped Care Model of Pain Management (SCM-PM) at VA Connecticut Healthcare System (VACHS) with goals of improving pain care services and aiding national implementation efforts. The study will evaluate processes of implementation to determine best practice models for broader dissemination and implementation
Role: PI

IIR 09-058 (Heapy) $ 07/2010-06/2014
VA HSR&D
Major Goals: IVR-based Cognitive Behavior Therapy for Chronic Low Back Pain
The primary purpose of this study is to test the efficacy of an innovative method, interactive voice response (IVR), for delivering an empirically validated psychological (cognitive behavior therapy [CBT]) treatment for chronic pain in order to improve access and sustainability of this intervention.
Role: Co-I

Midboe (Trafton) $ 10/2012-09/2014
VA Patient Safety Center of Inquiry
Promoting Patient Safety through improved Tools for Opioid Prescribing
Major Goals: The purpose of this project is to implement and evaluate the effectiveness of (1) a dashboard of metrics to assess facility-level adherence to recommended care practices in the VA/DOD Clinical Practice Guideline for Opioid Therapy for Chronic pain, and (2) ATHENA-OT, a computerized decision support system, to facilitate and guide use of these recommended care practices for reducing opioid-related adverse events and improving pain management.
Role: Co-I

HX001023-01 (Lewis) $ 01/2013-12/2014
VA QUERI RRP
Adherence to Practice Recommendations for Veterans with SUDs Receiving Opioids
Major Goals: This project will examine relationships between receipt of guideline-recommended practice for opioid therapy and adverse event and pain management outcomes in patients with SUDs.
Role: Co-I

VA RR&D (Weiner) 01/2013-12/2014
Pilot Merit Award
Low back pain in older veterans: Preparing for personalized care
Major Goals: This pilot study will gather data to prepare for a randomized controlled clinical trial that will determine, in older veterans with low back pain (LBP) who receive a lumbar MRI, the functional benefits of

personalized pain care administered in a Geriatric Evaluation and Management-Pain (GEM-Pain) clinic as compared to usual care.
Role: Co-I

CREATE 12-012 (Lorenz) $ 10/2012-09/2015
VA HSR&D
Effective Screening for Pain Study
Major Goals: Provide an evaluation of a highly scalable, efficient strategy for improving the assessment and documentation of pain (currently missing from many important specialty settings), and provide insight into an implementation strategy to guide that dissemination.

CREATE (Kerns, Co-PI) $ 10/2012-09/2016 VA HSR&D
$349,998
Musculoskeletal Diagnoses Cohort: Examining Pain and Pain Care in the VA
Major Goals: This project will identify and characterize Veterans with musculoskeletal diagnoses (MSD), assess variation in treatment and outcomes, and estimate the costs of MSD care, by patient, facility characteristics, and clinical characteristics.
Role: Co-I

IIR (Higgins/Kerns) $ 07/2013-06/2015
VA RR&D
Development of an Internet-based Behavioral Pain Management Intervention
Major Goals: The primary objectives of the proposed study are to: (1) develop an integrative, Internet-based, Veteran-centered behavioral intervention, the Veteran Pain Management Resource Center (VPMRC) for chronic low back pain (CLBP) and (2) examine preliminary efficacy, usability, and satisfaction of this intervention in a representative sample of Veterans with CLBP.
Role: Co-PI

1 R43 TR 000362-01A1(Kerns, Site PI) $ 09/2013-06/2014
NIH SBIR (Johnson, PI)
Evidence-Based Pain Intervention for Veterans: Leveraging Mobile & Social Media
Major Goals: The primary objective is to develop Sx3: Self Management of Pain, Sleep and Stress Management – a theoretically-grounded, mobile-optimized, Internet-based, interactive pain self-management program for chronic musculoskeletal pain.
Role: PI

IHX000911A (Hwang) $ 10/2013-09/2017
HSR&D
Analgesic Safety and Effectiveness in Older Veterans with Arthritis
Major Goals: Specific Aims (SA) comparing safety and effectiveness for this proposal are as follows: Determine the long-term safety of commonly used analgesic medications in older veterans diagnosed with arthritis, determine the effectiveness of commonly used analgesic medications in older veterans diagnosed with arthritis, and to determine the factors that predict positive and negative treatment outcomes for veterans diagnosed with arthritis.
Role: Co-I

<u>PENDING</u>
None

OMB Number: 4040-0001
Expiration Date: 06/30/2016

# RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

**ORGANIZATIONAL DUNS*:** 0636907050000

**Budget Type*:** ● Project ❍ Subaward/Consortium

**Enter name of Organization:** University of Alabama at Birmingham

**Start Date*:** 12-01-2014 **End Date*:** 11-30-2015 **Budget Period: 1**

**A. Senior/Key Person**

| | Prefix | First Name* | Middle Name | Last Name* | Suffix | Project Role* | Base Salary ($) | Calendar Months | Academic Months | Summer Months | Requested Salary ($)* | Fringe Benefits ($)* | Funds Requested ($)* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 . | | Jessica | | Merlin | M.D. | PD/PI | | 10.28 | | | | | |

**Total Funds Requested for all Senior Key Persons in the attached file**

**Additional Senior Key Persons:** File Name:

**Total Senior/Key Person**

**B. Other Personnel**

| Number of Personnel* | Project Role* | Calendar Months | Academic Months | Summer Months | Requested Salary ($)* | Fringe Benefits* | Funds Requested ($)* |
|---|---|---|---|---|---|---|---|
| 0 | Post Doctoral Associates | 0.00 | | | 0.00 | 0.00 | 0.00 |
| 0 | Graduate Students | 0.00 | | | 0.00 | 0.00 | 0.00 |
| | Undergraduate Students | | | | | | |
| | Secretarial/Clerical | | | | | | |
| 1 | Statistician | 0.36 | | | | | |
| 1 | Interviewer | 1.00 | | | | | |
| 1 | Research Assistant | 2.00 | | | | | |
| 1 | Qualitative Analyst | 1.20 | | | | | |
| **4** | **Total Number Other Personnel** | | | | | **Total Other Personnel** | |

**Total Salary, Wages and Fringe Benefits (A+B)**

RESEARCH & RELATED Budget {A-B} (Funds Requested)





Funding Opportunity Number: PA-14-049 . Received Date: 2014-04-24T11:32:34.000-04:00

# RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

**ORGANIZATIONAL DUNS*:** 0636907050000

**Budget Type*:** ● Project ❍ Subaward/Consortium

**Organization:** University of Alabama at Birmingham

**Start Date*:** 12-01-2014 **End Date*:** 11-30-2015 **Budget Period: 1**

| **C. Equipment Description** | |
|---|---|
| List items and dollar amount for each item exceeding $5,000 | |
| **Equipment Item** | **Funds Requested ($)*** |
| **Total funds requested for all equipment listed in the attached file** | |
| **Total Equipment** | |
| **Additional Equipment:** File Name: | |

| **D. Travel** | **Funds Requested ($)*** |
|---|---|
| 1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions) | |
| 2. Foreign Travel Costs | 0.00 |
| **Total Travel Cost** | |

| **E. Participant/Trainee Support Costs** | | **Funds Requested ($)*** |
|---|---|---|
| 1. Tuition/Fees/Health Insurance | | 0.00 |
| 2. Stipends | | 0.00 |
| 3. Travel | | 0.00 |
| 4. Subsistence | | 0.00 |
| 5. Other: | | |
| **Number of Participants/Trainees** | **Total Participant Trainee Support Costs** | **0.00** |

RESEARCH & RELATED Budget {C-E} (Funds Requested)

# RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

**ORGANIZATIONAL DUNS*:** 0636907050000

**Budget Type*:** ● Project ❍ Subaward/Consortium

**Organization:** University of Alabama at Birmingham

**Start Date*:** 12-01-2014 **End Date*:** 11-30-2015 **Budget Period: 1**

| F. Other Direct Costs | Funds Requested ($)* |
|---|---|
| 1. Materials and Supplies | 0.00 |
| 2. Publication Costs | 0.00 |
| 3. Consultant Services | 0.00 |
| 4. ADP/Computer Services | 0.00 |
| 5. Subawards/Consortium/Contractual Costs | 0.00 |
| 6. Equipment or Facility Rental/User Fees | 0.00 |
| 7. Alterations and Renovations | 0.00 |
| 8 . Participant Incentives | |
| 9 . Regulatory Assistance | |
| 10 . Programming / Transcription | |
| **Total Other Direct Costs** | |

| G. Direct Costs | Funds Requested ($)* |
|---|---|
| **Total Direct Costs (A thru F)** | |

**H. Indirect Costs**

| Indirect Cost Type | Indirect Cost Rate (%) | Indirect Cost Base ($) | Funds Requested ($)* |
|---|---|---|---|
| 1 . Modified Total Direct Cost | 8.00 | | |
| | | **Total Indirect Costs** | |

**Cognizant Federal Agency** (Agency Name, POC Name, and POC Phone Number): DHHS, Steven Zuraf (301)492-4855

| I. Total Direct and Indirect Costs | Funds Requested ($)* |
|---|---|
| **Total Direct and Indirect Institutional Costs (G + H)** | |

| J. Fee | Funds Requested ($)* |
|---|---|
| | **0.00** |

**K. Budget Justification*** File Name: 1234-BUDGET_JUSTIF_final.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)



Tracking Number: GRANT11635420 Funding Opportunity Number: PA-14-049 . Received Date: 2014-04-24T11:32:34.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

# RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

**ORGANIZATIONAL DUNS*:** 0636907050000

**Budget Type*:** ● Project ❍ Subaward/Consortium

**Enter name of Organization:** University of Alabama at Birmingham

**Start Date*:** 12-01-2015 **End Date*:** 11-30-2016 **Budget Period: 2**

**A. Senior/Key Person**

| | Prefix | First Name* | Middle Name | Last Name* | Suffix | Project Role* | Base Salary ($) | Calendar Months | Academic Months | Summer Months | Requested Salary ($)* | Fringe Benefits ($)* | Funds Requested ($)* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 . | | Jessica | | Merlin | M.D. | PD/PI | | 10.28 | | | | | |

**Total Funds Requested for all Senior Key Persons in the attached file**

**Additional Senior Key Persons:** File Name:

**Total Senior/Key Person**

**B. Other Personnel**

| Number of Personnel* | Project Role* | Calendar Months | Academic Months | Summer Months | Requested Salary ($)* | Fringe Benefits* | Funds Requested ($)* |
|---|---|---|---|---|---|---|---|
| | Post Doctoral Associates | | | | | | |
| | Graduate Students | | | | | | |
| | Undergraduate Students | | | | | | |
| | Secretarial/Clerical | | | | | | |
| 1 | Statistician | 0.36 | | | | | |
| 1 | Interviewer | 0.96 | | | | | |
| 1 | Research Assistant | 0.48 | | | | | |
| 1 | Qualitative Analyst | 2.16 | | | | | |
| 1 | Interventionist | 0.36 | | | | | |
| **5** | **Total Number Other Personnel** | | | | | **Total Other Personnel** | |

**Total Salary, Wages and Fringe Benefits (A+B)**

RESEARCH & RELATED Budget {A-B} (Funds Requested)





Funding Opportunity Number: PA-14-049 . Received Date: 2014-04-24T11:32:34.000-04:00

# RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

**ORGANIZATIONAL DUNS*:** 0636907050000

**Budget Type*:** ● Project ❍ Subaward/Consortium

**Organization:** University of Alabama at Birmingham

**Start Date*:** 12-01-2015 **End Date*:** 11-30-2016 **Budget Period: 2**

| **C. Equipment Description** | |
|---|---|
| List items and dollar amount for each item exceeding $5,000 | |
| **Equipment Item** | **Funds Requested ($)*** |
| **Total funds requested for all equipment listed in the attached file** | |
| **Total Equipment** | |
| **Additional Equipment:** File Name: | |

| **D. Travel** | **Funds Requested ($)*** |
|---|---|
| 1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions) | |
| 2. Foreign Travel Costs | 0.00 |
| **Total Travel Cost** | |

| **E. Participant/Trainee Support Costs** | | **Funds Requested ($)*** |
|---|---|---|
| 1. Tuition/Fees/Health Insurance | | |
| 2. Stipends | | 0.00 |
| 3. Travel | | |
| 4. Subsistence | | 0.00 |
| 5. Other: | | |
| **1 Number of Participants/Trainees** | **Total Participant Trainee Support Costs** | |

RESEARCH & RELATED Budget {C-E} (Funds Requested)

# RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

**ORGANIZATIONAL DUNS*:** 0636907050000

**Budget Type*:** ● Project ❍ Subaward/Consortium

**Organization:** University of Alabama at Birmingham

**Start Date*:** 12-01-2015 **End Date*:** 11-30-2016 **Budget Period: 2**

| F. Other Direct Costs | Funds Requested ($)* |
|---|---|
| 1. Materials and Supplies | 0.00 |
| 2. Publication Costs | 0.00 |
| 3. Consultant Services | 0.00 |
| 4. ADP/Computer Services | 0.00 |
| 5. Subawards/Consortium/Contractual Costs | 0.00 |
| 6. Equipment or Facility Rental/User Fees | 0.00 |
| 7. Alterations and Renovations | 0.00 |
| 8 . Participant Incentives | |
| 9 . Regulatory Assistance | |
| 10 . Transcription | |
| **Total Other Direct Costs** | |

| G. Direct Costs | Funds Requested ($)* |
|---|---|
| **Total Direct Costs (A thru F)** | |

**H. Indirect Costs**

| Indirect Cost Type | Indirect Cost Rate (%) | Indirect Cost Base ($) | Funds Requested ($)* |
|---|---|---|---|
| 1 . Modified Total Direct Costs | 8.00 | | |
| | | **Total Indirect Costs** | |

**Cognizant Federal Agency** (Agency Name, POC Name, and POC Phone Number): DNNS, Steven Zuraf (301) 492-4855

| I. Total Direct and Indirect Costs | Funds Requested ($)* |
|---|---|
| **Total Direct and Indirect Institutional Costs (G + H)** | |

| J. Fee | Funds Requested ($)* |
|---|---|
| | **0.00** |

**K. Budget Justification*** File Name: 1234-BUDGET_JUSTIF_final.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

# RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

**ORGANIZATIONAL DUNS*:** 0636907050000

**Budget Type*:** ● Project ❍ Subaward/Consortium

**Enter name of Organization:** University of Alabama at Birmingham

**Start Date*:** 12-01-2016 **End Date*:** 11-30-2017 **Budget Period: 3**

**A. Senior/Key Person**

| | Prefix | First Name* | Middle Name | Last Name* | Suffix | Project Role* | Base Salary ($) | Calendar Months | Academic Months | Summer Months | Requested Salary ($)* | Fringe Benefits ($)* | Funds Requested ($)* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 . | | Jessica | | Merlin | M.D. | PD/PI | | 10.28 | | | | | |

**Total Funds Requested for all Senior Key Persons in the attached file**

**Additional Senior Key Persons:** File Name:

**Total Senior/Key Person**

**B. Other Personnel**

| Number of Personnel* | Project Role* | Calendar Months | Academic Months | Summer Months | Requested Salary ($)* | Fringe Benefits* | Funds Requested ($)* |
|---|---|---|---|---|---|---|---|
| | Post Doctoral Associates | | | | | | |
| | Graduate Students | | | | | | |
| | Undergraduate Students | | | | | | |
| | Secretarial/Clerical | | | | | | |
| 1 | Statistician | 0.36 | | | | | |
| 1 | Interviewer | 0.66 | | | | | |
| 1 | Research Assistant | 0.42 | | | | | |
| 1 | Qualitative Analyst | 2.40 | | | | | |
| 1 | Interventionist | 1.15 | | | | | |
| **5** | **Total Number Other Personnel** | | | | | **Total Other Personnel** | |

**Total Salary, Wages and Fringe Benefits (A+B)**

RESEARCH & RELATED Budget {A-B} (Funds Requested)





Funding Opportunity Number: PA-14-049 . Received Date: 2014-04-24T11:32:34.000-04:00

# RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

**ORGANIZATIONAL DUNS*:** 0636907050000

**Budget Type*:** ● Project ❍ Subaward/Consortium

**Organization:** University of Alabama at Birmingham

**Start Date*:** 12-01-2016 **End Date*:** 11-30-2017 **Budget Period: 3**

| **C. Equipment Description** | |
|---|---|
| List items and dollar amount for each item exceeding $5,000 | |
| **Equipment Item** | **Funds Requested ($)*** |
| **Total funds requested for all equipment listed in the attached file** | |
| **Total Equipment** | |
| **Additional Equipment:** File Name: | |

| **D. Travel** | **Funds Requested ($)*** |
|---|---|
| 1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions) | |
| 2. Foreign Travel Costs | |
| **Total Travel Cost** | |

| **E. Participant/Trainee Support Costs** | | **Funds Requested ($)*** |
|---|---|---|
| 1. Tuition/Fees/Health Insurance | | 0.00 |
| 2. Stipends | | 0.00 |
| 3. Travel | | 0.00 |
| 4. Subsistence | | 0.00 |
| 5. Other: | | |
| **Number of Participants/Trainees** | **Total Participant Trainee Support Costs** | **0.00** |

RESEARCH & RELATED Budget {C-E} (Funds Requested)

# RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

**ORGANIZATIONAL DUNS*:** 0636907050000

**Budget Type*:** ● Project ❍ Subaward/Consortium

**Organization:** University of Alabama at Birmingham

**Start Date*:** 12-01-2016 **End Date*:** 11-30-2017 **Budget Period: 3**

| F. Other Direct Costs | Funds Requested ($)* |
|---|---|
| 1. Materials and Supplies | 0.00 |
| 2. Publication Costs | 0.00 |
| 3. Consultant Services | 0.00 |
| 4. ADP/Computer Services | 0.00 |
| 5. Subawards/Consortium/Contractual Costs | 0.00 |
| 6. Equipment or Facility Rental/User Fees | 0.00 |
| 7. Alterations and Renovations | 0.00 |
| 8 . Participant Incentives | |
| 9 . Regulatory Assistance | |
| 10 . Data Queries / Transcription | |
| **Total Other Direct Costs** | |

| G. Direct Costs | Funds Requested ($)* |
|---|---|
| **Total Direct Costs (A thru F)** | |

**H. Indirect Costs**

| Indirect Cost Type | Indirect Cost Rate (%) | Indirect Cost Base ($) | Funds Requested ($)* |
|---|---|---|---|
| 1 . Modified Total Direct Costs | 8.00 | | |
| | | **Total Indirect Costs** | |

**Cognizant Federal Agency** (Agency Name, POC Name, and POC Phone Number): DHHS, Steven Zuraf (301) 492-4855

| I. Total Direct and Indirect Costs | Funds Requested ($)* |
|---|---|
| **Total Direct and Indirect Institutional Costs (G + H)** | |

| J. Fee | Funds Requested ($)* |
|---|---|
| | **0.00** |

**K. Budget Justification*** File Name: 1234-BUDGET_JUSTIF_final.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

# RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

**ORGANIZATIONAL DUNS*:** 0636907050000

**Budget Type*:** ● Project ❍ Subaward/Consortium

**Enter name of Organization:** University of Alabama at Birmingham

**Start Date*:** 12-01-2017 **End Date*:** 11-30-2018 **Budget Period: 4**

**A. Senior/Key Person**

| | Prefix | First Name* | Middle Name | Last Name* | Suffix | Project Role* | Base Salary ($) | Calendar Months | Academic Months | Summer Months | Requested Salary ($)* | Fringe Benefits ($)* | Funds Requested ($)* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 . | | Jessica | | Merlin | M.D. | PD/PI | | 10.28 | | | | | |

**Total Funds Requested for all Senior Key Persons in the attached file**

**Additional Senior Key Persons:** File Name:

**Total Senior/Key Person**

**B. Other Personnel**

| Number of Personnel* | Project Role* | Calendar Months | Academic Months | Summer Months | Requested Salary ($)* | Fringe Benefits* | Funds Requested ($)* |
|---|---|---|---|---|---|---|---|
| | Post Doctoral Associates | | | | | | |
| | Graduate Students | | | | | | |
| | Undergraduate Students | | | | | | |
| | Secretarial/Clerical | | | | | | |
| 1 | Statistician | 0.36 | | | | | |
| 1 | Interviewer | 0.60 | | | | | |
| 1 | Qualitative Analyst | 1.80 | | | | | |
| **3** | **Total Number Other Personnel** | | | | | **Total Other Personnel** | |

**Total Salary, Wages and Fringe Benefits (A+B)**

RESEARCH & RELATED Budget {A-B} (Funds Requested)



Tracking Number: GRANT11635420
Funding Opportunity Number: PA-14-049 . Received Date: 2014-04-24T11:32:34.000-04:00

# RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

**ORGANIZATIONAL DUNS*:** 0636907050000

**Budget Type*:** ● Project ❍ Subaward/Consortium

**Organization:** University of Alabama at Birmingham

**Start Date*:** 12-01-2017 **End Date*:** 11-30-2018 **Budget Period: 4**

**C. Equipment Description**

List items and dollar amount for each item exceeding $5,000

| **Equipment Item** | **Funds Requested ($)*** |
|---|---|
| **Total funds requested for all equipment listed in the attached file** | |
| **Total Equipment** | |

**Additional Equipment:** File Name:

| **D. Travel** | **Funds Requested ($)*** |
|---|---|
| 1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions) | |
| 2. Foreign Travel Costs | |
| **Total Travel Cost** | |

| **E. Participant/Trainee Support Costs** | | **Funds Requested ($)*** |
|---|---|---|
| 1. Tuition/Fees/Health Insurance | | 0.00 |
| 2. Stipends | | 0.00 |
| 3. Travel | | 0.00 |
| 4. Subsistence | | 0.00 |
| 5. Other: | | |
| **Number of Participants/Trainees** | **Total Participant Trainee Support Costs** | **0.00** |

RESEARCH & RELATED Budget {C-E} (Funds Requested)

# RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

**ORGANIZATIONAL DUNS*:** 0636907050000

**Budget Type*:** ● Project ❍ Subaward/Consortium

**Organization:** University of Alabama at Birmingham

**Start Date*:** 12-01-2017 **End Date*:** 11-30-2018 **Budget Period: 4**

| F. Other Direct Costs | Funds Requested ($)* |
|---|---|
| 1. Materials and Supplies | 0.00 |
| 2. Publication Costs | 0.00 |
| 3. Consultant Services | 0.00 |
| 4. ADP/Computer Services | 0.00 |
| 5. Subawards/Consortium/Contractual Costs | 0.00 |
| 6. Equipment or Facility Rental/User Fees | 0.00 |
| 7. Alterations and Renovations | 0.00 |
| 8 . Participant Incentives | |
| 9 . Regulatory Assistance | |
| 10 . Programming / Data Queries / Transcription | |
| **Total Other Direct Costs** | |

| G. Direct Costs | Funds Requested ($)* |
|---|---|
| **Total Direct Costs (A thru F)** | |

**H. Indirect Costs**

| Indirect Cost Type | Indirect Cost Rate (%) | Indirect Cost Base ($) | Funds Requested ($)* |
|---|---|---|---|
| 1 . Modified Total Direct Cost | 8.00 | | |
| | | **Total Indirect Costs** | |

**Cognizant Federal Agency** (Agency Name, POC Name, and POC Phone Number): DHHS, Steven Zuraf (301) 492-4855

| I. Total Direct and Indirect Costs | Funds Requested ($)* |
|---|---|
| **Total Direct and Indirect Institutional Costs (G + H)** | |

| J. Fee | Funds Requested ($)* |
|---|---|
| | **0.00** |

**K. Budget Justification*** File Name: 1234-BUDGET_JUSTIF_final.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

## BUDGET JUSTIFICATION

***Personnel***

**Jessica Merlin, MD MBA (Principal Investigator): 10 calendar months, 80% effort, all years.** Dr. Merlin is an Assistant Professor of Medicine in the Divisions of Infectious Diseases and Gerontology, Geriatrics, and Palliative Care at the University of Alabama at Birmingham (UAB). Her training in infectious diseases and palliative care, role as the director of the 1917 HIV/Chronic Pain clinic, and significant expertise and national recognition in this area uniquely position her to be the Principal Investigator on the project described in this application. She will be primarily responsible for the conduct of the research, including finalization of study protocols; training of study staff; oversight of data collection, analysis, and manuscript preparation; and development of related grant applications. We are requesting the full salary allowed by the K23, plus associated fringe benefits at UAB's FY2015 rate, which is 27%.

Notably, NIMH policy necessitates a 4-year budget period for this project. We have taken advantage of this timeline to allow for both intervention development and testing during the study period.

**Michael Saag, MD (Sponsor and Primary Mentor): 0.0 calendar months.** Dr. Saag is a Professor of Medicine in the Division of Infectious Diseases at UAB. He is the national PI for the Center for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS) and Director of the UAB CFAR. Dr. Saag is a nationally and internationally renowned scientist with 25 years of experience in HIV outcomes research, including behavioral clinical trials. Dr. Saag will serve as Dr. Merlin's primary mentor, and will oversee her research and career development activities during the award period.

**TBN (Research Assistant): 2.0 calendar months, 17% effort, year 1; 0.48 calendar months, 4% effort, year 2; 0.42 calendar months, 3.5% effort, year 3.** A research assistant on staff with the Research and Informatics Service Center (RISC – see Facilities and Other Resources) will recruit participants from the 1917 Clinic. RISC research assistants are in the clinic full time to facilitate telephone recruitment in in-person screening. He/she will recruit patient participants for Aim 1 Steps 3 and 4 and Aim 2.

**Melonie Walcott, DrPh (Interviewer): 1 calendar month, 8.5% effort, year 1; 1 calendar month, 8.5% effort, year 2; 0.66 calendar months, 5.5% effort, year 3; 0.6 calendar months, 5% effort, year 4.** Dr. Walcott recently completed her DrPh in Health Behavior and joined the Research and Informatics Service Center (RISC) in early 2013. She is the study coordinator for Dr. Merlin's current institutional K12 career development award, during which she has conducted all study interviews and participated in qualitative data analysis. She has extensive experience conducting not only interviews, but also focus groups, in other studies. For this project, Dr. Walcott will similarly conduct all interviews and focus groups in Aims 1 and 2, and work with Drs. Merlin and Herbey (see below) on qualitative data analysis. Dr. Walcott will travel to PRIME in Year 1 to receive training in the Structured Clinical Interview for DSM (SCID) and to Indiana University in Year 2 to receive training on ensuring fidelity to intervention delivery (see Travel, below).

**TBN (Interventionist): 0.36 calendar months, 3% effort, year 2; 1.15 calendar months, 9.6% effort, year 3.** The UAB CFAR, RISC, and the 1917 clinic have several staff who have bachelors or masters level training (e.g., Social Worker, Nurse Case Manager) who actively participate in research activities and have served as behavioral interventionists on other studies within the UAB 1917 Cohort. We will recruit our study interventionist from this highly qualified pool. We have budgeted as if the pilot trial includes individual, rather than group, intervention sessions, which would require more of the interventionist's time.

**Ivan Herbey, PhD (Qualitative Analyst): 1.2 calendar months, 10% effort, year 1; 2.16 calendar months, 18% effort, year 2; 2.4 calendar months, 20% effort, year 3; 1.8 calendar months, 15% effort, year 4:** Dr. Herbey has worked closely with Drs. Merlin and Walcott on qualitative analyses for Dr. Merlin's K12. His role in this project will be similar. He will conduct qualitative analyses of all interviews and focus groups in conjunction with Drs. Merlin and Walcott.

**Andrew Westfall, MS (Statistician): 0.36 calendar months, 3% effort, all years.** Mr. Westfall is a statistician with 19+ years of experience in biostatistics and data analysis at UAB. He is the primary CFAR statistician, and has collaborated with numerous CFAR and CNICS investigators on analyses similar to those proposed for this

project. In particular, Mr. Westfall has worked with Dr. Merlin on all of her studies to date at the UAB 1917 Clinic Cohort, leading to 4 co-authored publications and 2 publications under review. Mr. Westfall will assist Dr. Merlin with organization and reporting of descriptive data in Aim 1 Steps 3 and 4, and randomization and quantitative analyses of the pilot trial in Aim 2.

***Non-Personnel Expenses***

**Travel Expenses**:

- Dr. Merlin will present results related to this study at 2 national conferences each year: $2,500/year.
- Dr. Merlin will travel to meet with her advisor Dr. Robert Kerns and engage in hands-on learning experiences at the PRIME Center for 2 weeks each year: $2000/year.
- Dr. Walcott will join Dr. Merlin during her trip to the PRIME Center, in order to receive training from Dr. Kerns and his team of psychiatrists/psychologists on the SCID interview: $1500 in Year 1.
- Dr. Merlin will participate in the Johns Hopkins Summer Research Institute on Developing Behavioral Interventions. This is an intensive 3 day course held on the Johns Hopkins campus: $2,500 in Year 2.
- Drs. Merlin and Walcott, and the interventionist, will travel to visit Dr. Bair to receive training on intervention delivery including fidelity: $3500 in Year 2.

***Other Expenses***

Coursework: The Johns Hopkins course requires tuition of $2500. The NIH Office of Behavioral and Social Science Research intensive course is provided without cost to participants. All UAB courses are free.

Data Queries: Data analysts in the RISC will perform complex data queries during years 1-3 to identify patients for recruitment. This will involve obtaining and cleaning data from 3 distinct databases, and creating the data query elements prior to queries monthly. Costs will total $ which will be billed in Years 3 and 4.

Programming: In Year 1, the RISC Informatics Core staff will program the Patient Reported Outcome measures (PROs) that are not routinely part of CNICS, and therefore must be programmed specifically for this study (e.g., Brief Chronic Pain Screening tool, SF-36). A fee of $ will be charged for this service.

Participant Incentives: *Aim 1, Step 3:* Forty patient participants will complete the structured interview/PROs and subsequent in-depth interview or focus group, totaling 2 hours. They will receive a $ incentive payment. We plan to enroll 10 providers/stakeholders in interviews/focus groups for which we will provide a $ gift card. *Aim 1, Step 4:* We plan to recruit 10 patient participants to enroll in the pre-test of the intervention. Each patient will participate in several study sessions (we will budget for six sessions, based on the number of sessions in the Pain Self-Management portion of SCAMP, see Section A, Significance). Patient participants will receive $ for each of these six sessions and for each follow-up interview. Providers participating in the pre-test focus group will receive a $ gift card. *Aim 2:* Patient participants will receive $ for each of the six pilot sessions and interviews at the beginning, midpoint, and end of the study. The total incentive budget is $ over the four-year award period.

***Regulatory***

Dr. Anne Zinski has more than four years of experience submitting IRB protocols, and managing all IRB submissions and regulatory issues for the RISC. Dr. Zinski will handle all regulatory aspects of this study, including creation and submission of the IRB Human Subjects Protocol and all revisions as needed. A standard fee of $ for the initial submission in year 1 and $ per year for renewals in years 2, 3, and 4 will be charged.

***Transcription***

Same Day Transcription will transcribe all patient and provider interviews and focus groups for this study. Cost will be $ per hour of recorded time, totaling $ for the entire project.

# RESEARCH & RELATED BUDGET - Cumulative Budget

| | Totals ($) |
|---|---|
| **Section A, Senior/Key Person** | |
| **Section B, Other Personnel** | |
| Total Number Other Personnel | 17 |
| **Total Salary, Wages and Fringe Benefits (A+B)** | |
| **Section C, Equipment** | |
| **Section D, Travel** | |
| 1. Domestic | |
| 2. Foreign | 0.00 |
| **Section E, Participant/Trainee Support Costs** | |
| 1. Tuition/Fees/Health Insurance | |
| 2. Stipends | 0.00 |
| 3. Travel | |
| 4. Subsistence | 0.00 |
| 5. Other | |
| 6. Number of Participants/Trainees | 1 |
| **Section F, Other Direct Costs** | |
| 1. Materials and Supplies | 0.00 |
| 2. Publication Costs | 0.00 |
| 3. Consultant Services | 0.00 |
| 4. ADP/Computer Services | 0.00 |
| 5. Subawards/Consortium/Contractual Costs | 0.00 |
| 6. Equipment or Facility Rental/User Fees | 0.00 |
| 7. Alterations and Renovations | 0.00 |
| 8. Other 1 | |
| 9. Other 2 | |
| 10. Other 3 | |
| **Section G, Direct Costs (A thru F)** | |
| **Section H, Indirect Costs** | |
| **Section I, Total Direct and Indirect Costs (G + H)** | |
| **Section J, Fee** | **0.00** |





Funding Opportunity Number: PA-14-049 . Received Date: 2014-04-24T11:32:34.000-04:00

# PHS 398 Cover Page Supplement

OMB Number: 0925-0001

## 1. Project Director / Principal Investigator (PD/PI)

Prefix:
First Name*: Jessica
Middle Name:
Last Name*: Merlin
Suffix: M.D.

## 2. Human Subjects

Clinical Trial? ● No ○ Yes
Agency-Defined Phase III Clinical Trial?* ○ No ○ Yes

## 3. Permission Statement*

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

● Yes ○ No

## 4. Program Income*

Is program income anticipated during the periods for which the grant support is requested? ○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

| Budget Period* | Anticipated Amount ($)* | Source(s)* |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

# PHS 398 Cover Page Supplement

## 5. Human Embryonic Stem Cells

Does the proposed project involve human embryonic stem cells?* ● No ❍ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

**Cell Line(s):** Specific stem cell line cannot be referenced at this time. One from the registry will be used.

## 6. Inventions and Patents (For renewal applications only)

Inventions and Patents*: ❍ Yes ❍ No

If the answer is "Yes" then please answer the following:

Previously Reported*: ❍ Yes ❍ No

## 7. Change of Investigator / Change of Institution Questions

❑ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:

First Name*:

Middle Name:

Last Name*:

Suffix:

❑ Change of Grantee Institution

Name of former institution*:

# PHS 398 Career Development Award Supplemental Form

OMB Number: 0925-0001

| | |
|---|---|
| **Introduction (if applicable)** | |
| 1. Introduction to Application (for RESUBMISSION applications only) | 1242-INTRODUCTION_TO_RESUB_Final.pdf |
| **Candidate Information** | |
| 2. Candidate's Background | 1243-Cand_Backgr_Final.pdf |
| 3. Career Goals and Objectives | 1244-Cand_Goals_Final.pdf |
| 4. Career Development/Training Activities During Award Period | 1245-Cand_Car_Dev_Final3.pdf |
| 5. Training in the Responsible Conduct of Research | 1246-Traing_Conduct_Res_Final.pdf |
| 6.Candidate's Plan to Provide Mentoring (as applicable) | |
| **Statements of Support** | |
| 7. Plans and Statements of Mentor and Co-Mentor(s) | 1247-MentorCoMentor_Ltrs_Final.pdf |
| 8. Letters of Support from Collaborators, Contributors, and Consultants | 1248-Advisors_Ltrs_Final.pdf |
| **Environment and Institutional Commitment to Candidate** | |
| 9. Description of Institutional Environment | 1249-Inst_Environ_Final.pdf |
| 10. Institutional Commitment to Candidate's Research Career Development | 1250-Institutional Committment Letter.pdf |
| **Research Plan** | |
| 11. Specific Aims | 1251-Spec_Aims_Final.pdf |
| 12. Research Strategy* | 1252-Res_Strategy_Final.pdf |
| 13. Progress Report Publication List (for RENEWAL applications only) | |
| **Human Subject Sections** | |
| 14. Protection of Human Subjects | 1253-Human_Subj_Final.pdf |
| 15. Inclusion of Women and Minorities | 1254-Incl_Women_Min_Final.pdf |
| 16. Inclusion of Children | 1255-Incl_Children_Final.pdf |
| **Other Research Plan Sections** | |
| 17. Vertebrate Animals | |
| 18. Select Agent Research | |
| 19. Consortium/Contractual Arrangements | |
| 20. Resource Sharing Plan(s) | |
| **Appendix (if applicable)** | |
| 21. Appendix | |

**Citizenship*:**

- ● U.S. Citizen or noncitizen national
- Non-U.S. Citizen with temporary U.S. visa
- Permanent Resident of U.S. (If a permanent resident of the U.S., a notarized statement must be provided by the time of award)
- Permanent Resident of U.S. Pending

**INTRODUCTION TO RESUBMISSION APPLICATION**

I am grateful for the thoughtful review provided by BSCH, and reviewers' enthusiasm for the need to not "delay important work needed to be carried out now" in an area that is "highly important." Reviewers described me as "outstanding," and "unique in her ability to address both HIV and chronic pain," and encouraged me to complement my biomedical background with mentoring and training in health psychology/mental health and chronic pain behavioral intervention development. They further underscored the importance of such expertise in revising the research approach, and the need to include a pilot trial. Together with my new mentorship team, I have taken this guidance to heart. With these new insights, we present our revisions by theme.

1. Mentorship: Needs mentoring in the "basic sciences of behavior and especially in health psychology and mental health" and a "senior person who has conducted intervention research related to chronic pain." In place of my epidemiology mentor, my team includes two new mentors. Mallory Johnson PhD, Professor of Medicine, UCSF, will serve as my health psychology/mental health mentor, and will work with me to incorporate mental health factors (depression, anxiety) into the intervention. Robert Kerns PhD, Professor of Psychology, Yale, will serve as my chronic pain behavioral intervention development and testing mentor, and will guide me step-by-step through the research I propose. Both are established investigators and mentors with strong theoretical backgrounds and clear ties to UAB. Together with my primary mentor Dr. Michael Saag, Drs. Johnson, Kerns, and I have revised my research strategy and training plan. I have also added Burel Goodin PhD as an advisor. Dr. Goodin is a UAB pain psychologist who trained with Dr. Kerns, and will provide ongoing practical opportunities "extending her chronic pain expertise" through supervision and shadowing (see below).

2. Scope/timeline: "It would be best for Dr. Merlin to appeal for a 5-year K23 award so that she could conduct a pilot trial." We agree with the need to speed this work. However, we have thoroughly explored this possibility with our Program Officer, and NIMH policy will not allow for a 5 year K. We appreciate the reviewers' suggestion that "more could be done in 4 years to get this ready more rapidly." Therefore, we have refocused our research strategy and aims on behavioral intervention development (Aim 1) and pilot testing (Aim 2). Preliminary data which we present has allowed us to eliminate the prior epidemiologic Aim.

3. Research Strategy: *3a. Intervention targets:* Reviewers noted concerns with our epidemiologic approach, and asked if there are "data already within CNICS [CFAR Network of Integrated Clinical Systems] that could be analyzed to find some of these associations between pain and mental health." We now present analyses of UAB CNICS data and qualitative studies that allow us to identify intervention targets, including depression/anxiety and use of prescription opioids for pain management. This streamlined approach allows us to refocus the training, mentoring, and research plans on health psychology/mental health and chronic pain behavioral intervention development and testing, including a pilot trial in Year 3. *3b. "Use of a single measure of depression … is a major limitation."* We now use the Structured Clinical Interview for DSM (SCID), in addition to instruments such as the PHQ-9, to better assess mental health "symptoms and syndromes" including depression. *3c. Need to address "how current medications for pain (or other treatments) will be taken into account."* Our revised approach addresses this by incorporating use of prescription opioids for pain management as an intervention target, specifically including individuals prescribed opioids, and collecting data on co-prescribed pharmacologic and non-pharmacologic treatments. *3d. Addition of a theoretical basis "integrated into the outcomes or data analysis":* While grounding in the Biopsychosocial (BPS) Framework was cited as a "strength," reviewers noted that "the description of the behavioral intervention framework suggests the need for additional mentoring in the basic sciences of behavior." Guided by my mentors, my approach is now grounded in Social Cognitive Theory within a BPS context, providing a theoretical basis for understanding how to effect change and improve outcomes in individuals with HIV and chronic pain.

4. Training plan: Following directly from the above, my revised training plan focuses on health psychology/mental health and chronic pain behavioral intervention development and testing, including behavioral clinical trials. My mentors are the cornerstone, and will provide me with regular project-specific and overall career guidance. They have also worked with me to design a customized training plan, including courses in my new areas of focus offered by the Department of Psychology and the Department of Health Behavior. *4a. Health psychology/mental health:* I will take four courses including Adult Personality/ Psychopathology (includes a DSM-based approach to mental illness) and Health Psychology and Assessment. *4b. Chronic pain behavioral intervention development and testing:* "The plan should include evidence of an understanding of the multidisciplinary approach to pain that is standard," including "effects of medications, involvement of physical therapy, etc." We have added an annual two-week hands-on experience with Dr. Kerns at the VA Connecticut Pain Clinic (multidisciplinary clinic including an anesthesiologist, physical medicine physician, clinical psychologist, physical therapist) and Opioid Reassessment clinic. Dr. Goodin will supervise me in my HIV/chronic pain clinic (1 session/mo), and I will shadow in his clinic (50 hours/yr). This is in addition to introductory and advanced behavioral science courses focusing on "theories of human behavior," and previously proposed behavioral intervention development/testing courses at UAB, Hopkins, and the NIH.

These concerns and additional minor concerns are addressed in the revised application in italics. We are confident that this revised program of mentoring, training, and research will allow me to develop into an independent investigator positioned to develop and test high impact interventions for HIV and chronic pain.

**Candidate's Background** I am strongly committed to a career in Patient-Oriented Research in HIV and chronic pain. At the end of my clinical fellowships in 2011, I took a faculty position at UAB, and made a career shift from clinical care to research. At UAB, I have received excellent mentorship and institutional support. However, I need further research training to achieve my goal of becoming an independent investigator. *A K23 will allow me gain expertise in health psychology/mental health and chronic pain behavioral intervention development and testing, including behavioral clinical trials.*

*I have built a strong foundation of clinical skills and expertise in the biomedical approach to HIV and chronic pain.* I first became interested in HIV and pain as a medical student on an international elective in Botswana. I vividly remember being surrounded by an entire ward of critically ill patients with an intense burden of untreated pain and emotional suffering. My experiences there led me to pursue an infectious diseases (ID) fellowship. As a fellow, I was surprised that the burden of chronic pain, co-occurring social challenges, and medical, psychiatric, and substance use comorbidities in my HIV-infected patients in West Philadelphia was also tremendous. In one especially challenging patient, as her HIV progressed due to suboptimal antiretroviral therapy (ART) adherence, and her crack cocaine use continued unabated, she would beg for something to treat her chronic pain. Inspired by a lack of published research on chronic pain in HIV-infected patients, I led a study at the University of Pennsylvania Center for AIDS Research (CFAR). We found high rates of pain among HIV-infected patients, especially those with psychiatric illness and substance use. This resulted in a first author publication,[1] and an American Academy of Hospice and Palliative Medicine Young Investigator Award. Concurrently, I completed Penn's certificate program in Clinical Epidemiology. In order to gain specialized training in the management of pain and psychosocial suffering, I completed a palliative care fellowship at the Mt. Sinai School of Medicine. I am one of only a few physicians trained and boarded in both ID and palliative care. I also spent time with and receive ongoing clinical mentorship from Glenn Treisman MD PhD, a leader in HIV psychiatry including chronic pain at Johns Hopkins, and Michael Hooten MD, a psychiatrist the Mayo Pain Rehabilitation program. As one of a few experts in HIV and chronic pain, I was asked to serve on the ID Society of America HIV/Pain guidelines panel, and join the Faculty of the International AIDS Society-USA.

My appreciation for the dearth of literature in this area led to me to transition from clinical care to research, and move to UAB due to its strong HIV research environment. During my 2½ years at UAB, I have focused on laying the foundation for my career as a researcher in HIV and chronic pain. I lead a chronic pain clinic within the UAB 1917 HIV Clinic, one of only a handful of such clinics in the US. This serves as a clinical laboratory for my research. Our group has published a paper on the characteristics of the chronic pain clinic and how it differs from the overall 1917 Clinic, on which I was the senior author.[2] Drawing on experiences from this clinic to generate research questions, I successfully competed for a UAB 1-year Center for Clinical and Translational Science pilot award and a 2-year institutional K12 Patient-Centered Outcomes Research Career Development Award. These grants have allowed me to collect preliminary data and begin my training. We have found that chronic pain occurs in up to one third of participants in the UAB 1917 Clinic Cohort, and in some participants, pain is associated with more 'no-show' visits to primary care. These results were presented at the International Workshop on HIV Observational Databases[3] and led to a first author publication.[4] We also demonstrated up to 10 times greater odds of impaired physical function in HIV-infected patients with pain, which was presented at the ID Society of America[5] and led to a first author manuscript.[6] Our initial research highlighted inadequacies in the methods used to measure chronic pain in primary care settings, including HIV clinics. Pain is typically measured during short time periods, such as a day or month, rather than trying to measure the clinically important syndrome of interest, chronic pain. I received psychometrics training and mentorship and took basic quantitative courses, providing me with the skills to evaluate the first Brief Chronic Pain Screening tool in HIV-infected patients, which we have published[7] and will be used in my K23. Concurrently, we adapted the Biopsychosocial (BPS) Framework to describe the unique context in which chronic pain is experienced by HIV-infected patients (Section A3, Significance).[8] I also took courses and received mentorship in qualitative and mixed methods techniques. This informed the conduct of 30 interviews exploring the relevance of individual factors from the BPS Framework. Together, these and other initial investigations have led to identification of intervention targets used in my K23 (Section C, Approach).

My short-term goal is to develop and test a behavioral intervention for chronic pain in HIV-infected patients. To accomplish this goal, and become an independent investigator, I need training beyond the psychometrics and qualitative focus of my K12. *My clinical and research experiences have also convinced me that my traditional biomedical training is insufficient to address chronic pain in HIV. Given the limited efficacy of medications, known benefits of behavioral interventions, and importance of mental health factors (e.g., depression, anxiety) in HIV-infected patients with chronic pain, I need training in health psychology/mental health and chronic pain behavioral intervention development and testing, including clinical trials.* If awarded this K23, I will commit 10 months each year (80% effort) to my research and career development. I will continue to lead the HIV/chronic pain clinic, in which I see patients ½ day per week and have substantial support, and participate in one month of inpatient service, where I also see patients with chronic pain. My background, expertise in HIV and chronic pain, and research to date in this area uniquely position me to be a leader in HIV and chronic pain research. A K23 will provide me with the mentorship and training I need to achieve this goal.

**Career Goals and Objectives**

*I have pursued extensive clinical training in the biomedical approach to HIV and chronic pain. My K12 has focused on psychometrics and qualitative methods. However, I have insufficient training to become an independent investigator.* My specific goals and objectives are:

1. My long-term goal is to become an independent investigator focusing on improving pain, physical, and emotional function in HIV-infected patients with chronic pain. *I will accomplish this by developing and testing behavioral interventions in this area, including conducting behavioral clinical trials.*
2. The focus of my K23 is to develop and test a behavioral intervention for HIV-infected patients with chronic pain. *Given this focus, I will develop expertise in health psychology/mental health and chronic pain behavioral intervention development and testing, including behavioral clinical trials, obtaining a Master of Science in Public Health (MSPH) in Health Behavior.*
3. *At the beginning of the 4th year of my K23, I will submit an R01 to assess the efficacy of the intervention in a national CNICS-wide randomized controlled trial (RCT).*

Here, I propose a comprehensive research and career development plan that directly addresses these goals and objectives. The support provided by a K23 and the opportunities for research and training it affords will prepare me to be an independent investigator and compete successfully for an R01.

**Candidate's Plan for Career Development/Training Activities During Award Period**

I will utilize a combination of mentorship, coursework, hands-on training, and seminars/conferences, in addition to the proposed research, to achieve my goals. *This plan will fill a gap in my training in health psychology/mental health and chronic pain behavioral intervention development and testing, including behavioral clinical trials.* My career development activities are summarized in Table 1.

**a) Mentorship Team:** I will be mentored by three outstanding investigators: Michael Saag MD (primary mentor, conduct of clinical trials within CNICS); *Mallory Johnson PhD (health psychology/mental health); and Robert Kerns PhD (chronic pain behavioral intervention development and testing).* Notably, Dr. Saag serves as a mentor on my institutional K12 Patient-Centered Outcomes Research Career Development Award, and will provide continuity between these two grants. *Drs. Johnson and Kerns are new additions to my mentorship team. Their complementary expertise, mentorship track record, close work with me on this grant, and dedication to my successful career development are reflected in my Research Strategy. Given our diffuse geography, we recognize the importance of regular virtual and in-person meetings as described in detail below. Additionally, we will arrange for a joint quarterly VideoSkype meeting of Drs. Saag, Johnson, and Kerns, and we will have an annual meeting of my entire mentor/advisor team to discuss my progress.*

a1. Michael Saag, MD is a Professor of Medicine, Director of the UAB Center for AIDS Research (CFAR), founder of the CFAR Network of Integrated Clinical Systems (CNICS), and a leader in HIV research. During his 25+ year career, he has mentored several clinician-investigators, including Dr. Michael Mugavero, whose work has advanced the field of HIV retention in care. Dr. Saag serves on the Board of Directors for the International AIDS Society-USA, the NIH Office of AIDS Research Advisory Council, and is the past president of the HIV Medicine Association. Dr. Saag has been my primary mentor over the past 2.5 years. Together, we have published 7 papers demonstrating a productive relationship. His knowledge of HIV research, stature as an established and well-regarded investigator, and our long-standing relationship, make Dr. Saag an ideal overall career mentor. Dr. Saag has extensive experience conducting clinical trials, including behavioral intervention trials, in CNICS. *His expertise and role as CNICS national PI will allow him to guide me as I pilot test the intervention in Aim 2 and submit an R01 to test the efficacy of the intervention in a national CNICS-wide RCT.* Our weekly mentorship meetings will include discussion of the Responsible Conduct of Research, good clinical practices for clinical trials, and how to effectively craft R-series grants.

*a2. Mallory Johnson PhD is a Professor of Medicine at the University of California, San Francisco (UCSF). He is a licensed psychologist with a PhD in clinical medical psychology emphasizing the intersection of mental and physical health. He completed an APA accredited internship at UCSF focused on mental health assessment and intervention. He is a leader in the development and testing of theory-based HIV behavioral interventions that address mental health factors, including depression and anxiety. This includes an intervention for symptom self-management in HIV-infected patients, which is closely related to the work I propose. He is recognized as an exceptional mentor and holds a K24 mentorship award from NIMH with a pending renewal from NIDA. Dr. Johnson's ties to UAB are strong. Dr. Johnson obtained his PhD in clinical medical psychology at UAB, and his formative experiences were at the 1917 clinic where he was Dr. Saag's mentee. I met Dr. Johnson at the 2013 International Association of Providers of AIDS Care (IAPAC) meeting. Since then, we have had regular email and phone discussions of my grant. He has several active collaborations that bring him to UAB at least annually. In 2/14, during Dr. Johnson's regular visit to UAB to update the CFAR on his research and lecture on mentorship, we met in person with Dr. Saag and my advisor Dr. Davies, and were joined by Dr. Kerns by phone. Given the identification of mental health factors, specifically depression/anxiety, as intervention targets, Dr. Johnson's role will be to provide mentorship on health psychology/mental health. I will meet with Dr. Johnson monthly via VideoSkype to discuss using the results of my analyses to guide incorporation of these targets. We will also meet at IAPAC/CNICS meetings.*

*a3. Robert Kerns PhD is Yale Professor of Psychiatry, Neurology and Psychology, VA National Advisor for Pain Research, and Director of the Pain Research, Informatics, Multimorbidities, and Education (PRIME) Center at the VA Connecticut Healthcare System. He is a pioneer in chronic pain behavioral intervention development and testing research, and has conducted foundational empirical and theoretical work. This includes 30+ years developing and testing Social Cognitive Theory-based, interdisciplinary self-management interventions to improve pain and function in special populations with chronic pain, such as individuals with multiple sclerosis and post-traumatic stress disorder. He is also an expert in the use of prescription opioids for pain management, and currently serves as Chair for the Department of Health and Human Services National Action Plan for Opioid-Related Adverse Drug Events. Dr. Kerns has an important connection to UAB through Dr. Goodin (advisor). I met Dr. Kerns through my advisor Dr. Bair in 9/13, and have been an active participant in the VA Pain Research Work Group which he leads. I visited Dr. Kerns at PRIME in 1/14, which I will continue to do annually. We have met several times by phone, including twice with Drs. Johnson and Saag. I will meet with Dr. Kerns monthly via VideoSkype and annually at the American Pain Society (APS) conference. He will guide me step-by-step through the intervention development and testing process I propose.*

**b) Panel of Advisors:** My advisors will each provide input on a specific topic area relevant to my proposal. I will meet monthly with each advisor, and they will join my mentorship meetings as often as needed.

b1. Susan Davies, PhD is an Associate Professor in the Department of Health Behavior and a behavioral scientist at the UAB SOPH, who will advise me on the intervention mapping (IM) methodology I will use in Aim 1. Dr. Davies has 10+ years of experience using IM to design behavioral interventions, during which she has collaborated with Dr. Saag and other CNICS investigators. Dr. Davies will teach my introductory behavioral intervention development course and advanced independent study, both focusing on IM.

b2. Matthew Bair, MD, MSc is an Associate Professor of Medicine at Indiana University. He conducted the randomized controlled trial of the Stepped Care for Affective Disorders and Musculoskeletal Pain (SCAMP) intervention that will inform the development of my intervention, and has since tested elements of SCAMP in a variety of settings. Dr. Bair will provide expertise on using SCAMP as a starting point for my intervention. Dr. Bair and I have been in regular communication for nearly a year. I will visit Dr. Bair at Indiana University with my study team during Year 2 to obtain training on intervention delivery based on his experience with SCAMP.

b3. Stefan Kertesz, MD MSc is an Associate Professor and addiction physician in the UAB Division of Preventive Medicine, and an advisor on my K12. His NIDA and VA funded research focuses on substance use and primary care among the homeless. *We identified substance use, alongside depression/anxiety and use of prescription opioids for pain management, as a key intervention target. Dr. Kertesz complements my mentors' expertise in these other areas and will provide input on incorporating substance use into the intervention.*

*b4. Burel Goodin PhD is an Assistant Professor of Psychology at UAB, who completed his internship with Dr. Kerns at Yale and works at the UAB-Highlands Pain Treatment Clinic. He is included to enhance my grounding in psychological approaches to chronic pain, which will be essential as I develop the behavioral intervention. Dr. Goodin already participates in my HIV/chronic pain clinic's interdisciplinary team meetings, where we review difficult cases (4/month). Beyond this, he will provide practical opportunities to extend my chronic pain expertise and follow patients' responses to psychological approaches longitudinally. Specifically, he will supervise me in my HIV/chronic pain clinic and help me to better identify and address mental health concerns in my patients (1 session/month, the usual frequency of follow-up); and I will shadow him in his pain clinic (1 session/week, the usual frequency of follow-up, for 3 consecutive months, 50 hours/year).*

**Table 1: Research and Career Development Timeline and Benchmarks**

| **Activities by month** | **1-6** | **7-12** | **13-18** | **19-24** | **25-30** | **31-36** | **37-42** | **43-48** |
|---|---|---|---|---|---|---|---|---|
| *Aim 1 (Development)* | | | | | | | | |
| *Aim 2 (Pilot RCT)* | | | | | | | | |
| *Apply for R01* | | | | | | | | |
| *Manuscript submission* | | | | | | | | |
| Mentorship Team, area of expertise, and meeting frequency | • **Primary mentor, conduct of clinical trials in CNICS**: Michael Saag MD; weekly<br>• ***Health psychology/mental health:*** *Mallory Johnson, PhD; monthly*<br>• ***Chronic pain behavioral Intervention development/testing:*** *Robert Kerns, PhD; monthly*<br>*(includes joint quarterly mentor team meetings)* | | | | | | | |
| *Advisors, area of expertise, and meeting frequency* | • ***Intervention mapping:*** *Susan Davies PhD; monthly*<br>• ***SCAMP****: Matthew Bair MD MSc; monthly*<br>• ***Substance use****: Stefan Kertesz MD, MSc; monthly*<br>• ***Extending chronic pain expertise****: Burel Goodin PhD; monthly*<br>*(includes joint meetings with mentors as needed)* | | | | | | | |
| Coursework | HB 636,<br>*PY 740*<br>GRD 717* | *HB 624*<br>*PY 731*<br>Hopkins** | HB 698 | BST 625<br>*PY 769*<br>NIH** | *PY 791* | *EPI 703* | | |
| *Hands on training* | • *Review of difficult cases, clinical supervision, and shadowing with Dr. Goodin*<br>• *Annual 2 week visits to PRIME (Integrated Pain Clinic, Pain Rehab School, Opioid Clinic, SCID)* | | | | | | | |
| Seminars | • **HIV:** Weekly 1917 Clinic Cohort and monthly CFAR seminars; weekly ID conferences<br>• **Chronic pain:** Monthly Palliative Care Center Scholars meeting<br>• **Methods:** COERE-monthly; *CCTS (grant writing)-monthly* | | | | | | | |
| Conferences | **HIV**: IAPAC, CNICS **Health Psychology/Mental Health**: SBM, *APS1* **Pain**: APS2 **Substance Abuse**: CPDD | | | | | | | |

*Principles of Scientific Integrity; see Responsible Conduct of Research section. **Summer intensive courses, see below.

**c) Coursework and hands-on training**: *Following directly from the above, my training plan focuses on health psychology/mental health and chronic pain behavioral intervention development and testing. My mentors are the cornerstone, and will provide me with regular project-specific and overall career guidance. I am currently completing core quantitative courses in epidemiology, biostatistics, and study design. With that foundation, they have worked with me to design a customized training plan. This includes combined didactic training with the College of Arts and Sciences' Department of Psychology and the SOPH's Department of Health Behavior, which will result in an MSPH in Health Behavior, and hands-on training opportunities.*

*c1. Health psychology/mental health: PY 740 Adult Personality and Psychopathology reviews the epidemiology, genetics, and neurobiology of psychopathology, and incorporates a DSM-based approach to disorders (e.g., depression, anxiety) that are relevant to the intervention. PY 731 Health Psychology and Assessment, is a core PhD-level psychology course. Taught by my advisor Dr. Goodin, it covers the interaction between behavior, mental states, emotions, culture, and physical health, and includes the biomedical vs biopsychosocial model. PY 769 Cognitive Behavioral Therapy reviews the underlying theory/skills required for*

*CBT – the basis of pain self-management interventions (Section A6). PY 791 Addictions and their Treatment Course will explore the etiology, prevention, and treatment of addiction.*

*c2. Chronic pain behavioral intervention development and testing: c2a. Chronic pain intervention development: I will visit Dr. Kerns at PRIME for 2 weeks/year. This will allow me to gain an appreciation for interdisciplinary interventions to improve pain and function. I will gain hands-on experience from the interdisciplinary clinical, research and training programs at VA Connecticut, including the Integrated Pain Clinic (includes an anesthesiologist, physical medicine physician, clinical psychologist, and physical therapist) and Pain Rehabilitation School (integrates group CBT and physical therapy). Given my interest in use of prescription opioids for pain management, I will also spend time in the Opioid Reassessment clinic, which assesses risk vs. benefit of opioid prescription (staff include an internist, addiction psychiatrist, and advanced practice nurse). In Year 1, I will be joined by my study interviewer, and we will obtain training on the Structured Clinical Interview for DSM (SCID) from Dr. Kerns' team of psychiatrists and psychologists (Research Strategy). c2b. Behavioral intervention development/testing, including clinical trials:* HB 636 Developing Interventions to Promote Public Health is taught by my advisor Dr. Davies. It reviews behavioral science theories including Social Cognitive Theory and their relevance to intervention development, and provides instruction in intervention mapping (Aim 1). The Johns Hopkins Summer Research Institute on Developing Behavioral Interventions is a well-respected 3 day intensive course designed for junior investigators, and will extend what I learn in HB 636. Topics include intervention design and analysis, fidelity, and implementation. *HB 624 Advanced Theory and Practice in Behavioral Science will provide an advanced review of behavioral science theories.* HB 698 Independent Study with Dr. Davies will involve weekly readings on advanced concepts in intervention mapping, including behavior maintenance and behavioral outcome measurement. BST 625 Design and Conduct of Clinical Trials will provide an overview of their design, implementation and evaluation, preparing me for the NIH Office of Behavioral and Social Sciences Research (OBSSR) course. The NIH OBSSR Summer Institute on Randomized Behavioral Clinical Trials is a 12-day intensive course. If accepted to participate, I will learn to design and conduct future behavioral trials of the intervention*. If not accepted, I will create an independent study with my mentors. EPI 703 Grant Writing will assist me as I write my R01.*

**d) Seminars and Conferences:** I will attend 1. HIV, pain, methodology, and writing seminars through the 1917 Cohort, CFAR, ID division, CCTS, COERE, and Center for Palliative and Supportive Care at least weekly, and 2. conferences including the IAPAC/NIMH Adherence Conference, *CNICS,* Society of Behavioral Medicine (SBM), *American Psychosomatic Society (APS1),* American Pain Society (APS2), and the College on Problems of Drug Dependence (CPDD). I will submit at least 2 abstracts and 2 manuscripts annually.

**e) Time Commitment:** I am committed to a career in Patient-Oriented Research. A K23 would allow me to commit 10 months (80% of my full time effort) to research and career development. I will continue to lecture monthly to residents and fellows on HIV and chronic pain; rotate on the inpatient medicine and palliative care services for two 2-week blocks; and direct the ½ day per week (10% effort) HIV/chronic pain clinic, which contributes to my research by maintaining my involvement in the care of individuals with HIV and chronic pain.

**Training in the Responsible Conduct of Research**

To date, my training in the Responsible Conduct of Research includes online training from the Collaborative Institutional Training Initiative (CITI) (8/2011); a CITI refresher course (7/2013); and a Financial Conflict of Interest course (July 2012). Discussion of research ethics and the Responsible Conduct of Research has been a regular topic during meetings with my primary mentor, Dr. Michael Saag. Dr. Saag and I have developed a training plan for the Responsible Conduct of Research during my K23 award. This includes:

1. Principles of Scientific Integrity (GRD 717): *Format:* This is a formal didactic course offered through UAB that I will take in the first semester of my K23 award. This three-credit hour course provides systematic instruction on ethical issues and principles in the practice of science through reading, case discussions, and lectures. The textbook is *Introduction to the Responsible Conduct of* Research by Nicholas Steneck, and has been modified to reflect more recent changes in rules and regulations. Course material is made available online approximately one week before the class meeting. In-class time is spent in teams of 6 to 7 students, taking quizzes to measure comprehension of course materials, followed by discussion of case studies. *Subject Matter:* Topics covered in GRD 717 include the nature, extent, and causes of fraud in science; UAB policies on fraud; ideals of good science including scientists as public policy advisors and the societal impacts of scientific research; the responsibilities of authorship and peer review; potential problems raised by the commercialization of research; and ethical issues involved in research with human and animal subjects in clinical trials. *Faculty Participation:* The course is taught by Jeff Engler, PhD, Associate Dean for Academic Affairs and Professor of Biochemistry and Molecular Genetics. In addition, other faculty provide content-specific contributions as in-class guest facilitators. *Duration of Instruction:* This is a semester-long course that provides 40 contact hours of instruction. *Frequency of Instruction*: I will read the textbook, watch slide presentations and videos on the class web site, and attend weekly course sessions.

2. UAB Center for Clinical and Translational Science (CCTS) continuing education seminars: *Format:* The UAB NIH-funded CCTS has numerous opportunities for career development related to the Responsible Conduct of Research, including a) biannual Clinical Training Academy lectures that are meant to be mini-refresher courses focusing on practical applications of what I will learn in GRD 717; and b) an annual 2-day Ethics Conference targeted at experienced investigators, in conjunction with the Center for Ethics and Values in the Sciences. *Subject Matter:* Topics for the Training Academy will include ethical authorship, data acquisition and management, ethics of research execution, and research in special populations. Topics for Ethics Conferences will include conflicts of interest in research, authorship and publishing, defining misconduct, and working with vulnerable populations. *Faculty Participation:* These seminars feature faculty from across UAB's research campus. *Duration of Instruction:* The Training Academy includes two hours of instruction quarterly, while the research conference includes 20 hours of instruction over 2 days. *Frequency of Instruction:* The Training Academy meets quarterly, and the Ethics Conference meets annually.

3. Online Training: *Format:* I will participate in 8 self-directed online training modules through the UAB CCTS and online maintenance of CITI training. *Subject Matter:* Topics include defining research with human subjects, assessing risk, privacy and confidentiality, and informed consent. *Faculty Participation:* N/A *Duration of Instruction:* Together, the CCTS and CITI modules provide a total of 12 hours of instruction. *Frequency of instruction:* I will complete this annually.

4. Teaching Ethics to Medical Residents: I am teaching faculty in the ethics curriculum for the medical residents. This allows me to review important ethical concepts in the conduct of research. *Format:* I attend and participate as faculty in all sessions of this course, which have both didactic and case-based content. Additionally, I lead two sessions on Research Ethics. *Subject Matter:* These conferences cover broad clinical and research ethics topics applicable to residents. In particular, my session on Research Ethics includes mentor/mentee responsibilities and relationships, responsible authorship and publication, peer review, research misconduct, and conflicts of interest. *Faculty Participation:* This course is directed by Dr. Thomas Huddle, an internist and ethicist at UAB. *Duration of Instruction:* I will participate in 12 hours of instruction over the course of one year, including two hours dedicated to Research Ethics content. *Frequency of Instruction:* This course meets monthly.

In addition to these opportunities, Dr. Saag and I will continue to discuss the Responsible Conduct of Research as it pertains to my project, especially with regard to issues that may arise in the context of a large cohort such as the Center for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS). During his more than 30 year career in research, and in his current role as the director of the UAB CFAR and the national PI of CNICS, Dr. Saag has substantial formal training and experience in the Responsible Conduct of Research. In addition, in his role as mentor to many junior faculty over the last 30 years and as teaching faculty in the CFAR "Mentoring the Mentor" program, he is very familiar with Responsible Conduct of Research requirements for junior investigators. Therefore, Dr. Saag is well suited to provide mentorship on the Responsible Conduct of Research*. Importantly, in my meetings with my chronic pain behavioral intervention development and testing mentor Dr. Kerns, we will address unique issues related to the Responsible Conduct of Research in individuals with chronic pain. For example, this will include how clinics can obtain information about whether persons are abusing prescription pain medications without risking expulsion from the clinic.*

UAB CENTER FOR AIDS RESEARCH

Dear Committee Members: *April 23, 2014*

I am pleased to express my enthusiastic support of Dr. Jessica Merlin's K23 Patient-Oriented Research Career Development Award Resubmission, and affirm my continued commitment as her primary mentor.

I have been Jessie's primary mentor since her arrival at UAB in August, 2011. Along with our division director, Dr. Edward Hook, I recruited her to UAB and to our Center for AIDS Research (CFAR). Over the past 2 years, I have also served as the primary mentor on her UAB Center for Clinical and Translational Science (CCTS) Pilot grant and K12 Patient-Centered Outcomes Research Career Development Award. What is absolutely clear to me is Jessie's unwavering dedication to improving the care of patients with HIV and chronic pain through research, and to a career as an investigator in this area. I am thrilled to continue to serve as her mentor during her K23.

I have mentored many junior faculty over the last 20 years, and Jessie is in the top 2-3 of all the investigators I have mentored. Jessie's drive to push the science of HIV and chronic pain forward is palpable. Jessie has an incredibly unique training record, as one of the only physicians in the country with formal training in both infectious diseases and palliative care. Even as an Infectious Diseases fellow at the University of Pennsylvania, with no research training or experience, she honed in on HIV and chronic pain as a critical gap in the literature, and set out to address it. With her team of mentors there, during a busy second clinical year of fellowship, she presented her work on HIV, pain, and psychological symptoms at the Infectious Diseases Society of America conference, which was then published in the Journal of Pain and Symptom Management. She was awarded an American Academy of Hospice and Palliative Medicine Young Investigator Award for this work. As a clinical fellow, she developed a niche in this area, and a national reputation. She was asked to serve on the Infectious Diseases Society of America Guidelines Panel for HIV and chronic pain, write a "Cases on the Web" module about HIV and chronic pain for the International AIDS Society-USA and join the core faculty, and author a book chapter on HIV and palliative care for the HRSA Women's Guide to Primary Care. In a desire to receive more training in pain and symptom management, she pursued a palliative care fellowship at the Mt. Sinai School of Medicine, which has one of the top programs in the field. As a result of these early accomplishments, the physician who directed our HIV/chronic pain clinic at the UAB 1917 HIV Clinic identified Jessie as someone who would be an excellent and important addition to our team. When I met her, it was clear that her nuanced understanding of this challenging patient population and passion for advancing scientific knowledge in this poorly studied area would position her well to rapidly become a leading HIV and chronic pain researcher. We were thrilled to recruit her to UAB.

When Jessie came to UAB, she did so with the specific purpose of making a career shift from clinical care to research, and focusing on HIV and chronic pain. Just after her arrival at UAB, she was awarded a pilot (CCTS) grant. Using this award, she has shown the significant impact of chronic pain on retention in HIV primary care and physical function, which she has published in the Journal of Acquired Immune Deficiency Syndromes and Pain Medicine, and presented at the International Conference on HIV Observational Databases in Athens, Greece. This has drawn additional attention to the importance of chronic pain in the field, and allowed Jessie to continue to build her national reputation as an expert in this area. While completing this work, Jessie again recognized an important gap in the field of chronic pain research – the lack of a widely used screening tool that could be used in clinic and cohort settings to identify HIV-infected patients with chronic pain, and lack of literature on the pain experience in HIV-infected patients. Building on her prior work to justify a need for research in this area, she successfully competed for a 2-year institutional Patient-Centered Outcomes Research K12 Career Development Award, on which I serve as her primary mentor. During her K12, Jessie has qualitatively investigated and pilot tested a Brief Chronic Pain Screening tool in HIV-infected patients, and qualitatively investigated the chronic pain experience in this patient population. She has actively engaged other faculty, including local experts in psychometrics and qualitative research, to collaborate and advise her. She has also taken one class in each of these disciplines.

Over the past year and a half, Jessie has developed an excellent research team. Since her original K23 submission, she has continued to be extremely productive with regard to disseminating her findings. She has already published her formative qualitative work on her Brief Chronic Pain Screening tool in AIDS Pt Care and STDs, which she is also presenting at the American Pain Society meeting next week. In addition, she has submitted manuscripts on the quantitative testing of her Brief Chronic Pain Screening tool, and on the psychological aspects of the chronic pain experience in HIV-infected patients, which will be presented at the International Association of Providers of AIDS Care (IAPAC) conference in June. Her amazing productivity over the last several months has even allowed her to identify targets for her proposed intervention, so that she can move right to development and pilot testing. Not surprisingly, Jessie has met all research, career development, and publication benchmarks from her K12 grant.

During the past two and a half years, I have gotten to know Jessie quite well, and have met with her on a twice monthly basis. Jessie has demonstrated a careful thoughtfulness about her research and career development, and an ability to connect with other investigators who may be potential mentors and collaborators, in a manner that is outstanding for someone so early in her career. She has also accomplished an impressive amount during a short period of time – she has only been at UAB for two and a half years, and during that time has received K12 and pilot grant funding and has published 9 manuscripts. Jessie's body of research is highly innovative and important to the field of HIV research. Prior to Jessie's work, chronic pain in HIV-infected patients was not on clinicians' or researchers' radars as an important target of investigation and intervention. That chronic pain in HIV-infected patients is a condition that warrants attention and intervention is a highly innovative concept, and one that has not been previously pursued by other investigators.

Importantly, I have worked closely with Jessie as she has, in her usual manner, carefully and thoughtfully prepared her K23 resubmission. She is committed to pursuing additional training in health psychology/mental health and chronic pain behavioral intervention development and testing, including clinical trials. Given Jessie's natural talents in networking, and presentations at national conferences and other institutions especially over the past year, she has gotten to know leading researchers in this area who have expertise in chronic pain, and in HIV. In particular, she has developed ties with Dr. Mallory Johnson, who she met at IAPAC, and Dr. Robert Kerns, who she met through her K23 advisor Dr. Matthew Bair. For a detailed description of these new co-mentors' involvement, please see Nature and Supervision of Mentoring, below.

Jessie's K12 has provided her with an opportunity to advance the science of HIV and chronic pain research, and begin her formal research training and mentorship. As very few investigators have chosen to focus on this area, the potential for Jessie to contribute fundamentally to this field is great. Given that, and Jessie's outstanding track record, I am absolutely confident that she will achieve her goal of becoming a leading independent investigator in this area. However, with limited formal research training, and only two and a half years out of fellowship, her career is in an early, formative stage. A K23 career development award will be critical to her successful transition to research independence.

**Mentorship Experience and Plans During the Training Period**

Qualifications and previous mentorship experience:

I am uniquely suited to be Jessie's primary mentor. I am the Director of the UAB Center for AIDS Research (CFAR), and immediate past-Chair of the HIV Medicine Association (HIVMA). I founded the UAB 1917 HIV Clinic in 1988, and serve as the national Principal Investigator for the CFAR Network of Integrated Clinical Systems (CNICS), an NIH funded research platform that merges discreet analyzable clinical data from Electronic Medical Records at 8 CFAR sites for research purposes. I have extensive experience in HIV/AIDS behavioral and outcomes research, with over 300 articles published in peer-reviewed journals. I have mentored over 30 medical students, residents, fellows, and faculty into careers as independent investigators (see summary in Table for selected mentees over the past 10 years).

**Table. Summary of Selected Mentees Within the Past 10 years.**

| Name | Mentorship dates | Research topic | Current Position |
|---|---|---|---|
| Ellen Eaton, MD | 2014- present | Health-related Outcomes Research / Cost | Fellow, Infectious Diseases |
| Ricardo Franco, MD | 2011-present | HIV/HCV-related Outcomes Research | Assistant Professor, UAB |
| Amanda Willig, PhD | 2010-2011 | HIV-related Nutrition and Outcomes Research | Assistant Professor, UAB |
| Greer Burkholder, MD, MSPH | 2008-2012 | HIV-related Outcomes Research | Assistant Professor, UAB |
| Michael Mugavero, MD, MHSC* | 2006-2012 | HIV-related Outcomes Research | Associate Professor, UAB |
| Paula Seal, MD | 2008-2010 | HIV-related Outcomes Research | Assistant Professor, Louisiana State University School of Medicine |
| James Willig, MD, MSPH | 2004-2009 | HIV-related Outcomes Research | Assistant Professor, UAB |
| Stephanie Baer, MD | 2007-2009 | HIV-related Outcomes Research | Asst Prof, Medical College of Georgia |
| James McKinnell, MD | 2007-2009 | HIV-related Outcomes Research | Asst Prof, UCLA School of Medicine |

*indicates recipient of NIH K-series award.

Nature of supervision and mentoring:

Jessie's long-term goal is to become an independent investigator focusing on HIV and chronic pain. Therefore, it is very important for her to have a primary mentor who has extensive experience in HIV research, including clinical trials. Given my long career in HIV outcomes research, and more recently, clinical trials (including behavioral trials) within CNICS, I am an ideal match for Jessie. My role as Jessie's primary mentor will be to oversee the progress of her research and career development, and to bring expertise related to the conduct of clinical trials, which she plans to perform during her subsequent R-series awards. We plan to meet on a weekly basis during her K23 award, during which we will discuss these topics in detail. We will assess how these activities are going and whether there is a need for additional or different activities that will better help her achieve her goals. Additionally, we have worked hard to select an excellent group of esteemed co-

mentors and advisors to provide specific content and methodologic expertise relevant to Jessie's application. As Jessie plans to develop a skill set in health psychology/mental health and chronic pain behavioral intervention development and testing, we were incredibly fortunate to expand our mentorship team to include two of the foremost leaders in these areas, Drs. Mallory Johnson and Robert Kerns, respectively. I am convinced that this team's enhanced expertise provides the optimum mentorship that Jessie needs to achieve her K23 goals. As she describes in her application, and as Drs. Kerns and Johnson write in their letters, both have met regularly with Jessie and I for several months, which has intensified since they joined her mentorship team. This includes an in-person meeting with Jessie, Dr. Johnson, and myself in February at UAB which Dr. Kerns joined by phone, and VideoSkype meetings with Jessie, Drs. Johnson and Kerns, and myself in March and April. In addition, I have a long track record with Dr. Johnson – I mentored Dr. Johnson during his formative years when he was a PhD student just getting interested in HIV research, and have continued to collaborate with him. Dr. Johnson visits UAB approximately annually due to his collaborative relationships here, and he and I are both actively involved in the CFAR-wide mentoring program. I am equally impressed by Dr. Kerns and am confident he is the best choice to be Jessie's chronic pain mentor. Drs. Johnson's and Kerns' influence is reflected in Jessie's revised Research Approach; their expertise has made her grant even stronger.

It is important to acknowledge that my 2 co-mentors are not at UAB. Given Jessie's extremely unique mentorship needs, it was essential to look outside of UAB. Jessie, Drs. Johnson and Kerns, and I are extremely dedicated to making this mentorship arrangement work. All three of us recognize the importance of her work, and of her potential to have a substantial impact on the field of HIV and chronic pain. This, along with a long-standing dedication to mentoring junior investigators, motivates us to work closely with Jessie as her career develops. Notably, Drs. Johnson and Kerns have a track record of working with Jessie, substantial experience mentoring junior faculty, and strong ties to UAB, as they describe in their letters.

Jessie also has a panel of advisors who will work closely with us. Dr. Susan Davies is a behavioral scientist with extensive experience in developing interventions in HIV-infected populations including intervention mapping. I have worked closely with Dr. Davies to mentor Dr. Michael Mugavero during his K23 award. Drs. Bair and Kertesz will provide expertise regarding using the SCAMP intervention as a starting point and addiction, respectively, and Dr. Goodin will provide supervision and shadowing opportunities extending Jessie's expertise in chronic pain. We have all been in regular email, phone, and in the case of Dr. Davies, in-person correspondence regarding Dr. Merlin's K23 revision. In order to solidify our team's relationships, our three-person mentorship team will meet quarterly, and will be joined when needed by individual advisors. I will call for a joint meeting of all of Jessie's mentors and advisors annually.

**Plan for Candidate Training and Research Career Development**

Jessie's time will be protected so that she will commit 10 months per year (80% of her full time effort) to the research and career development activities described in her K23 award. In addition, she will continue to lead the 1917 HIV/chronic pain interdisciplinary clinic, a role that directly contributes to her career development and facilitates hypothesis generation in this area. This is a very well-supported clinic, which includes a registered nurse, nurse practitioner, physical therapist, and fellows, which minimizes the time Jessie needs to spend on clinic activities between her half day per week clinic sessions. It should be noted that this role is unique – this is one of only a handful of such clinics in the US, further enhancing Jessie's uniqueness as an investigator in this area. In addition, Jessie will continue to spend 2 weeks on the inpatient general medicine/ID service and 2 weeks on the inpatient palliative care service. This will allow her to maintain professional ties to these fields, as well as see patients with chronic pain in an inpatient setting. Jessie will continue to lecture to the medical residents on Research Ethics and Professionalism, and teach medical students, residents, and fellows at UAB about HIV and chronic pain.

<u>Research</u>

Jessie is proposing highly innovative work that will advance the science of HIV and chronic pain research. Her research and career development plans are ambitious, but Jessie has already demonstrated an ability to accomplish a lot in a short period of time. I have full confidence that she will exceed the goals she has set for herself. Additionally, the skill set she will learn during her K23 will prepare her to be a leader in this area. Specifically, she will gain expertise in health psychology/mental health and chronic pain behavioral intervention development and testing, including behavioral clinical trials. She will conduct this research at the UAB 1917 HIV Cohort/CNICS site. As the national CNICS PI, I can assure that she will have access to local CNICS data and infrastructure, and for her subsequent R01, I will work with her as she expands her research CNICS-wide.

<u>Coursework and Hands-on Training</u>

In addition to excellent mentorship, Jessie will participate in a customized program of didactic training. She will be a student in the UAB Master of Science in Public Health (MSPH) program in Health Behavior. By the time she begins her K23 she will have completed the necessary quantitative coursework, in addition to her initial psychometric and qualitative coursework, to complete her proposed project. She has worked with her mentors, in conjunction with the School of Public Health's Department of Health Behavior and the College of

Arts and Sciences' Department of Psychology, to devise a customized, hybrid program that allows for substantive coursework in both departments. This is in addition to courses at Johns Hopkins and the NIH as she has outlined in her Career Development section. Jessie will participate in hands on training during her annual 2 week visits with Dr. Kerns at his Pain Research, Informatics, Multimorbidities, and Education (PRIME) center. There, she will learn more about interdisciplinary approaches to chronic pain, and focus on use of prescription opioids for pain management in the Opioid Reassessment Clinic. In addition, she will participate in numerous content and methods seminars through the UAB CFAR, CCTS, and Center for Outcomes and Effectiveness Research (COERE), and attend national conferences (see Benchmarks below). Jessie has also outlined a rigorous plan for training in the Responsible Conduct of Research that includes a course through the School of Public Health, and teaching research ethics to the medical residents.

Expectations and benchmarks

Jessie is an ambitious young investigator, and by the end of her four year K23, her goal is to achieve research independence. In order to assure a smooth transition from this mentored stage of her career to independence, we have worked together to develop a set of research and career development benchmarks as follows: 1. Achieve the research goals she has outlined in the Career Development portion of her grant; 2. Finish an Master of Science in Public Health by year 3 of the award; 3. Present her findings at 2 national conferences annually; 4. Write 2 corresponding manuscripts per year; 5. Present a summary of her work annually at our co-sponsored Infectious Diseases/Center for AIDS Research grand rounds and at external grand rounds; 6. Submit an R01 award by the 4th year of this K.

Career progression to independence

I believe it is very important for Jessie to develop the skills she will need for research independence early on. I have already begun and will continue to work to help her:
1. navigate difficult situations that arise in clinical research;
2. discuss the responsible conduct of research specifically as it applies to her work;
3. share approaches for deciding when to submit additional grants, to which funding agencies, and via which mechanisms; and
4. strategize about how to continue to grow her national visibility through presentations at national conferences, lectures at other universities, and publications.

When her K ends, she will have already started her own research program in HIV and chronic pain. In order to monitor Jessie's progress, I will do the following:
1. Review the expectations and benchmarks stated below with her every 6 months, especially the progress of her coursework and her publications;
2. Seek feedback from her other mentors and advisors every 6 months in order to provide her with additional guidance on how she is doing; and
3. Check in frequently about her progression to writing an R01 during the 3$^{rd}$ and 4$^{th}$ years of her K.
4. Provide annual evaluations on Jessie's progress as required in the annual progress report.

**Sources of Support**

The budget that Jessie constructed for this K23 award will cover the costs of the research she proposes. However, it is common for funding needs to exceed the originally budgeted costs. If this occurs, I am able to fund an additional $  per year of Jessie's K23 award toward research expenses. I am a full Professor, with ample independent funding through the UAB CFAR. In addition, I currently provide Jessie with additional salary support through the UAB CFAR, so her research effort represents 80% of her time, in excess of the 75% required by her K12 award. I will continue this support during all 4 years of her K23. Please see the Institutional Commitment letter for information about additional funds for Jessie through our Division.

**Summary**

In summary, Dr. Jessica Merlin is a bright, motivated young investigator who has achieved a great deal in a short period of time already at UAB, and will make a substantial impact on the field of HIV and chronic pain. I look forward to mentoring her and seeing her achieve her potential.

Most Sincerely,

Michael S. Saag, M.D.,
Professor of Medicine and Director
UAB Center for AIDS Research

UCSF
University of California
San Francisco
advancing health worldwide

Dear Committee Members: March 30, 2014

I am writing this letter to express my unwavering support for Dr. Jessica Merlin's K23 resubmission application, and to affirm my dedication to serve as her co-mentor. I am a clinical health psychologist with expertise in developing theory-based behavioral interventions for HIV-infected patients, and incorporating mental health comorbidities such as depression and anxiety. I met Dr. Merlin at the IAPAC conference in June, 2013. She impressed me as a thoughtful new investigator with a passion for a very important topic that has received little attention, and I was thrilled when she asked me to be her mentor.

I am impressed by Dr. Merlin's proactive and mature approach to this resubmission. Dr. Merlin has embraced the need for mentoring and training in both health psychology/mental health and chronic pain behavioral intervention development/testing, which she sees as fundamental to her career goals. Though I have known Dr. Saag since he mentored me as a PhD student in the 1917 HIV Clinic, Dr. Merlin immediately arranged for the members of her new mentorship team not previously acquainted to get to know each other and her application. Dr. Merlin arranged a joint in-person meeting between me, Dr. Saag, and Dr. Susan Davies, which was joined by Dr. Kerns via telephone, during my recent visit to UAB in February 2014. Since then, I have met several times by phone with Drs. Merlin, Saag, and Kerns to help Dr. Merlin revise her application, which is substantially improved. It is apparent that her mentors and advisors have the complementary expertise that Dr. Merlin needs, and we all work very well together. Also, the intervention mapping process that Dr. Merlin chose for this project, and on which Dr. Davies will advise, is an excellent fit and very consistent with my prior approaches to intervention development. Most importantly, Dr. Merlin doesn't just want to design an intervention and "get it done," she wants to do it "right." Her enthusiasm for elevating her biomedical knowledge through what she learns from Dr. Kerns and me, and the training experiences we have helped her select, is evident. This bodes well for the success of this project and her career as a physician-scientist in the behavioral arena.

I will meet monthly with Dr. Merlin and quarterly with Drs. Merlin, Kerns, and Saag to guide her on how to incorporate mental health factors that emerge from her analyses, especially depression and anxiety, into the intervention. Additionally, I have many active and planned collaborations with UAB faculty, which provide rich opportunities to interact with Dr. Merlin. We will also meet in person at annual IAPAC and CNICS meetings and during my annual trip to UAB.

I have enjoyed mentoring 17 early career fellows and faculty, including as primary mentor on six NIH K awards. I have published on institutional strategies to improve mentoring, have been awarded a K24 by NIMH to provide mentoring (with a pending renewal from NIDA), and have been recognized at UCSF with the 2011 Distinction in Mentoring Award. As Dr. Merlin's co-mentor, I will avail the full spectrum of my resources to her.

Mallory Johnson, PhD

---

Yale University

Dear Committee Members: April 9, 2014

I am honored to serve as a mentor to Dr. Jessica Merlin in her K23 career development award. I am a clinical health psychologist with over 30 years of experience developing behavioral interventions for chronic pain, and I have mentored six faculty on career development awards. I have known Dr. Merlin for the past eight months. We were introduced by her advisor Dr. Bair; she quickly became an active participant in my national VA Pain Research Working Group. We have met once and sometimes twice a week since I joined her mentorship team in January. I have been impressed by her genuine interest in developing a chronic pain behavioral intervention that is scientifically rigorous. During our meetings, I recommended several texts, including Dr. Dennis Turk's formative work on pain psychology, and Dr. Alfred Bandura's books on Social Cognitive Theory and related interventions. Dr. Merlin has read the chapters most salient to her work and with my guidance has incorporated them into her research approach. Also with my guidance and input from Drs. Johnson and Davies, her intervention mapping approach is now grounded in Social Cognitive Theory. Dr. Merlin is the rare physician who can bridge the worlds of medicine and psychology. As someone known for my contributions and success in interprofessional education and training, I am extraordinarily enthusiastic about my role in mentoring Dr. Merlin. I am committed to meeting with her monthly, joined by Drs. Saag and Johnson quarterly, to guide her step by step as she develops a chronic pain intervention tailored to HIV-infected individuals. She and her study staff will receive training at my PRIME Center, and we will also meet in person at the American Pain Society meeting and as other opportunities arise. I enjoy working with Dr. Merlin and look forward to continuing to mentor her during this K23.

Robert D. Kerns, PhD

UAB SCHOOL OF PUBLIC HEALTH

Dear Review Committee Members, March 1, 2014

I am an Associate Professor in the Department of Health Behavior at the UAB School of Public Health. My role in Dr. Merlin's K23 is as an advisor providing expertise on intervention mapping (IM). I use IM in my work, including developing theory-based behavioral interventions in HIV-infected patients. IM is an excellent fit for Dr. Merlin's project, as she describes in her approach. I teach the introductory class on this topic, which will be one of the first classes Dr. Merlin takes during her K23, and I will teach her IM independent study.

Dr. Merlin and I have been meeting on a bimonthly basis for the past 9 months to develop her approach. During the past 3 months, this has included a joint meeting with Dr. Saag and co-mentors Drs. Johnson and Kerns. IM is a technique that fits in well with Drs. Johnson and Kerns' prior intervention development experience, and one which they have embraced. I am committed to working with Drs. Johnson and Kerns to advise Dr. Merlin on IM. This will include monthly meetings with Dr. Merlin and joint meetings with her mentors whenever needed. Dr. Merlin's K23 project will make an important contribution to the field, and I am happy to serve as one of her advisors.

Susan Davies, PhD

---

SCHOOL OF MEDICINE
INDIANA UNIVERSITY

Dear Review Committee Members: April 12, 2014

I am an Associate Professor of Medicine at the Indiana University School of Medicine. I conducted a randomized controlled trial of the Stepped Care for Affective Disorders and Musculoskeletal Pain (SCAMP) intervention, and have tested SCAMP in a variety of populations and settings. Dr. Merlin will use SCAMP as a starting point to develop a much needed behavioral intervention for chronic pain in HIV. My role will be to advise her based on my experiences testing SCAMP. As she describes in her Research Approach, Dr. Merlin and I have been meeting for almost a year. I have provided her with intervention manuals, and will be a training site for her research team to learn about intervention delivery. We will meet monthly and hold additional joint meetings with her mentors, including my colleague Dr. Kerns, as needed. I look forward to being a part of Dr. Merlin's intervention, which given her mentorship, training plan, and approach, will no doubt be a success.

Matthew Bair, MD, MSc

---

UAB SCHOOL OF MEDICINE
Department of Medicine

April 21, 2014
Dear Review Committee members,

I am Associate Professor at the UAB School of Medicine. My research has focused on understanding patterns of illicit drug use among persons who have been homeless, and tailoring primary care delivery to this population. I began advising Dr. Merlin more than a year ago on psychometric and qualitative methods for her K12 career development award. I am thrilled to serve as her substance abuse advisor for her K23. Specifically, given the role substance abuse plays in chronic pain, and Dr. Merlin's identification of substance use as an intervention target, I will advise Dr. Merlin on its incorporation into the intervention. To do this, I will meet with Dr. Merlin at least monthly. I am pleased to work with Dr. Merlin on this important project.

Stefan Kertesz, MD, MSc

---

UAB COLLEGE OF ARTS AND SCIENCES
Department of Psychology

Dear Members of the Review Committee: 3/30/2014

I am an Assistant Professor of Psychology and a clinical health psychologist, and completed my clinical internship under the primary supervision of Dr. Robert Kerns. I am a pain psychologist at the UAB-Highlands Pain Clinic. I provide a host of services including cognitive-behavioral pain management. I met Dr. Merlin shortly after arriving at UAB, and have interacted with her regularly. I am pleased to provide her with opportunities to extend her chronic pain expertise. This will include supervision in her HIV/chronic pain clinic where I will guide her as she works to incorporate her patients' mental health comorbidities into their treatment plans. I also participate in her HIV/chronic pain interdisciplinary team meetings, and she will shadow me in my pain clinic. I look forward to working together.

Burel Goodin, PhD

**INSTITUTIONAL ENVIRONMENT**

The University of Alabama at Birmingham (UAB) is a leading national research university. It is the ideal environment for me to begin my research career in chronic pain behavioral intervention development and testing in individuals with HIV. My appointment as Assistant Professor is within the Department of Medicine, and Division of Infectious Diseases. My primary mentor, Dr. Michael Saag, is a Professor within the Division. Our Division has a strong track record of mentoring junior investigators to career independence. During my four-year K23, I will be provided with the full support of the Division as outlined in the Institutional Commitment letter. I will also take advantage of the rich research and career development resources at UAB (Facilities and Other Resources), and I will receive mentorship/advisement from outstanding senior investigators (Career Development/Training Activities).

I am in the ideal environment to accomplish my research and career development goals. UAB has a strong, well-established HIV research program centered in the UAB Center for AIDS Research (CFAR). The UAB CFAR is one of 20 CFARs in the US, and provides me with substantial research support. As a CFAR investigator, I have collaborated with Mr. Andrew Westfall, the CFAR statistician, on all of my projects. My research at UAB to date has been conducted at the UAB 1917 Clinic Cohort, a cohort of more than 2000 HIV-infected participants from the UAB 1917 Clinic, which collects detailed demographic and clinical data. The UAB 1917 Clinic Cohort is led by Dr. Michael Mugavero, who has written one of my letters of recommendation and is a national leader in HIV research. In addition, UAB is one of only 8 sites for the national CFAR Network of Integrated Clinical Systems (CNICS) cohort, founded and led by my primary mentor Dr. Michael Saag. CNICS provides the infrastructure for collection of pre-set and project-specific Patient Reported Outcome (PRO) data, in addition to integration of clinical data across cohorts. CNICS, and specifically the UAB site (1917 Clinic Cohort) have proved to be excellent cohorts for the development and testing of behavioral interventions. My office is in the same suite as Drs. Saag and Mugavero to facilitate mentorship and collaboration. In addition, the UAB 1917 Clinic Cohort has a well-developed multidisciplinary team of scientists from numerous Departments and Schools at UAB and multiple cores of the UAB CFAR. The team includes behavioral scientists and epidemiologists that meet regularly to discuss ongoing and potential collaborations. In addition to extensive research support through the CFAR, I receive administrative, grants management, and project management support through the co-located HIV Research Informatics Service Center (RISC), which has substantial expertise in carrying out qualitatively-based studies.

With the CFAR as my research "center," my career development activities will leverage an integrated web of resources across campus. For example, in 2012-2013, I received a pilot grant from the UAB Center for Clinical and Translational Science (CCTS). Co-sponsored by the CFAR, this pilot grant enabled me to collect preliminary data on HIV and chronic pain. The UAB CCTS also provides numerous educational activities in which I participate, including biostatistics seminars, career development workshops, training in the responsible conduct of research, and a K23 nascent projects panel in which I have received feedback on this application. If awarded the K23, I will pursue a Master of Science in Public Health in Health Behavior at the UAB School of Public Health (SOPH). Consistently listed among the top Public Health schools in the nation, the school's faculty is research intensive, ranking 11$^{th}$ nationally in research support. My advisor Dr. Susan Davies is faculty in the SOPH's Department of Health Behavior. *I will also take courses in the UAB Department of Psychology's APA-sponsored Clinical Medical Psychology program, and will receive clinical supervision from and engage in shadowing opportunities with Dr. Burel Goodin, a pain psychologist at the UAB-Highlands Pain Treatment Clinic who trained with my mentor Dr. Kerns.* I am also an investigator in the Center for Outcomes and Effectiveness Research and Education (COERE) where I participate in numerous informal training opportunities, including works in progress and methods seminars. Additionally, my K12 career development award, administered through the COERE, includes seminars specifically for K12 awardees focused on the transition from junior faculty to independent investigator. UAB's Center for Palliative and Supportive Care (CPSC) is recognized as one of the leading palliative care programs in the US. I co-founded and co-direct the Palliative Care Center Scholar's Program, a forum that brings pain and palliative care researchers from across campus together monthly to discuss collaborations and works in progress.

In sum, these substantial resources, and my carefully designed Career Development/Training Activities, will provide me with ample opportunity for further collaboration, intellectual interaction, mentorship, and career development. The depth of resources and mentorship in my research environment will support a successful transition to independent investigator status *and achievement of R01 funding by the conclusion of my K23.*

UAB SCHOOL OF MEDICINE

*Department of Medicine*

Dear Committee Members: April 3, 2014

It is our pleasure to provide our enthusiastic and unreserved support for Dr. Jessica Merlin's resubmission application for a K23 Mentored Patient-Oriented Research Career Development Award. As a candidate for a K23, Dr. Merlin combines her formal training in both Infectious Diseases and Palliative Care with abundant enthusiasm and intellectual curiosity as a superb foundation to embark on a research career in chronic pain in individuals with HIV. We recruited her with this goal in mind and fully support her in this endeavor. During her two and a half short years since joining us, Dr. Merlin has demonstrated academic excellence and a consistent commitment to her goal of becoming an independent investigator. She is an ideal candidate for a K23.

Since joining our faculty just 2 ½ years ago, Dr. Merlin has become the Director of our HIV/chronic pain clinic, which will serve as her "laboratory" and provide her with access to the patients she will study during the research described in this application. To assist her efforts, we have provided and will continue to provide her with support staff including a nurse practitioner and a physical therapist. She has already achieved a high degree of research productivity in this setting. After just one year at UAB, she was awarded an internal Center for Clinical and Translational Science (CCTS) pilot grant, and a 2 year K12 Patient Centered Outcomes research Career Development award. With the support of her K12, Dr. Merlin has spent approximately 80% of her time on research and career development. At this time she is one and a half years into her K12 and she has made excellent progress, publishing 6 papers related to HIV and chronic pain during this time, with 4 additional papers under review, and 1 in preparation.

Dr. Merlin will not be asked to achieve her goals without continuing support. As mentioned above, we have already created an environment that will facilitate Dr. Merlin's success. Complementing this, Dr. Merlin has assembled a strong team of mentors and collaborators, including Dr. Michael Saag, her primary mentor. Dr. Saag is an internationally renown HIV investigator, and the PI for the UAB Center for AIDS Research (CFAR) and the CFAR Network of Integrated Clinical Systems (CNICS). Drs. Merlin and Saag have been meeting regularly, and together they have developed a mentorship plan to help Dr. Merlin's transition to being an independent investigator. This plan includes specific mentorship related to health psychology/mental health and chronic pain behavioral intervention development and testing, including the conduct of behavioral clinical trials, in addition to pre-determined benchmarks such as conference attendance and paper publication. Dr. Merlin's office is located in the same office suite as Dr. Saag to facilitate scientific growth. She has also developed a close relationship with the School of Public Health including Dr. Susan Davies. We have also provided Dr. Merlin with start-up funds of $[redacted] per year for her first three years (ending August 2014) to cover conference and research-related expenses as well as office and grants management support also co-located in the same office suite. Dr. Merlin recently won a research award for top performance in the Department in terms of funded grants (her K12), publications, and external talks. This award came with an additional $[redacted] for her research. All of these funds may be carried forward if not spent. In addition, to further indicate commitment to her research success, we have matched a portion of her grants with divisional funds for research expenses. From these sources, by Fall 2014, she will have ~$[redacted] in a discretionary account.

Dr. Merlin will continue to have 80% of her time protected to devote to research and career development during her K23, including coursework to receive a Master of Science in Public Health. In addition, she will continue to direct the HIV/chronic pain clinic, which contributes directly to her research, keeping the time commitment in clinic limited to the half day she spends there per week.

Dr. Merlin is already becoming a national leader in HIV chronic pain research. Her productivity and passion for her research have impressed us all, and as a result, we have worked hard to create an environment in which she can thrive. Her stellar mentor and advisor team, and UAB's intellectual environment and institutional commitment have her poised for success. We are committed to her success, development, advancement, and retention as faculty at UAB irrespective of whether she receives a K23 award. She is an integral part of our clinical research team, and with support from a K23 Career Development Award, her potential for success is unlimited.

Sincerely,

Edward W. Hook, III, M.D.
Professor and Director, Division of Infectious Diseases, Department of Medicine

Seth Landefeld, M.D.
Professor and Chair, Spencer Chair in Medical Science Leadership, Department of Medicine

**SPECIFIC AIMS**

A key component of this four-year mentored career development award is the conduct of original research in HIV and chronic pain. Therefore, building on my proposed training and in close collaboration with my mentorship team, I will develop and pilot test a tailored, theory-based intervention for chronic pain in HIV-infected patients. Chronic pain is a common chronic illness associated with substantial functional impairment.[9] Defined as pain lasting longer than three months,[10,11] chronic pain affects up to 30% of the US population.[9] It often occurs in patients with complex chronic illness, including medical, psychiatric, and substance use comorbidities.[12-16] However, chronic pain is not simply a symptom of these comorbidities. Its distinct neurobiologic basis and substantial impact on physical and emotional function make it a serious illness in itself. In recognition of its importance, the Institute of Medicine has called chronic pain a "public health crisis," and identified research on chronic pain, particularly in populations most burdened by this condition, to be a priority.[9]

The burden of chronic pain in HIV-infected patients is substantial. Prevalence estimates of chronic pain in HIV-infected patients are as high as 39-85%.[1,4,17-23] Mounting evidence suggests that chronic pain in HIV is often associated with psychiatric illness, especially mood disorders such as depression,[1,2,4,23] and has serious health consequences, including up to 10 times greater odds of functional impairment.[5]

Non-pharmacologic, behavioral interventions to decrease pain and improve physical and emotional function in HIV-infected patients with chronic pain are needed. A consensus panel identified pain, physical, and emotional function to be the most important outcomes of chronic pain interventions.[24] Commonly used pharmacologic therapies, including opioids, often do not result in substantial improvement in these outcomes,[25,26] and carry risks including misuse, abuse, and addiction.[26] In HIV, opioids may actually be associated with worse pain,[27] and adversely interact with antiretrovirals.[28] Behavioral interventions are among the most effective and safe non-pharmacologic treatments for chronic pain in the general medical population. *These include Social Cognitive Theory-based cognitive behavioral interventions that focus on self-management strategies to relieve pain and achieve functional goals.*[29-31]

While there is much to be learned from existing interventions, it is critical to develop a behavioral intervention specifically tailored to HIV-infected patients with chronic pain. The success of a behavioral intervention is heavily influenced by how well it is tailored to the target population's biological, psychological, and social context.[32] We recently adapted the Biopsychosocial (BPS) Framework to describe the unique context in which chronic pain is experienced by HIV-infected patients.[8] *Our present goal is to develop and test a behavioral intervention tailored to improve pain and function in HIV-infected patients with chronic pain. Our work will be guided by Social Cognitive Theory in the context of the BPS Framework.* Our Specific Aims are:

*Aim 1: Use intervention mapping to systematically develop and pre-test a tailored behavioral intervention for chronic pain in HIV-infected patients.*

*Aim 2: Conduct a two-arm pilot randomized controlled trial of the behavioral intervention compared to routine HIV and pain care, to determine feasibility, acceptability, and preliminary impact.*

In Aim 1, we will use intervention mapping, which is a series of steps that allows for systematic development of a tailored intervention.[32,33] These steps will include an iterative process of: 1. selection of intervention targets *(e.g., depression/anxiety, substance use, use of prescription opioids for pain management)*; 2. identification of existing theory-based interventions that can be used as a starting point; 3. qualitative investigation involving patients, providers, and key stakeholders guided by the results of steps 1 and 2 to produce the intervention manual; and 4. pre-testing intervention sessions in 10 participants and conducting qualitative investigations in these participants to further refine it*. In Aim 2, the intervention will be piloted in a small randomized controlled trial (20 participants/arm) to assess feasibility, acceptability, and preliminary impact. If the findings are promising, the intervention will be tested in an R01-funded randomized controlled trial to evaluate efficacy at the conclusion of the K23.*

*I have significant clinical training and expertise in the biomedical approach to HIV and chronic pain. However, health psychology/mental health and chronic pain behavioral intervention development and testing, including clinical trials, represent major gaps in my training.* My mentorship team includes leaders in these areas. I will conduct this work at the UAB 1917 Clinic Cohort/CFAR Network of Integrated Clinical Systems (CNICS) site under the guidance of my primary mentor and CNICS national PI, Dr. Michael Saag. This cohort allows for the efficient recruitment and prospective capture of extensive study-specific data including qualitative data,[34-36] and has an excellent track record of behavioral intervention development and testing. *My team will also include health psychology/mental health co-mentor Mallory Johnson PhD, Professor of Medicine, University of California, San Francisco (UCSF), who will work with me to incorporate mental health factors (e.g., depression, anxiety) into the intervention, and chronic pain behavioral intervention development and testing co-mentor Robert Kerns PhD, Professor of Psychology, Neurology, and Psychology, Yale, who will work with me step-by-step as I develop and test the intervention. Both are established investigators and mentors with strong theoretical backgrounds and clear ties to UAB, who have been working closely with me over the past six months. I will continue to work with Dr. Saag as I complete Aim 2 and prepare to conduct an R01-supported national CNICS-wide randomized controlled trial.* This work and corresponding career development will launch my career as an independent investigator in HIV and chronic pain research.

## RESEARCH STRATEGY

### A. SIGNIFICANCE:

**A1. Chronic pain is a chronic illness.** Chronic pain is defined as persistent pain lasting longer than 3 months, beyond the period of normal tissue healing.[10,11,37] It often occurs in patients with complex chronic illness**,** including medical, psychiatric, and substance use comorbidities.[12-15] However, chronic pain is not simply a symptom of these comorbid conditions. Rather, it has a unique neurobiologic basis. Chronic pain involves processes that heighten sensitivity in peripheral receptors, and cause perception of pain in the absence of local inflammation.[38-40] Chronic pain occurs in up to 30% of individuals in the general population,[9,41-43] costs more than heart failure or cancer,[9] and is associated with impaired physical and emotional function.[44] In a recent report, the Institute of Medicine described chronic pain as a chronic illness in itself and a "public health crisis," and called for research among populations most affected.[9]

**A2. Chronic pain in HIV is unique from chronic pain in the general population.** Chronic pain occurs in 39-85% of HIV-infected patients,[1,4,17-23] and is associated with deleterious outcomes. HIV-infected patients with chronic pain have up to 10 times greater odds of impaired physical function,[5] and in some, 1.5 times greater odds of 'no-showing' to primary care visits,[4] compared to those without pain (Section C1).

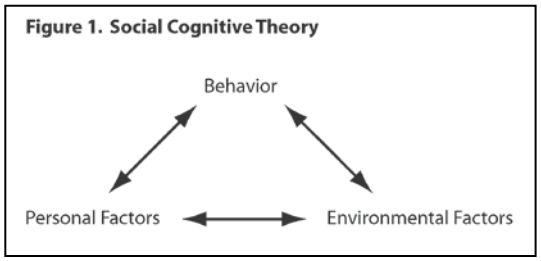
Chronic pain in HIV includes the classically described syndromes of HIV neuropathy[45] and avascular necrosis,[46] as well as other regional musculoskeletal pain and widespread pain (e.g., fibromyalgia).[2,23,47] Regardless of the etiology, chronic pain in HIV-infected patients is distinct from chronic pain in the general population for two reasons. First, chronic pain in HIV-infected individuals is biologically distinct from chronic pain in HIV-uninfected individuals. Several studies have established that the HIV virus causes inflammation around peripheral neurons.[48-51] A growing body of basic science literature has also found a specific biologic basis for the development of both neuropathic and non-neuropathic chronic pain in HIV-infected patients, involving activation of astrocytes in the spinal dorsal horn.[52,53] Second, HIV-infected individuals with chronic pain experience not only a unique biological, but also a distinct psychological and social context,[54,55] which we have described in our adapted Biopsychosocial Framework for Chronic Pain in HIV.[8]

**A3. The Biopsychosocial (BPS) Framework provides a context for our work.** The BPS is an explanatory Framework that has been applied to medical and psychiatric diseases,[56,57] including chronic pain.[58] To explain the unique context experienced by HIV-infected individuals with chronic pain, we deliberately cast a broad net and identified biological, psychological, and social factors common to individuals with HIV and individuals with chronic pain.[8] Based on this process, we describe chronic pain in HIV within the context of pain diagnosis, comorbid medical[59-61] and psychiatric illness,[12,61-65] chronic opioid use,[25,27,66] substance use[62,65,67-70], stigma,[71,72] traumatic life events,[73-77] and environmental challenges such as housing,[78,79] employment,[80-83] and social support.[84-87] This adapted BPS Framework will provide the context for tailoring a Social Cognitive Theory-based chronic pain behavioral intervention to individuals with HIV. In Section A4, we present our rationale for why a tailored behavioral intervention is needed, and in Section A5, we explain our choice of Social Cognitive Theory as its theoretical basis.

**A4. Non-pharmacologic, behavioral interventions tailored to HIV-infected patients with chronic pain are needed.** Medications are commonly used to treat individuals with chronic pain, but have significant limitations. The most commonly prescribed medications for pain in the US are opioids, which have increased in use dramatically over the past 10 years.[88] Opioids are more commonly prescribed for HIV-infected individuals with chronic pain than HIV-uninfected individuals.[89] Despite their frequency of use, a recent Cochrane review concluded that many participants in studies of chronic opioid therapy discontinue the opioid due to insufficient pain relief or side effects.[25] Among participants who continued the opioid, results were insufficient to draw conclusions regarding function, and there was only weak evidence to support improvement in pain. Likewise, HIV-infected individuals with chronic pain on chronic opioid therapy have worse pain than those not on chronic opioid therapy.[27] In addition to these major efficacy concerns, opioids carry serious risks. These include medical complications such as cardiovascular disease,[90,91] fractures,[92] hypogonadism,[93] misuse and overdose[94] (especially in individuals with a history of substance abuse[94,95]), and adverse interactions with antiretrovirals.[28] Long-term use of other pharmacologic therapies such as non-steroidal anti-inflammatory drugs and acetaminophen is also challenging because of cardiovascular, renal, hematologic, and gastrointestinal risks.[96-101] Anticonvulsants such as gabapentin are only modestly effective for neuropathic pain,[102] and are ineffective in musculoskeletal pain. Antidepressants such as duloxetine may be beneficial, but have only modest effect sizes in some patients,[103] and are ineffective in others.[104]

*Because these medications are commonly prescribed, we should take their use into account as we develop our intervention.* However, a purely pharmacologic approach is limited by the safety and efficacy concerns described above, and does not help patients learn how to overcome disability associated with chronic pain.[105,106] Behavioral interventions are among the most effective chronic pain treatments in the general population,[44] and the success of a behavioral intervention is heavily influenced by how well it is tailored to the target population's biological, psychological, and social context.[32] Therefore, within the context of our adapted BPS framework, we will develop a theory-based behavioral intervention for chronic pain in HIV.

***A5. Theoretical basis of the intervention.*** *Guided by my mentors, I have selected Social Cognitive Theory as the intervention's theoretical basis (Figure 1). The process of using Social Cognitive Theory to inform the intervention has involved integration of my biomedical background with my mentors' expertise in health psychology/mental health and chronic pain behavioral intervention development. To reflect that process, we explain Social Cognitive Theory using a common clinical example encountered in individuals with chronic pain.*




*Social Cognitive Theory is the most widely cited basis for chronic pain behavioral interventions.[107] Social Cognitive Theory is a learning theory, and asserts that even in the setting of a stressor (pain), people can learn to change their behavior (e.g., to engage in regular physical activity despite the fear of pain or re-injury).[108] Learning can occur by observing others; for example, observing an instructor who describes, explains, or even models that behavior. Additionally, behaviors are influenced by personal and environmental factors (e.g., depressive symptoms may lead to reluctance to engage in regular physical activity). Reciprocal determinism argues that individuals have the power to change these personal and environmental factors (e.g., seek treatment for depression), and furthermore, that changes in personal and environmental factors can influence each other and influence behaviors (e.g., improvement in depressive symptoms can help someone engage in regular physical activity despite ongoing pain). Behavioral change should in turn lead to improvements in downstream outcomes of interest. Based on an evidence-based consensus statement from the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), these downstream outcomes include not only pain severity, but also physical and emotional function.[24,109]*

*Therefore, to develop a Social Cognitive Theory-based intervention, we propose to target relevant personal or environmental factors, and incorporate behaviors that promote improvement in pain and functional outcomes. To tailor the intervention to individuals with HIV and chronic pain, we identified personal and environmental factors from our adapted BPS Framework. We conceptualized pain diagnosis, comorbid medical and psychiatric illness, chronic opioid use, and substance use as personal factors, and stigma, traumatic life events, and environmental challenges such as housing, employment, and social support as environmental factors. We have conducted preliminary investigations of these factors in individuals with HIV and chronic pain to pare down this list, and identify initial targets on which to focus our intervention development process (Section C1). Salient behaviors draw from the chronic pain literature, and include physical activity despite fear of pain/re-injury as in the example given above, cognitive symptom management behaviors such as positive self-talk and relaxation, and communication with clinicians about pain.[105,110,111] Addressing these behaviors is a key component of effective Social Cognitive Theory-based chronic pain interventions (Section A6).*

***A6. Social Cognitive Theory-Based chronic pain interventions from the general population can inform development of an intervention tailored to HIV-infected individuals.*** *Social Cognitive Theory-based cognitive behavioral interventions for chronic pain have been developed and tested in the general population and can inform our work.*

*Cognitive Behavioral Therapy (CBT) is the most widely studied behavioral approach to chronic pain.[112,113] CBT is a therapeutic approach that helps individuals change behavior by identifying and disputing maladaptive thoughts and cognitive distortions.[114] CBT for chronic pain promotes an individual's acceptance of responsibility for change and development of adaptive behaviors such as those described in Section A5 (e.g., engagement in physical activity), while addressing their maladaptive counterparts (e.g., avoiding physical activity due to fear of pain or re-injury[112,115]).*

*The adaptive behaviors that are an important focal point of CBT for chronic pain are often called "pain self-management behaviors," and CBT-based interventions are often referred to as Pain Self-Management (PSM) programs. This re-labeling accommodates the likelihood that such interventions may not be delivered in a typical office setting by a psychologist, and focuses attention on the desired outcome of the intervention (self-management) rather than its cognitive and behavioral components. Many PSM interventions have been developed for use in specific chronic pain syndromes, including low back pain, arthritis, and fibromyalgia. Despite the diversity of these pain conditions, protocols are often similar, and address behaviors that are important in all chronic pain conditions as described above. Numerous RCTs and meta-analyses of effective PSM interventions have been published.[111,116-118]*

*We are aware of two small CBT-based chronic pain intervention studies in individuals with HIV in the current treatment era. One consisted of a single arm psychologist-administered CBT intervention in HIV-infected individuals with any chronic pain diagnosis, and demonstrated modest effects on pain and functional outcomes.[119] An earlier randomized trial focused on peripheral neuropathy showed greater improvement in individuals receiving CBT than those receiving supportive psychotherapy.[120] Notably, both suffered from poor adherence, and neither was tailored to HIV-infected individuals. Neither has undergone further investigation.*

**A7. Stepped Care for Affective Disorders and Musculoskeletal Pain (SCAMP) is a Pain Self-Management protocol that can be used to develop a chronic pain intervention for HIV-infected patients.**

We reviewed the general chronic pain literature to find an effective theory-based cognitive behavioral / Pain Self-Management (PSM) intervention protocol. The intervention that most closely met our needs was the Social Cognitive Theory-based Stepped Care for Affective disorders and Musculoskeletal Pain (SCAMP).[121,122] SCAMP was initially developed as an intervention for patients with depression and chronic musculoskeletal pain (back, hip, knee with pain severity ≥ 4/10) in primary care settings. The intervention was delivered in two parts. The first part was pharmacologic management of depression using antidepressant therapy delivered over 12 weeks. The second part was a six-session Social Cognitive Theory-based PSM program delivered over 12 weeks. The program was delivered by a trained nurse care manager and included sessions on all the pain self-management behaviors described in Section A5. A randomized controlled trial of SCAMP found that the intervention group was much more likely to achieve a 30% or greater reduction in pain at 12 months (42% of intervention patients vs. 17% of usual care patients, RR 2.4, Number Needed to Treat 4.1).[122] Patients also experienced significantly less pain interference, functional impairment, and depression.

SCAMP has important limitations that preclude it from being directly applied to HIV-infected patients. The SCAMP study excluded patients with bipolar disorder, schizophrenia, and current alcohol or other substance use, conditions which are common in patients with HIV. SCAMP was also not specifically tailored to patients with HIV, which is important for the reasons explained above. However, given SCAMP's strengths – its theoretical basis, specific targeting of patients with depression, and inclusion of a Pain Self-Management program – it serves as a starting point for our intervention development.

**A8. Summary/Significance of Proposed Aims** Chronic pain in HIV-infected patients is unique from chronic pain in the general population. Behavioral interventions play a key role in chronic pain treatment, but have not been tailored to HIV-infected patients. The Specific Aims of this proposal will address that gap. *In Aim 1, guided by Social Cognitive Theory in a BPS context and with SCAMP as our starting point, we will use intervention mapping to develop and pre-test the intervention. In Aim 2, we will conduct a pilot trial.*

**B. INNOVATION** This K23 application is innovative because: *1. I will be the first investigator to develop and test a behavioral intervention for chronic pain that is theory-based, and specifically tailored to HIV-infected patients.* 2. Overall, this line of inquiry represents a novel approach to chronic pain in patients with HIV. To date, investigations of chronic pain in HIV have regarded pain as a symptom. Synthesizing knowledge from the chronic pain and HIV literatures, I approach chronic pain in HIV as a chronic illness, which can be addressed with behavioral interventions. *3. As the first physician trained in both HIV and pain/palliative care, I will also be the first to extend that specialized training to include mental health/health psychology and chronic pain behavioral intervention development and testing, uniquely preparing me to meet my career goals.*

**C. APPROACH**

**C1. Preliminary Studies** Using our adapted BPS Framework to generate hypotheses, we have conducted extensive initial investigations in the 1917 Clinic/CNICS Cohort. This has led to the identification of important factors, especially personal factors, relevant to chronic pain in HIV-infected individuals. This has allowed us to generate an initial set of intervention targets that will be used during the intervention development process. *Further studies are needed to investigate how to incorporate these targets into the intervention (Section C2, Study Design).*

*UAB HIV/Chronic Pain Interdisciplinary Subspecialty Clinic[2]: We conducted a chart review study of patients referred to my HIV/chronic pain clinic between 4/08 – 6/11, and used CNICS Patient Reported Outcomes to assess symptoms of depression and anxiety/panic (PHQ-9 and PHQ-A respectively[123]), and substance use (ASSIST[124]). Pain types included neuropathic pain (15, 12%), back pain (26, 21%), and other regional musculoskeletal pain syndromes (e.g., leg, hip, shoulder, neck, joints, < 10% each). Depressive symptoms (43, 35%), anxiety/panic (40, 32%), and current (17, 14%) or prior (59, 48%) substance use occurred at higher rates in patients attending the HIV/chronic pain compared to the overall HIV clinic (p< 0.05). Fifty percent of patients were prescribed opioids at the time of referral. These data highlight the need for our intervention to address the wide variety of chronic pain syndromes seen in our patients. Additionally, high rates of opioid prescription followed by the need to refer to such an intensive pain clinic underscores that opioids do not serve to fully address chronic pain in this population. Finally, we infer that these patients' mental health factors (depression/anxiety) and substance use may have made chronic pain management within a biomedical model difficult, prompting referral to our clinic. Therefore, depression/anxiety, substance use, and opioids emerge as important targets for intervention development.*

*Use of Prescription Opioids for Pain Management and Aberrant Drug-Related Behaviors: As described above, opioids are commonly prescribed for chronic pain in individuals with HIV. Using UAB 1917 HIV Clinic Cohort/CNICS data, we investigated the number of individuals who have been prescribed opioids for > 90 days ending in the year 2012. We excluded opioids co-formulated with cough suppressants (e.g., guaifenesin with codeine) and methadone prescribed for maintenance in individuals with opioid addiction. We found that 408/1658 individuals (25%) in our Cohort were prescribed chronic opioids during this time. We also conducted a separate qualitative study of the medical record which suggests that aberrant drug related behaviors in HIV-*

*infected individuals on chronic opioid therapy, ranging from more minor (e.g., lost/stolen prescriptions, patterns of dose escalation) to more severe (illicit substance use, diversion), are commonly encountered.[125] They are often troubling to providers and difficult to manage. This suggests that our intervention should consider addressing use of prescription opioids for pain management. Given the large numbers of individuals in our cohort prescribed opioids, we will be able to adequately recruit patients with perspectives on this issue.*

*The Chronic Pain Experience in HIV-infected Patients: Little work to date has investigated the chronic pain experience in HIV-infected patients. Using the BPS Framework (Section A3) to inform our interview guide, we conducted 30 qualitative interviews to understand the role that biological, psychological, and social factors play in affecting patients' pain and function. Psychological themes predominated and included the close relationship between depression, anxiety, and pain; mood and pain in the context of living with HIV; use of alcohol/drugs to self-medicate for pain; and opioid medications, especially in the context of illicit substance use. These results underscore the importance of targeting depression/anxiety, substance use, and use of prescription opioids for pain management as we develop our intervention (manuscript under review).[126] This work also suggests that patients with HIV and chronic pain are willing to openly discuss these challenging topics, which will be crucial to the success of our intervention development process (Section C2).*

Role of Substance Use in Chronic Pain and Retention in HIV Primary Care:[4] Among 1521 participants in our cohort between 4/08 and 6/11 with at least 1 year of follow-up, the relationship between pain and HIV primary care 'no-show' appointments (a marker of retention) was explored. Pain was associated with increased odds of a no-show in participants without substance use [aOR 1.4 (95%CI 1.1-1.9)], and reduced odds of a no-show in participants with substance use [aOR 0.4 (95% CI 0.2-0.9), p for interaction<0.05]. A possible explanation for these results is that in patients without substance use, pain acts as a deterrent from attending HIV primary care visits. However, patients with pain and substance use may have more complex chronic pain, and may be prescribed opioids more frequently and at higher doses.[127] This may lead the patient and/or provider to seek closer follow-up. *This suggests that different strategies may be needed to reach HIV-infected individuals with and without substance use who have chronic pain.*

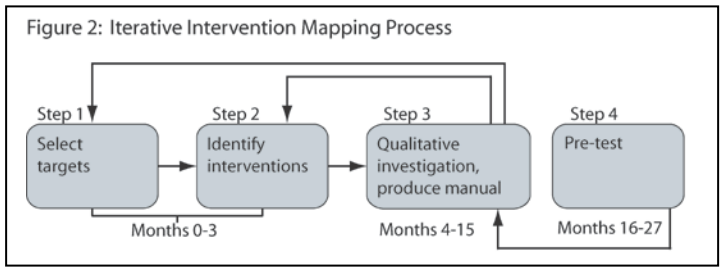
Chronic Pain and Physical Function[5]: Among 1903 participants in the Cohort between 4/08 and 6/11, 37% reported moderate or extreme pain "today" on the EuroQOL pain question.[128] Of participants with pain, 43% reported impaired mobility, 10% impaired self-care, and 41% impaired ability to perform usual activities. Pain was independently associated with up to 10 times greater odds of impaired physical function [aOR 10.5 (CI 7.6-14.6) for mobility, aOR 4.0 (CI 2.2-7.4 for self-care, and aOR 5.5 (4.0-7.4) for usual activities].[6] These findings are consistent with IMMPACT recommendations (Section A5) and reinforce that physical function, in addition to pain, will be an important outcome of our intervention.

Implications of Preliminary Studies: ***Depression/anxiety, substance use, and use of prescription opioids for pain management are initial targets that will be used during intervention development.*** *While not exhaustive, this list is a starting point. Our approach is flexible and will allow other targets to emerge.*

**C2. Study Design by Aim**

***Aim 1: Use intervention mapping to systematically develop and pre-test a tailored behavioral intervention for chronic pain in HIV-infected patients.***

We have chosen the intervention mapping (IM) process to systematically develop and pre-test our intervention. IM is a time-intensive, systematic, iterative behavioral intervention development process, *on which I will receive guidance from my advisor Dr. Davies, in collaboration with my mentors Drs. Johnson and Kerns.[32,33]* IM is a good methodologic fit for this project. *It will allow us to focus on and prioritize key targets identified in prior studies (Section C1) while also exploring how other factors from Social Cognitive Theory may be incorporated into an intervention, allowing new potential intervention targets to emerge.* Figure 2 summarizes the preliminary plan for our 4-step IM process, and underscores its iterative nature.




Step 1. Select intervention targets. *We have already begun this step by identifying depression/anxiety, substance use, and use of prescription opioids for pain management as intervention targets. We do not yet know precisely how the intervention will address these targets. Rather, these targets will be focal points of our qualitative intervention development process (Steps 3 and 4 below). Additionally, the IM process is iterative (Figure 2). We will conduct qualitative investigations to explore how other factors from Social Cognitive Theory, including other personal factors and environmental factors, may be incorporated into the intervention. We will allow new targets to emerge, and re-visit Step 1 as needed.*

Step 2. Identify existing theory-based interventions with efficacy in the general population of individuals with chronic pain that can be used as a starting point. We have also begun this step. We will use the Social Cognitive Theory-Based Pain Self-Management portion of SCAMP as our starting point (Section A7). Our team will further consider how the intervention targets we selected relate to existing SCAMP content. *For example,*

*although not included in SCAMP, Dr. Kerns' expertise in opioid use will allow him to advise us as we investigate how to incorporate the use of prescription opioids for pain management into the intervention.*

Step 3. Conduct a qualitative investigation of patients, providers, and key stakeholders guided by the results of Steps 1 and 2 to produce the intervention manual. *We will synthesize the results of interviews/focus groups in patients and providers/stakeholders to develop the intervention manual. Descriptive data collected to characterize our sample will inform recruitment, and provide clinical context for the analysis.*

*Setting:* Aim 1 Step 3 will be conducted at the UAB 1917 Clinic Cohort/CNICS Site.

*Inclusion/Exclusion criteria:* For patients, inclusion criteria will be having consented to CNICS, age ≥ 19, and having chronic pain based on the 2-question Brief Chronic Pain Screening tool we have studied.[7,129] Because physical function is an important intervention outcome (Sections A4 and C1), we will require patient participants to have chronic pain and at least moderate functional impairment (SF-36 physical function subscale score of < 40, one standard deviation below the mean,[130] or a Brief Pain Inventory [BPI] interference score of ≥ 4, considered to be clinically meaningful[131]). For providers/key stakeholders, inclusion criteria will be involvement in HIV care at UAB for ≥ 12 months. Participants will be excluded if they do not speak English.

*Sampling: Participants will be sampled to include the spectrum of those with important perspectives on our initial intervention targets. For patients (N≈40), in addition to recruiting only individuals with chronic pain and functional impairment, we will set minimum recruitment goals using CNICS comorbidity and prescription data for patients with histories of depression (at least 12), anxiety (at least 12), substance use history excluding marijuana (at least 20) including some patients with active substance use (at least 5), and chronic opioid therapy (at least 20). These numbers are based on the composition of our HIV/chronic pain clinic (Section C1), as we believe this most closely represents the target population. Collection of detailed descriptive data on each participant via structured interviews, PROs, and medical record data (Table 3) will allow us to further characterize our sample and explore sub-group differences. This will also provide clinical context for the qualitative analysis. We will review descriptive data at the 25%, 50%, and 75% recruitment marks and adjust recruitment strategies, if needed.* For provider/stakeholder interviews (N≈10), we will recruit the spectrum of HIV primary care providers, including physicians, nurse practitioners, social workers, pharmacists, and counselors. Stakeholders include others with important perspectives on programs for HIV-infected patients with chronic pain, such as front desk staff, leaders of the clinic's Patient Advisory Board, and the clinic director.

*It is important to note that patient participants will be alike in some ways, and different in others. All will have HIV and chronic pain, and we have presented the rationale for tailoring the intervention to this population. However, to represent the population who would seek treatment for chronic pain in an HIV clinic, we are not limiting enrollment by characteristics other than functional impairment. For example, we expect to include individuals with chronic musculoskeletal pain and individuals with neuropathy, because these are two common categories of pain seen in our preliminary studies (Section C1). We know that Social Cognitive Theory-based interventions have evidence of efficacy in both types of pain (Section A6). Additionally, existing Pain Self-Management interventions often incorporate similar content across chronic pain diagnoses (Section A6) – tailoring by pain diagnosis is likely to be less important than tailoring to HIV-infected patients. Therefore, we assert that our inclusive approach will result in an intervention that is broadly applicable in HIV settings.*

*Approach and Data Collection: For patient participants, we will begin with in-depth interviews. Given the sensitive nature of topics such as depression/anxiety, substance use, and use of prescription opioids for pain management, interviews are critical to providing rich individual perspectives.[132,133] Additionally, if we identify important sub-group differences in the analyses of interview data, we will consider stratifying focus group recruitment and subsequent analyses by subgroup (e.g., by individuals with depression).* Then, in order to prioritize themes raised during interviews, we will recruit unique participants for Nominal Group Technique (NGT)-based focus groups.[134] NGT is a formal idea-generating and consensus-oriented technique that promotes even rates of participation and equally weights the input from all group members.[135] In addition to clarifying the relative priorities of themes relating to the content and the format of the intervention raised during the interviews, *focus groups will also provide the opportunity to discover new themes that may emerge through the process of group discussion and interaction. For provider participants, to maximize comfort with providing candid views on this challenging topic, we will conduct focus groups stratified when feasible by provider type. In order to capture their individual perspectives, we will conduct in-depth interviews with key stakeholders.*

*Our interview/focus group guide for both patients and providers/stakeholders will focus on intervention targets identified based on preliminary data (Section C1). We will specifically inquire as to how these factors should be incorporated into the intervention. We will also include probes on how to incorporate other personal and environmental factors from Social Cognitive Theory (Section A5 - e.g., stigma, non-opioid pharmacologic and non-pharmacologic therapies).* At any time, new emerging themes may cause us to revisit Steps 1 and 2, and adjust our Step 3 recruitment and interview/focus group guide accordingly. We will also probe the perceived usefulness of SCAMP's Pain Self-Management-based behavioral components; which setting would be best for the intervention (e.g., clinic, community); mode of delivery (e.g., in-person, one-on-one, group, phone); frequency of delivery; who should deliver the intervention (e.g., doctor, nurse, counselor, social worker); and barriers/facilitators of the intervention. *We include a sample patient interview guide (Appendix).*

*In addition to basic demographics (age, race, sex) and routinely collected HIV clinical and behavioral data (HIV transmission risk factor, CD4+ T-cell count, viral load < 200[147,148]; adherence measured by the AACTG,[149] and retention measured by no-show visits during the past year[4,150-153]) we will also characterize our patient participants using descriptive data collected based on Social Cognitive Theory (Table 3). These data will be used to gain an in-depth understanding of the population in which the intervention is being designed. CNICS's infrastructure allows us to accomplish this using Patient Reported Outcome (PRO) measures programmed by our study team into CNICS and medical record data, in addition to structured interviews. PROs were selected for the current study on the basis of sufficient prior validation work in individuals with chronic pain, individuals with HIV, and based on IMMPACT recommendations (Section A5).[24,109] Due to the importance of mental health in individuals with chronic pain, it is important to assess not just psychiatric symptoms (as captured by PROs such as the PHQ-9 and GAD-7 listed in Table 3), but also psychiatric syndromes/comorbidities. My mentors have recommended performing the Structured Clinical Interview for DSM Disorders (SCID) to confirm diagnoses of depression, anxiety, substance use, and psychotic disorders.[136] Dr. Kerns and his team of psychiatrists/psychologists have extensive experience using the SCID and training others, and will train Dr. Walcott and I. Demographics (age, race, sex, degree/role in the clinic) will be collected from providers/stakeholders.*

***Table 3. Descriptive Data Collection based on Social Cognitive Theory***

| | ***Measurement*** | ***Source*** |
|---|---|---|
| *Personal Factors* | | |
| *Chronic pain diagnosis* | *E.g., osteoarthritis, peripheral neuropathy, fibromyalgia* | *MR** |
| *Pain therapies w/in past year* | *Prescribed opioids for at least 90 consecutive days in the past year[66]; other analgesic therapies (NSAIDS, acetaminophen, gapabentin, pregabalin) for at least 90 consecutive days in the past year; Non-pharmacologic therapies: Physical therapy, pain procedures (e.g., spinal injections)* | *MR* |
| *Psychiatric symptoms/ comorbidities* | *Comprehensive assessment: SCID[136]; Depressive symptoms: PHQ-9[123]; Anxiety symptoms: GAD-7[137]* | *Structured interview; PROs*** |
| *Medical comorbidities* | *Comorbidity count[138,139]* | *MR* |
| *Substance use* | *SCID; Tobacco: Tobacco use questionnaire[34,140]; Alcohol: AUDIT-C[141]; Illicit substances other than marijuana (intravenous drugs, amphetamines, cocaine, opioids): ASSIST[35]* | *Structured interview; PROs* |
| *Environmental Factors* | | |
| *Stigma* | *Stigma Scale for Chronic Illness [142,143]* | *PRO* |
| *Traumatic life events* | *Modified Life Events Survey[74,144]* | *PRO* |
| *Environmental stressors* | *Housing, employment, social support* | *MR* |
| *Behaviors* | | |
| *Physical activity, cognitive symptom management, communication with clinicians about pain* | *Pain self-management behavior questionnaire[110,111]* | *PRO* |
| *Outcomes* | | |
| *Pain severity* | *SF-36 bodily pain score[145]; Brief Pain Inventory pain severity subscale score[146]* | *PRO* |
| *Physical function* | *SF-36 physical functioning score[145]; Brief Pain Inventory pain interference subscale score[146]* | *PRO* |
| *Social/emotional function* | *SF-36 social and emotional role functioning subscales[145]* | *PRO* |

** MR = Medical Record. **PRO = Electronic Patient Reported Outcome measure.*

*While an active area of investigation, a widely accepted pain biomarker has not yet been developed. We will be attentive to the literature and if one is developed during the study period we will collect it if feasible.*

*Analysis and synthesis:* For qualitative data, digital audio recordings will be transcribed by a professional transcription company. Transcripts will be loaded into a qualitative data management software program, NVivo 10.0. I will collaborate with Drs. Melonie Walcott and Ivan Herbey, who participated in qualitative research I conducted during my K12.[7,126] We will perform content analysis to identify important themes representing majority and minority views on the topics raised.[154] *We will code according to personal, environmental, and behavioral constructs from Social Cognitive Theory (Section A5). We will also include new themes and concepts that emerge from the data, and will emergently determine whether stratification/subgroup analyses are warranted. For example, if we detect interesting differences in responses and themes for men and women, we will conduct sub-group analyses to explore differences in the data by gender. We will write a detailed analytical report on each theme that emerges from the interviews and focus groups. Patient and provider/stakeholder interviews and analyses will be completed concurrently, and we will do side-by-side comparison of patient and provider perspectives on main themes and subthemes. These results will be reviewed by Drs. Johnson, Kerns, and Davies, all of whom are experienced in qualitative analyses. The most common, richest themes will be given the highest level of consideration for incorporation into the intervention.*

We will develop our intervention manual using the SCAMP manual provided by my advisor Dr. Bair, and apply a Flesch-Kinkaid readability test at the 5th grade level. My team will review this draft and provide feedback to create a second draft. We will also create a checklist of intervention attributes that must be consistently delivered (e.g., content covered, responses to common questions, how to handle conflict). *Categorical data will be presented as frequencies, and continuous data as means/standard deviations.*

*Sample Size:* We will recruit ≈40 patients. Initially we will recruit 20 patients for interviews, analyzing the qualitative data concurrently, assessing for theme saturation and adjusting our recruitment targets and sample

size accordingly. We will then conduct 2 focus groups with 8 patients each, and pursue additional focus groups as needed if our analyses suggest stratification is important. Due to their smaller numbers, our goal is to recruit ≈10 providers/stakeholders, who will participate in 2 focus groups and 3 interviews.

*Logistics:* Based on CNICS PRO data collected every six months, we will identify patients with pain in the past six months and at least moderate functional impairment on the EuroQOL.[155] *Using CNICS comorbidity data, we will also generate lists of individuals with and without depression, anxiety, and substance use, and who are prescribed opioids (Sampling, above). Potential participants will be called by telephone. Following a standard phone protocol used by the 1917 Clinic Cohort, they will be pre-screened by the Research Assistant (RA) using the Brief Chronic Pain Screening tool.* Those who screen positive will be invited for an in-person screen, at which time they will be included or excluded after administration of the Brief Chronic Pain Screening Tool, SF-36, and BPI. Based on data suggesting a chronic pain prevalence of 30% in our Cohort,[4,129] EuroQOL data suggesting half of patients with HIV and chronic pain have substantial functional impairment,[5], and prior experience of 80% enrollment after screening, *we will use the infrastructure afforded to us by CNICS to phone screen 12-13 participants for every 1 enrolled (500 to enroll 40).* It will take patients two hours to complete study procedures. Providers/stakeholders will be approached by email for the hour-long interview/focus group.

*SCID interviews, qualitative interviews, and focus groups will be conducted Melonie Walcott DrPH. Dr. Walcott performed all of my K12 qualitative interviews, and also has extensive experience leading NGT-based focus groups. I am unable to conduct the interviews/focus groups myself, because study participants may also be my patients or colleagues. However, Dr. Walcott and I will review all audio tapes together. We will also receive rigorous training in performing the SCID with my mentor Dr. Kerns' team during Year 1.* We expect to enroll 2 patients/week, and to enroll providers/stakeholders concurrently.

Study ramp-up and Steps 1 and 2 will be completed during months 0-3. We will then develop the interview/focus group guide for Step 3 and train Dr. Walcott on it. Allowing for the iterative nature of the qualitative analysis, and potential for revisiting Steps 1 and 2, Step 3 will take 12 months to complete and last from months 4-15. Reimbursement will be $ for patients, and $ gift cards for provider/stakeholders.

Step 4. Pre-test the intervention in potential participants. *Study design:* We will deliver each proposed session (we anticipate at least six like SCAMP) to a group of patients. Dr. Walcott (not the interventionist) will conduct individual interviews after each session for feedback. We have chosen this design prior to pilot testing the entire intervention to allow for iterative modification. For example, after feedback from the first part of the intervention, we may decide to modify and repeat that part, or modify the next part prior to proceeding. If new themes are raised, we may return to Step 3 for additional formative work before continuing with pre-testing.

*Setting:* Like Step 3, Step 4 will take place at the UAB 1917 Clinic Cohort.

*Inclusion/Exclusion criteria:* Same as for Step 3; in addition, patient participants in Step 3 will be excluded to gain fresh perspectives.

*Sampling:* We will use the same sampling strategy as in Step 3, described in detail above.

*Delivery of the intervention:* To allow for iterative modification and repetition of intervention sessions, we will deliver the pre-test in a group setting (ultimately, we will use the results of our qualitative investigations to determine the optimal setting). SCAMP consisted of six sessions; we anticipate needing approximately this many sessions, but will adjust based on the results of our qualitative analyses during this step.

We will recruit an interventionist with training and skills in communication and patient education (e.g., Social Worker, Nurse Case Manager) who has been an interventionist in other 1917 studies. I will travel with Dr. Walcott and the interventionist at the beginning of Year 2 to Indiana University to receive training from my advisor Dr. Bair. This training will be drawn from Dr. Bair's experience with SCAMP, and will focus on the delivery of the behavioral intervention and the use of an intervention manual/checklist to ensure fidelity. Dr. Walcott will observe each session to ensure the manual is followed, review the checklist, and provide real-time feedback to the interventionist. *It will also be audiotaped, which will allow me to provide feedback without my presence disrupting the session.* If a patient participant misses a session, we will conduct a telephone make-up session and solicit feedback on phone delivery of the intervention.

*Data collection: At study entry, descriptive data will be collected to provide clinical context for the analysis (Table 3).* After each session, Dr. Walcott will interview each participant to obtain structured feedback based on a modified version of the Step 3 interview guide. If the session was conducted by phone, we will specifically probe about barriers to attending in person. Although they will not be present for the sessions, we will conduct a provider/stakeholder focus group in which we will describe the intervention and use NGT to build consensus about benefits and drawbacks of the intervention as designed.

*Analysis:* Our analytic approach will mirror that described in Step 3. Guided by my mentor/advisor team, we will modify the intervention manual iteratively after each session.

*Sample size:* We will pre-test the intervention in 10 patient participants. This is small enough to allow for interaction in the group, and large enough to provide a cushion against participant dropout. We will aim to recruit the 10 providers/key stakeholders enrolled in Step 3.

*Logistics:* We will recruit patients by phone, and providers/stakeholders by email as described in Step 3. Given the need to train study staff, and the highly iterative process of pre-testing, we anticipate that Step 4

will last from months 16-27. Patients will be reimbursed $ for the initial descriptive data collection visit, each intervention visit, and each interview. Provider/stakeholders will be reimbursed $ (gift card).

***Aim 2:* Conduct a two-arm pilot randomized controlled trial (RCT) of the behavioral intervention compared to routine HIV and pain care, to determine feasibility, acceptability, and preliminary impact.**

*Study design: In Aim 1, we propose a systematic process of intervention development/pre-testing that we assert maximizes the intervention's likelihood of being feasible, acceptable, and efficacious. In Aim 2, we will conduct a 2-arm pilot RCT to test its feasibility, acceptability, and preliminary impact compared to routine HIV care and pain care, in preparation for an R01-funded study to assess its efficacy.*

*Setting: Like the prior Aim, the pilot RCT will take place at the UAB 1917 Clinic Cohort/CNICS Site.*

*Inclusion/Exclusion criteria: Same as for Aim 1; patients who participated in the pre-test will be excluded, as their receipt of the pre-test may affect the results of their participation in the pilot RCT. Additionally, we will exclude participants who plan to begin a new pain treatment (e.g., surgery, new medication) that could interfere with the behavioral intervention.*

*Sampling: We will use the same sampling strategy as in Aim 1, described in detail above.*

*Delivery of the intervention: The interventionist who delivered the pre-test will also deliver the pilot. The content and format (individual vs group) of the intervention will be determined by Aim 1 and cannot yet be fully described. We anticipate six sessions over 12 weeks (like SCAMP). The intervention will be free of charge.*

*Participants in both arms and their providers will be given a handout recommending continuation with ongoing pain treatment as usual if prescribed (e.g., medications, physical therapy). Since we will enroll patients with chronic pain, there should be no need for urgent changes to the pain management plan during the study. However, this will ultimately be left up to providers' discretion. If an alteration must be made (e.g., adjustment in opioid dose, surgery), this data will be recorded, and the patient will remain in the study.*

*Data collection: We will collect descriptive data at the beginning of the pilot as in Aim 1 (Table 3), which includes both pharmacologic and non-pharmacologic pain treatments. Then, we will collect data on the feasibility/acceptability of the intervention using qualitative interviews at the midpoint and the conclusion of the intervention. This will include participants' assessment of intervention content, the hardest part of participating (e.g., logistical constraints such as transportation), and homework burden. We will record the length of time to recruit participants, number of participants screened vs. enrolled, adherence to the intervention, and willingness to be randomized. Preliminary impact will be evaluated using the SF-36 to assess physical/emotional function and the BPI to assess pain severity initially and at 0 and 3 months after completion of the intervention. Exploratory outcomes include virologic suppression (viral load<200[147,148]), adherence to ART (AACTG),[149] and retention in HIV primary care (no-show visits during the past year[4,150-153]).*

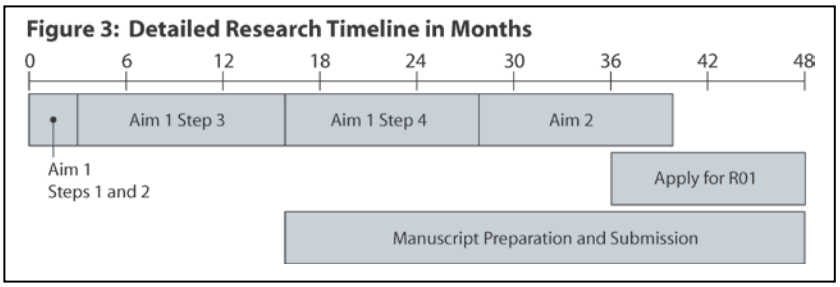
*Analysis: Qualitative data will be analyzed as described in Aim 1. Descriptive data will be reported for the intervention and control group. Categorical data will be presented as frequencies, and continuous data will be presented as means/standard deviations. Outcomes will be compared between groups using the chi squared test for categorical variables and 2-sample t-tests for continuous variables.*

*Sample size: We will recruit 20 participants per arm for the pilot RCT. We have chosen this number based on prior experience with what we believe is feasible during the study period. Subjects will be randomized 1:1 in a standard fashion. As described in Aim 1, we will be able to recruit 2 participants per week; therefore, it will take 5 months to recruit the whole sample, and the remaining 7 months will be used to complete the study (see Logistics, below). We are not powered to detect clinically relevant differences between groups. Rather, the purpose of our pilot is to determine the feasibility and acceptability of the intervention.[156] In order to investigate preliminary impact, we will also explore trends in our outcome data, recognizing the limitations of using those trends to inform sample size calculations.*

*Logistics: As described in Aim 1, we will recruit participants by phone who will be reimbursed $25 for each intervention visit and each interview. The pilot will last from months 28-39 (1 month startup; participant recruitment over 5 months; administration of sessions over 3 months; and collection of 3 month follow-up data).*

**C3. Potential Limitations** Selection bias: It is possible that the most challenging patients – those with the most substantial physical or emotional impairment from chronic pain or co-occurring conditions – may choose not to participate in this study. However, such patients would likely also be too impaired to participate in a behavioral intervention for chronic pain. This is not to say that these patients are beyond help. Rather, other strategies, perhaps involving community outreach to patients whose impairment keeps them from being able to engage in care for chronic pain, are needed to reach this population. *Scope: We recognize that behavioral interventions for chronic pain are not delivered in isolation. How to incorporate our intervention into patient-centered, integrated, interdisciplinary care, including other pharmacologic and non-pharmacologic therapies, will be an important component of our future work. Generalizability: Behavioral intervention development is often conducted in one setting, and if effective, adapted to others. UAB is representative of HIV-infected patients nationally, except with regard to substance use. Rates of substance use across the board are lower at UAB than in other CNICS cohorts.[157] As above, we will sample patients with substance use to ensure their inclusion during intervention development. We believe this will ensure that the intervention developed will be able to be tested in HIV-infected patients in other clinics in the US, and adapted if needed.*

**C4. Study Summary/Future Directions** By the conclusion of this K23, we will have developed and pilot tested a behavioral intervention for chronic pain in HIV-infected patients. At the beginning of Year 4, I will apply for an R01 to test the intervention's efficacy in a *national CNICS-wide RCT (Figure 3, Research Timeline).*



## PROTECTION OF HUMAN SUBJECTS

### A. Risks to Human Subjects

### A.1. Human Subjects' Involvement, Characteristics, and Design

This is non-exempt human subjects research.

Characteristics of participants: This study will be conducted at the UAB 1917 Clinic Cohort / Center for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS) site. This is a 2186 patient prospective cohort of HIV-infected patients. Aim 1 will involve patient, provider, and key stakeholder participants from this site. *Aim 2 will involve only patient participants.* Participants will not be selected or excluded on the basis of age, race, sex, or ethnicity.

*Aim 1, Steps 1 and 2* do not involve recruiting participants.

*Aim 1, Step 3* involves developing the behavioral intervention. For patients, inclusion criteria will be current enrollment in CNICS, HIV infection, age ≥ 19, chronic pain based on the Brief Chronic Pain Screening Tool, and the SF-36 physical function subscale score < 40 or BPI ≥ 4. For providers and key stakeholders, inclusion criteria will be involvement in HIV care at UAB for ≥ 12 months. Participants will be excluded if they do not speak English. Our goal will be to recruit ≈40 patients for qualitative data collection (≈20 interviews, 2 focus groups of ≈8 participants each). We may recruit additional participants if theme saturation is not reached, or if our analyses suggest stratification of focus groups is important and additional focus groups are needed. Due to their smaller numbers, our goal is to recruit ≈10 providers/stakeholders, who will participate in 2 focus groups and 3 interviews.

*Aim 1, Step 4* involves pre-testing the behavioral intervention. Inclusion/exclusion criteria will be the same as for Aim 1 Step 3, and patients who participated in Aim 1 Step 3 will be excluded. We will recruit 10 patient participants for this Aim. This is a small enough number of participants to allow for interaction during group sessions, and a large enough number to allow for some individuals who drop out of the study. We will also conduct a focus group of providers and key stakeholders who participated in Aim 1 Step 3.

*Aim 2 involves pilot testing the intervention that was developed in Aim 1. Inclusion criteria will be the same as for Aim 1. We will exclude patients who participated in the pre-test (Aim 1, Step 4). Additionally, we will exclude participants who plan to begin a new pain treatment (e.g., surgery, new medication) that could interfere with the behavioral intervention. We will recruit 20 participants per arm of the pilot.*

Sampling plan, recruitment, and retention:

*Aim 1, Steps 1 and 2* do not involve recruiting participants.

*Aim 1, Step 3:* For this Aim, we will recruit participants from the UAB 1917 Clinic Cohort/CNICS site. Patient participants will be sampled to include the spectrum of those with important perspectives on our initial intervention targets: will set minimum recruitment goals for depression (at least 12), anxiety (at least 12), substance use history excluding marijuana (at least 20) including some patients with active substance use (at least 5), and chronic opioid therapy (at least 20) according to CNICS medical record data. These numbers are based on the composition of our HIV/chronic pain clinic, as this most closely represents the target population. Efforts will be made to recruit the spectrum of HIV primary care providers, including physicians, nurse practitioners, social workers, pharmacists, and counselors. Stakeholders will include others with an important perspective on programs for HIV-infected patients with chronic pain, such as front desk staff, leaders of the clinic's Patient Advisory Board, and the clinic director.

*Aim 1, Step 4:* For this Aim, the sampling plan and recruitment strategy will be the same as for Aim 1 Step 3. Efforts to retain individuals who do not arrive in person will be made by conducting study visits over the phone, for which participants will be reimbursed the same as if they had arrived in person.

*Aim 2: For this Aim, the sampling plan and recruitment strategy will be the same as for Aim 1 Step 3.*

Involvement of special vulnerable populations: We will not specifically seek to include individuals from special vulnerable populations. However, we will not specifically exclude pregnant women, or women who become pregnant during the study period.

*Assignment to a study group: This does not apply to Aim 1. For Aim 2, our team will utilize a 1:1 ratio for allocation to the intervention and control arms. Our study statistician, Mr. Andrew Westfall, will use SAS to generate the randomization scheme. We will use block randomization with randomly selected block sizes to ensure equal numbers in each arm throughout study enrollment. Envelopes with study assignment will be used to ensure allocation concealment until after enrollment and the initial study visit. At the end of the initial study visit, study staff will unmask both study personnel and patients to treatment arm assignment and proceed accordingly.*

*Participants in both arms and their providers will be given a handout recommending continuation with medical pain treatment as usual during the study. Since we will enroll patients with chronic pain, there should be no need for urgent changes to the medical pain management plan. However, this will ultimately be left up to providers' discretion. If the patient's pain treatment plan is changed during the course of the pilot (e.g.,*

*adjustment in opioid dose, surgery), this data will be recorded, and the patient will be allowed to remain in the study if s/he chooses.*

*As the intervention will be designed in Aim 1, it is not possible to fully describe it. However, we anticipate that participants will receive a six-session intervention delivered over 12 weeks. Participants in the intervention and control arms will have full access to all available clinical services at the 1917 Clinic.*

**A.2. Sources of Materials**

For patient participants, data will be collected from the following sources: CNICS (including electronic medical record and Patient-Reported Outcome data); qualitative sources (in-depth interviews and focus groups); *and structured interviews (Structured Clinical Interview for DSM or SCID).* Intervention sessions will be audiorecorded but not transcribed, so that the PI can provide feedback to the interventionist. These sessions will not be analyzed formally.

Data containing identifying information will be available only to the PI (Dr. Jessica Merlin) and research personnel directly involved with this study (e.g., Dr. Melonie Walcott, qualitative interviewer, Dr. Ivan Herbey, qualitative analyst). Information about the study will be shared without individual identifiers.

CNICS Data: Data will be collected from the UAB 1917 Clinic Cohort/CNICS Site in accordance with the UAB CNICS Protocol. This will include demographic data (e.g., age using month and year only so as to avoid potentially identifying birth date information, race, sex) and other electronic medical record data (e.g., CD4+ T-cell count, viral load, number of no-show visits during the past year). In addition, we will collect Patient Reported Outcome measures (PROs). This study involves participant completion of both PROs used extensively in prior CNICS studies (e.g., PHQ-9), and PROs specific to this project (e.g., Brief Chronic Pain Screening Tool, SF-36). For a detailed list of data to be collected, see Section C2, Step 3, and Table 3. This data is collected from participants in electronic format on a web-based server, and will be stored on secure servers at the UAB CFAR. It will be transmitted when needed through an encrypted file sharing process to individuals directly involved in the study.

Participant Interviews and Focus Groups: During the consent process, participants will be alerted that interviews and focus groups will be audiorecorded. Digital audio files will be downloaded from the tape recorder onto the UAB CFAR server and immediately deleted from the recorder. They will then be transmitted securely to an outside contracted transcription company whose staff have completed Human Subjects training. Audio recordings will be transcribed by persons who do not have access to identifying information on the participants. Personal identifying information will be removed during the transcription process, and the transcript will be sent back to UAB study personnel for coding using NVivo 10.0. Transcripts and NVivo files will also be stored on the secure CFAR server. The recordings will be destroyed after the transcriptions have been completed and verified, approximately one year after this verification.

For providers and key stakeholders, qualitative data from in-depth interviews and focus groups will be collected in the same manner as is used for patients, above. Additional data as to the individual's basic demographics (age, race, sex) and degree/role in the clinic (e.g., clinic director, nurse practitioner, pharmacist) will be collected.

*Structured Interviews (SCID): The SCID is a structured interview that allows for determination of psychiatric diagnoses. Dr. Melonie Walcott will be trained by Dr. Kerns' team of psychiatrists and psychologists, who have extensive experience in both conducting the SCID and training others on its use. Dr. Walcott will take notes during the interview, which will also be audiorecorded and transcribed in the method described above for qualitative interviews. However, SCID interviews will not be subject to qualitative analyses, but rather will be audiotaped in case additional clarification is needed later, and for periodic review for fidelity and quality assurance. Psychiatric diagnoses are established in real time during the interview, and Dr. Walcott will enter the diagnoses into the study database at the end of the session.*

**A.3. Potential Risks**

Breach of Confidentiality: The main potential risk of this study is breach of confidentiality. This is one of the most common risks of participation in clinical research. Accordingly, our team has designed a strategy to protect participant confidentiality. All participants will be informed of study procedures and gauged for understanding of study tasks. In addition, study personnel will follow regulatory guidelines for obtaining informed consent. All interviews and intervention activities will be conducted in a private space. For all participants, research data will be stored using a code (sequence number based on entry to the study) instead of names or other personal identifiers. Consent forms with links to participant study numbers will be kept in a in a locked file in a locked room with the PI or research assistant. According to UAB regulatory policy, records relating to research, including informed consent documents, shall be securely retained for one year after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or sponsor agency at reasonable times and in a reasonable manner. All electronic study data are kept on UAB secure encrypted password protected servers, and will only be available to research personnel for this project. All study personnel will complete HIPPA and human subjects training in

accordance with UAB Institutional Review Board policy.

Psychological Distress: As participants will be asked to discuss chronic pain, and other potentially sensitive subjects such as psychiatric illness and substance use, there is a risk of psychological distress. Participants will be informed that they may stop the study visit at any time if they feel uncomfortable. Additionally, if a participant appears to be in emotional distress, study staff will inquire as to the participant's well-being and whether they wish to stop the study visit. Participants who opt to stop the study visit, or who disclose potentially harmful information (e.g., suicidality) will be immediately referred for an assessment by a clinic social worker, psychologist, or counselor. We will enact the Clinic's emergency protocol for persons who need immediate attention for escort to the UAB Emergency Department.

*Alternative Treatments and Procedures: Participants in the intervention and control arms will have full access to all available standard of care clinical services at the 1917 Clinic, and are permitted to withdraw or refuse participation at any time.*

**B. Adequacy of Protection Against Risks**

**B.1. Recruitment and Informed Consent**

Recruitment: We will approach individuals who have already consented to the main CNICS protocol so that we may utilize the CNICS platform, and so that demographic and medical record data can be linked to the PROs used in this study. However, this study is separate from the main CNICS protocol and will require that we individually enroll and consent each participant.

*For both Aims, patients with pain in the past 6 months and at least moderate functional impairment will be identified based on routinely collected CNICS data (EuroQOL). Using CNICS comorbidity data, we will also generate lists of individuals with and without the comorbidities on which we are sampling. With the permission of the clinic medical director, we will request a waiver of consent for preexisting data to the UAB IRB for screening purposes, which is our standard procedure for contacting potential participants. This includes a phone script that confirms the patient's identity that will be approved by the UAB IRB. Potential participants will be called using the number on file with the clinic. Following initial salutation, the potential participant will be asked to provide at least 2 data elements to confirm their identity (e.g., full name, date of birth). We will let them know that a research study is available and provide a brief description. We will ask if they would be willing to participate in a brief phone pre-screen. Interested individuals will be pre-screened for chronic pain using the 2-question Brief Chronic Pain screening tool. Individuals with chronic pain on this screen will be invited for an in-person screening visit. Phone-collected data will not be analyzed – it will be used only for screening eligibility purposes. To minimize participant burden, we will attempt to schedule the in-person screening visit on the same date as an upcoming clinic visit when possible, or at another convenient time per patient request. At the in-person visit, potential participants will be further screened with the administration of the Brief Chronic Pain Screening Tool, SF-36, and BPI.*

*Based upon an anticipated chronic pain prevalence of 30% and EuroQOL data suggesting that half of patients with chronic pain have substantial functional impairment, we anticipate screening approximately 12-13 patients for every 1 enrolled. We will accomplish this volume of phone recruitment using the existing team infrastructure afforded to us through CNICS, which has yielded efficient identification of potential participants by experienced research staff in prior studies.*

*Reimbursement:* In Aim 1 Step 3, patient participants in the structured interview and subsequent in-depth interview or focus group (2 hours total) will be reimbursed $50. Providers/stakeholder participants will be given a $ gift card. In Aim 1 Step 4, patient participants will be reimbursed $ for the initial hour-long descriptive data collection visit, each hour-long intervention visit (whether in person or by phone), and each hour-long interview. Provider/stakeholders will be given a $ gift card. *In Aim 2, participants will be reimbursed $ for each hour-long intervention visit and each hour-long interview.*

Informed consent: For patients or providers/stakeholders eligible for any part of the study, informed consent will be obtained prior to participation in study-related procedures following prescreening. Informed consent procedures for both patient and provider participants will take place in a private space. Study staff will be trained to communicate all components of the informed consent clearly so that potential participants understand that their consent is voluntary and to avoid coercion. Consent will use clear language that explains that the participant's relationship with the clinic or medical team will not be affected by his/her decision to participate or not participate in this study. The informed consent forms will be written at no greater than a 6$^{th}$ grade reading level and may be read aloud to the potential participant. During the creation of the informed consent document, research staff will embed a series of basic questions to gauge the potential participant's understanding of study procedures. In order to assure that participants are able to comprehend the details of the study, if the potential participant fails to answer these questions appropriately, he/she will not be enrolled into the study. Only trained study personnel with appropriate Human Subjects training will detail the requirements of the consent form and study participation with potential enrollees.

**B.2. Protections Against Risk**

Our team will make every effort to protect all participants' confidential and private information in order to minimize possible study-associated risks. All findings related to any research will be available and provided to study participants in accordance with standard practices. We will also inform all participants that their participation is voluntary, and we will utilize study identification codes in place of personal identifiers on study materials. We will also employ storage and encryption techniques in compliance with UAB Data Security standards to safeguard all electronic data, as well as the protections outlined in Subpart C of title 45, part 46 of Code of Federal Regulations. All study personnel are required to renew Human Subjects trainings biannually. No data will be accepted from or distributed to investigators or study staff if regulatory training is not current. Additionally, participants who report psychological distress will be immediately referred for an assessment by a clinic social worker, psychologist, or counselor.

**C. Potential Benefits of the Proposed Research to Human Subjects and Others**

Participants may benefit directly from enrolling in this study. Patient, provider, and key stakeholder participants will help to inform the development and testing of the behavioral intervention. Benefits of participation include the satisfaction of participating in research that may help HIV-infected patients with chronic pain achieve better outcomes. Additionally, patient participation in study interviews or focus groups may provide patient participants with additional insight into their chronic pain and ways to address it. For patients who participate in pre-testing or pilot testing the intervention, benefits may include improvement in chronic pain, functional outcomes, adherence to antiretroviral therapy (ART), or retention in HIV primary care. Risks to participants are related primarily to breach of confidentiality and psychological distress. As the risk to individual participants is small and potential benefits are significant, the risk/benefit ratio is favorable.

**D. Importance of the Knowledge to be Gained**

Chronic pain in HIV-infected patients is an extremely common, impairing condition. The results of this research will inform the development of a behavioral intervention for chronic pain in HIV-infected individuals. As the risk to individual participants is small and potential benefits are significant, the risk/benefit ratio is favorable.

**E. ClinicalTrials.gov Requirements**

Aim1 Step 3 and Aim 2 do not qualify as clinical trials. Rather, they involve pre-testing and pilot testing the proposed intervention, do not involve evaluating safety or efficacy, and would not be registered at clinicaltrials.gov.

**Inclusion of Women and Minorities**

**1. Inclusion of Women**

Selection of the study population will be independent of gender. Based on my prior work from the UAB CNICS Cohort,[6] approximately 23% of individuals will be women, which is representative of the HIV epidemic nationally.

**2. Inclusion of Minorities**

Selection of participants for inclusion in the study will be completely independent of ethnicity or race. Based on my prior work from the UAB CNICS Cohort,[6] we expect that 47% of participants will be white. Fifty-three percent will be non-white, the vast majority of whom (>95%) are African-American. Only a total of 54 participants in our cohort identify as Asian, Pacific Islander, Native American, or other. Hispanics comprise < 3% of our cohort. These numbers reflect the demographics of our local community. Although future multisite studies should aim to include these minority populations, these groups are unlikely to comprise a significant percentage of participants in this study.

OMB Number: 0925-0002

# Planned Enrollment Report

**Study Title:** Aim 1 Step 3: Conduct a qualitative investigation of patients, providers, and key stakeholders guided by the results of Steps 1 and 2 to produce the intervention manual.

**Domestic/Foreign:** Domestic

**Comments:** Patient Enrollment

| Racial Categories | Ethnic Categories | | | | Total |
|---|---|---|---|---|---|
| | Not Hispanic or Latino | | Hispanic or Latino | | |
| | Female | Male | Female | Male | |
| American Indian/Alaska Native | 0 | 0 | 0 | 0 | **0** |
| Asian | 0 | 0 | 0 | 0 | **0** |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 | **0** |
| Black or African American | 5 | 16 | 0 | 0 | **21** |
| White | 4 | 15 | 0 | 0 | **19** |
| More than One Race | 0 | 0 | 0 | 0 | **0** |
| **Total** | **9** | **31** | **0** | **0** | **40** |

Study 1 of 5





Funding Opportunity Number: PA-14-049. Received Date: 2014-04-24T11:32:34.000-04:00

OMB Number: 0925-0002

# Planned Enrollment Report

**Study Title:** Aim 1 Step 3: Conduct a qualitative investigation of patients, providers, and key stakeholders guided by the results of Steps 1 and 2 to produce the intervention manual.

**Domestic/Foreign:** Domestic

**Comments:** Provider Enrollment

| Racial Categories | Ethnic Categories | | | | Total |
|---|---|---|---|---|---|
| | Not Hispanic or Latino | | Hispanic or Latino | | |
| | Female | Male | Female | Male | |
| American Indian/Alaska Native | 0 | 0 | 0 | 0 | **0** |
| Asian | 0 | 0 | 0 | 0 | **0** |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 | **0** |
| Black or African American | 1 | 1 | 0 | 0 | **2** |
| White | 4 | 4 | 0 | 0 | **8** |
| More than One Race | 0 | 0 | 0 | 0 | **0** |
| **Total** | **5** | **5** | **0** | **0** | **10** |

Study 2 of 5





Funding Opportunity Number: PA-14-049. Received Date: 2014-04-24T11:32:34.000-04:00

OMB Number: 0925-0002

# Planned Enrollment Report

**Study Title:** Aim 1 Step 4: Pre-test the intervention in potential participants.

**Domestic/Foreign:** Domestic

**Comments:** Patient enrollment

| Racial Categories | Ethnic Categories | | | | Total |
|---|---|---|---|---|---|
| | Not Hispanic or Latino | | Hispanic or Latino | | |
| | Female | Male | Female | Male | |
| American Indian/Alaska Native | 0 | 0 | 0 | 0 | **0** |
| Asian | 0 | 0 | 0 | 0 | **0** |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 | **0** |
| Black or African American | 1 | 1 | 0 | 0 | **2** |
| White | 4 | 4 | 0 | 0 | **8** |
| More than One Race | 0 | 0 | 0 | 0 | **0** |
| **Total** | **5** | **5** | **0** | **0** | **10** |

Study 3 of 5





Funding Opportunity Number: PA-14-049. Received Date: 2014-04-24T11:32:34.000-04:00

OMB Number: 0925-0002

# Planned Enrollment Report

**Study Title:** Aim 1 Step 4: Pre-test the intervention in potential participants.

**Domestic/Foreign:** Domestic

**Comments:** Provider enrollment

| Racial Categories | Ethnic Categories | | | | Total |
|---|---|---|---|---|---|
| | Not Hispanic or Latino | | Hispanic or Latino | | |
| | Female | Male | Female | Male | |
| American Indian/Alaska Native | 0 | 0 | 0 | 0 | **0** |
| Asian | 0 | 0 | 0 | 0 | **0** |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 | **0** |
| Black or African American | 1 | 1 | 0 | 0 | **2** |
| White | 4 | 4 | 0 | 0 | **8** |
| More than One Race | 0 | 0 | 0 | 0 | **0** |
| **Total** | **5** | **5** | **0** | **0** | **10** |

Study 4 of 5





Funding Opportunity Number: PA-14-049. Received Date: 2014-04-24T11:32:34.000-04:00

OMB Number: 0925-0002

# Planned Enrollment Report

**Study Title:** Aim 2: Conduct a two-arm pilot randomized controlled trial of the behavioral intervention compared to routine HIV and pain care, to determine feasibility, acceptability, and preliminary impact.

**Domestic/Foreign:** Domestic

**Comments:**

| Racial Categories | Ethnic Categories | | | | Total |
|---|---|---|---|---|---|
| | Not Hispanic or Latino | | Hispanic or Latino | | |
| | Female | Male | Female | Male | |
| American Indian/Alaska Native | 0 | 0 | 0 | 0 | **0** |
| Asian | 0 | 0 | 0 | 0 | **0** |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 | **0** |
| Black or African American | 5 | 16 | 0 | 0 | **21** |
| White | 4 | 15 | 0 | 0 | **19** |
| More than One Race | 0 | 0 | 0 | 0 | **0** |
| **Total** | **9** | **31** | **0** | **0** | **40** |

Study 5 of 5





Funding Opportunity Number: PA-14-049. Received Date: 2014-04-24T11:32:34.000-04:00

**Inclusion of Children**

In general, the UAB 1917 Clinic does not provide care to children. However, the clinic does provide care for patients between ages 18 and 21 years, and the UAB CFAR Network of Integrated Clinical Systems (CNICS) recruits participants who are 19 years of age and older (the legal age of majority in Alabama). Therefore, children ages 19-21 will be eligible for study participation, although there are no specific recruitment strategies for inclusion of these patients. Children less than 19 years of age will not be included in this study since there are too few children in this group to draw valid conclusions. Further, children less than 19 years of age are likely to have different needs related to behavioral interventions for chronic pain. These individuals are at a different developmental stage and therefore, are likely to respond differently to chronic pain behavioral interventions than individuals 19 years of age or older. Therefore, a separate study in these children would be necessary.

**SUMMARY STATEMENT**

**PROGRAM CONTACT:**
**Michael Stirratt**
**301-443-6802**
**stirrattm@mail.nih.gov**

**( Privileged Communication )**

***Release Date:*** **08/10/2014**

***Application Number:*** **1 K23**

**Principal Investigator**

**MERLIN, JESSICA S MD**

**Applicant Organization: UNIVERSITY OF ALABAMA AT BIRMINGHAM**

***Review Group:*** **BSCH**
**Behavioral and Social Consequences of HIV/AIDS Study Section**

***Meeting Date:*** **07/09/2014**
***Council:*** **OCT 2014**
***Requested Start:*** **12/01/2014**

***RFA/PA:*** **PA14-049**
***PCC:*** **9A-ASGA**
***Dual PCC:*** **CX/WMA**
***Dual IC(s):*** **DA, AI**

***Project Title:*** **Development of a Behavioral Intervention for Chronic Pain in Individuals with HIV**

***SRG Action:*** **Impact Score:**
***Next Steps:*** **Visit http://grants.nih.gov/grants/next_steps.htm**
**Human Subjects:** **30-Human subjects involved - Certified, no SRG concerns**
**Animal Subjects:** **10-No live vertebrate animals involved for competing appl.**
***Gender:*** **1A-Both genders, scientifically acceptable**
***Minority:*** **1A-Minorities and non-minorities, scientifically acceptable**
***Children:*** **1A-Both Children and Adults, scientifically acceptable**
**Clinical Research - not NIH-defined Phase III Trial**

| Project Year | Direct Costs Requested | Estimated Total Cost |
|---|---|---|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| TOTAL | | |

**ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.**

**1K23MH104073-01A1 Merlin, Jessica**

**RESUME AND SUMMARY OF DISCUSSION:** This application for a patient-oriented career development award seeks funding to establish the applicant as an independent researcher capable of conducting behavioral clinical trials for HIV-infected patients with chronic pain. Dr. Merlin's career development plan includes training in clinical epidemiology, behavioral intervention development, and the conduct of behavioral clinical trials. The primary mentor, Dr. Michael Saag, and the co-mentors, Drs. Johnson and Kerns provide the candidate with a very strong mentorship team. The committee continues to find that Dr. Merlin is an excellent candidate and she has been productive with several peer-reviewed publications. Her career development plan is strong and it will provide the needed training to fill the gaps in her expertise. The applicant has been responsive to the prior concerns about her mentorship team and the addition of Drs. Johnson and Kerns to the team has addressed these concerns. In addition, concerns about the research plan were addressed. Therefore, the committee expressed the highest enthusiasm for this responsive resubmission.

**DESCRIPTION (provided by applicant):** The overall goal of this 4-year K23 proposal is to support Jessica Merlin, MD, MBA to become an independent investigator in the field of HIV and chronic pain, with a focus on health psychology/mental health and chronic pain behavioral intervention development and testing. Chronic pain is a chronic condition with a unique neurobiologic basis, which has a substantial impact on physical and emotional function. Chronic pain in HIV-infected patients is common, and associated with serious health consequences, including up to 10 times greater odds of impaired physical function. Many pharmacologic therapies, including opioids, often do not lead to improved pain and function, and carry significant risk. Evidence-based behavioral interventions are among the most effective and safe non-pharmacologic chronic pain treatments investigated in the general medical population. Therefore, behavioral interventions to improve pain, physical, and emotional function in HIV-infected patients are needed. There is much to be learned from existing interventions. However, the success of a behavioral intervention is heavily influenced by how well it is tailored to the target population's biological, psychological, and social environment. Therefore, the Specific Aims of this proposal are: Aim 1: Use intervention mapping to systematically develop and pre-test a tailored behavioral intervention for chronic pain in HIV-infected patients. Aim 2: Conduct a two-arm pilot randomized controlled trial of the behavioral intervention compared to routine HIV and pain care, to determine feasibility, acceptability, and preliminary impact. Based on preliminary studies, our proposed intervention targets include depression/anxiety, substance use, and use of prescription opioids for pain management; new targets may emerge during the intervention mapping process. The proposed research represents the first study to address chronic pain as a chronic disease in HIV-infected patients, and to develop and test a behavioral intervention specifically tailored to this population. At the completion of the pilot trial in Aim 2, the intervention will be ready to be tested in an R01 to evaluate its efficacy. This proposal represents a 4-year comprehensive mentoring, training, and research plan to transition the candidate, Dr. Merlin, to a career as a successful independent investigator. By the end of the award period, Dr. Merlin will have contributed substantially to the field of HIV and chronic pain behavioral research. Already an expert on biomedical approaches to chronic pain in HIV-infected individuals, she will be positioned to become a leader in developing and testing behavioral interventions in this area, including conducting behavioral clinical trials.

**PUBLIC HEALTH RELEVANCE:** Due to its specific pathophysiology and impact on health outcomes, the Institute of Medicine has described chronic pain as a complex chronic disease and a national public health crisis. The unique neurobiological basis and psychosocial context of chronic pain in HIV-infected patients underscores the importance of developing a behavioral intervention specifically tailored to this population. The project described in this application will develop and pilot test such an intervention, which can then be further tested in an R01- supported randomized controlled trial.

**CRITIQUE 1:**

Candidate:
Career Development Plan/Career Goals /Plan to Provide Mentoring:
Research Plan:
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):
Environment Commitment to the Candidate:

**Overall Impact:** Dr. Merlin aims to become an independent investigator focusing on HIV and chronic pain. The K23 will fill gaps in her knowledge and skills by receiving training in health psychology/mental illness and behavioral intervention development. Her training plan includes courses, seminars and meetings with mentors, and will be reinforced by her research activities. The application is very well written and very responsive to prior reviews. The career development plan and research plan are closely woven together. The applicant is outstanding and has unique training in HIV and pain/palliative care. Her plan to become an expert in pain management among HIV+ patients is very important and challenging, and is a field with little research. Therefore, she would have an opportunity to make a substantial contribution to the field. She has impressive accomplishments to date, but makes a compelling case for obtaining new skills and knowledge. Her mentorship team is outstanding. The research plan is well described and the aims are a logical progression of her work to date. Completion of the research plan will place Dr. Merlin in an optimal position to obtain an R01.

**1. Candidate:**

**Strengths**

- Dr. Merlin is an outstanding candidate with unique and excellent training, including a fellowship in infectious diseases and further training in pain/palliative care. With this training she is quite unique in her ability to address both HIV and chronic pain
- Dr. Merlin has already established herself with many successes, including having obtained a K12 award and a pilot grant from the UAB CTSA.
- Dr. Merlin has 11 peer-reviewed publications, and she is first author on 9 of them. Her manuscripts have been published in high-quality journals.
- Dr. Merlin has already been acknowledged as a leader in the field of HIV and chronic pain. She is a core faculty member of IAS-USA, served on a national guideline panel that focused on HIV and pain, wrote a module for the NIH Pain Consortium Center of Excellence, and has been a peer reviewer for several journals.
- Dr. Saag's letter regarding Dr. Merlin is particularly impressive, especially given his experience mentoring junior faculty.

**Weaknesses**

- None

**2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:**

**Strengths**

- The career development plan is responsive to prior reviews, comprehensive, well-described, and addresses areas in which Dr. Merlin has gaps in knowledge and skills.

- She will complete her master's degree, which will now include courses tailored to her specific areas of skill development (health psychology/mental illness and behavioral intervention development)
- The career development plan includes an appropriate mix of formal courses, mentorship meetings, local seminars, and national conferences and seminars.
- The skills that Dr. Merlin will obtain are closely tied to her research project and aims.

**Weaknesses**

- None

**3. Research Plan:**

**Strengths**

- The research plan follows a logical progression of Dr. Merlin's work thus far.
- Aims build on each other and will lead to a very well-developed and refined behavioral intervention that will be innovative and will likely have substantial clinical significance. The intervention will be tailored to HIV infected individuals, and is based on an existing efficacious intervention.
- The research plan includes using qualitative and quantitative methods.
- The intervention will address important factors known to be associated with pain and HIV outcomes (e.g. substance abuse, depression/anxiety)
- Aim 2 will provide an effect size that will be helpful in guiding a future R01 grant application.

**Weaknesses**

- It is not entirely clear why individual qualitative interviews and focus groups are necessary.
- It's not clear why a substantial amount of quantitative data will be collected for participants who are involved in Aim 1, steps 3 and 4. There is little discussion about why these data are needed and what they will add to the qualitative analyses.
- The analysis section for Aim 2 is a bit anemic and includes simple chi square and t-tests. Although the course work and training goals are responsive to the prior reviews, learning about and applying more sophisticated analytic techniques to Aim 2 have been lost. The inclusion of repeated measure analyses and/or complex analyses (e.g. clustering for the possibility of a group-based intervention) would strengthen the application.
- Participants will be paid for attending intervention visits, which is likely to affect the feasibility of the study and potentially affect the outcomes.

**4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):**

**Strengths**

- The mentorship team is outstanding. Dr. Saag has decades of experience mentoring junior faculty. He is well-positioned to provide mentorship regarding clinical trials, to advocate for Dr. Merlin, and to provide opportunities for her to grow as a researcher.
- The co-mentors and advisors will provide mentorship that is distinct from one another and that are necessary for Dr. Merlin to become an independent investigator and carry out the proposed research.
- Dr. Merlin has established relationships with the mentorship team, including several publications with her mentors.

**Weaknesses**

- Both co-mentors are geographically far from UAB; however, Dr. Merlin recognizes this as a limitation and has addressed this as best as possible.

**5. Environment and Institutional Commitment to the Candidate:**

**Strengths**

- The environment is excellent.
- The institutional commitment is clear based on letters from the Department Chair and Division Chief. In addition, Dr. Merlin already has demonstrated commitment from her institution as exemplified by her K12 and CTSA pilot grant awards.
- Dr. Merlin directs the HIV Pain clinic, and has clinical resources (nurse, physical therapist, fellows) to help her maintain the clinic, which serves essentially as her research lab.

**Protections for Human Subjects:**

Acceptable Risks and Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

**Inclusion of Women, Minorities and Children:**

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C1A - Children and Adults, Acceptable

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Resubmission:**

- Highly responsive to prior reviews.

**Training in the Responsible Conduct of Research:**

Acceptable

Comments on Format (Required):

- Acceptable - Activities range from formal courses to less formal meetings with mentors.

Comments on Subject Matter (Required):

- Dr. Merlin will take a formal course on Principles of Scientific Integrity. In addition, she will attend seminars on responsible conduct of research that are offered by the CTSA. She will continue to take on-line modules from the CITI, and she will teach ethics to medical residents.

Comments on Faculty Participation (Required; not applicable for mid- and senior-career awards):

- During their regular weekly meetings, Dr. Merlin will regularly discuss research ethics issues with Dr. Saag as they emerge.

Comments on Duration (Required):

- The duration of these activities is appropriate and adequate.

Comments on Frequency (Required):

- Activities will differ in frequency, ranging from annual trainings (CITI) to monthly seminars (teaching ethics to residents) to weekly sessions (formal course). The frequency of activities is appropriate.

**Budget and Period of Support:**

Recommend as Requested

**CRITIQUE 2:**

Candidate:
Career Development Plan/Career Goals /Plan to Provide Mentoring:
Research Plan:
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):
Environment Commitment to the Candidate:

**Overall Impact:** Surprisingly, there are very few (if any) empirically-validated behaviorally-based interventions for persons living with HIV and chronic pain. The Candidate's proposed research may eventually yield a behavioral intervention to reduce pain in persons living with HIV and chronic pain. As such, the Candidate's planned research could have considerable impact on the AIDS care field. This K23 will also support a physician with training in both infectious disease and palliative care and who ultimately seeks to independently conceptualize, conduct, and evaluate interventions to reduce pain in the large and growing population of persons living with HIV and chronic pain. She is a very strong candidate and her skills and expertise would be an asset to the HIV behavioral research community.

**1. Candidate:**

**Strengths**

- The Candidate has several publications in the area of HIV and pain that are directly relevant to the planned project.
- The Candidate is one of only a few physicians trained in infectious disease and palliative care.
- The Candidate has led the chronic pain clinic within the UAB 1917 HIV Clinic. This experience has likely helped the Candidate learn more about everyday pain experiences in people living with HIV/AIDS and shaped her research interests in a practical way.

**Weaknesses**

- None

**2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:**

**Strengths**

- The Candidate indicates that the areas in which she needs additional training and mentoring are health psychology/mental health and the conduct of clinical trials designed specifically to mitigate pain in people living with HIV/AIDS. Her training plan will clearly augment her knowledge and skills in these areas.
- The Candidate already has considerable training in biomedical approaches to managing pain in people living with HIV/AIDS.
- The Candidate will obtain a Master's of Science in Public Health during her K23-funded training.
- The Candidate's training will consist of mentorship, coursework, hands-on training, and seminars/conferences.
- The formal coursework the Candidate plans to take is reasonable in scope, directly relevant to her planned research, and provides training in important areas that may have not been addressed directly during her training in medical school.

**Weaknesses**

- None

**3. Research Plan:**

**Strengths**

- The Candidate's research plan involves developing and pilot testing a contextualized intervention to reduce pain in people living with HIV/AIDS who report chronic pain. There is an urgent need for interventions of this sort.
- The research plan uses a relatively cautious and iterative one. This is a reasonable approach given the aims of this formative/pilot research.
- The Candidate has conducted preliminary research in the area of HIV and chronic pain. It is clear that this formative research has informed appropriate parts of the planned research.
- The data to be collected and analyzed in the proposed research is rich and diverse, ranging from self-reports, to medical records, to Electronic Patient Reported Outcome Measures.
- The Candidate shows a clear appreciation for the need for research to be theoretically-driven.
- This reviewer was a bit dubious regarding the Candidate's repeated statement that she will be one of the first, if not the first, to develop a behaviorally-based intervention to reduce pain in HIV-infected persons. However, a search of various databases (e.g., PubMed) did indeed demonstrate that there really aren't many (if any) publications reporting on empirical investigations of this type of intervention. As such, this research is high in innovation (and significance).

**Weaknesses**

- Following the theoretical framework(s) that will guide the study was, at times, a little difficult, perhaps because so many frameworks were discussed, ranging from the BSP to CBT to SCT to SCAMP. That said, perhaps what is more important is that the Candidate recognizes and appreciates the need for this research to be grounded in a solid theory (or theories). This reviewer was convinced that the Candidate and her team will ensure that the behavioral intervention is grounded in a solid theoretical framework.
- The Candidate appropriately indicates that the two-arm pilot RCT will assess acceptability, feasibility, and preliminary impact. However, it is unclear how "acceptability" and "feasibility" will be operationalized and assessed.

**4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):**

**Strengths**

- The Candidate's mentors consist of Michael Saag, M.D., Mallory Johnson, Ph.D., and Robert Kerns, Ph.D. Dr. Saag has mentored the Candidate for the past 2.5 years and they co-authored several manuscripts together.
- All Mentors are highly accomplished and very well respected. Their areas of expertise, ranging from intervention expertise, to health psychology/behavioral medicine, to pain management will greatly facilitate the training and research efforts of the Candidate.
- There was a clear and convincing plan that outlined how the Candidate would interact with her mentors, both face-to-face and virtually.

**Weaknesses**

- None

**5. Environment and Institutional Commitment to the Candidate:**

**Strengths**

- The environment provided by UAB is extremely strong. The letter of support also demonstrates a high degree of institutional support to the Candidate and the proposed research.

**Weaknesses**

- None

**Protections for Human Subjects:**

Acceptable Risks and Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

**Inclusion of Women, Minorities and Children:**

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C1A - Children and Adults, Acceptable

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Resubmission:**

- The Candidate was highly responsive to previous concerns.

**Training in the Responsible Conduct of Research:**

Acceptable

Comments on Format (Required):

- The Candidate will enroll in a formal, didactic, three-hour course at UAB on the responsible conduct in research. The Candidate will also participate in 8 self-directed on-line modules through the CCTS and on-line maintenance of CITI Training. The Candidate also teaches ethics to medical residents.

Comments on Subject Matter (Required):

- Subject matter to be included in the above-referenced course addresses fraud in science, UAB policies related to scientific fraud, ideals of good science, the responsibilities of authorship and peer review, and potential problems raised by the commercialization of research.

Comments on Faculty Participation (Required; not applicable for mid- and senior-career awards):

- UAB faculty will be actively involved in the conduct of training in the responsible conduct of research.

Comments on Duration (Required):

- The duration of the course in which the candidate will enroll in one semester (likely 15 weeks) with approximately 40 contact hours of instruction.

Comments on Frequency (Required):

- The formal course on the responsible conduct of research meets weekly.

**Budget and Period of Support:**

Recommend as Requested

**CRITIQUE 3:**

Candidate:
Career Development Plan/Career Goals /Plan to Provide Mentoring:
Research Plan:
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):
Environment Commitment to the Candidate:

**Overall Impact:** In this highly responsive revision, this application continues to be from a very strong applicant who proposes to develop skills related to treating those with HIV. The candidate has a clear interest in clinical research and has added both didactic and mentored experiences to her training program to address concerns raised in a previous review.

**1. Candidate:**

**Strengths**

- Dr. Merlin is a very strong candidate whose career trajectory is clearly consistent with the goals of the proposed period of support.

**Weaknesses**

- None

**2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:**

**Strengths**

- The career development plan continues to be clear and include a combination of formal coursework and experiential activities. She now plans to complete a degree in health behavior.

**Weaknesses**

- Although the additions of Drs. Johnson and Kerns to the mentoring team bring excellent expertise to the mentoring team, they are not at UAB, and it is not clear that monthly conferences via Skype will be a replacement for more direct contact.

**3. Research Plan:**

**Strengths**

- The revision of the research plan is strong in the area in which the biopsychosocial model is integrated with social cognitive theory although the link to CBT pain interventions is not made explicitly, and how social cognitive theory is directly implemented in the SCAMP intervention is not clear.
- The research plan now includes a clearer integration of the qualitative work with the development/adaptation of the intervention.

**Weaknesses**

- As noted above, but these are minor issues.

**4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):**

**Strengths**

- The additions of Drs. Johnson and Kerns are important additions to the mentoring team that was previously considered strong.

**Weaknesses**

- None

**5. Environment and Institutional Commitment to the Candidate:**

**Strengths**

- The institutional commitment to the candidate is strong, and the environment is excellent.

**Weaknesses**

- None noted

**Protections for Human Subjects:**

Acceptable Risks and Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

- No data safety or monitoring plan is included

**Inclusion of Women, Minorities and Children:**

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C1A - Children and Adults, Acceptable

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Training in the Responsible Conduct of Research:**

Acceptable

Comments on Format (Required):

- Good combination of didactic and mentored experiences, including the opportunity to teach ethics to medical residents.

Comments on Subject Matter (Required):

- Broad and appropriate content.

Comments on Faculty Participation (Required; not applicable for mid- and senior-career awards):

- Good

Comments on Duration (Required):

- Good

Comments on Frequency (Required):

- Good

**Budget and Period of Support:**

Recommend as Requested

**THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:**

**PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE**

**INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE**

**INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE**

**INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE**

**COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.**

---

**NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at**

**http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.**

**MEETING ROSTER**

**Behavioral and Social Consequences of HIV/AIDS Study Section**
**AIDS and Related Research Integrated Review Group**
**CENTER FOR SCIENTIFIC REVIEW**
**BSCH**
**July 09, 2014 - July 10, 2014**

## CHAIRPERSON

PATTERSON, THOMAS L, PHD
PROFESSOR
DEPARTMENT OF PSYCHIATRY
UNIVERSITY OF CALIFORNIA, SAN DIEGO
LA JOLLA, CA 92093

## MEMBERS

BOGART, LAURA M, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF MEDICINE
HARVARD MEDICAL SCHOOL
BOSTON, MA 02215

BULL, SHEANA S, PHD
PROFESSOR
DEPARTMENT OF COMMUNITY AND BEHAVIORAL HEALTH
SCHOOL OF PUBLIC HEALTH
UNIVERSITY OF COLORADO, DENVER
AURORA, CO 80045

COOK, ROBERT L, MPH, MD
PROFESSOR
DEPARTMENT OF EPIDEMIOLOGY
UNIVERSITY OF FLORIDA
GAINESVILLE, FL 32610

CORSI, KAREN F, SCD *
ASSOCIATE PROFESSOR
DEPARTMENT OF PSYCHIATRY
SCHOOL OF MEDICINE
UNIVERSITY OF COLORADO, DENVER
DENVER, CO 80262

CUNNINGHAM, CHINAZO , MD
ASSOCIATE PROFESSOR
DIVISION OF GENERAL INTERNAL MEDICINE
MONTEFIORE MEDICAL CENTER
ALBERT EINSTEIN COLLEGE OF MEDICINE
BRONX, NY 10467

DWORKIN, SHARI , PHD *
DIRECTOR
DOCTORAL STUDIES PROGRAM IN SOCIOLOGY
DEPARTMENT OF SOCIAL AND BEHANIORAL SCIENCES
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
SAN FRANCISCO, CA 94118

GAROFALO, ROBERT , MD
PROFESSOR
DEPARTMENT OF PEDIATRICS
CHILDREN'S MEMORIAL HOSPITAL
FEINBERG SCHOOL OF MEDICINE
NORTHWESTERN UNIVERSITY
CHICAGO, IL 60614

GIORDANO, THOMAS P, MPH, MD
ASSOCIATE PROFESSOR
DEPARTMENT OF MEDICINE
BAYLOR COLLEGE OF MEDICINE
HOUSTON, TX 77030

GO, VIVIAN F, PHD *
ASSOCIATE PROFESSOR
GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH
UNIVERSITY OF NORTH CAROLINA
CHAPEL HILL, NC 27599

GOGGIN, KATHY J, PHD *
PROFESSOR
DEPARTMENT OF PSYCHOLOGY
UNIVERSITY OF MISSOURI, KANSAS CITY
KANSAS CITY, MO 64110

GWADZ, MARYA , PHD *
SENIOR RESEARCH SCIENTIST
COLLEGE OF NURSING
NEW YORK UNIVERSITY
NEW YORK, NY 10003

HECKMAN, TIMOTHY GLENN, PHD *
PROFESSOR
HEALTH PROMOTION AND BEHAVIOR
COLLEGE OF PUBLIC HEALTH
UNIVERSITY OF GEORGIA
ATHENS, GA 30602

HIRSHFIELD, SABINA , PHD *
SENIOR RESEARCH SCIENTIST
PUBLIC HEALTH SOLUTIONS
NEW YORK, NY 10013

KERR, THOMAS , PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF MEDICINE
BRITISH COLUMBIA CENTRE
FOR EXCELLENCE IN HIV/AIDS
UNIVERSITY OF BRITISH COLUMBIA
VANCOUVER, BC V6Z, 1Y6
CANADA

LEHMAN, WAYNE E K, PHD *
SENIOR RESEARCH SCIENTIST
INSTITUTE OF BEHAVIOIRAL RESEARCH
TEXAS CHRISTIAN UNIVERSITY
FORT WORTH, TX 76129

LI, XIAOMING , PHD
PROFESSOR
DEPARTMENT OF PEDIATRICS
SCHOOL OF MEDICINE
WAYNE STATE UNIVERSITY
DETROIT, MI 48201

MERCHANT, ROLAND C, SCD, MD *
ASSOCIATE PROFESSOR
DEPARTMENT OF EMERGENCY MEDICINE
WARREN ALPERT MEDICAL SCHOOL
BROWN UNIVERSITY
PROVIDENCE, RI 02903

MIMIAGA, MATTHEW JAMES, SCD, MPH
ASSOCIATE PROFESSOR
DEPARTMENT OF EPIDEMIOLOGY
SCHOOL OF PUBLIC HEALTH
HARVARD UNIVERSITY
BOSTON, MA 02115

MUSTANSKI, BRIAN , PHD *
ASSOCIATE PROFESSOR
DEPARTMENT OF MEDICAL SOCIAL SCIENCES
NORTHWESTERN UNIVERSITY
CHICAGO, IL 60622

NYAMATHI, ADELINE M, PHD
DISTINGUISHED PROFESSOR
SCHOOL OF NURSING
UNIVERSITY OF CALIFORNIA, LOS ANGELES
LOS ANGELES, CA 90095

OWNBY, RAYMOND L, MD, PHD
PROFESSOR AND CHAIR
DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL MEDICINE
COLLEGE OF OSTEOPATHIC MEDICINE
NOVA SOUTHEASTERN UNIVERSITY
FORT LAUDERDALE, FL 33314

PESKIN, MELISSA , PHD *
ASSISTANT PROFESSOR
HEALTH PROMOTION AND BEHAVIORAL SCIENCES
UNIVERSITY OF TEXAS SCHOOL OF PUBLIC HEALTH
HOUSTON, TX 77030

REYNOLDS, NANCY R, PHD
PROFESSOR
SCHOOL OF NURSING
YALE UNIVERSITY
NEW HEAVEN, CT 06536

ROURKE, SEAN BRENDAN, PHD *
PROFESSOR
DEPARTMENT OF PSYCHIATRY
UNIVERSITY OF TORONTO
TORONTO, ONTARIO, M5B1W8
CANADA

SOLOMON, SONDRA ELICE, PHD
ASSOCIATE PROFESSOR
DEPARTMENT OF PSYCHOLOGY
UNIVERSITY OF VERMONT
BURLINGTON, VT 05405

ST LAWRENCE, JANET S, PHD *
PROFESSOR
DEPARTMENT OF PSYCHOLOGY
MISSISSIPPI STATE UNIVERSITY, MERIDIAN
MERIDIAN, MS 39307

VAN DEN BERG, JACOB J, PHD *
ASSISTANT PROFESSOR
MIRIAM HOSPITAL
THE WARREN ALPERT MEDICAL SCHOOL
BROWN UNIVERSITY
PROVIDENCE, RI 02906

VREEMAN, RACHEL CHRISTINE, MD *
ASSOCIATE PROFESSOR
DEPARTMENT OF PEDIATRICS
INDIANA UNIVERSITY SCHOOL OF MEDICINE
INDIANAPOLIS, IN 462025140

WALDROP-VALVERDE, DRENNA , PHD
ASSOCIATE PROFESSOR
NELL HODGSON WOODRUFF SCHOOL OF NURSING
EMORY UNIVERSITY
ATLANTA, GA 30322

ZEA, MARIA CECILIA, PHD *
PROFESSOR
DEPARTMENT OF PSYCHOLOGY
GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC 20052

## SCIENTIFIC REVIEW ADMINISTRATOR

RUBERT, MARK P, PHD
SCIENTIFIC REVIEW OFFICER
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

## GRANTS TECHNICAL ASSISTANT

BOGLEY, DAVID M
LEAD EXTRAMURAL SUPPORT ASSISTANT
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.