Frequently Asked Questions

A. Biosketch
   1. What biosketch format is used for NIH biosketches? The FOA requires biosketches to be submitted in the most current NIH format. See Biosketch Format Pages, Instructions and Samples for details on the required biosketch format.
   2. Where can I find a sample of biosketches? The samples provided are simply examples of compliant biosketches. Applicants must follow FOA instructions for pdf attachments (font, paper size, margins, etc.), as well as, the biosketch instructions themselves.
   3. Should biosketches be included for all individuals listed in the application? Biosketches are required for all individuals in the application listed as Senior/Key Personnel.

B. Budget
   1. If funded, can I re-budget if necessary? Yes, but depending on the type of changes necessary it can be time consuming. It is best to budget appropriately from the beginning because certain requests for re-budgeting may appear to change the scope of work, which is not allowed since awards are based on what was submitted in the original application. Changes from the original budget which do no change the scope of word are subject to review and must receive approval from the Center for Translational Medicine’s Translational Pilot Program. A justification for the reason(s) that necessitates a re-budget is required.

C. Effort
   1. What is the minimum level of effort required for the PD/PI? UTSW’s minimum level of effort requires 3% for PD/PIs; however, each PD/PI must have sufficient effort to achieve the proposed goals of the project.
   2. How do I determine the level of effort for individuals involved in the project? It depends on the project. You need to show that sufficient time is devoted to the success of the project. As mentioned above, the level of effort must be adequate to achieve the proposed goals of the project.

D. Eligibility
   1. Are external agencies eligible to apply? Faculty from UT Southwestern and the following institutions may apply:
      - Children’s Medical Center
      - Dallas Veterans Affairs Medical Center
      - Moncrief Cancer Institute
      - Parkland Health & Hospital System (PHHS)
      - Seton/UT Southwestern Clinical Research Institute of Austin
      - Southern Methodist University (SMU)
      - Texas Scottish Rite Hospital for Children (TSRHC)
      - Texas Tech University Health Sciences Center
      - University of North Texas Health Sciences Center, Dallas Fort Worth (UNTHSC)
      - University of Texas at Arlington (UTA)
      - University of Texas at Dallas (UTD)
      - University of Texas Health Science Center at Houston, School of Public Health, Dallas Regional Campus
      - UT Southwestern Medical Center
2. Are applicants with foreign status eligible to apply? Applicants with foreign status are not eligible to apply. Only U.S. citizens, non-citizen nationals or individuals lawfully admitted for permanent residence at the time an offer of an award is made, are eligible to apply. Individuals who have been lawfully admitted for permanent residents must have currently valid Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. Individuals expecting to be admitted as a permanent resident by the award date listed in the FOA may submit an application with the acknowledgement that no award will be made until legal verification of permanent resident status is provided to the NIH. **NOTE:** The submission of documentation concerning permanent residency is not required as part of the initial application. If a candidate’s citizenship status changes after submission of an application, the new status should be reported in the candidate’s Personal Profile in the eRA Commons. In all cases involving any type of Permanent Residency status, when an application is selected to receive an award, prior to any award being issued, a notarized statement will be required that documents that a licensed notary has seen the candidate’s valid Permanent Resident Card or other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S. Permanent residency status must remain eligible for the entire project period of the award.

E. Funding

1. When and how will I know if my application will be funded? The Center for Translation Medicine anticipates distribution of awards to be made on May 1, 2017. At which time, a Notice of Award (NOA) will be sent by email to the Project Director/Project Investigator (PD/PI). However, please note that it may take additional time between the initial peer review meeting and selection committee to know with some certainty whether the application will be funded.

2. When will funds be available? Funds will be available to successful applicants immediately upon issuance of the NOA.

3. The NOA indicates that funding period is for one year. What if I need more than one year? Projects should have aims that can be met within one year of the start date, otherwise this is not the mechanism for you. You can, however, breakup your research into multiple projects and apply again in another cycle for additional funding.

2. If funded, what if I do not spend all my money within the budget period? As indicated in the FOA, this award period aligns with the FY for the Center for Translational Medicine’s CTSA award from the NIH. All grant funds must be either encumbered or expensed prior to the expiration of the project period. Accordingly, principal investigators should propose a project that can be completed within that time frame. We understand, however, that some portions of the project (such as analyzing results) could extend beyond the term of the award. As such, a no-cost extension may be considered provided that the award is in good standing at the time of the request (i.e., funds are expended and the proposed aims are completed).

3. Can I include salary support for collaborators and/or co-investigators? This award does not provide salary support to PI/PDs, collaborators and co-investigators.
F. Human Subjects Research
   1. How do I determine if I am doing Human Subjects Research? The involvement of human subjects in your application is determined by the greatest involvement of human subjects in any single research activity. Refer to the NIH examples to help you determine whether your proposed research involves human subjects. The types of examples provided by NIH describes what is considered Human Subjects Research, Exempt Human Subjects Research, and Not Human Subjects Research.
   2. Who needs to receive required education on the protection of human subjects? Individuals who will be involved in the design or conduct of human subjects’ research must fulfill the educational requirement. These individuals are considered to be "Key Personnel" on research involving human subjects, and this includes the Principal Investigator(s), all individuals responsible for the design or conduct of the study, and those individuals identified as key personnel of consortium participants or alternate performance sites.
   3. Will the requirement for IRB be acceptable if the project is VA IRB approved? It will be acceptable provided that the study is registered with UTSW IRB and the evidence of registration is provided with the application. In addition, if the project is conducted solely at the VA, and the Principal Investigator also has an appointment (Adjunct, or Instructor, etc.) at UTSW, then the study will need to be submitted to the UTSW IRB as a “registration only” study. The eIRB smart form will guide in this submission which is only a “registration” of the study with UTSW and not an IRB review.
   4. Will the Program accept IRB with stipulations? IRBs with stipulations will not be considered. It is imperative that you submit for IRB approval well in advance of the application deadline so all stipulations may be addressed in full.

G. Project
   1. I have submitted previously, but this is a slightly new project with a new title. Can I still submit for this FOA? Yes, previous applicants can apply.
   2. I am currently funded under the same Translational Pilot Program grant and would like to apply for an additional award. Is that allowed? If your current (or previous) award is in good standing and you completed the proposed aims which were previously funded, you are eligible for additional funding if the application proposes new or additional aims that will further progress on the project.
   3. Can the project involve animal research? The research can involve animals that include classifications under the T1-T4 spectrum. The description of the classification for T1-T4 is illustrated in the Harvard Catalyst website. In addition, it must be translational in nature and not a basic research project. Your application should describe in detail how the project is or will translate to research in humans.

H. Senior/Key Personnel
   1. The application states to indicate whether listed individuals identified in the application are Key Personnel. Who should be designated as Senior/Key Personnel in the application? Key Personnel include the program director/principal investigator (PD/PI) and other individuals who contribute
to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation.

2. **Can Other Significant Contributors (OSC) be listed as Key Personnel?** OSCs are individuals who commit to contribute to the scientific development or execution of the project, but do not commit any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at effort of “zero person months” or "as needed." Individuals with measurable effort should be listed as Key Personnel and not as Other Significant Contributors (OSCs).