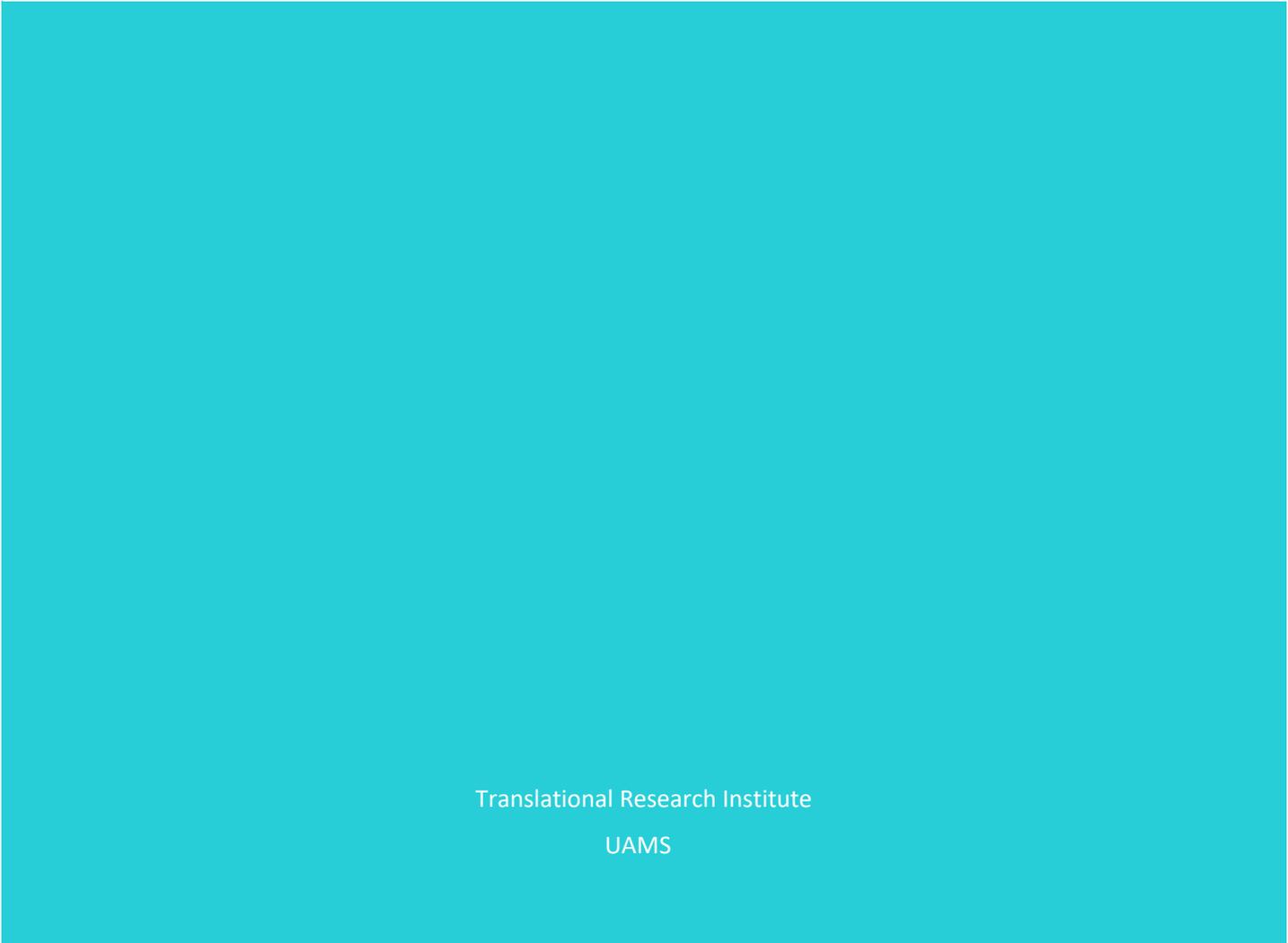




KL2 Program  
Scholar Handbook  
2020



Translational Research Institute

UAMS

## TRI CAREER DEVELOPMENT PROGRAM (KL2) HANDBOOK

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### About TRI

The UAMS Translational Research Institute (TRI), funded by the CTSA, provides infrastructural and personnel support to researchers from TRI hub sites (UAMS, CAVHS, UAMS-NW and ACH/ACRI). The goal is to accelerate the diffusion of medical advancement from bench to the bedside.

### Program Leadership and Staff

W. Brooks Gentry, MD – Director. Dr. Gentry is Professor of Anesthesiology and Pharmacology and Toxicology, and Chief Medical Officer of InterveXion Therapeutics, a Bioventures company. He was previously Chairman of the UAMS Department of Anesthesiology and has been a translational clinician scientist for 28 years. Dr. Gentry directs a translational research team at UAMS that is working to develop new immunotherapeutic medications (antibodies and vaccines) to treat methamphetamine abuse.

Elisabet Børsheim, PhD – Co-Director. Dr. Børsheim is Professor of Pediatrics and Geriatrics. She leads the translational research team “Physical Activity, Bioenergetics and Metabolism”, and directs two research cores at the Arkansas Children’s Nutrition Center and the Arkansas Children’s Research Institute. She has several decades of experience in studies of energy and substrate metabolism and prevention of metabolic disturbances across the lifespan.

Nia Indelicato, MNO – Assistant Director of Programs, TRI. Ms. Indelicato will provide high-level administrative support to the Program and Scholars.

Miesha Hall, MHA CHAA – Program Manager- Ms. Hall will provide administrative support for the KL2 Program, the Directors, and the Scholars. She will be responsible for the day to day activities of the KL2 program.

### The KL2 Mentored Research Development Program

The vision of TRI is to be a thriving translational research ecosystem that catalyzes discoveries into health solutions for rural and underrepresented populations. Our mission is to develop new knowledge and novel approaches that will measurably address the complex health challenges of rural and underrepresented populations.

The overarching goal of our **KL2 Scholar Program** is to increase the number of outstanding translational scientists who conduct innovative research on health issues that impact the residents of Arkansas and the U.S. The KL2 Scholar Program is designed to support the research career development of promising early career faculty and enhance successful transition into research independence and leadership at their respective

institutions and nationally. The Program focuses on the *very best of the best* junior faculty who are committed to a research career in clinical and translational science.

KL2 Scholars will dedicate **75 percent effort** to participate in a **two-year program** that includes both didactic and practical research training. Candidates must identify a primary mentor and mentoring committee, propose and execute a feasible research project, and outline a career development plan that includes didactic training based on needs and interest and as related to their research and career development plans.

This training can take several forms including enrollment in: 1) selected university courses; 2) continuing education courses; or 3) short/concentrated courses/tutorials in areas of expertise. These educational resources are used to individualize the formal training for each scholar and enhance their capacity to excel in their chosen research. Successful KL2 Scholars will have submitted a federal grant as principal investigator and published results from their research by the conclusion of the two-year period of support.

## Program Eligibility

Qualifications for the KL2 Scholar Program:

- Candidate must be a U.S. citizen, non-citizen national or permanent resident. Individuals on temporary or student visas are not eligible.
- A doctoral-level degree in a health discipline that can be applied to clinical or translational research. These degrees include, but are not limited to, M.D., Ph.D., Pharm.D., D.N.P., Dr. P.H., or D.O.
- Candidates must be committed to a career focused on multidisciplinary clinical or translational research.
- Full-time faculty at UAMS, UAMS Northwest Campus, Arkansas Children's Hospital and its Research Institute (ACRI), or the Central Arkansas Veterans Healthcare System (CAVHS) who hold non-temporary positions at the rank of instructor or above are eligible for TRI Pilot Awards.
- Candidates must be able to devote 75% professional effort to the program for a minimum of two years (surgeons and some other specialists with large clinical burdens may request a lower level of support, but not less than 50 percent).
- Candidates must have the support of a mentoring team approved by the program, and the approval of their department chair.
- Candidates are not allowed to have served as principal investigator on a National Institutes of Health (NIH) R01, or subproject of a Program Project (P01) or Center (P50, P60, U54) grant, have a career development grant (K23, K08, K01), or other equivalent grant award.
- Applicants who are dually employed by UAMS and the Veterans Administration may be restricted from the KL2 Scholar award, depending upon the extent of commitment (percent effort) to the VA. Federal salaries cannot be considered part of the required 75 percent KL2 institutional commitment.
- The KL2 Scholar Program welcomes and encourages members of under-represented minority groups, individuals with disabilities, and individuals from NIH-defined disadvantaged backgrounds to apply.

## Awardee Responsibilities

The TRI KL2 Scholar Awards are associated with awardee responsibilities. Failure to adhere to the awardee responsibilities will result in suspension of the project and the Scholar being ineligible to receive future support from any TRI program.

### NIH Requirements

- **NCATS Prior Approval:** All projects must be approved by NCATS through the Prior Approval Process before subject recruitment can begin and research funds can be released. TRI program staff will coordinate this process with each Scholar individually.
- **Regulatory Approval:** Scholars must provide current documentation of all necessary regulatory approvals (e.g., Institutional Review Board (IRB) and Department of Occupational Health and Safety).

- **Compliance:** Scholars must comply with the Health Insurance Portability and Accountability Act (HIPAA) (45 C.F.R. Parts 160 and 164) and other research and confidentiality requirements described in the University of Arkansas for Medical Sciences (UAMS) Administrative Guide.

## Required Activities

- **Orientation Meeting:** Scholars are required to attend a KL2 Program orientation meeting. Information regarding program requirements and available TRI resources and services will be presented at this mandatory meeting.
- **KL2 Training Meetings:** Scholar attendance and participation is required at all TRI Research and Career Development Seminar Series meetings, Research Fundamentals seminars, Work In Progress presentations, and quarterly Directors' Meetings.
- **Changes in Scope:** Changes in the scope of work, mentor changes, and significant budget changes must be approved in writing by the Program Director and TRI's Assistant Director of Programs. The Scholar must notify the Program Director and TRI's Assistant Director of Programs in writing if they are unable to complete the project and must terminate the award.
- **RCR Training:** Scholars must complete the NIH requirement of Responsible Conduct of Research training within the two-year award period.
- **Annual ACTS Meeting:** Scholars are required to attend the annual Translational Science Meeting of the Association for Clinical and Translational Science (ACTS) and submit an abstract for this conference each year. Grant funds may be used for this purpose.
- **Team Science Training:** Scholars must attend TRI-sponsored seminars on team science.
- **K to R (KTR) Program:** Scholars must complete the online *K-Paseo* program, which is an 8-session series that covers each section of a K-grant application in detail.

## Reporting

Scholars are required to provide progress reports on a quarterly and annual basis, providing updates on research progress, coursework, mentor meetings, RCR training, etc. A report from the primary mentor on behalf of the mentoring team will also be required twice yearly. The program manager will email the Scholar instructions for completing the progress report, which is due two weeks after notification. Depending on the progress in achieving appropriate milestones, a Scholar could be required to submit additional progress reports.

- **Final Report:** A final research report and a final expenditure report are due within 60 days following the close of the grant term.
- **Annual Reports (Post-Scholarship):** Scholars are required to submit progress reports annually for the two years following the project completion date.

## Mentor/Mentee Relationship

A good mentor/mentee relationship is key to your success as a KL2 Scholar. Developing a strong mentoring plan is a vital step in establishing how your mentoring team can best help you with your goals.

- **Mentor/Mentee Contract:** Primary mentors must sign a mentor contract. Scholars are expected to meet with their primary mentor at least weekly for the duration of their KL2 Program.
- **Individualized Career Development Plan:** Scholars must meet with the KL2 Co-Directors and mentoring team bi-annually to review their IDP plan and progress in meeting goals of the plan, as well as address any problems that may occur.

## Evaluation and Assessment

Scholars will complete a Core Competency Assessment to identify strengths and gaps that will direct ongoing development of a Scholar's training program. Scholars and Mentors will also both engage in mentor/mentee assessments at different points during the two-year program.

## Scholarly Expectations

- **Publications:** As part of the successful execution of the project, Scholars are expected to submit at least 3 manuscripts to peer-reviewed scientific journals by the end of year two of the KL2 Program. Two should be first or second author, and two should represent original research.
- **Grant Submissions:** A K- or R- level proposal should be submitted or under development by the end of year two.
- **TRI Acknowledgments:** Scholars must acknowledge support of TRI and award numbers TR003107 and KL2 TR003108 as the funding source in any news releases, articles, or publications relating to the funded project or its results, and a copy of these materials must be provided to TRI. Failure to properly acknowledge TRI may result in the scholar being ineligible to receive future support from any TRI program. TRI requests that you use the following language when acknowledging studies supported by TRI funding:  
 “The project described was supported by the Translational Research Institute (TRI), grant **[insert appropriate award number(s)]** through the National Center for Advancing Translational Sciences of the National Institutes of Health (NIH). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.”

## KL 2 Core Competencies

KL2 scholars are expected to acquire specific competencies during the program. Program activities are designed to help scholars identify gaps in skills and knowledge and address them. Core competencies and the KL2 program components that support development are included below:

Domain	Core Competencies	Program Activities
Research Design & Methodology	Critically evaluate research literature Formulate hypotheses and aims Construct an experimental study design Select measurements and apply operational definitions Understand sample size, power and sampling techniques Understand methods of experimental control, internal/external validity Knowledge of human laboratory procedures and techniques	Mentor/mentor team meetings Co-Directors meetings Grant writing course K Paseo program TRI RCD and RF seminars Tailored didactic coursework
Human Subjects Protection & Research Ethics	Develop strong foundation in best practices and ethical standards for conducting clinical research Understand ethical considerations specific to patient-centered research, especially in vulnerable populations Understand professional ethics, e.g., authorship, conflicts of interest	Mentor meetings CITI program RCR training program Tailored didactic coursework TRI ethics consultations
Data Collection, Management, Analysis and Interpretation	Construct plan for data collection and entry Construct data file management plan Understand statistical and clinical significance Use common statistical tests & software packages; interpret output	Mentor/mentor team meetings TRI biostatistics consults Tailored didactic coursework Bioinformatics training and consults TRI RCD seminars

Dissemination of Research Findings	Display outcomes data Prepare/submit conference abstracts Prepare/submit journal manuscripts and respond to critiques Integrate findings into existing literature Provide clear written and oral interpretation of results Create and deliver oral and poster presentations	Mentor meetings OGSP consultations Preparation and presentation at CTS and other professional meetings Tailored didactic coursework Community Engagement consults
Research Administration	Secure and maintain IRB approval Build/participate on multidisciplinary research team(s) Develop/revise study timelines Prepare/manage study budgets Supervise research staff Interact with university clinical, financial & research admin personnel	Mentor/mentor team meetings Co-Directors meetings TRI RCD and RF seminars Tailored didactic coursework
Grant Writing	Understand R-series funding opportunities (R03, R21, R01) and equivalents (VA, DOD, voluntary health organizations) Understand funding sources, mechanisms, forms, and formats, submission requirements, cycles and review procedures Demonstrate proficient grant writing skills	Mentor meetings Grant-writing course, consultations K Paseo TRI RCD seminars Tailored didactic coursework
Professional Development and Challenges	Understand career phases and academic expectations Understand promotion & tenure requirements and cycles Expand circle of collaborators, consultants and networking Demonstrate efficient time management Handle potential conflicts of interest and/or commitment	Mentor/mentor team meetings Co-Directors meetings TRI RCD seminars TRI/UAMS Professional Development seminars

# Mentoring, Mentored Research and Career Development Plan

## Primary Mentor and Mentoring Committee

KL2 Scholar candidates must identify a primary research mentor and mentoring committee and submit a feasible research proposal and research career development plan in their chosen field of study. The selection of a research mentor is one of the most important components of the application. The primary mentor must have expertise in the Scholar's area of research, current extramural research funding, a history of successful mentoring, and be willing to provide opportunities for the Scholar to conduct the research project and provide oversight of the Scholar's research and research career development. The primary mentor must sign a contract agreeing to serve as the primary mentor, express a strong commitment to the Scholar's successful career development, serve as primary supervisor for the Scholar's research project, seek opportunities to promote the scholar's scientific career, and be willing and able to meet with the scholar at least weekly for the duration of their KL2 program. TRI will pay 5 percent of the primary mentor's salary for the duration of the scholar's involvement in the KL2 Scholar Program.

Candidates for a KL2 Award must also have a mentoring committee (up to 4 members) who will provide feedback and additional mentoring in selected areas. At least one member of the mentoring team must be from a different department, division, or discipline than the mentee. Identifying a primary mentor and one or more co-mentors can be accomplished by utilizing knowledge of existing research programs, **or** you may contact the KL2 Leadership Team for assistance in identifying potential mentors.

## Research Project

Applicants must propose and execute a feasible clinical or translational research project that is supervised by a primary mentor and mentoring committee. The research project should be designed as a pilot project to set the stage for an individual K-award application, or otherwise establish a foundation for a subsequent individual R-award application.

TRI defines **translational science** as that which transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical applications to reduce disease incidence, morbidity, and mortality. TRI conceptualizes translational research as occurring on a bi-directional continuum of T1 through T4 research that addresses human health questions and creates human health interventions.

**T1** research is the transfer of discovery of disease mechanisms in the laboratory to the development of new methods of diagnosis, therapy and prevention, and the first testing in humans. This is where basic science discoveries are applied to human health and early clinical trials usually occur (Phase 1).

**Testing of therapeutics using established animal models of disease is considered T1 research, but is not funded through the KL2 Scholar Program.**

**T2** is the translation of results from early clinical studies into everyday clinical practice and health decision making. Research is expanded to larger patient populations in Phase 2 and 3 clinical trials, observational studies or survey research in target populations. New discoveries can result in the need for more translational research in basic sciences (T2→T1), or influence T3 research (T2→T3).

**T3** attempts to improve the incorporation of research discoveries into day-to-day clinical care. During this stage, dissemination and implementation research are used to answer such questions as: “Is treatment X being used in the community at large, and if not, why?” This stage focuses on the identification of new clinical questions, barriers and gaps in care related to treatment X.

**T4** seeks to evaluate the real world health outcomes of population health practice. This stage includes new policy or outcomes research, such as whether existing laws for insurance reimbursement allow equal access or implementation of treatment X to target populations, or how treatment X compares to other standard-of-care practices. If T1→T3 studies reach their goals and data indicate efficacious practices or results, new policy or outcomes research is engendered in T4.

### **Research Career Development Plan**

Applicants must propose and execute a research career development plan developed by the candidate with their primary mentor and mentoring committee. The career development plan outlines the research interests/goals and how and why the KL2 Program is important to and will help achieve these objectives as well as future research career success. The career development plan may include planned participation in lab meetings or journal clubs; attendance at research conferences; formal coursework on clinical and translational science topics; participation in additional training experiences in clinical or basic science; or informal educational activities such as short courses or workshops. The career development plan also includes a timeline of plans for the development and submission of an extramural grant application for continued career development or other research support.

# Appendices

## **TRI KL2 Individual Development Planning (IDP) Questionnaire**

**Objective:** The TRI KL2 seeks to provide an individually-tailored training experience targeting trainee development towards personal career goals. The IDP represents a working document that defines the career goals and guides the career development plan by enhancing trainee strengths and minimizing barriers to goal attainment. The IDP also monitors progress towards career development milestones.

### **1. Briefly Define your Career Goals**

- Plan “A”:
  
- Plan “B”:

### **2. In more detail outline your career goals**

- What type of work would I like to be doing 5 years from now (e.g., research, education, policy, regulation)?
  
- What type of work environment would I be working in at that time (e.g., academic, industry, government, other)?
  
- How do personal issues (e.g., family, lifestyle, illness, financial, etc) affect my career goals and their attainment?

### **3. Assess your current skills related to your career goals**

- What are my goal-congruent personal and professional strengths?
  
- What am I doing currently to enhance my strengths?
  
- Am I using my strengths in my current training environment?

- What are my goal-congruent personal and professional weaknesses/deficiencies?
- How do my weaknesses/deficiencies impact the attainment of my career goals?
- What am I doing to strengthen my areas of weakness/deficiency?
- What can the TRI Career Development Scholars Program do for you to aid the attainment of your career goals?

#### **4. Outline a career development plan**

- What specific new skills do I need to attain my career goals?
- What work environment experiences would be useful to inform my career choices and enable my post-training placement?
- What are the perceived barriers (e.g., writing, speaking, publications, training, mentoring) to attaining my career goals?

# KL2 Career Planning Document

Name:

Date:

## Year One Vision

In one paragraph describe your overall short-term goals for the first year of the Program.

## YEAR ONE PLANNING TABLE (Short-Term Goals)

(Use several pages if needed)

ACTIVITY	SPECIFIC OBJECTIVES	HOW TO ACHIEVE?	DOCUMENTATION OR EVIDENCE	WHO IS MENTOR FOR THIS ACTIVITY?
CLINICAL (if applicable)				
TEACHING (if applicable)				
RESEARCH (if applicable)				
ADMINISTRATION (if applicable)				
QUALITY & SAFETY				

Are there any essential resources or assistance you presently do not have but need in order to achieve the objectives in your one year plan?

## Year Two Vision

In one paragraph describe your overall Mid-Range goals for the second year of the Program.

### **YEAR TWO PLANNING TABLE (Mid-Range Goals)**

(Use several pages if needed)

ACTIVITY	SPECIFIC OBJECTIVES	HOW TO ACHIEVE?	DOCUMENTATION OR EVIDENCE	WHO IS MENTOR FOR THIS ACTIVITY?
CLINICAL (if applicable)				
TEACHING (if applicable)				
RESEARCH (if applicable)				
ADMINISTRATION (if applicable)				
QUALITY & SAFETY				

**Are there any essential resources or assistance you presently do not have but need in order to achieve the objectives in your one year plan?**

### Three to Five Year Vision

In one paragraph describe your overall three to five year career plan.

### THREE TO FIVE YEAR PLANNING TABLE (Long-Term Goals)

(Use several pages if needed)

ACTIVITY	SPECIFIC OBJECTIVES	HOW TO ACHIEVE?	DOCUMENTATION OR EVIDENCE	WHO IS MENTOR FOR THIS ACTIVITY?
CLINICAL (if applicable)				
TEACHING (if applicable)				
RESEARCH (if applicable)				
ADMINISTRATION (if applicable)				
QUALITY & SAFETY				

Are there any essential resources or assistance you presently do not have but need in order to achieve the objectives in your one year plan?

### TRI KL2 Program Work-in-Progress (WIP) Guidelines\*

Works-In-Progress: Multidisciplinary group process with your peers and mentors can make your work product better, and you can learn a lot by participating in the decisions your colleagues are wrestling with.

#### Role of Scholars:

- Either present or review: **Everyone has a job.**
- **Everyone** in the WIP group is expected to be familiar with the materials presented.
- Help problem-solve; provide connections and follow-up; develop collaborations
- Share helpful resources, materials, and mentors

#### Role of Program Faculty

- Identify decision points
- Lead discussion to involve every scholar and to broadly cover the relevant issues
- Help identify UAMS/TRI or other relevant experts to assist
- Assign loose ends for follow-up
- Guide timely and satisfying wrap-up

Appropriate Material: **Whatever the Scholar wants input/feedback on** in order to advance your research and career goals. As the name of this session suggests, the emphasis should be on “Work in Progress,” not on nearly completed products. Feedback is usually most helpful when the work is still in its formative stages. Some suggestions:

#### Conducting Research

- Defining/refining the research question
- Choosing the study design
- Choosing the study population and input on recruiting
- Developing data collection methods/instruments
- Carrying out the research/challenges with implementing a study protocol
- Analyzing the data, deciding between statistical methods
- Interpreting results

#### Preparing Oral and Written Presentations of your Research

- Abstracts
- Meeting presentations (oral; poster)

Manuscripts (often helpful to point us to where input is needed – presentation of data, discussion, etc.)

- Responding to manuscript reviews

#### Writing grant applications

- Developing ideas for grants/responding to a specific announcement
- Specific Aims/Significance/Innovation sections
- Responding to grant reviews
- Full grant applications – (again helpful to point us to where input is needed as these are longer documents)

#### Career decisions

- Brainstorming new areas of research
- Managing your research team
- Managing other career decision/issues (mentors, promotions, new job opportunities)

#### Suggestions for presenters

- **Distribute a short set of materials in advance (ideally early in the week), with a cover note that specifies the main questions you would like to answer in the WIP**
- Minimize presentation time, maximize interaction
- Also
  - Share your pain
  - Share your successes
  - Don't be defensive
  - Invite mentors and experts to some sessions

#### Suggestions for reviewers

- Read the readings; be constructive; try thinking outside the box
- **Pencil in 2 major and 3 minor suggestions** (or more)

\*WIP Guidelines based on similar material developed for UCSF KL2 program and available on the CTSA website: <http://ctsi.ucsf.edu/our-work/k-scholars-program> and <http://ctsi.ucsf.edu/our-work/k-scholars-program>

**SUMMARY OF ACTIVITIES and SELF ASSESSMENT to guide KL2 Program Mentoring Meetings**  
(Modification of the Postdoc Annual Evaluation & Development Form  
Office of Post Graduate Affairs, Washington University in St Louis)

To be completed by trainee and turned in to mentoring committee one week prior to meeting

**Since the last meeting/review/evaluation:**

Write an overview of your Research Project and Major Accomplishments (1/2 page max)

List scholarships, grants, honors or awards (applied for, received or pending; indicate start & end dates)

List all Publications (including Journal Articles or Abstracts and include submitted and accepted/in press) and Presentations

List all new Collaborations internal and external to the KL2 Program

List all Manuscript/Grant Writing and Teaching training experiences

List National or other professional meetings attended and presentations

List Teaching Activities (if applicable)

List Research Goals for the next period

What is your level of satisfaction with your research progress?

List Career Development Goals for the next year

## 2020 KL2 Mentor Agreement

This agreement states that you have agreed to serve as the primary mentor for \_\_\_\_\_ on their KL2 Scholar research project.

### **Mentor Responsibilities include:**

1. Complete initial and follow-up KL2 mentor competency assessment tools
2. Ensure that a mutually agreed upon set of expectations and goals are in place at the onset of the KL2 mentoring relationship
3. Establish and review IDP milestones
4. Ensure sufficient protected time
5. Help to navigate systems
6. Help to develop effective time-management skills
7. Communicate weekly for the duration of Scholar participation in the KL2 program to discuss progress on project and provide direct feedback
8. Manage disagreements and conflicts
9. Identify and resolve barriers
10. Provide formative evaluation on competences in research, mentoring, and working with teams
11. Critically review research data and guide Scholar interpretation
12. Review research plans and aim for feasibility and appropriateness
13. Review and edit scientific communications, publications, grant applications
14. Dedicate substantial time to ensure personal and professional development for the KL2 Scholar
15. Help Scholar seek opportunities to promote career in translational science research
16. Strive to maintain a relationship with the KL2 Scholar that is based on trust and mutual respect
17. Help the Scholar present information at an approved conference, on-campus symposium, or in a peer-reviewed journal
18. Review proposed research plans for sound methods, ethical integrity and completion in a reasonable time frame
19. Demonstrate ethical standards when conducting research and regularly discuss professional and research ethics issues with the KL2 Scholar, including compliance with institutional and federal regulations as they relate to responsible conduct of research, privacy, human subjects research issues, and laboratory safety
20. Help solve scientific challenges that arise
21. Encourage Scholar scientific independence
22. Meet with KL2 Directors to review Scholar progress
23. Assist Program Director and other TRI Staff with the collection of data required for any and all grant progress reports or applications.

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(Signature of KL2 Mentor)

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(Date)