Center for Translational Medicine

Translational Pilot Program
Grant Award 2017-2018

JEFFREY KAHN, M.D., PH.D.
PROFESSOR AND CHIEF OF PEDIATRIC INFECTIOUS DISEASE
DIRECTOR, CTM TRANSLATIONAL PILOT PROGRAM
AGENDA

1. INTRODUCTION
2. PRESENTATION
3. QUESTION AND ANSWERS
TPP provides funding for junior investigators to conduct innovative clinical and translational research projects with the aim of securing extramural funding.

**Goals**
- Promote and support the development and testing of new research ideas;
- Stimulate novel translational ideas of young investigators;
- Encourage interdisciplinary collaboration; and
- Assess the feasibility of new approaches to translational research through inter-disciplinary collaboration that lead to extramural funding.

**Project supports**
- Translational Research
- Clinical Research
- Community-based Research
- Health Services Research
- Team Science
Project must address at least one of the following:

- **Translational Research**
  - Includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

- **Clinical Research**
  - Includes clinical trials with human subjects to test intervention safety and effectiveness, behavioral and observational studies, outcomes and health services research, and the testing and retirement of new technologies. The goal of many clinical trials is to obtain regulatory approval for an intervention.

- **Community-Based Research**
  - Is a collaborative effort between academic researchers and non-academic based community members that aims to generate social action and positive social change through the use of multiple knowledge sources and research methods. Ideally, the research questions originate from off-campus communities and the process involves meaningful participation by all partners in every stage of the research.

- **Health Services Research**
  - Examines how people get access to health care, how much care costs, and what happens to patients as a result of this care. The main goals of health services research are to identify the most effective ways to organize, manage, finance, and deliver high quality care; reduce medical errors; and improve patient safety.

- **Team Science**
  - Is used to refer to a collaborative approach that draws concepts and technologies from multiple fields to develop a new perspective on answering research questions or solving complex problems. While traditional single-investigator driven approaches are ideal for many scientific endeavors, coordinated teams of investigators with diverse skills and knowledge may be especially helpful for studies of complex social problems with multiple causes.
**FUNDING**

<table>
<thead>
<tr>
<th><strong>SOURCE</strong></th>
<th>Funded in part by the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH)</th>
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</thead>
<tbody>
<tr>
<td><strong>ANTICIPATED NUMBER OF AWARDS</strong></td>
<td>Approximately 6 awards</td>
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<tr>
<td><strong>AWARD BUDGET</strong></td>
<td>$50,000</td>
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<td><strong>PROJECT PERIOD</strong></td>
<td>May 1, 2017 to April 30, 2018</td>
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<td><strong>NUMBER OF APPLICATIONS</strong></td>
<td>One application per applicant</td>
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</table>
### Non-approved Uses of Funds

- PI Salary and Fringe
- Travel
- Indirect Costs (F&A), including subcontracts with CTSA partnering institutions. (An F&A waiver is required for partnering institutions)

### Other Funding Restrictions

- No clinical trial activity beyond phase IIA using CTM pilot awards is permitted.
## ELIGIBILITY

### ORGANIZATIONS
- Children’s Medical Center
- Dallas Veterans Affairs Medical Center
- Moncrief Cancer Institute
- Parkland Health & Hospital System (PHHS)
- Southern Methodist University
- Texas Scottish Rite Hospital for Children (TSRHC)
- Texas Tech University Health Sciences Center
- University of North Texas Health Sciences Center, DFW
- University of Texas at Arlington
- University of Texas at Dallas
- University of Texas Health Science Center at Houston, School of Public Health, Dallas Regional Campus
- UT Southwestern Medical Center

### INDIVIDUALS
- Junior investigators (trainee or faculty member who has completed doctoral training, up to and including assistant professor level)
- Formal participants in the CTM’s Education Program (KL2 and Clinical Scholars Program)
CRITERIA FOR FUNDING

The main criteria for funding will be the scientific quality, innovation, sustainability (i.e., the likelihood of obtaining future extramural funding), and environment. Therefore, it is particularly important for mentored applicants to provide details of the sustainability of the research environment to ensure a high likelihood of success. Applicants will also be judged based on their career trajectory and the quality and suitability of the research-training environment.
REQUIRED PREREQUISITES

**LETTER OF INTENT (LOI)**
- 1-Page LOI is required to be submitted by **September 15, 2016** to Center of Translational Medicine.
  - Must include:
    - Summary of research project (including specific aims)
    - Confirmation - Junior investigator or a formal participant in the CTM’s Education Program (KL2 and Clinical Scholars Program)
    - Summary of career plan (1/2 page)
    - Bio-sketch in current NIH format (5 pages maximum)

**REGISTRATIONS**
- All PI(s) must have an eRA Commons account.
- Obtaining an eRA Commons account can take up to 2 weeks.

**IRB or IACUC APPROVAL**
- IRB or IACUC approval must be in place prior to submission of an application for funding.
- Strongly recommended that study approval be submitted to the appropriate review office as soon as possible to allow sufficient time for board review and approve by the submission deadline of December 15, 2016.
<table>
<thead>
<tr>
<th>FORM</th>
<th>RESEARCH PLAN</th>
<th>HUMAN SUBJECTS RESEARCH</th>
<th>BIOSKETCH FORMS</th>
<th>LETTER OF SUPPORT</th>
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<tbody>
<tr>
<td>✓ Face Page</td>
<td>✓ Hypothesis and Specific Aims (1 page)</td>
<td>✓ Funding support explanation (2 pages)</td>
<td>✓ Current NIH Form (5 pages Maximum)</td>
<td>✓ Research Mentor (if post-doc, resident, or fellow)</td>
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<td>✓ Co-Investigators/</td>
<td>✓ Background &amp; Rationale (1 page)</td>
<td>✓ Human subjects section (1 page)</td>
<td></td>
<td><strong>Must address the following:</strong></td>
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<tr>
<td>Collaborators</td>
<td>✓ Study Design &amp; Methods (4 pages)</td>
<td>✓ Inclusion section (1 page)</td>
<td></td>
<td>- Trainees potential</td>
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<tr>
<td>✓ Current Committed Effort</td>
<td>✓ Multidisciplinary Team Approach (2 pages)</td>
<td>✓ Data Safety Monitoring Plan (3 pages)</td>
<td></td>
<td>- Trainees ability</td>
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<tr>
<td>✓ Budget Page</td>
<td>✓ Next Steps (2 pages)</td>
<td>✓ Attachments (no limit)</td>
<td></td>
<td>- Environment</td>
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<tr>
<td>✓ Budget Justification</td>
<td>✓ Literature Cited (no limit)</td>
<td>- IRB protocol</td>
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<td>- Contribution to Goals</td>
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<td>- Informed consent</td>
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<td>- Mentor eval/approval</td>
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<td>- Product Information</td>
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<td>- Scientific oversight</td>
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<td>- IND-exempts or IDE waived, if applicable</td>
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<td>- Access to research</td>
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<td>- Targeted enrollment</td>
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<td>- table/inclusion data</td>
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<td>- IRB Approval/Exemption Letter</td>
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<td><strong>NOTE:</strong> If animal research, IACUC Approval/Exemption Letter is required.</td>
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**LETTER OF SUPPORT**

- **Research Mentor** (if post-doc, resident, or fellow)
- **Must address the following:**
  - Trainees potential
  - Trainees ability
  - Environment
  - Contribution to Goals
  - Mentor eval/approval
  - Scientific oversight
  - Access to research

- **Department Chair or Chief**
- **Must address the following:**
  - Time protected
  - Salary supported
  - Commitment to return unspent funds
IMPORTANT DATES

LAUNCH
• August 1, 2016

TOWN HALL MEETINGS
• August 2, 2016 (South Campus)
• September 1, 2016 (North Campus)

LETTER OF INTENT DUE
• September 15, 2016

APPLICATION DUE
(by invitation only)
• DECEMBER 15, 2016
  5:00 PM (EST)

Submit to: CTMTranslationalPilotProgram@UTSouthwestern.edu

NOTICE OF AWARD & EARLIEST START DATE
May 1, 2017
REVIEW PROCESS

- NIH study section-like process
- Initial review by 2-3 reviewers with appropriate expertise
- Top half of grant applications discussed in study section
- Funding determined by the Translational Pilot Program Grant Council

Review criteria

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment
- Sustainability
- Budget
## COMMON APPLICATION MISTAKES

### THINGS TO AVOID:

- Not completely filling out the Face Page.
- Including unallowable expenses in the budget.
- Not providing or having an insufficient budget justification.
- Not providing required attachments for price quotes.
- Not matching quotes with budget.
- Exceeding page limitations for research plan and biosketches.
- Incomplete Human Subjects Research section and attachments.
- Using incorrect biosketch form.
- Not providing biosketches for all key personnel listed on the application.
- Not providing letter of support that addresses FOA requirements.
- Not getting a letter of support from acceptable source as required in FOA.
A list of frequently asked questions is available on the Center for Translational Medicine website at:

http://www.utsouthwestern.edu/research/translational-medicine/funding-opportunities/pilot-grant-awards-program.html
Provide assistance and administrative support on applications.

Held during the months of October 18th through December 8th 2016 (every Tuesday and Thursday). Schedule an appointment by email to: ctmtranslationalpilotprogram@utsouthwestern.edu

Time and venue to be determined.

Office hours information will be announced campus-wide and to partnering institutions and available on CTMs website at: http://www.utsouthwestern.edu/research/translational-medicine/funding-opportunities/pilot-grant-awards-program.html
CONDITIONS OF ACCEPTING AWARD

- PI is required to attend a Pre-Award meeting.
- If clinical trials, PI must promptly inform CTM of adverse events related to the research. Clinical trials must also be registered in clinicaltrials.gov.
- PI is required to present at a future CTM Translational Science Forum.
- Submit quarterly and final reports. This tracks and evaluates program’s impact on project including additional funding; inventions, patents or licenses; publications; and other that results from the pilot project.
- Return any unspent funds back to TPP if project is unfeasible, not completed, or funds are no longer required for the project.
- All publications must be registered with PubMed Central and all TPP grant recipients must acknowledge the Center for Translational Medicine in all publications, presentations, and posters by stating “Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under the Center for Translational Medicine’s award number UL1TR001105. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.”
OTHER FUNDING OPPORTUNITIES

Service Package Grants
- Awards up to $5,000
- 3-month Period
- Funds can be used for service providers (core facilities), research supplies, and other research-related expenses.
- Applications Due (upcoming):
  - October 15, 2016
  - January 15, 2017

Vouchers for Biostatistical Consultations
- Vouchers for biostatistical consultation analysis, up to a designated amount of hours based on a quote.
- No budget period, vouchers valid until hours are used.
- Applications accepted anytime.
- Applicants may reapply as needed.

Patient-Centered Outcomes Research (PCOR)
- Award up to $20,000
- 12-month Period
- Helps investigators conduct preliminary work in PCOR and comparative effectiveness research for extramural funding potential.
- Applications received/reviewed on a rolling basis.
- Details will be available soon on the PCOR Center homepage:
  http://www.utsouthwestern.edu/research/patient-outcomes/index.html

Information on SPG and Biostatistical is available on the CTM website at:
http://www.utsouthwestern.edu/research/translational-medicine/funding-opportunities/pilot-grant-awards-program.html
<table>
<thead>
<tr>
<th><strong>Application Submission Contact</strong></th>
<th><strong>Grants Management Contacts</strong></th>
<th><strong>Financial Management Contact</strong></th>
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<tbody>
<tr>
<td><strong>Debbie Diaz</strong></td>
<td><strong>Debbie Diaz</strong></td>
<td><strong>Sarah Christian</strong></td>
</tr>
<tr>
<td>CTSA Outreach Assistant, Translational Pilot Program</td>
<td>CTSA Outreach Coordinator, Translational Pilot Program</td>
<td>Financial Analyst</td>
</tr>
<tr>
<td><a href="mailto:debbie.diaz@utsouthwestern.edu">debbie.diaz@utsouthwestern.edu</a></td>
<td><a href="mailto:debbie.diaz@utsouthwestern.edu">debbie.diaz@utsouthwestern.edu</a></td>
<td>Center for Translational Medicine</td>
</tr>
<tr>
<td>McDermott (Building B) 3rd floor</td>
<td>McDermott (Building B) 3rd floor</td>
<td><a href="mailto:sarah.christian@utsouthwestern.edu">sarah.christian@utsouthwestern.edu</a></td>
</tr>
<tr>
<td>5323 Harry Hines Blvd.</td>
<td>5323 Harry Hines Blvd.</td>
<td>McDermott (Building B) 3rd floor</td>
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<tr>
<td>Dallas, TX 75390-9007</td>
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<td>5323 Harry Hines Blvd.</td>
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<tr>
<td>214.648.2726 phone</td>
<td>214.648.2718 phone</td>
<td>214.648.0328 phone</td>
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<td>214.648.6710 fax</td>
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**Lisa Fleming**
Manager, Center for Translational Medicine
lisa.fleming@utsouthwestern.edu
McDermott (Building B) 3rd floor
5323 Harry Hines Blvd.
Dallas, TX 75390-9007
214.648.2718 phone
214.648.6710 fax
QUESTIONS AND ANSWERS