Document Checklist for NCATS Prior Approval of Delayed Onset Research Involving Human Subjects

CTSA Institution		
CTSA Grant #		**Type of Proposed Project**: ☐ Pilot ☐ KL2
CTSA Grant PI		
Title of Proposed Clinical Study Protocol (pilot project or KL2 project)		
Title of Proposed Clinical Study Protocol Submitted to IRB (if different than above)		
Title and PI of Parent Study (if proposed clinical study is ancillary to another study)		
Name of Pilot Project Investigator or KL2 Scholar		
Contact Information for Pilot Project Investigator or KL2 Scholar		
Name of Authorized Organization Representative (AOR)		
Contact Information for AOR		
NCATS Grants Management Specialist		
NCATS Program Director		
Date Submitted to NCATS		

PRIOR APPROVAL OF DELAYED ONSET RESEARCH INVOLVING HUMAN SUBJECTS
Requests for prior approval of planned research involving human subjects conducted through NCATS UL1 pilot projects and KL2 scholar projects must be submitted in writing to NCATS no later than 30 days before the proposed implementation of research involving human subjects.

Documentation must be submitted by an Authorized Organization Representative (AOR) (NIH Grants Policy Statement, chapter 8.1.3). This requirement also applies to research conducted by KL2 scholars, if supported by NCATS funding.

The request should be submitted to the appropriate NCATS Grants Management Specialist via e-mail, with a cc: to the appropriate NCATS Program Director, and include the complete grant number in the subject line.

The following documents must be attached to the e-mail request as individual files (either PDF or Word documents) and follow the specified naming conventions (e.g., "CTSA_InvestigatorLastNameFirstInitial_ProtocolShortTitle_document_YYYMMDD"; refer to the accompanying document on File Naming Conventions for additional information):

Brief Summary of the Proposed Project (500 words or less):

1. **The NIH Biosketch for the pilot project investigator or the KL2 scholar who is conducting the research**
   ☐ Yes

   (example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Biosketch**_20160125.pdf*")

2. **The complete clinical research protocol**
   ☐ Yes

   (example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Protocol**_20160125.pdf*")

3. **The informed consent document (and assent document, if applicable)**
   ☐ Yes (informed consent document) ☐ Assent document not applicable
   ☐ Yes (assent document)

   (example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Consent**_20160125.pdf*")
   (example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Assent**_20160125.pdf*")

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**
   ☐ Yes ☐ Not applicable

   (example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**NCATS Support ID**_20160125.pdf*")

5. **An explanation of exactly what is being supported by NCATS pilot or KL2 scholar funding, if the proposed clinical research protocol is considered an amendment to a parent protocol**
   ☐ Yes ☐ Not applicable

   (example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**NCATS Support Explain**_20160125.pdf*")

6. **Product information such as the clinical investigator brochure, package insert, or description of the device, if a clinical trial is proposed**
   ☐ Yes ☐ Not applicable

   (example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Product Info**_20160125.pdf*")

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**
   ☐ Yes ☐ Not applicable

   (example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**IND IDE**_20160125.pdf*")

8. **A new or revised "Protection of Human Subjects" section for the pilot or K scholar 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 detailed 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 or KL2 scholar project**

☐ Yes

(example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**HS Section**_20160125.pdf*")

9. **Inclusion Plans for Women, Minorities, and Children**

☐ Yes ☐ Not applicable

(example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Inclusion**_20160125.pdf*")

10. **Targeted Enrollment Table or Inclusion Data Record (IDR)**

☐ Yes ☐ Not applicable

☐ No, specify:

(example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Enrollment**_20160125.pdf*")

11. **Data and Safety Monitoring Plan (DSMP)**

☐ Yes ☐ Not applicable

(example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Safety**_20160125.pdf*")

12. **Assurance or 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**

☐ Yes ☐ Not applicable

(example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**HS Edu**_20160125.pdf*")

13. **IRB approval of the proposed clinical study (while encouraged, IRB approval is not required at the time of the prior approval request submission in order to allow for parallel processing; however, any NCATS approval of delayed onset research involving human subjects will be contingent upon final IRB approval, and NCATS reserves the right to request IRB-approved documentation before issuing a final decision)**

☐ Yes ☐ Pending

(example: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**IRB Approval**_20160125.pdf*")