Guidance for Submitting Documents for Prior NIH Approval of Human Subjects Research

WHY PRIOR APPROVAL IS NEEDED

Your CTSI Pilot award is supported by the parent grant UL1TR001436 from the Clinical and Translational Science Award (CTSA) program of the National Institutes of Health National Center for Advancing Translational Sciences (NCATS). Since your study involves human subjects research, we are required to submit documentation to NCATS requesting *Prior NIH Approval.*

Please visit the NIH website Prior NIH Approval of Human Subjects Research FAQs for details.

WHAT TO SUBMIT

Required documents, where applicable, are indicated below. **This list is also found on the DOCUMENT CHECKLIST where you must indicate which documents are being included in your submission.** Please submit your completed CHECKLIST along with all applicable documents below.

Collect and/or prepare the following documents (many will be available from your IRB submission):

1. The NIH Biosketch for the pilot project investigator who is conducting the research
2. The complete clinical research protocol
3. The informed consent document (and assent document, if applicable)
4. Identification of the specific amendment/ancillary study or portion of the protocol that is supported by NCATS funding, if the entire parent protocol is included in the submission
5. An explanation of exactly what is being supported by NCATS pilot funding, if the proposed clinical research protocol is considered an amendment to a parent protocol
6. Product information such as the clinical investigator brochure, package insert, or description of the device, if a clinical trial is proposed
7. Documentation that an IND or IDE has been obtained, or letter from the FDA that the study is IND-exempt or the IDE has been waived, if a clinical trial is proposed
8. A new or revised "Protection of Human Subjects" section for the pilot project that
   (A) clearly describes the risk, protections, benefits and importance of the knowledge to be gained by the revised or new activities (as required in the Notice of Award and explained in "Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan" of the NIH competing application instructions), and
   (B) clearly identifies the information relevant to the pilot project
9. Inclusion Plans for Women, Minorities, and Children
   Note: an inclusion plan is, in general, required unless women, minorities and children could not be subjects for your research.
10. Targeted Enrollment Table or Inclusion Data Record (IDR)
    Note: a targeted enrollment table or IDR is, in general, required unless women, minorities and children could not be subjects for your research.

11. Data and Safety Monitoring Plan (DSMP), if applicable
12. Assurance or certification that the pilot project awardee and any Key Personnel directly involved in the study have taken appropriate education in protection of human subjects (e.g. CITI training certification)
13. IRB approval of the proposed clinical study. If pending, please check the appropriate box on section 13 of the checklist.

HOW TO SUBMIT

1. Name and save the required documents listed above according to the File Naming Conventions found on the next page
2. Email the required documents to Christine Zeller, Program Manager of the CTSI Pilot Award Program: czeller@mcw.edu
3. For questions, contact Christine Zeller at 414-955-2524

PLEASE REVIEW THE FILE NAMING CONVENTIONS ON THE NEXT PAGE

File Naming Conventions

- For documents for submission to Prior NIH Approval of Human Subjects Research
- Use in conjunction with the "Document Checklist"
- Files should be named as in the following example:

  MCWCTSI_InvestigatorLastNameFirstInitial_ProtocolShortTitle_Document_YYYYMMDD.pdf or .doc(x)

  example: MCWCTSI_AndersonM_Ped Resp Infection Genomic Determinants_Biosketch_20160125.pdf

Element		Ex
MCWCTSI		Name of the funded CTSA hub
InvestigatorLastNameFirstInitial		Name of the pilot project investigator or KL2 scholar performing the proposed clinical study (e.g., Mark Anderson would be 'AndersonM'; Jennifer Black-Egan would be 'Black-EganJ')
ProtocolShortTitle		Short identifier for proposed clinical study (e.g., Framingham Heart Study could be 'FHS'; Fecal Transplantation in recurrent C. difficile infection could be 'CDiff Fecal Transplant')
Document		Identifies the type of document being submitted:
	Biosketch	NIH Biosketch of the pilot project investigator or KL2 scholar performing the proposed clinical study
	Protocol	Complete clinical research protocol
	Consent	Informed consent document
	Assent	Assent document, if applicable
	NCATS Support ID	Identification of the specific amendment/portion of the protocol supported by NCATS funding (if entire parent protocol is included in the submission)
	NCATS Support Explain	Explanation of exactly what is being supported by NCATS pilot or KL2 scholar funding (if proposed clinical research protocol is considered an amendment to a parent protocol)
	Product Info	Product information, such as the clinical investigator brochure, package insert, or description of the device, if a clinical trial is proposed
	IND IDE	Documentation that an IND or IDE has been obtained, or letter from the FDA that the study is IND-exempt or the IDE has been waived, if a
	HS Section	New or Revised human subjects section that clearly describes the risk, protections, benefits and importance of the knowledge to be gained by the revised or new activities (as described in Part II of NIH competing
	Inclusion	Inclusion plans for women, minorities, and children, if applicable
	Enrollment	Targeted Enrollment Table or Inclusion Data Record (IDR) (optional)
	Safety	Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable
	HS Edu	Certification that the pilot project awardee or KL2 scholar and any Key Personnel directly involved in the study have taken appropriate education in protection of human subjects, if not provided previously
	IRB Approval	Most recent IRB approval of the proposed clinical study (including IRB approvals from each participating site, if proposing a multi-site trial)
YYYYMMDD		Identifies the date the document is sent to NCATS (e.g., January 25, 2016, would be 20160125)