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.

NIH Research Grants (R Series)

1. Cover Letter
2. Project Summary/Abstract*
3. Project Narrative - Relevance Statement
4. Facilities & Resources
5. Equipment
6. Research Plan
   i. Specific Aims*
   ii. Research Strategy*
      Please note the new NIH requirements for this section around Rigor and Reproducibility: http://grants.nih.gov/reproducibility/faqs.htm#4834
      a. Significance
      b. Innovation
      c. Approach
   iii. References Cited and Bibliography/Progress Report Publication List*
   iv. Vertebrate Animals
   v. Select Agent Research
   vi. Multiple PD/PI Leadership Plan
   vii. Consortium/Contractual Agreements
   viii. Letters of Support*
   ix. Resource Sharing Plan(s)
   x. Authentication of Key Biological and/or Chemical Resources
   xi. Appendix
   xii. Human Subjects and Clinical Trials Information
   xiii. Inclusion of Women and Minorities
   xiv. Planned Enrollment Report
   xv. Inclusion of Children
7. Biosketch*

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