MANDATORY NOTE for applicants*

Our definition of clinical and translational research aligns with the NIH definition that includes: (1) Patient-oriented research, (2) Epidemiologic and behavioral studies and (3) Outcomes research and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. This area of research includes: 1) mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials; and 4) the development of new technologies. Excluded from this definition are in vitro studies that utilize human tissues but do not deal directly with patients. In other words, patient-oriented research is research in which it is necessary to know the identity of the patients from whom the cells or tissues under study are derived. Pre-clinical research, connecting the basic science of disease with human medicine, is not reviewed by the ICTS NIH MSS.

Career Development Awards (K Series)
Grant Application Sections

1. Candidate Information*
   i. Candidate’s Background
   ii. Career Goals & Objectives
   iii. Candidate’s Plan for Career Development & Training Activities During Award Period
   iv. Candidate’s Plan to Provide Mentoring *(if required in FOA)*

2. Research Plan Section*
   Please note the new NIH requirements for this section around Rigor and Reproducibility:
   i. Specific Aims
   ii. Research Strategy
      a. Significance
      b. Innovation
      c. Approach
   iii. References Cited/Bibliography
   iv. Training in the Responsible Conduct of Research

3. Mentor, Co-Mentor, Consultant, Collaborators Section*
   i. Plans and Statements of Mentor and Co-Mentor(s)
   ii. Letters of Support

4. Environment and Institutional Commitment to Candidate*
   i. Description of Institutional Environment
   ii. Institutional Commitment to Candidate’s Research Career Development

5. Human Subject Sections
   i. Protection of Human Subjects
   ii. Inclusion of Women and Minorities
   iii. Inclusion of Children

6. Biosketch*

7. References*

*Mandatory requirement for participation in the mock study section. Your proposal must align with NIH CTS research.