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 Fellowship Programs (F Series)
Grant Application Sections

1. Cover Letter
2. Project Summary*
3. Project Narrative – Relevance Statement
4. References Cited and Bibliography*
5. Facilities & Resources
6. Equipment

7. Fellowship Supplemental Form
   i. Applicant's Background and Goals for Fellowship Training*
   ii. Research Training Plan Section*
   iii. Specific Aims*
   iv. Research Strategy
   v. Respective Contributions*
   vi. Selection of Sponsor and Institution*
   vii. Responsible Conduct of Research*
   viii. Sponsor and Co-Sponsor Statements*
   ix. Letters of Support from Collaborators, Contributors and Consultants*
   x. Description of Institutional Environment and Commitment to Training (F30 and F31 applications only)
   xi. Protection of Human Subjects
   xii. Data Safety Monitoring Plan
   xiii. Inclusion of Women and Minorities
   xiv. Inclusion of Children
   xv. Vertebrate Animals
   xvi. Select Agent Research
   xvii. Resource Sharing Plan(s)
   xviii. Authentication of Key Biological and/or Chemical Resources
   xix. Inclusion Enrollment Report

8. Appendix
9. Biosketch*

* Mandatory requirement for participation in the mock study section review.