K AWARD INFORMATIONAL ROUNDTABLE

Moderated by Mary Aitken, M.D., M.P.H.

Featuring Joshua Kennedy, M.D. and Taren Swindle, Ph.D.

General Requirements and Resources

- General Resources and Guidelines
- Mechanisms
- Citizenship
- Responsible Conduct of Research
- Deadlines
- UAMS Resources and Procedures

NIH K KIOSK

- https://researchtraining.nih.gov/programs/career-development

Submission Deadlines

- Unless otherwise stated in the program announcement, these are the Standard deadlines:

  Standard K deadlines (new applications):
  Feb. 12, June 12, and Oct. 12

  Standard K deadlines (for resubmissions):
  March 12, July 12, Nov. 12

  Standard AIDS/AIDS-related deadlines:
  May 7, Sept. 7, Jan. 7

NIH Requirements: Citizenship

- By the time of award, all K award applicants must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status).

NIH Requirements: Citizenship

- **Citizenship Exception: NIH K99/R00 award only:** U.S. citizenship or permanent residency is required for all K awards except for the K99/R00 postdoc-to-faculty transition award>>

- **Visa Information**. The K99/00 allows for an applicant to be on a visa that allows them to remain in the country long enough to complete the research project. If you have questions on your visa or status, have your department administrator contact the Bechtel International Center >>. You can also check the Visas for Postdoctoral Scholars Office of Postdoctoral Affairs webpage >> or the DoResearch website Research Policy Handbook RPH 10.3 >> on Postdoctoral Scholars for more information.

NIH Requirements: Required Effort

- By the time of award, all CDA recipients must have a **full-time appointment** at the applicant institution

- Mentored CDA recipients are required to devote a **minimum commitment equivalent of 9 calendar person months (75% or their full-time appointment** at the applicant institution) to the career development and research objectives of the program specified in each FOA.

NIH Requirements: Required Effort

- The remaining 3 person months (25% effort), if applicable, can be divided among other research, clinical, and teaching activities only if these activities are consistent with the goals of the mentored CDA, i.e., the recipient's development into an independent investigator.

NIH Requirements: Required Effort

- For programs that require a 75% effort minimum (equivalent to 9 person months), an awardee can request a reduction to no less than 50%. Circumstances requiring such a change in effort might include personal or family situations such as parental leave, child care, elder care, medical conditions, or a disability. **Not allowed for more clinic, moves, etc.**

- Some NIH ICs allow less than 75% (but not lower than 50%) effort for **certain clinical specialties**, with written permission.

NIH Requirements: Required Effort

- Provided they remain in a mentored status, mentored CDA recipients in the **final two years** of their support period are permitted to reduce the level of effort required for the CDA when they have competed successfully for peer-reviewed research awards from NIH or any Federal agency, if programmatic policy of the other Federal agency allows such an arrangement.

Scored Review Criteria

- Candidate
- Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring
- Research Plan
- Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s); and for non-Mentors the Mentoring Plan
- Environment and Institutional Commitment to the Candidate

Review Criteria

- https://grants.nih.gov/grants/peer/guidelines_general/Review_Criteria_at_a_glance.pdf

- https://grants.nih.gov/grants/peer/critiques/K_D.htm#k_01

NIH Requirements: RCR

- **Responsible Conduct of Research (RCR)**
  The NIH requires formal training in the responsible conduct of research. Per the NIH, Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. UAMS has courses to meet this requirement.

- https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-122.html#

- http://med.stanford.edu/rmg/forms/gg_NIH_RCR_policy.pdf

Resources

- K-PASEO
  - https://iims.uthscsa.edu/ed_kpaseo_workshop.html
- University of California SF
  - https://accelerate.ucsf.edu/training/K-grant-writing

Additional Resources

- Stanford K award resources:
  - https://www.youtube.com/watch?v=FOqITv2QKwg
  - http://med.stanford.edu/rmg/funding/nih_kawards.html#steps

- https://www.slideshare.net/jebyrne/carol-mangione-md-msph-navigating-the-nih-k-award-process

MY JOURNEY TO AN NIH K08 CAREER MENTORED DEVELOPMENT AWARD

- Joshua Kennedy, MD
- Assistant Professor Pediatrics and Internal Medicine
- Allergy and Immunology
- Lung Cell Biology Laboratory
- University of Arkansas for Medical Sciences
- Arkansas Children's Research Institute

Disclosures

- **Employment:** University of Arkansas for Medical Sciences; Arkansas Children's Hospital; Arkansas Children's Hospital Research Institute
- **Grant/Research Support:** NIH NIAID K08 Career Mentored Development Award; NIH NIGMS (COBRE Pilot); NIH CTSA KL2 scholar; NIH CTSA Western Consortium; UAMS Medical Research Endowment; Arkansas Biosciences Institute
- **Speaker's Bureau:** None
- **Consultant:** None

Objectives

- Provide my timeline to K08 funding

- Discuss a nuts and bolts approach to taking an idea to a grant in the format of a Career Mentored Development Award

My Timeline

- KL2 award September 2013- August 2015
- Started process towards K08 August 2014
- 1st Submission February 2015
- Found out scores in April 2015- 27
  - Funding line 26
  - No funding... Now what?
- Resubmission October 2015
- Found out scores in December 2015
  - 14- WOOHOO!
  - Payline was 20 now.
- NOGA by April 2016 and money first of May 2016

What?

- Career *Mentored* DEVELOPMENT Award
  - Start with an idea and get it down on paper
  - This is a DEVELOPMENT AWARD
    - Science is important,
      - **but it is not ALL important**

  - Find your **MENTORS** as quickly as possible
    - Because the mentors are probably more important than the science

  - Put together your Elevator Speech

Where?

- Talk with Scientific Research Officers for institutions you are considering
  - Gauge interest in your idea

- Think about your own connections and the connections of your considered mentors

When?

- AS EARLY AS POSSIBLE
  - This can take months
    - 6 months for me

  - The sooner, the better

How?

- Remember that idea you had and the elevator speech you created?
  - Turn it into a specific aims page
  - Make sure to incorporate everyone you are including in the grant
  - Be specific
  - Write it and destroy it several times!

How?

- Career Goals and Objectives
  - Immediate and Long-term goals are important
  - The goal of a Mentored Career Development Award is to become an *INDEPENDENT INVESTIGATOR* by…
    - Say it… Say it again… Say it one more time.

How?

- Create a specific aims style draft of a Mentor Development Plan
  - Education and Training
    - Meetings
    - Academics
      - Yes… you have to go back to class…
    - Sabbaticals
    - **BE SPECIFIC**
    - **MAKE A TABLE**

How?

- Mentors
  - When, where, and why you will meet
  - Team approach
  - Can have multiple people involved… just make sure its believable
    - Primary Career Development Mentor
    - Three Scientific Co-Mentors
    - Scientific Advisory Committee
    - Department of Pediatrics Mentoring Committee
  - **BE SPECIFIC**
  - **MAKE A TABLE/CALENDAR**

How?

- Take both specific aims pages (Science and Mentor Development Training) to your Mentors
  - Destroy them… several times over

How?

- The rest of the grant…
  - Really does fall into place once you have specific aims and have plans in place

Pitfalls

- Make sure you start early enough…
  - Mentors are helpful, but many have not had experience with mentored awards.
    - They take a while…
    - Many moving parts…

Pitfalls

- Talk with your Scientific Review Officer
  - Early and Often…
  - Ask them if they think your idea fits the institution…
  - Maybe you are an emailer… STILL call…

Pitfalls

- Connect all of the dots…
  - Don't make people look for things…
  - Say important things multiple times… (redundancy is great)
    - Skimming is the only way to get through as many grants as the reviewers need to complete in the time they have.
  - If something is complex, MAKE A TABLE OR CHART

Pitfalls

- Expect a "call-back"- Revise and Resubmit
  - Confidence, but not over confidence…
  - It is ok to not make the cut on the first try (and the second try)…
    - If at first you don't succeed… *you know the rest
  - Follow up on EVERY comment in the review
  - Keep your rebuttals short and sweet

Lessons

- Criticism is important
  - If you aren't getting it, you may have the wrong mentors.

- Collaboration is important
  - If others aren't interested in your project, you may have the wrong project.

- Connections are important
  - "Treat everyone as if they are going to be in the White House one day…" Dr. Anthony Fauci (Director of NIAID)

K01 SUBMISSION PROCESS

Taren Swindle, Ph.D.
Assistant Professor, Family and Preventative Medicine

Disclosures

- **Employment:** University of Arkansas for Medical Sciences
- **Grant/Research Support:** NIH K01 DK110141-01; NIH CTSA KL2 scholar; COBRE pilot project with the Childhood Center for Obesity Prevention NIGMS P20GM109096; Lincoln Health Foundation; Arkansas Biosciences Institute
- **Consultant:** none

Objectives

- Discuss my (very detailed!) 5-month timeline for K01 submission

  - Outline key tactics along the way

- Offer overarching strategies I found helpful

- Suggest resources to support your application

Spring 2015

- Meetings with "others" on campus
  - Get outside my unit
- Geoff Curran
- Meeting Susan Johnson at EB
  - Intentional conferencing
- Translational Science
  - Writing K submissions
  - Mock Review

June 2015

- North Carolina Visit (planned/funded by KL2)
  - Leading experts in childcare nutrition interventions
  - Implementation Scientists
  - Well-funded (objective) scholars with mentoring experience
- Strong Feedback

July 2015

- Mentor Requests /Meetings
  - Johnson from UC Denver
  - Curran and Whiteside-Mansell from UAMS
- Completed:
  - Biosketches
- Brainstorm of RQs

- Emails/Calls with PO
- Requests for funded proposals from ALL UAMS and NIDDK K scholars
- Drafted:
  - Background
  - Career Goals and Objectives
  - Mentoring Plan
  - Training Plan

August

- SciCom Request
    - Provided outline and tips
- Drafted
    - Specific Aims
    - Significance and Innovation
    - Preliminary Studies
    - Research Strategy
    - Preliminary Budget

- Completed:
    - Training plan
    - First full internal review
    - WIP update
   - *Eeek! More strong feedback!*

September

- K-club
  - Refinements
- GC Motivation
- Sent for Training Plan and Research Strategy for External Review
  - KL2 re-budget for $500
  - 2 week request

- Completed:
  - Budget/Budget Justification
  - LOS drafts and requests
    - Don't underestimate
    - 15
  - "Pieces"
    - Institutional Environment, Inclusion of Children/Women & Minorities, Protection of Human Subjects, Facilities/Resources, Equipment, Targeted Enrollment, Resource Sharing, RCR, Other Support documents

October

- Completed
  - Final Edits
  - Narrative
  - Cover Letter
  - Referee Letters
    - Think about these sooner!
  - Project Summary
  - Internal Routing
  - Submission by the 12th!
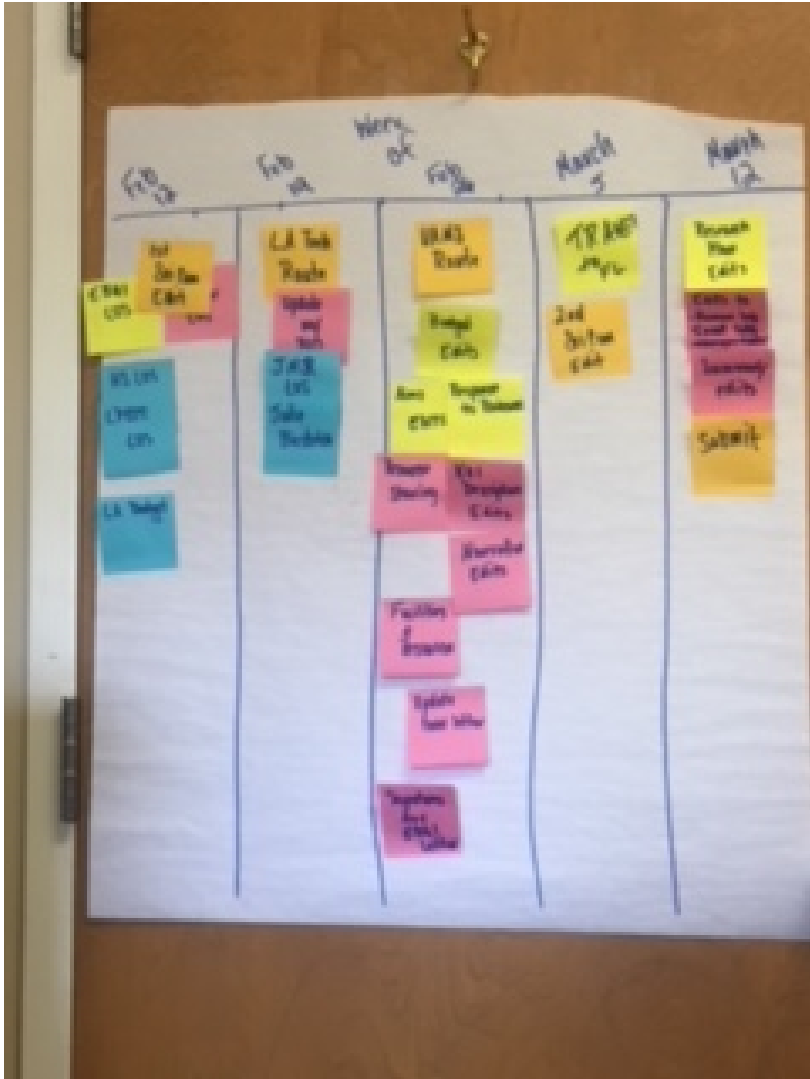
Final Stage

Post Submission

- Review in Jan
  - Get something accepted for publication. You can give an update before review
- Score received – March 11
- JIT Request – March 25
- Summary Statement – April 6
- PO Meeting – Translational Science, April 14
- PO Phone Call – April 22
- Response – May 11
  - 2 pages to all comments
  - New LOS
- Council – May 17

Helpful Strategies

- Solicit feedback in chunks
  - Targeted questions and requests
- Timeline
  - Submitted 5 other proposals with overlapping timelines
- Protect time
  - Most of it
- Detailed to-do lists and "task sprints"
- Time off
  - Only wrote on 2 weekends
- SciCom Grant writing workshop

Model Successful Applicants

- Funded Scholars
  - Personal contacts
  - KL2 program files
  - Active projects lists and email requests
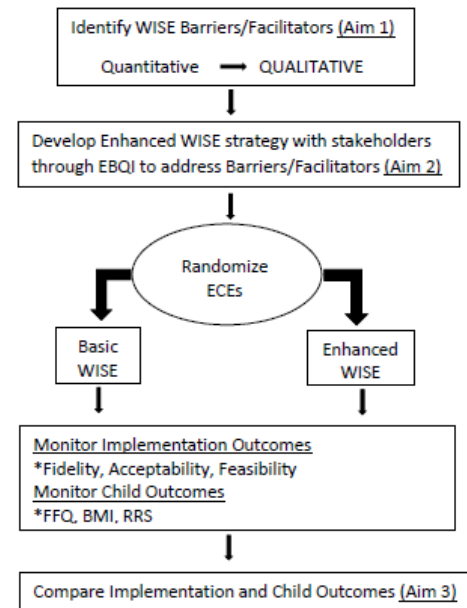   - https://projectreporter.nih.gov/reporter_searchresults.cfm
  - Resulted in 5 examples

TABLES and FIGURES!

Table 1: Timeline of Training and Research Activities

Career Development	Year 1	Year 2	Year 3	Year 4
Objective 1: Implementation Science				
Complete IS directed study	7%	5%	2%	2%
Attend TIDRH	-	2%	-	-
Attend & present at DNI conference	2%	2%	2%	2%
Objective 2: Child Nutrition				
Complete MSCN degree	5%	-	-	-
Complete field study at CEL lab	2%	2%	2%	-
Attend & present at SNEB/ ISBNPA	2%	2%	2%	2%
Objective 3: Community Engagement				
Attend VCU workshops	2%	-	-	-
Complete CE directed study	5%	7%	2%	2%
Establish & sustain RED CAB	-	3%	2%	2%
Research				
Research Activities	35%	32%	35%	25%
Mentoring and Development				
Mentoring meetings	5%	5%	5%	5%
Additional ongoing research	16%	16%	11%	11%
Teach Graduate course in Survey Research	7%	7%	7%	7%
Teach/Consult with CIR			5%	5%
Service activities	2%	2%	2%	2%
Manuscript/Grant Preparation				
Manuscript Preparation	5%	10%	10%	15%
Grant applications (e.g., R01)	5%	5%	13%	20%

Table 2: Research Project Timeline

	Year 1	Year 2	Year 3	Year 4
Specific Aim 1				
Identify ECEs for interviews (quant)				
Recruit ECEs and complete interviews				
Analyze interview content (QUAL)				
Specific Aim 2				
Form panel & Prepare materials for EBQI				
Complete EBQI iterations				
Design materials for enhanced strategy				
Specific Aim 3				
Train ECEs in WISE				
Implement Enhanced Strategy				
Collect Implementation data				
Collet Child data				
Analyze data to compare conditions				
Prepare R01				

Identify WISE Barriers/Facilitators (Aim 1)

Quantitative → QUALITATIVE

Develop Enhanced WISE strategy with stakeholders through EBQI to address Barriers/Facilitators (Aim 2)

Randomize ECEs

Basic WISE — Enhanced WISE

Monitor Implementation Outcomes
*Fidelity, Acceptability, Feasibility
Monitor Child Outcomes
*FFQ, BMI, RRS

Compare Implementation and Child Outcomes (Aim 3)

Transition to the K Lifestyle

Questions?