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

Type of Proposed Research:	☐ **Pilot Study** ☐ **KL2 project**
CTSA Institution	The Medical College of Wisconsin, Inc
CTSA Grant #	UL1TR001436
CTSA Grant PI(s)	Reza Shaker, MD
Title* of Proposed DO Research Protocol ***This must match the title submitted to IRB for approval***	
Title and PI of Parent Study (if proposed DO research is ancillary to another study)	
Name of Pilot Study Investigator or KL2 Scholar	
Contact Information for Pilot Study Investigator or KL2 Scholar	
Name of Authorized Organization Representative (AOR)	April Haverty, JD
Contact Information for AOR	(414) 955-8563; aor@mcw.edu
NCATS Grants Management Specialist	Julia Shriner
NCATS Program Official	Patricia Jones
Date Submitted to NCATS	

INSTRUCTIONS FOR SUBMITTING PRIOR APPROVAL REQUESTS FOR DELAYED ONSET RESEARCH INVOLVING HUMAN SUBJECTS

Requests for prior approval of planned research involving human subjects conducted through NCATS UL1 pilot studies and KL2 scholar projects must be submitted in writing to NCATS at least 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 studies to be conducted by KL2 scholars, if supported by NCATS funding.

Prior approval requests should include this checklist and should be submitted to the appropriate NCATS Grants Management Specialist via e-mail, with a copy to the appropriate NCATS Program Official. E-mailed requests should include the complete grant number in the subject line. Specific documents must be attached to the e-mail request as individual files (either PDF or Word documents) and follow the naming convention below:

"**CTSA hub_InvestigatorLastNameFirstInitial_ProtocolShortTitle_document name_YYYYMMDD**"

If your institution is using the electronic prior approval system (ePAS), submit this checklist and the individual files, with your request. To assist in tracking and coordination of prior approval requests, each page of the documents submitted should include a footer that provides identifiers such as the document name, page number, and last name of the pilot study investigator or KL2 scholar. If no identification exists, a footer should be added to each page (e.g. DSMP, Page 2, LastName).

Please respond to the following questions and provide the corresponding documents with your request:

1. **Has IRB approval been received for the proposed human subjects research?**

   Note that certification of IRB approval is required at the time of the prior approval request

   ☐ Yes

(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**IRB Approval** _20160125.pdf*")

2. **Does your request include a summary of the pilot study or KL2 project being proposed for support by NCATS (≤ 500 words)?**

   ☐ Yes

(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_ **Summary** _20160125.pdf*")

3. **Have you included the research protocol approved by the IRB?**

   ☐ Yes

(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Protocol**_20160125.pdf*")

4. **If the proposed research is considered an amendment or is a sub-study/ancillary study to an IRB-approved parent protocol, have you included a summary of the parent protocol with an explanation of how the NCATS-supported amendment or sub-study connects to it?**
   Please do not include the entire parent protocol.

   ☐ Yes, a summary is included with this request

(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Parent Study Summary**_20160125.pdf*")

5. **Have you included the IRB approved informed consent-related documents?**
   Check all that apply.

   ☐ Written informed consent
   ☐ Parental permission document
   ☐ Assent document
   ☐ Verbal informed consent (provide transcript)
   ☐ Documentation of IRB waiver of informed consent

(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Consent**_20160125.pdf*")
(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Parental Permission**_20160125.pdf*")
(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Assent**_20160125.pdf*")
(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Waiver**_20160125.pdf*")

6. **Have you provided inclusion plans for women, minorities, and children?**

   ☐ Yes ☐ No**,** a justification for exclusion is included with this request

(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Inclusion**_20160125.pdf*")

7. **Have you included targeted enrollment table(s) or inclusion data record(s) (IDR)?**
   ☐ Yes ☐ No, a justification for exclusion is included with this request

(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Enrollment**_20160125.pdf*")

8. **Have you included an NIH Biosketch for the pilot study investigator or the KL2 scholar who will conduct the NCATS-supported research?**
   ☐ Yes

(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Biosketch**_20160125.pdf*")

9. **Have you included documentation that the pilot study investigator or KL2 scholar and any Key Personnel directly involved in the study have taken appropriate education in protection of human subjects?**
   ☐ Yes

(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**HS Edu**_20160125.pdf*")

10. **For research involving clinical trials, have you included a data and safety monitoring plan (DSMP)?**
    ☐ Yes, a copy is included with this request

*(file name format: "UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Safety**_20160125.pdf")*

11. **Does the proposed research require an investigational new drug (IND) application?**
    ☐ Yes
    ☐ No
    a. **If "Yes", have you provided the following documentation?**
       I. **A letter from the FDA that includes the IND number**
       II. **The approved product label, the investigator brochure, as applicable.**
       ☐ Yes, the specified documentation is included with this request

(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**IND**_20160125.pdf*")
(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Product Info**_20160125.pdf*")

12. **Does the proposed research require an investigational device exemption (IDE)?**
    ☐ Yes
    ☐ No

    a. **If "Yes", have you provided the following documentation?**
       I. **A letter from the FDA that includes the IDE number, or**
       II. **Documentation from the FDA or IRB indicating that the device involved is deemed to be non-significant risk (NSR).**
       III. **The approved product label, or the device description, as applicable.**
       ☐ Yes, the specified documentation is included with this request

(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**IDE**_20160125.pdf*")
(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Product Info**_20160125.pdf*")

13. **Have you included a line item budget for the proposed research that lists the supplies, services, and personnel that will be supported by NCATS?**
    For brevity, no more than ten budget line items should be listed.
    ☐ Yes, a copy is included with this request

(file name format: "*UCollege_AndersonM_Ped Resp Infection Genomic Determinants_**Budget**_20160125.pdf*")

VERIFICATION OF COMPLIANCE WITH REGULATIONS AND POLICY REQUIREMENTS

The following section serves as a reminder of requirements that may be specified in the Notice of Award and as an assurance to NCATS that you plan to comply with these requirements, in conjunction with pilot studies and KL2 projects. Please check the appropriate boxes. No additional documentation needs to be provided for the items in this section.

1. **Domestic sites of multi-site studies conducting non-exempt research involving human subjects should use a single IRB of record. Does your pilot study (KL2 projects are not expected to use a single IRB) include non-exempt human subjects research that will be conducted at more than one site in the U.S.?**
   - ☐ Yes
   - ☐ Yes, and one or more sites has been granted an exception from single IRB review by NIH
   - ☐ No, the proposed research involves a single site
   - ☐ No, the research will be conducted at foreign sites exclusively

2. **Research that generates human or non-human genomic data, may fall under the NIH Genomic Data Sharing Policy (see: Supplemental Information to the National Institutes of Health Genomic Data Sharing Policy), and requires a genomic data sharing plan.**
   a. **Has a genomic data sharing plan been submitted in the parent application?**
      - ☐ Yes
      - ☐ No, the research does not fall under the NIH Genomic Data Sharing Policy. Continue to question #3.

   b. **If "Yes", will large-scale genomic data be submitted to an NIH-designated data repository (e.g., dbGaP, GEO, SRA, the Cancer Genomics Hub)?**
      - ☐ Yes

   c. **Does the IRB-approved informed consent document address consent for broad sharing and future research with de-identified data or specimens?**
      - ☐ Yes

3. **Does the proposed research involve an NIH-defined clinical trial?**
   - ☐ Yes
   - ☐ No. You do not need to answer the remaining questions in this section.

   a. **All NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials must be trained in Good Clinical Practice (GCP). Have the appropriate individuals received GCP education?**
      - ☐ Yes

   b. **All NIH-funded clinical trials are expected to register and submit results information to Clinicaltrials.gov, as per the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Do you have a plan for the dissemination of NIH-funded clinical trial information?**
      - ☐ Yes
      - ☐ No, the research does not involve an NIH-defined clinical trial
      - ☐ No, and a justification has been approved by NIH