**NCATS HUMAN SUBJECTS RESEARCH PRIOR APPROVAL ADDENDUM**

All NCATS [Prior Approval requests](http://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1_changes_in_project_and_budget.htm#Requests) must include this addendum as an attachment under Section 5.1 of the Electronic Research Administration (eRA) [Human Subjects System](https://era.nih.gov/hss_overview.cfm) (HSS) module. The information entered below will complement the information entered into the HSS module and assist in the review of the request.

|  |  |
| --- | --- |
| **Name of Pilot Study Principal Investigator (PI) or KL2-Scholar *(Designated Study PI)*** | test |
| **Type of Proposed Research:** | [ ]  **Pilot Study** [ ]  **KL2 Project** |
| **Title\* of Proposed Research Protocol***\*This must match the title* *on the IRB-Approval documentation* | Click here to enter text. |
| **Title and PI of Parent Study (if proposed research is ancillary to another study)** | Click here to enter text. |

**Use the text boxes provided to complete each item or insert a PDF document (drag or paste document into the section box).**

1. Insert the Institutional Review Board (IRB) Approval for the proposed research (required).

Click here to enter text or insert file.

1. Provide a brief (< 500 words) summary of the specific aspects of the proposed study that will be supported by NCATS funds and include a line item budget for each aspect (list supplies, services, and personnel costs). Please note: KL2 scholar salaries should not be included in the budget.

Click here to enter text or insert file.

1. If the proposed research is considered an amendment or is a sub-study/ancillary study to an IRB-approved parent protocol, provide a summary of the parent protocol with an explanation of how the proposed study connects to it.

Click here to enter text or insert file.

1. **NIH Biosketches are required for the Study PI and for each Key Personnel involved in the proposed human subjects research study. In the box below: 1. List names of Key Personnel involved in the study and state whether their Biosketch is included in the grant application or inserted here; and 2. Insert any Biosketches not included in the grant application.**

Click here to enter text or insert file.

**5. NIH policy (**[**NOT-OD-00-039**](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html) **&** [**NOT-OD-01-061**](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html)**) requires education on the protection of human research participants for all key personnel submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for projects involving human research participants and a letter signed by the official authorized to represent the institution that documents completion of the education. The letter must describe education completed in the protection of human subjects for the Study PI and each individual identified as “key personnel” in the proposed research. Insert the signed letter.**

Click here to enter text or insert file.

1. **Insert Additional Documents. For proposed studies that are greater than minimal risk; an NIH-defined clinical trial or clinical investigation; or involve pregnant women, human fetuses or neonates, prisoners, children, or individuals with impaired decision-making capacity, insert the following documents: IRB-Approved Protocol and IRB-Approved Informed Consent, Verbal Informed Consent Transcript, Assent and Parental Permission documents, or Documentation of IRB Waiver, as applicable.**

Click here to enter text or insert file.

**RESOURCES**

[HSS User Guide](https://era.nih.gov/files/HSS_user_guide.pdf)

<https://ncats.nih.gov/ctsa/funding/prior-approval-faq>

**For assistance, please contact:** **NCATSDOPAinquiry@mail.nih.gov**