CLINICAL AND TRANSLATIONAL SCIENCE AWARD (CTSA)
KL2 SCHOLARS PROGRAM

2020 – 2024
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Welcome

Welcome to the Stanford’s Center for Clinical and Translational Research and Education (Spectrum) and your Mentored Career Development Award Program (KL2). This program, supported by the National Institutes of Health (NIH) Clinical and Translational Science Award (CTSA), provides individualized, competency-based training in rigorous research methodologies for the design and conduct of high-quality translational research. The KL2 Scholars Program provides courses, seminars, workshops, and experiential training to build essential translational research skills in team science, leadership, stakeholder engagement, and communication.

Our primary goal is to support the next generation of multi-disciplinary clinical and translational researchers.

This handbook points you to important information that will help you throughout your time within the KL2 program. However, if you have questions that are not answered here, do not hesitate to contact any of us.
Program Faculty & Staff

Leadership

**Ruth O’Hara, MD**  
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Senior Associate Dean for Research, Stanford School of Medicine  
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Director, KL2 Mentored Career Development Program  
Professor of Medicine (Primary Care and Population Health)  
Director, Center for Innovation to Implementation (ci2i), VA Palo Alto Health Care System  
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**Steve Goodman, MD, PhD**  
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KL2 Program Academic/ Career Mentors

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Urology

Bonnie Maldonado, MD  
Pediatrics – Infectious Diseases & Epidemiology and Population Health

Lee Sanders, MD  
Pediatrics – General Pediatrics

Glenn Chertow, MD, MPH  
Medicine – Nephrology

Mark McGovern, PhD  
Psychiatry and Behavioral Sciences & Public Mental Health and Population Sciences

Gary Shaw, MD, MSc  
Pediatrics – Neonatal and Developmental Medicine

Mary Goldstein, MD, MSc  
Medicine – Center for Health Policy/Center for Primary Care and Outcomes Research (CHP/PCOR)

Arden Morris, MD, FACS  
Surgery – General Surgery

Sara Singer, MD  
Medicine – Primary Care and Population Health

Mary Hawn, MD, FACS  
Surgery

Mark Musen, MD  
Medicine – Biomedical Informatics

Melinda Telli, MD  
Medicine – Oncology

Mark Hlatky, MD  
Health Policy/Health Services Research & Medicine – Cardiovascular Medicine

Sandy Napel, PhD  
Radiology

PJ Utz, MD  
Medicine – Immunology and Rheumatology

James Kahn, MD  
Medicine – Primary Care and Population Health

Doug Owens, MD, MSc  
Medicine – Center for Health Policy/Center for Primary Care and Outcomes Research (CHP/PCOR)

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Abby King, PhD  
Epidemiology and Population Health & Medicine – Stanford Prevention Research Center (SPRC)

Latha Palaniappan, MD, MS  
Medicine – Primary Care and Population Health

Darrell Wilson, MD  
Pediatrics – Endocrinology and Diabetes

Karl Lorenz, MD, MSHS  
Medicine – Primary Care and Population Health

Julie Parsonnet, MD  
Medicine – Infectious Disease & Epidemiology and Population Health

Paul Wise, MD  
Pediatrics – Neonatal and Developmental Medicine

Sean Mackey, MD  
Anesthesia – Perioperative and Pain Medicine

Rita Popat, PhD  
Epidemiology and Population Health

Mary Goldstein, MD, MSc  
Medicine – Center for Health Policy/Center for Primary Care and Outcomes Research (CHP/PCOR)
Expectations for KL2 Scholars

The KL2 Scholars Program provides an opportunity for Scholars to jump-start their careers as multidisciplinary clinical researchers with protected time for research and training. We have developed a number of expectations for the Scholars that will help ensure success.

Scholars are expected to:

- Attend all KL2 Seminars. These serve as an opportunity for Scholars to communicate with KL2 Leadership and other Scholars.
- Attend the CTR Summer Bootcamp and optional Intensive Course in Clinical Research: Study Design and Performance.
- Participate in at least 10 career development workshops and evaluate each.
- Attend at least one Route to Getting Grants (R2G2) seminar.
- Develop a mentorship team and meet with assigned Academic/Career mentors quarterly and K Advisors bi-annually.
- Complete the Responsible Conduct of Research (RCR - Med 255) Training during their award period.
- Complete the electronic research administration (eRA) training appointments within 10 days of receipt of award.
- Provide semi-annual updates on research and career development progress and complete annual reports for the KL2 Research Performance Progress Report (RPPR) submitted to NCATS.
- Submit at least one multidisciplinary extramural grant of any size by the end of the second year (typically R01, R21, R03, or other federal, state, foundation, industry, or intramural grant).
  - Please forward all Proposal Intake Forms (PIF) to Ellen Orasa (eorasa@stanford.edu), KL2 Program Manager.
- Submit 3 original research multidisciplinary peer-reviewed publications, two of these as first or last author.
- Submit individual K or R series applications within two years post-KL2 award.
- Link OrcID and KL2 Grant number to all publications, abstracts, chapters, and/or posters.
  - Comply with the NIH Public Access Policy.
- Complete an online customized career development plan upon acceptance of the KL2 award and update it throughout the program.
- Complete KL2 annual RPPR survey requests for 15 years after completion of their KL2.
Program Requirements

Period of Support: This award is for a minimum of 2 years offered in consecutive 12-month appointments. The KL2 funds are non-transferable beyond the specified period and all unexpended funds will be returned to the CTSA Program at the end of the award period.

I. Time Commitment and Support Overview

a. Time Commitment: Devote 75% of full-time professional effort to the KL2 program for training and clinical research activities. The remaining 25% effort can be divided among other clinical, administrative, and teaching responsibilities that are consistent with the proposed goals of the KL2 program. Exceptions to the 75% effort requirement may be made for limited specialties (e.g., 50% effort for surgeons and other procedural-based specialties requiring greater clinical effort to maintain clinical skills such as ENT, Orthodontics).

b. Travel: $2,000 per year for travel is provided to scholars to attend the Association of Clinical and Translational Science (ACTS) Conference held in Washington, D.C. or an alternative conference approved by the KL2 Program Director. Travel costs include scholar registration, airfare, hotel, and associated transportation (to and from the airport, tolls, parking), meals, and incidentals.

Travel expenses must be compliant with Stanford University and NIH policies regarding travel, an overview of which can be found at: https://fingate.stanford.edu/business-travel-expenses/business-and-travel-expense-policies

For travel reimbursement or any financial transaction, contact your department financial administrator (DFA).

See Travel costs – Registration, Planes, Hotel and Food

c. Research Development and Support: $20,000 per year for the two-year term of your award is available to support research expenses, such as supplies, equipment, technical personnel, certificate programs, and tuition. Awarded funds intended to support the scholar’s Research and Development activities may not be used to provide additional KL2 scholar salary support or provide salary for the primary mentor.

See Guidelines for Use of Career Development Funds.

II. KL2 Seminars

Scholars are required to attend weekly 1.5-hour Career Development Seminars that take place on Fridays from 12:00 PM to 1:30 PM. These seminars are uniquely designed for junior faculty who are engaged in clinical and translational research.
The Seminar Series includes educational seminars presented by senior faculty in an informal setting where there is ample opportunity for discussion and questions. The series also includes current research project progress (Works in Progress; WIP), and opportunities to critique colleagues’ research projects.

Each Seminar will have one of the following formats:

a. **Scholar Work-in-Progress/ Progress Report**

   Scholars are expected to present a progress report on their status to the KL2 Program Directors and fellow KL2 scholars twice during the award period. The presenting scholars’ primary mentor(s) are expected to attend these presentations. The scholar work-in-progress presentation should follow the below format:
   1. Start with a ‘Pitch’ < 5 minutes
   2. Research Progress – 5 minutes
   3. Progress on goals in the CDP – 5 minutes
   4. Mentors report on progress – 5 minutes
   5. Q&A – 10 minutes

b. **Professional Development Presentations**

   Throughout the year, Stanford faculty leaders will be present and discuss select areas of career development. Topics to include:
   1. Scientific Writing
   2. Statistical Analysis in Basic & Clinical Science
   3. Time Management – when and how to say “no”
   4. How to Set-up a Lab and Evaluate postdoc candidates
   5. Transition to independence and setting up collaborations
   6. Budget and Multi-Investigator Grants
   7. Trajectory of a Physician Scientist
   8. Research Reproducibility

c. **Route to Getting Grants, Writing Group Sessions, and Mock Review**

   1. **Route to Getting Grants (R2G2)** is a monthly seminar series specially designed for junior faculty. Sessions cover all aspects of grant writing, delivered through panel sessions, workshops, and focused talks. R2G2 will also provide unique networking opportunities, enabling cross-faculty collaborations and multidisciplinary partnerships. R2G2 ensures that junior faculty have all the tools and strategies to lead them to grant success and on to independent research careers.

   Join the mailing list: [https://mailman.stanford.edu/mailman/listinfo/r2g2series](https://mailman.stanford.edu/mailman/listinfo/r2g2series)

   2. **Writing Group Sessions** Scholars will be assigned to a small group of peers. On a monthly basis, one member of each group will submit their one-page Specific Aims for review by their group. Groups are expected to review the Aims in advance of the seminar and come prepared to provide feedback. Statisticians will also be present to review the Aims.
III. Additional Training

a. Scholars are required to attend, report, and evaluate 10 CTR-related seminars or educational workshops with half outside the scholar’s direct area of concentration, including 2 Bioethics Seminars, during the award period.

b. University-wide CTR-related Seminars:
   1. Early Translational:
      - TRAM Seminar Series
      - Frontiers in Cardiovascular Science
      - SPARK
   2. Clinical Research:
      - Essentials of Clinical Research
      - Workshops in Biostatistics
      - Research in Progress Seminar
      - Epidemiology Research Seminar
      - Data, Society and Inference Seminar
      - Clinical Research Operations Program
      - QSU Research Methods Seminar
   3. Population Health/ Implementation Research:
      - CHP/ PCOR
      - VA HSR&D Cyberseminars
      - VA Center for Innovation to Implementation (Ci2i)
      - PHS Seminars
   4. Other Broad Resources:
      - Biomedical Ethics Seminars
      - UCSF-Stanford Center of Excellence in Regulatory Science and Innovation (UCSF-Stanford CERSI)
      - Data Studio
      - Intensive Course in Clinical Research
      - Academic Chats

IV. Mentoring

a. Develop a mentorship team
The scholar must select a lead mentor who will have the overall responsibility for helping the scholar develop an independent career in clinical and translational research. The lead mentor will provide guidance, track the scholar’s career progress, and ensure their research time is properly protected. Co-mentors from other disciplines should be selected to provide multidisciplinary input on the scholar’s research program and activities. All mentors must have a demonstrated track record of successfully developing junior investigators.
b. **Coordinated and Monitored Mentorship**
   - Scholars are required to meet with their primary research mentor at a **minimum monthly**.
   - Scholars are required to meet with the assigned KL2 program mentor at a **minimum quarterly**.
   - All Scholars will meet **no less than bi-annually** with either the KL2 faculty program director or one of the KL2 advisors to ensure that their mentorship arrangements are satisfactory.

V. **Career Development Plan (CDP)**
Scholars will complete an online Career Development Plan (CDP) at the start of the KL2 program. In consultation with both the primary research and KL2 academic mentors, each scholar will be required to create a career development plan that includes goals, intermediate steps, and a timetable for specified milestones. Once the CDP is complete, it will be reviewed by mentors and KL2 Advisors. The CDP will be regularly updated and reviewed throughout the year by the trainee, mentoring team, and program directors. The CDP serves as a tool to tailor the research needs for each KL2 Scholar and provides an opportunity for Scholars to outline a vision for their research career, setting goals to capitalize on their strengths and address their own development needs (Go to page 27 for additional details).

VI. **Course Requirement**
   a. **Responsible Conduct of Research (Med 255).** This course is designed to engage participants in productive discussions about ethical issues that are commonly encountered during their research careers.
      1. To enroll visit: [https://med.stanford.edu/bioethics/education/rcr.html](https://med.stanford.edu/bioethics/education/rcr.html)
      2. Recommended to complete within the first year of the award.

VII. **Additional Courses**
   a. **Clinical and Translational Research (CTR) Summer Bootcamp (Year 1).** The goal of the CTR Bootcamp is to establish a common foundation for all scholars and provide an opportunity to identify individual areas where skill-building or teaching is needed.

   b. **Mock Study Section Summer Bootcamp (Year 2).** The purpose of the one-hour mock review session is to provide a scientific review of grant applications that scholars plan to submit for external funding.

   c. **Intensive Course in Clinical Research (ICCR).** The Intensive Course in Clinical Research (ICCR) is a one-week immersion course for new clinical investigators, senior residents, fellows, and junior faculty (Assistant Professor and below from any faculty line) interested in pursuing careers in clinical and translational research and who have not had formal training in clinical research as part of a Masters or PhD degree program in Public Health or Epidemiology. The course takes place annually in September. For more information, visit: [https://med.stanford.edu/spectrum/education-and-training/intensive-course-in-clinical-research.html](https://med.stanford.edu/spectrum/education-and-training/intensive-course-in-clinical-research.html)
VIII. Written Progress Reports

Scholars and their mentors are required to provide semi-annual updates on the scholar’s research and career development progress as well as complete annual reports for the KL2 Research Performance Progress Report (RPPR). Scholars also agree to complete annual KL2 RPPR survey requests for 15 years after completion of their KL2 award period.

IX. Other Support Entries

a. Other Support – sample entry
KL2 TR003143 (Asch) 7/1/2020 – 6/30/2022 9.0 CM*
NIH/NCATS $xx,xxx*
*The Stanford Center for Clinical and Translational Research (Spectrum) – KL2 Mentored Career Development Award*
The Clinical and Translational Science (CTS) Scholars Program provides multi-disciplinary career development training, including didactic instruction and mentored research experience, to investigators preparing for careers in clinical and translational science.
Role: Scholar

b. NIH Biosketch – sample entry
KL2 TR003143 (Asch) 7/1/2020 – 6/30/2022* NIH/NCATS
*The Stanford Center for Clinical and Translational Research (Spectrum) – KL2 Mentored Career Development Award*
The Clinical and Translational Science (CTS) Scholars Program provides multi-disciplinary career development training, including didactic instruction and mentored research experience, to investigators preparing for careers in clinical and translational science.
Role: Scholar

*Note: Ask the KL2 Scholars Program staff for dates and funding amounts specific to your KL2 award.*

X. Clinical Trials

- K award funds cannot be used to support clinical trials research beyond Phase IIA. Exceptions may be granted for rare diseases, but requires NIH prior approval and issuing of a revised Notice of Grant Award.
- Scholars must comply with all NIH data and safety monitoring (DSM) requirements for clinical trials. Each clinical trial must have NCATS approved DSM plan/board before any grant resources (funds) used to support the clinical trial.
- Clinical trials must be registered at ClinicalTrials.gov.
  a. For assistance, contact Clinical Research Quality – Clinical Trials Disclosure:
     https://med.stanford.edu/spectrum/study-team-resources/clinical-research-quality-crq/crq-clinicaltrials-gov-support-services.html
  c. ClinicalTrials.gov Overview class. See Research Office Education Catalog.
XI. Acknowledging the Grant
All manuscripts, abstracts, chapters, and/or posters resulting from your time as a KL2 scholar must acknowledge the KL2 grant using this language:

Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number KL2TR003143. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

- Publications must be compliant with the NIH Public Access Policy. This policy requires that researchers submit final peer-reviewed journal manuscripts that have been supported by NIH funds to PubMed Central immediately upon acceptance for publication, in order to advance science and improve human health.
- Link OrcID to all publications, papers, and presentations in order to comply with NIH-NCATS reporting guidelines.
- Publications resulting from the use of Stanford CTSA resources or services must also acknowledge the Stanford CTSA grant UL1TR003142 using this language:
Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR003142. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

XII. Press Releases
Prior to issuing press releases concerning KL2 research, contact your KL2 Program Advisor. NIH requires advance notice of press releases to allow for coordination.

XIII. Submit applications for K and R Awards
KL2 Scholars will be expected to submit individual K- or R-series (R01, R21 applications, or the equivalent) within 2 years of the KL2 award end date.
NIH Public Access Policy

Publications resulting from your time as a KL2 scholar must comply with the National Institutes of Health’s Public Access Policy. Direct all questions regarding complying with this policy to Ellen Orasa, KL2 Program Manager, at eorasa@stanford.edu.

Creating/updating a Bibliography

There are several ways to populate a My Bibliography collection:
(1) using a search tool in My Bibliography to add PubMed citations,
(2) uploading citations from a file, or
(3) using a template for publications not found in PubMed.

(1) Adding PubMed citations in My Bibliography: Use the My Bibliography search tool to add PubMed citations:

- Sign in to My NCBI and go to My Bibliography. Click “Manage My Bibliography.”

- Click on ‘+Add citations’ and select ‘From PubMed.’

- Enter the PMID number, the author’s full name, or last name and initials in the search box, and click “Search PubMed.”

- Select the citations you wish to add to your My Bibliography collection and click “Add to My Bibliography.” Close the window and the newly added citations will immediately display in My Bibliography.

(2) Adding citations from a file: Use a file that has your article citations in either the MEDLINE or RIS format to add citations to your My Bibliography collection.

- Sign in to My NCBI and go to My Bibliography. Click “Manage My Bibliography.”

- Click on ‘+Add citations’ and select ‘From a file.’
• Upload a file with citations in either MEDLINE or RIS format. A confirmation message indicates the number of citations added to your My Bibliography collection.

![Processing uploaded file]

• In the cases where a file has citations in a format other than MEDLINE or RIS, a message will indicate that the format is not supported.

(3) Adding Citations Manually: Use My Bibliography templates to create citations for publications not found in PubMed:

• Sign in to My NCBI and go to My Bibliography. Click “Manage My Bibliography.”
• Click on '+Add citations' and select 'Manually.'

• Select the type of publication to be entered manually: journal articles, books/chapters, meeting abstracts, presentations, patents, dataset/database, software, preprint articles, and non-standard citations. Enter the publication information in the fields provided. All required fields are denoted with a red asterisk.

![Choose the type of citation to create]

![Add Another Author]

![Add Citation]
Associating Funding to your Publications

- **Click “Add Award.”**


- In the “Search/Add other awards” tab, search for the award by using the grant number KL2 TR003143 and check the box.

Checking your Publications Compliance Status

- **Select the “eRA Commons” signing option in the NCBI login page, log in using your eRA Commons credentials, and proceed to link your eRA account to an existing NCBI account, or register for a new NCBI account.**

- On the NCBI homepage go to the My Bibliography widget and click “Manage My Bibliography.”
  - **Note:** The icon verifies that an eRA account has been linked to an NCBI account.

- In the My Bibliography banner, check the citation compliance status bar for immediate feedback on the number of your publications that are non-compliant, not defined, in process, or complete.

  In the example below, Theodore Smith has two articles which are non-compliant, 29 not defined, two in process, and 190 articles compliant to the NIH Public Access Policy.
• Citations that have the Public Access Compliance information color-coded in red are either non-compliant or not defined. The compliance process can be started by clicking “Edit Status.”

**Note:** Non-compliant article citations have awards associated to them, but the research article manuscripts have not been submitted to the NIH Manuscript Submission (NIHMS) system. Non-compliant article citations do not display a PMCID.

![Image](image_url)

- You will be directed to a compliance status pop-up form where you will be able to begin an article submission to the NIHMS, provide the NIHMS ID for your publication to change article compliance status to in process, confirm that other arrangements have been made with journal publishers or PubMed Central, or determine if your articles are exempt from the NIH Public Access policy.

**Note:** For peer-reviewed publications with NIH funding that a journal has not submitted to PMC, click **Begin submission in the NIHMS**. Follow the step-by-step instructions. You will need the last author submission (accepted version), not the journal's formatted PDF.
NIH Prior Approval and Notification – Policies & Procedures

**Background:** In 2012, NIH issued new notices that advised investigators that in certain circumstances NIH prior approval must be obtained before spending NIH research funds on a new or modified research protocol involving human subjects. The full notices are available at:


As a scholar or trainee provided with pilot funding through the NIH/NCATS-funded Clinical and Translational Science Institute (CTSI), these policies apply to you.

**Note:** Human subjects’ protocols that qualify for an exemption (categories 1-8) *without* a foreign component, and animal studies entailing IACUC approval, require formal NIH notification but not prior approval. See the table below for Human Subjects’ Research (HSR) study categories and process types (as of January 7, 2022).

---

### New Pilot Projects & KL2 Projects with Human Subjects

1. Enter study & documents into NIH eRA HSS
2. Email to GMS, PO, & NCATSPriorApprovalRequest@mail.nih.gov

**ALL Category 1 OR Category 2 with a foreign component**

- Requires ‘Official’ NCATS Prior Approval
- Study may NOT start until official NCATS Prior Approval is received from GMS*
  
  *follows standard 30-day time clock. COVID-19 submissions are expedited.

**Category 2 without a foreign component**

- Requires ‘Notification’ to NCATS of Prior Approval
- Study may begin upon ‘Notification’* to NCATS

*NCATS may ask for additional information or require site to stop human subjects activities if submitted information does not support the Category 2 risk determination.
Procedures: To comply with these requirements, all KL2 Scholars are required to notify KL2 Program Manager Ellen Orasa (eorasa@stanford.edu) in advance whenever planning to submit a new or modified protocol to the IRB or APLAC. New protocols for which you are the KL2 Principal Investigator will automatically require NIH prior approval. For modifications, you will be asked for information to determine whether the change constitutes a significant change in scope.

To expedite things as much as possible, it is advisable to prepare your NIH prior approval paperwork in advance, at the same time you submit your IRB or APLAC approval. As soon as you get your IRB or APLAC protocol approved, the prior approval request can then be submitted to NIH. Expect prior approval to take 1-2 months to obtain after IRB or APLAC approval. Contact Ellen Orasa for information about the forms to complete and the expected timeline for approval.

NIH Prior Approval and Notification – Human Subjects Research

New KL2 Scholar Projects that include human subjects research deemed by the Institutional Review Board (IRB) require entry of the study into the eRA HSS and official notification from NCATS of NCATS’ Prior Approval before the project can begin.

Resources and Additional Information

- [NCATS-New-Projects-with-Human-Subjects-Research-Addendum-and-Instructions-for-PIs-and-SOs-v3- Updated 01.07.2022](#)
- Documents should be uploaded to the NIH eRA HSS. Signing Official (i.e., Research Management Group Institutional Official) should notify NCATS Program Official and Grants Management Specialist via email that the prior approval request has been submitted to the NIH eRA HSS. Do not re-send the documents via email. (Updated 04.09.2020)
- [Post-Award Grant Actions: Prior Approval and Reporting of Research with Human Subjects and/or Vertebrate Animals](#)
SUMMARY OF NCATS REQUIRED DOCUMENTS & eRA HSS SECTIONS TO BE COMPLETED

<table>
<thead>
<tr>
<th>NCATS REQUIRED DOCUMENTS</th>
<th>Category 1</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STUDY CATEGORY</strong></td>
<td>Clinical Trial</td>
<td>Greater Than Minimal Risk Study</td>
</tr>
<tr>
<td><strong>COMPLETE HSS SECTIONS</strong></td>
<td>1-6</td>
<td>1, 2, 3.1 &amp; 3.2</td>
</tr>
<tr>
<td>Addendum</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Certification of IRB-Approval</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Institutional Exemption Determination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biosketches for PI and key personnel</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Institutional letter attesting to completion of Human Subjects Training for PI and key personnel</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>IRB-Approved Protocol</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>IRB-Approved informed consent, verbal consent transcript, assent and parental permission documents, or documentation of IRB waiver (as applicable)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Specified NCATS Required Document PDFs should be combined and attached in HSS Sections</td>
<td>5.1</td>
<td>2.7</td>
</tr>
<tr>
<td></td>
<td>(Study Timeline attachment box must be used to attach the Study Timeline plus the NCATS-specified documents.)</td>
<td></td>
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</tbody>
</table>

1Category 1 Human Subjects Research that meets the NIH definition of a clinical trial. Answered “Yes” to all the questions in HSS Section 1.4 - Clinical Trial Questionnaire. OR Human Subjects Research study deemed Greater than Minimal Risk by IRB.

2Category 2 Human Subjects Research study deemed Minimal Risk by the IRB or study has been determined by the institution to meet the criteria for Exemptions 1-8 under 45CFR46.

3All NIH-defined clinical trials are considered Category 1 research even if proposed research might otherwise be considered Minimal Risk.

4Institutional letter attesting to completion of Human Subjects Training for PI and key personnel: NIH policy (NOT-OD-00-039 & NOT-OD-01-061) requires education on the protection of human research participants for PI and all key personnel; insert signed letter.

5Utilize G.500 – PHS Human Subjects and Clinical Trials Information as a guide during the preparation of any HSS Section required for Category 1 or Category 2 Prior Approval submissions.

6Existing data with identifiers is included in this category.
<table>
<thead>
<tr>
<th>STUDY CATEGORY</th>
<th>Category 1(^1)</th>
<th>Category 2(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clinical Trial</td>
<td>Greater Than Minimal Risk Study</td>
</tr>
<tr>
<td>1.1 Study Title</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>1.2 Is this Study Exempt from Federal Regulations?</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>1.3 Exemption Number</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>1.4 Clinical Trial Questionnaire</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>1.5 Provide the ClinicalTrials.gov Identifier</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>HSS Section 1 – Basic Information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1 Conditions or Focus of Study</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2.2 Eligibility Criteria</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2.3 Age Limits</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2.3.a Inclusion of Individuals Across the Lifespan</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2.4 Inclusion of Women &amp; Minorities</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2.5 Recruitment and Retention Plan</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2.6 Recruitment Status</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2.7 Study Timeline</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2.8 Enrollment of First Participant (Section 6.3)</td>
<td>✓(^4)</td>
<td>✓(^4)</td>
</tr>
<tr>
<td>2.9 Inclusion Enrollment Report(s)</td>
<td>✓(^7)</td>
<td>✓(^7)</td>
</tr>
<tr>
<td><strong>HSS Section 2 – Study Population Characteristics</strong></td>
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<tr>
<td>3.1 Protection of Human Subjects</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>3.2 Is this a multi-site study?</td>
<td>✓(^5)</td>
<td>✓(^5)</td>
</tr>
<tr>
<td>3.3 Data and Safety Monitoring Plan</td>
<td>✓</td>
<td>Optional</td>
</tr>
<tr>
<td>3.4 Data and Safety Monitoring Board</td>
<td>✓</td>
<td>Optional</td>
</tr>
<tr>
<td>3.5 Overall Structure of the Study Team</td>
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<tr>
<td><strong>HSS Section 3 – Protection and Monitoring Plans</strong></td>
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<td>4.1 Study Design</td>
<td>✓</td>
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<tr>
<td>4.1.a Detailed Description</td>
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<td>✓</td>
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<tr>
<td>4.1.b Primary Purpose</td>
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<tr>
<td>4.1.c Interventions</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>4.1.d Study Phase</td>
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<td>✓</td>
</tr>
<tr>
<td>4.1.e Intervention Model</td>
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<td>✓</td>
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<tr>
<td>4.1.f Masking</td>
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<td>✓</td>
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<tr>
<td>4.1.g Allocation</td>
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</tr>
<tr>
<td>4.2 Outcome Measures</td>
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</tr>
<tr>
<td>4.3 Statistical Design and Power</td>
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</tr>
<tr>
<td>4.4 Subject Participation Duration</td>
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<td>4.5 FDA-Regulated Intervention? (IND/IDE)</td>
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<tr>
<td>4.7 Dissemination Plan</td>
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<td>✓</td>
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<td><strong>HSS Section 4 – Protocol Synopsis</strong></td>
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<td>5.1 Other Clinical Trial Attachments</td>
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</tr>
<tr>
<td><strong>HSS Section 5 – Other Clinical Trial Attachments</strong></td>
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<td></td>
</tr>
<tr>
<td>6.1 Study Primary Completion Date</td>
<td>✓(^8)</td>
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</tr>
<tr>
<td>6.2 Study Final Completion Date</td>
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<tr>
<td>6.3 Enrollment and Randomization</td>
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<td>✓(^8)</td>
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<tr>
<td>6.4 Completion of primary endpoint data analyses</td>
<td>✓(^8)</td>
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</tr>
<tr>
<td>6.5 Reporting of results in ClinicalTrials.gov</td>
<td>✓(^8)</td>
<td></td>
</tr>
<tr>
<td>6.6 Is this an applicable clinical trial under FDAAA?</td>
<td>✓(^8)</td>
<td></td>
</tr>
</tbody>
</table>
1 Category 1 Human Subjects Research that meets the NIH definition of a clinical trial (Answered "Yes" to all the questions in HSS Section 1.4 - Clinical Trial Questionnaire) OR Human Subjects Research study deemed Greater than Minimal Risk by IRB.

2 Category 2 Human Subjects Research study deemed Minimal Risk by the IRB or study has been determined by the institution to meet the criteria for Exemptions 1-8 under 45 CFR 46.

3 All NIH-defined clinical trials are considered Category 1 research even if proposed research might otherwise be considered Minimal Risk.

4 Section 2.8 Enrollment of First Participant: This field is now Section 6.3 in HSS. Do not complete this field if you answered “YES“ to the question “Using an Existing Data Set or Resources?” in the Inclusion Enrollment Report.

5 Section 3.2 Multi-site Studies: Answer "Yes/No;“ or select N/A only if: a. You answered “Yes” to “Question 1.2 Is this Study Exempt from Federal Regulations?” or b. You are a training grant applicant; or c. You are a fellowship applicant (sIRB policy does not apply to situations b, and c.). If you answer "YES" - Multi-site studies using the same protocol: Attach Plan describing how you will comply with the NIH policy on the use of single-IRB for multi-site research. N/A should be checked for K scholars.

6 Utilize G.500 – PHS Human Subjects and Clinical Trials Information as a guide during the preparation of any HSS Section required for Category 1 or Category 2 Prior Approval submissions.

7 Section 2.9 Inclusion Enrollment Report(s) is not required for KL2 Scholar projects and Category 4 Exempt HSR.

8 Section 6.3 Anticipated Enrollment of 1st participant is required for all prior approval submissions except Exempt Category 4. Even though Section 6 was initially created for clinical trials, the enrollment start/end dates must be included and updated for ALL HSR projects before submitting the RPPR.

For clinical trials, the other fields in Section 6 will populate when the NCT number is entered in Section 1.5 and the ‘populate’ button is pushed. However, this is not required for prior approval submission but must be populated within 21 days of enrollment of the first participant. The information from clinicaltrials.gov will populate the HSS fields so ensure the clinicaltrials.gov entry is current upon HSS completion.

9 Existing data with identifiers is included in this category.
NIH Inclusion Monitoring

Scholars engaged in human subjects’ research must comply with NIH’s requirement for monitoring and reporting the inclusion of individuals based on sex/gender, race, and ethnicity.

For general information:
http://grants.nih.gov/grants/funding/women_min/women_min.htm

For a decision tree on types of research to which the policy applies:
http://grants.nih.gov/grants/funding/women_min/Women_and_Minorities_Inclusion_Decision_Tree.pdf

Data will be solicited each year as part of the KL2 annual report to NIH, and scholars will be asked to provide an Inclusion Enrollment Report for each of their applicable protocols, using the form below.
NIH Prior Approval and Notification – Live Vertebrate Animal Research

Requests for prior approval of planned research involving vertebrate animals conducted through NCATS KL2 scholar projects must be submitted in writing to NCATS no later than 30 days before the proposed implementation of research involving live vertebrate animals. Documentation must be submitted by an Authorized Organizational Official (See Grants Policy Statement Section 8.1.3.) to NCATSPriorApprovalRequest@mail.nih.gov with a copy to the assigned NIH Grants Management Specialist (GMS) and NIH Program Officer (PO). The request should be submitted via email including the complete grant number in the subject line.

Resources and Additional Information

- **NCATS CTSA Program Instructions for Submitting Prior Approval Requests for Planned Research Involving Live Vertebrate Animals**
- Additional guidance has been posted here.
- NIH FAQs have been posted here.
- **NIH Worksheet for Applications Involving Animals**: This worksheet describes the information that must be included in applications submitted to NIH for activities involving the care and use of animals. It provides an overview of the requirements, a checklist for applicants and reviewers, detailed instructions, responsibilities of applicants, reviewers, and NIH staff, and an example of an acceptable application.
Guidelines for Use of KL2 Career Development Funds

Introduction

This guide describes Stanford University and NIH policies that govern the use of the $40,000 awarded to you for research and career development costs under the KL2. Pay special attention to the HIGHLIGHTED NOTES; these are common mistakes that have caused scholars time, money, and frustration in the past.

A FEW PRELIMINARY DO’S AND DON’Ts...

<table>
<thead>
<tr>
<th>Please DO...</th>
<th>.. and please DON’T</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use your department financial team as a resource! Check with the CTSA Financial Team if there are any questions.</td>
<td>Buy anything with your own money before checking with your financial team; some things are not allowable and can’t be reimbursed.</td>
</tr>
<tr>
<td>Keep original receipts and turn them in promptly for reimbursement.</td>
<td>Allow someone to work on your research and try to figure out how to pay them later. Always talk to your department first about options for hiring and paying people – it can be complicated.</td>
</tr>
<tr>
<td>Plan your spending to use funds effectively throughout the year. Pay attention to your monthly reports. Don’t wait until the last minute.</td>
<td>Obtain bio-materials or data without first getting a materials transfer agreement or data use agreement.</td>
</tr>
</tbody>
</table>

Career Development

Internal

- Stanford Medicine courses. Send an inquiry to the register for how faculty on grants can take a course.
  - Contact: medregistrar@stanford.edu
- Stanford University courses – Audit. Contact individual instructors.
  - [https://exploredegrees.stanford.edu/academicpoliciesandstatements/#auditingtext](https://exploredegrees.stanford.edu/academicpoliciesandstatements/#auditingtext)
- View a list of Stanford University courses: [http://explorecourses.stanford.edu](http://explorecourses.stanford.edu)

External

You may attend classes, workshops, certificate programs outside Stanford University. Send KL2 program staff a description of the course for approval.
Research Costs – Supplies, Services, and People

Ensure compliance with Stanford University Financial Policies with regards to Supplies, Services, People, Data and Biomaterial Purchases, Travel, and Books. Contact your DFA or Financial team for assistance.

Travel costs – Registration, Planes, Hotels, and Food

$2,000/ Year: **The KL2 now limits conference travel expenses to $2,000 per year, including registration fees, air fare, lodging and per diem. Plan accordingly.

Note: Travel expenses must be compliant with Stanford University policies regarding travel, an overview of which can be found at: http://fingate.stanford.edu/staff/travel/policy_notes.html.

Receipts: **When submitting receipts for your conference travel, include the name of the conference, dates of travel, and an itemized list of all receipts that should be reimbursed. Send to your DFA or financial representative for reimbursement.

Registration Fee – Pay the registration fee personally (i.e., use your own credit card), and you will be reimbursed only after the event is complete.

Flights – You will only be reimbursed for flights directly to and from the event. If you are flying to another event before flying back to Stanford, notify your financial team.

Advance Payment: **Registration fees and flight costs are allowable costs only for conferences that will be attended during the same budget year (ending June 30th). KL2 funds cannot be used to pay in advance for conferences that will occur after the end of the current KL2 budget period, except in cases when a scholar will be reappointed for a subsequent year.

Hotel – You can be reimbursed for conference stays only after travel is complete. You must provide an itemized hotel checkout slip or zero balance printout. Allowable charges are limited to room charges, taxes, and internet service only.

Academic Costs - Tuition

As a KL2 Scholar, you may use a portion of your KL2 funds (i.e., $20,000 per year) to pay for tuition and fees. Inform KL2 staff when you register for classes that you want to use your KL2 funds to pay for them.

If you add or drop a class, email us and let us know to earmark the extra bill and keep a record of refunds.
Association for Clinical and Translational Science (ACTS) Conference

http://www.actscience.org/

The Association for Clinical and Translational Science (ACTS) is the premier organization in the field and is active in the realms of:

- **Research** – improving the efficiency with which new therapies may reach the public
- **Education** – serving as the academic home for all educational activities for the full spectrum of translational sciences
- **Advocacy** – engaging at all levels with other professional organizations
- **Mentoring** – facilitating collaboration and professional relationships between trainees and mentors

ACTS holds an Annual Meeting that brings together all the disciplines involved in clinical and translational research and all the participants in the field—including trainees, investigators, educators, as well as representatives from industry and government. Due to the multidisciplinary and multidimensional nature of the field, collaboration and interfacing are practically a prerequisite for success—and the Annual Meeting provides an ideal opportunity for networking and advancement.

**KL2 Scholars are required to attend the annual meeting** unless a compelling reason not to attend is provided. Scholars can use their KL2 travel funds to assist with the conference expenses.

Scholars consistently have provided positive feedback on the conference with regard to career development.

- **Inspiring** – Participants are inspired by stories of success in clinical and translational research and its positive impacts on people’s lives
- **Informing** – Attendees learn of the most up-to-date and valuable information in the field
- **Supporting** – Trainees are provided with a supportive forum to present their research to a broad array of investigators
- **Providing resources** – Participants are presented with novel methods, best practices, and resources to achieve successful translation
- **Developing** – The meeting offers high-quality career development programs for trainees and mentors to progress in their roles

Recent plenary presentations have featured directors of Clinical and Translational Science Institutes (CTSI) at universities across the country, and officials in the Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), the FDA, as well as advocacy organizations for pharmaceutical research companies.
Evaluation/Tracking

Purpose of Evaluation/Tracking
The Stanford CTSA KL2 Scholars Program takes several steps to continuously evaluate the KL2 Scholars Program. Through year-round evaluation and tracking, we are able to identify strengths and weaknesses of the program, chart career progress of Scholar outcomes, determine appropriate modifications to the program, and comply with NIH requirements for rigorous evaluation. Timely Scholar participation in the evaluation process is greatly valued and crucial to the continued success of the program.

Evaluation Mechanisms
The Stanford CTSA KL2 Scholars Program has several mechanisms to help ensure that evaluation is thorough and multi-faceted. These include:

Annual surveys of Scholars and Mentors – these surveys are critical to the evaluation of the program and assist in the evaluation of milestone completion and objectives of Scholars, mentor-mentee relationships and academic productivity. These survey also allow for tracking of new appointments and/or promotions of Scholars.

Course and seminar evaluations - evaluation of courses and seminars developed for this program are important for determining what aspects are most beneficial during Scholar training.

Example Outcomes
The Stanford CTSA KL2 Scholar Program is required by NIH to track a number of short- and long-term outcomes. Below is a list of some examples that highlight the main goals of our evaluation strategy:

Short-Term Outcomes
- Scholars’ satisfaction with the program (didactic training and mentored research)
- Percentage of Scholars submitting grant applications to NIH or other agencies
- Percentage of Scholars dedicated to careers in multidisciplinary clinical/translational research

Long-Term Outcomes
- Percentage of current effort in multidisciplinary research
- Grant funding on multidisciplinary projects
- Number of presentations and publications
- Number of individuals in core faculty positions held at a multidisciplinary center or institute
Career Development Plans, Progress Reviews, and Scholar Milestones

Schedule

August

- All KL2 scholars create or update a career development plan (CDP) by August 31. A suggested template for the CDP is attached.

January/February

- All K scholars update their career development plan for review with their mentors and with their K Advisor (see below) by the end of January.
- Mentors also meet with the KL2 Advisor and the status of the career development plan is reviewed at a KL2 faculty meeting in February. The KL2 Advisor prepares a one-page written assessment summarizing the KL2 scholar's progress and goals in various areas and this is reviewed and approved by the scholar and the scholar's mentors and becomes a part of the scholar's file.

The semi-annual reviews in August and January are the main opportunities to discuss ways to enhance the scholar's career development infrastructure and to identify actions the scholar needs to take to assure continuation in the program the following July.

Scholar Milestones

Since the shared goal is for scholars to become independently funded by the end of their K award period (or earlier), these general guidelines for scholars are set:

By the end of the 2nd year, and each year thereafter:

- 3 original research multidisciplinary peer-reviewed publications submitted, two of these as first or last author
- One multidisciplinary extramural grant of any size submitted (typically R01, R21, R03, or other federal, state, foundation, industry, or intramural grant).

**Note:** Please forward all **Proposal Intake Forms (PIF)** to Ellen Orasa (eorasa@stanford.edu), KL2 Program Manager. If your proposal is funded, the KL2 team will confirm with the NIH Program Officer whether the effort on your extramural grant can be counted towards the required minimum 75% effort (or 50% for surgeons) of your KL2 award or if an effort reduction will be required.
Suggestions for Completing the Career Development Plan

Goals: Succinctly describe long-term (~10 years) goals.

1. The Scientific/Clinical goal should reflect your vision of how your research will ultimately improve human health. For example, one goal could be "To improve the early detection of patients with multiple sclerosis."

2. The Career Goal should reflect a leadership role you may want, such as Chief of a Division or leader of an enterprise. For example, a goal could be "To lead a Center for the Study of Pediatric Obesity".

Objectives: For each goal, specify 2 to 5 objectives that are important to achieving your scientific or career goals. These objectives may include mastery and application of a technique that is applied to the condition of interest. For example, one objective could be "To apply cost-effectiveness analyses to tests to select cancer patients for use of very expensive chemotherapies." A career objective may include promotion.

Educational/training activities: For each Objective, indicate any training you need. For example, if you plan to apply cost-effectiveness analyses to the selection of cancer patients for treatment, you may want training in cost-effectiveness analysis. Regarding leadership, you may want to participate in a leadership training program for academic medicine.

Research activities: For each Objective, indicate any projects that will assist you in meeting the Objective. For example, if you want to study congestive heart failure in young adults, you may want to 'develop a registry of young adults with congestive heart failure with DNA and imaging studies.'

Other related career activities: For each Objective within the career goal, list related activities that may be important for allowing you to achieve this objective, including specific administrative or leadership opportunities.

Products: For each Objective, indicate what individual products (degrees, publications, presentations, grants) are expected to contribute to achieving the Objective. For example, if studying CHF in young adults, you may want to complete a 'Systematic review of genetic studies of CHF in young adults.' Keep the scholar milestones (listed on the first page) in mind as you consider these products and include the expected date of completion.

Career Development Activities Checklist
(checklist for discussion with your Academic/Career Mentor and KL2 Advisor)

1. Resources: What financial, staff, laboratory, clinical, and space resources are provided to you by your mentors, department, etc? Are they meeting your needs? If not, what else would be helpful?

2. Coursework/Training: What courses, seminars, conferences, lab meetings, etc. do you participate in? Are they meeting your needs? If not, what else would be helpful?

3. Clinical Duties: How much, in percent effort? Is this sufficient for maintaining/enhancing skills? Are these duties interfering with research productivity?

4. Teaching Duties: How much, in percent effort? Is this sufficient for developing multidisciplinary academic skills? Are these duties interfering with research productivity?

5. Administrative and Other Duties: How much, in percent effort? Do these duties have a positive impact on your career, or are they interfering with research productivity?
6. Protected Time for Research: Do you have 75% of your workweek available for research, training, and career development? If not, we need to take steps to correct this to maximize your KL2 experience and minimize audit risk.

7. Mentoring:
   a. How often are you meeting with your Primary Mentor? Is this sufficient?
   b. How often are you meeting with Co-Mentors? Is this sufficient?
   c. How often are you having Multidisciplinary Team meetings? (ie, meeting with 2 or more members of your multidisciplinary teams (mentor and/or collaborators, simultaneously)
   d. What else would be helpful?

8. Personal Issues (optional):
   a. Work environment: How are things at work? Any problems with financial/administrative issues, colleagues, infrastructure that we can help with?
   b. Home environment: Are there stresses or problems at home that we can help with? How are things going generally? How is your quality of life?

Click the link below to complete the REDCap Initial Survey as a new KL2 Scholar and we will send the email invitation for the KL2 CDP Form:

https://redcap.link/2zmp16he
MENTOR AGREEMENT

Mentoring is critical to career success in research. Each scholar will have a primary mentor who will be an accomplished independent investigator and committed to the career development of their mentees. The scholar will have at minimum monthly contact and meetings with their primary mentors (often more frequently). In addition, each scholar will be assigned a KL2 Program Advisor who oversees the scholar’s progress in the KL2 Program, an Academic/Career Mentor who serves in a role complementary to the primary research mentor, and a Methods advisor who assists with study design and analytic plans as appropriate to the specific research project. Each of these mentors will be from different disciplines, forming a multidisciplinary team.

We will obtain written commitments from all of the mentors to have continuous involvement with the scholars throughout the program. Because the KL2 Program is promoting team science through the conduct of multidisciplinary research and the use of team mentoring for mentees, the entire mentoring team will meet with the mentee at least annually to design and plan research projects, discuss progress, provide advice on project management, and help guide data collection, analysis, and manuscript preparation.

Expectations for Mentors

- **Team meetings with the mentee.** There should be a minimum of one hourly meeting of the KL2 Academic/Career mentor and mentee per quarter, one hourly meeting of the KL2 Methods Advisor and mentee per quarter, and one hourly meeting per year with the entire mentoring team.
- **Attending scholar’s presentations.** The mentoring team is expected to attend at least one meeting or seminar in which the mentee is presenting.
- **Evaluation.** The mentoring team will participate in biannual evaluations and assessments of mentoring relationships.
- **Confidentiality.** The content of all exchanges between the team mentors and the mentee is subject to the expectations of professional confidentiality.
- **KL2 Career Development Plan (CDP).** The mentors are expected to review, approve, and monitor the progress of the mentee’s CDP.

Expectations for Mentees

- **Team meetings with mentors.** There should be a minimum of one hourly meeting with the KL2 Academic/Career mentor once per quarter, one hourly meeting with the KL2 Methods Advisor once per quarter, and at least one hourly meeting with the entire mentoring team annually.
- **Training.** The scholars participate in the half-day training to obtain skills in working with mentors in a team science environment.
- **Scholar Work-in-Progress.** The scholars present their work at research-in-progress meetings and seminars with the mentoring team in attendance.
- **Evaluation.** The scholar will participate in biannual evaluations and assessments of the mentoring relationships.
- **Confidentiality.** The content of all exchanges between the team mentors and the mentee is subject to the expectations of professional confidentiality.
- **KL2 Career Development Plan (CDP).** Develop CDP, review CDP with the mentor and KL2 director, and review progress.