NCATS Prior Approval Award Checklist

GHUCCTS' KL2 Scholar Project is required to comply with the National Center for Advancing Translational Sciences (NCATS) policy regarding research involving human subjects. According to the policy, NCATS must review and approve all KL2 projects that involve human subjects before funding can be released and work on the project can begin. If your application is deemed fundable by the KL2 Executive Committee, and it proposes human subjects research, it will proceed to a second level of review by NIH-NCATS. For your reference, the supplemental NIH-NCATS checklist and required documentation are below. All required prior approval documents are due no later than 30 days after award notification. GHUCCTS' KL2 administration facilitates submission of these materials to NCATS. **Once received, NCATS anticipates a minimum of 30 days for review. Please refer to the NCATS FAQ page for answers to common questions:** https://ncats.nih.gov/funding/grantees/approval-faq. To help determine if your project would be considered human subjects research, use this NIH tool.

What you need to know:

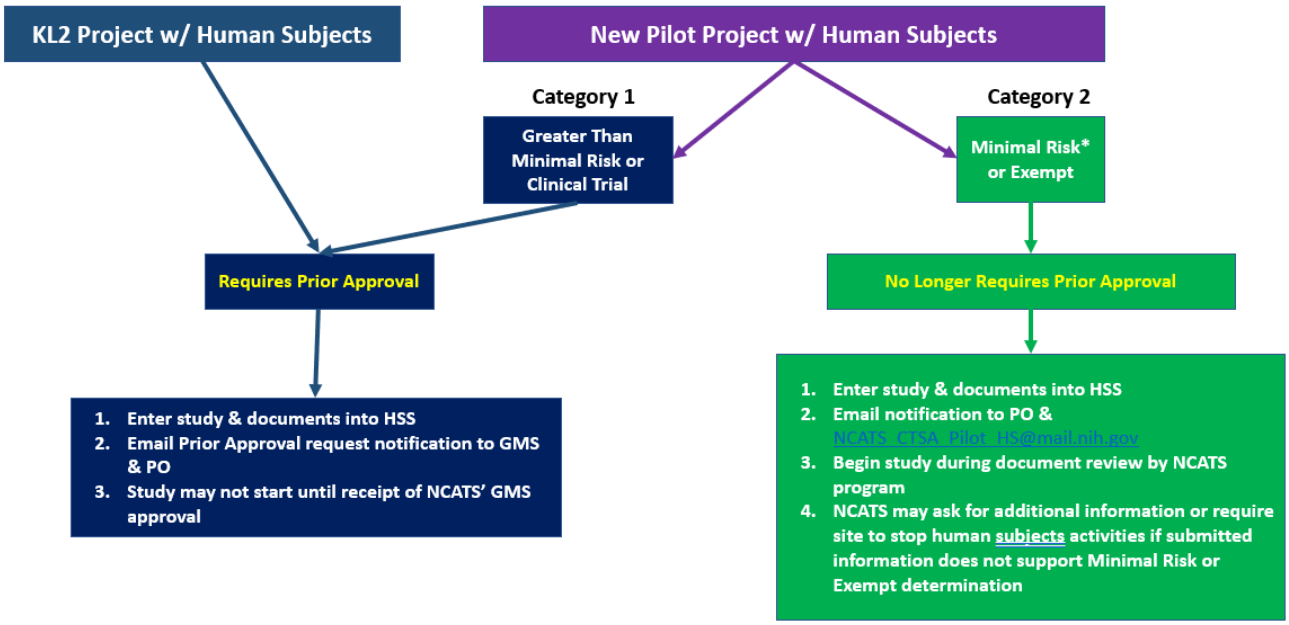
- **NIH Definition of Clinical Research**
  - Research with human subjects that is: 1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies. 2) Epidemiological and behavioral studies. 3) Outcomes research and health services research.
- **NIH Definition of Clinical Trial**
  - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
- **NIH Definition of Human Subjects Research**
  - According to 45 CFR 46 Link to Non-U.S. Government Site - Click for Disclaimer, a human subject is "a living individual about whom an investigator (whether professional or student) conducting research:
    - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
    - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
    -
- **NCATS Phase III Clinical Trial Policy (NIH Guide Notice NOT-TR-18-025)**
  - NCATS is prohibited from direct funding of a Phase III CT unless the target is a rare disease or condition, and must follow certain steps prior to funding (public notice for ≥120 days)

- **Accurate Completion of the Human Subjects System "PHS Human Subjects and Clinical Trials Information" Section, including accurate identification of clinical trials**
    - NCATS continues to identify inaccurate study information submitted to HSS, which leads to incomplete submission of required documents and delays in review and approval.
- **Research Involving Prisoners**
    - In addition to Subpart C of the Common Rule (45 CFR 46), an institution that intends to conduct HHS-supported research involving prisoners as subjects must certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a), including the finding that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a)(2).
- **Foreign Components**
    - Adding a foreign component under a grant to a domestic or foreign award requires NCATS prior approval. This includes the addition of a performance site or research project in a country other than that specified in the competing application and/or a change in the performance site within a foreign country. The transfer of work by a domestic award recipient to a foreign entity also requires NCATS prior approval. For more information on the submission of a prior approval request to add or change a foreign component, please refer to the NCATS website (here).
- **Human Fetal Tissue Policy**
    - CTSA Hubs must contact the assigned Program Officer and Grants Specialist of any potential use of human fetal tissue prior to submitting the research project in to the HSS system. Any proposed use of human fetal tissue research supported via direct funding and/or voluntary committed cost share requires NCATS prior approval before the study may begin. Please refer to recent guidance issued by NIH on the proposed use of human fetal tissue. (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-137.html).

Definitions:

- **Category 1**: Greater Than Minimal Risk studies and all NIH-defined Clinical Trials; even if proposed research might otherwise be considered Minimal Risk
    - Category 1 studies/trials require Prior Approval
    - The HSR study/trial may not begin until approval is received from the Grants Management Specialist (GMS)
- **Category 2**: Minimal Risk and Exempt Studies
    - All NIH-defined clinical trials are considered Category 1 research even if proposed research might otherwise be considered Minimal Risk
    - Category 2 studies do not require Prior Approval, unless a new foreign component is proposed. If a new foreign component is proposed, the Category 2 project must be submitted for Prior Approval.
    - The HSR study may begin following the entry into HHS and email notification to NCATS

Process Overview



**All NIH-defined clinical trials are considered Category 1 research even if proposed research might otherwise be considered Minimal Risk.*

Addendum

Name of UL1 Pilot Study Principal Investigator (PI) or KL2 Scholar *(Designated Study PI)*	Click here to enter text.
Title* of Proposed Research Protocol **This must match the title on the IRB-Approval documentation*	Click here to enter text.
Type of Proposed Research	☐ **UL1 Pilot Project** ☐ **KL2 Scholar Project**
UL1 PILOT PROJECTS	
Category 1 Research **Require Prior Approval by GMS before start**	☐ **Greater Than Minimal Risk** *(as designated by institution and/or IRB)* ☐ **Clinical Trial (NIH-defined)** *(regardless of the risk level, based on NIH definition)*
Category 2 Research *(as designated by institution and/or IRB)* **Requires entry & document upload into HSS and notification of NCATS before start, unless a new foreign component is proposed, which requires Prior Approval.**	☐ **Exempt** **Exemption # ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8** ☐ **Minimal Risk** *All NIH-defined clinical trials are considered Category 1 research even if proposed research might otherwise be considered Minimal Risk.*
KL2 SCHOLAR PROJECTS ***All require Prior Approval by GMS before start. Follow instructions for Category 1 Research.***	
☐ **Greater Than Minimal Risk** *(as designated by institution and/or IRB)* ☐ **Clinical Trial (NIH-defined)** *(regardless of the risk level, based on NIH definition)* ☐ **Exempt** **Exemption # ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8** ☐ **Minimal Risk** *All NIH-defined clinical trials are considered Category 1 research even if proposed research might otherwise be considered Minimal Risk.*	
Title and PI of Parent Study (if proposed research is ancillary to another study)	Click here to enter text.
Is this study collecting genomic data? **See:** NIH Genomic Data Sharing	☐ Yes ☐ No
Translational Stage(s) of Research (definitions)	☐ Preclinical ☐ Clinical ☐ Clinical Implementation ☐ Public Health
NCATS Program Director/Program Officer	Click here to enter text.
NCATS Grants Management Specialist (GMS)	Click here to enter text.
Institutional Signing Official (SO)	Click here to enter text.

Checklist for NCATS Required Documents

NCATS REQUIRED DOCUMENTS	Category 1[1]		Category 2[2]
STUDY CATEGORY	Clinical Trial	Greater Than Minimal Risk Study	Minimal Risk[3] or Exempt Study
COMPLETE HSS SECTIONS (see below for details)	1-5	1, 2, 3.1 & 3.2	1, 2, 3.1 & 3.2
Addendum	√	√	√
Certification of IRB-Approval	√	√	√ or √
Institutional Exemption Determination			
Relevant biosketches not contained in the CTSA grant appl.	√	√	
Institutional letter attesting to completion of Human Subjects Training for PI and key personnel[4]	√	√	
IRB-Approved Protocol	√	√	
IRB-Approved informed consent, verbal consent transcript, assent and parental permission documents, or documentation of IRB waiver (as applicable)	√	√	
Specified NCATS Required Document PDFs should be combined and attached in HSS Sections	*5.1*	*2.7 (Study Timeline attachment box must be used to attach the Study Timeline plus the NCATS-specified documents.)*	

Definitions

[1]**Category 1 Human Subjects Research** that meets the NIH definition of a clinical trial. *Answered "Yes" to all the questions in HSS Section 1.4 - Clinical Trial Questionnaire.* OR Human Subjects Research study deemed Greater than Minimal Risk by IRB.

[2]**Category 2 Human Subjects Research** study deemed Minimal Risk by the IRB or study has been determined by the institution to meet the criteria for Exemptions 1-8 under 45CFR46

[3]**All NIH-defined clinical trials are considered Category 1** research even if proposed research might otherwise be considered Minimal Risk.

[4]**Institutional letter attesting to completion of Human Subjects Training for PI and key personnel**: NIH policy (NOT-OD-00-039 & NOT-OD-01-061) requires education on the protection of human research participants for PI and all key personnel; insert signed letter.

Question Prompts:

- **Complete #1, #2, & #3 for all UL1 Pilot Project and KL2 Scholar Project requests. Complete #4 for Category 1 UL1 Pilot Projects and KL2 Scholar Project Prior Approval requests.** ***Reminder:*** *All NIH-defined clinical trials are considered Category 1 research even if proposed research might otherwise be considered Minimal Risk.*

1. **Provide a brief (< 500 words) summary of the specific aspects of the proposed study that will be supported by NCATS funds.**

   Click here to enter text.

2. **List a line item budget for each specific aspect to be supported with NCATS funds (list supplies, services, and personnel costs). Please note: KL2 Scholar salaries should not be included in the budget.**
   Click here to enter text.

3. **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.

4. **NIH Biosketches are required for the Study PI and for each Key Personnel involved in the proposed Category 1 UL1 Pilot Project or KL2 Scholar Project. List names of Key Personnel involved in the study and state whether their Biosketch is included in the CTSA grant application. For biosketches not included in the CTSA grant application, see Section III below.**
   Click here to enter text.

Definitions:

[1]**Category 1 Human Subjects Research** that meets the NIH definition of a clinical trial (*Answered "Yes" to all the questions in HSS Section 1.4 - Clinical Trial Questionnaire)* OR Human Subjects Research study deemed Greater than Minimal Risk by IRB.

[2]**Category 2 Human Subjects Research** study deemed Minimal Risk by the IRB or study has been determined by the institution to meet the criteria for Exemptions 1-8 under 45 CFR 46

[3]**All NIH-defined clinical trials are considered Category 1** research even if proposed research might otherwise be considered Minimal Risk.

[4]**Section 2.8 & Inclusion Enrollment:** Do not complete this field if you answered "YES" to the question "Using an Existing Data Set or Resources?" in the Inclusion Enrollment Report. KL2 Scholar Projects do not require inclusion enrollment.

[5]**Section 3.2 Multi-site Studies**: Answer "Yes/No;" or select N/A only if: a. You answered "Yes" to "Question 1.2 Is this Study Exempt from Federal Regulations?" or b. You are a career development applicant; or c. You are a training applicant; or d. You are a fellowship applicant (sIRB policy does not apply to situations b, c, and d.). If you answer "YES" - Multi-site studies using the same protocol: Attach Plan describing how you will comply with the NIH policy on the use of single-IRB for multi-site research.

eRA HHS SECTIONS to be COMPLETED		Category 1[1]		Category 2[2]
	STUDY CATEGORY	Clinical Trial	Greater Than Minimal Risk Study	Minimal Risk[3] or Exempt Study
HSS Section 1 – Basic Information				
1.1	Study Title	√	√	√
1.2	Is this Study Exempt from Federal Regulations?	√	√	√
1.3	Exemption Number	√	√	√
1.4	Clinical Trial Questionnaire	√	√	√
HSS Section 2 – Study Population Characteristics				
2.1	Conditions or Focus of Study	√	√	√
2.2	Eligibility Criteria	√	√	√
2.3	Age Limits	√	√	√
2.4	Inclusion of Women, Minorities and Children	√	√	√
2.5	Recruitment and Retention Plan	√	√	√
2.6	Recruitment Status	√	√	√
2.7	Study Timeline	√	√	√
2.8	>Enrollment of First Subject & >Inclusion Enrollment Report(s)	√[4]	√[4]	√[4]
HSS Section 3 – Protection and Monitoring Plans				
3.1	Protection of Human Subjects	√	√	√
3.2	Is this a multi-site study?	√[5]	√[5]	√[5]
3.3	Data and Safety Monitoring Plan	√	Optional	Optional
3.4	Data and Safety Monitoring Board?	√	Optional	Optional
3.5	Overall Structure of the Study Team	√	Optional	Optional
HSS Section 4 – Protocol Synopsis				
4.1	Brief Summary	√		
4.2.a	Narrative Study Description	√		
4.2.b	Primary Purpose	√		
4.2.c	Interventions	√		
4.2.d	Study Phase	√		
4.2.e	Intervention Model	√		
4.2.f	Masking	√		
4.2.g	Allocation	√		
4.3	Outcome Measures	√		
4.4	Statistical Power and Design	√		
4.5	Subject Participation Duration	√		
4.6	FDA-Regulated Intervention? (IND/IDE)	√		
4.7	Dissemination Plan	√		
HSS Section 5 – Other Clinical Trial Attachments				
5.1	Other Clinical Trial Attachments	√		

Useful Links/Assistance

- https://humansubjects.nih.gov/
- 45CFRPart46
- https://era.nih.gov/hss_training.htm
- https://era.nih.gov/files/HSS_user_guide.pdf
- https://era.nih.gov/files/assist_user_guide.pdf
- https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format- attachments.htm **(required format of attachments)**
- https://ncats.nih.gov/ctsa/funding/prior-approval-faq
- https://grants.nih.gov/policy/clinical-trials/human-subjects-system.htm
- https://humansubjects.nih.gov/sites/hs/pdf/HS-Scenarios-for-Forms-E.pdf
- https://ncats.nih.gov/ctsa/funding/prior-approval-faq#clarification
- https://grants.nih.gov/grants/funding/inclusion-basis-on-sex-gender-race-ethnicity-faq.htm#5510
- https://grants.nih.gov/grants/funding/women_min/inclusion_training.htm
- https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf
- https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/multi-project-forms-e.pdf

For assistance with this Addendum or requested content, please contact NCATSDOPAinquiry@mail.nih.gov

For assistance with the eRA HSS, please contact the eRA Service Desk

https://grants.nih.gov/support/index.html

Toll-free: 1-866-504-9552 (Press 1 for eRA Commons or ASSIST)

Phone: 301-402-7469 (Press 1 for eRA Commons or ASSIST)

Hours: Mon-Fri, 7 a.m. to 8 p.m. ET (closed on federal holidays)