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| **Purpose:** This form is designed to help facilitate review of protocols that are funded or sponsored by any source (external or internal). |

**Instructions:** Use this form when a study involving human subjects is funded/sponsored or an application for funding/sponsoring is in process.

If applicable, include a copy of the grant proposal(s) methodology portion specific to human subjects research.

* NIH Clinical Trial Reminder: If the research project is considered a clinical trial, the project needs to be registered on ([http://ClinicalTrials.gov](http://clinicaltrials.gov/)). If you have questions regarding whether the project is considered a clinical trial and is required to be registered, please contact your program officer at NIH.

Save this form to your computer before proceeding.

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| --- | --- | --- | --- | --- | --- | --- |
| 1. Study and Investigator Information | | | | | | |
|  | | | | | | |
| Principal  Investigator (PI): |  | | | Today’s Date: |  | |
| Faculty Advisor |  | | | Protocol number: |  | |
| Study Title: |  | | | | | |
| 1. Funding and Sponsorship | | | | | |
| * 1. Has this research received Approval-in-Principle from RCS? | | | | | | |
| Yes  No | | If “yes”, list protocol number: |  | | | |
| * 1. Is or will the funds or sponsorship be from an internal UO source (UO department, Summer Fellowship, other)? | | | | | | |
| Yes  No | | If “yes”, provide the following: | | | | |
|  | | Source name: |  | | | |
|  | | Source grant number: |  | | | |
| * 1. Is or will the funds or sponsorship be from an external source (federal agency, NIH, NSF, non-profit, other)? | | | | | | |
| Yes  No | | If “yes”, provide the following: | | | | |
|  | | Source name: |  | | | |
|  | | Source grant/contract number: |  | | | |
|  | | Title of grant (if different from above): |  | | | |
|  | | Principal Investigator listed on the funding/sponsorship application: |  | | | |
| * 1. Will Sponsored Project Services (SPS) oversee the distribution of the funds? | | | | | | |
| Yes  No | | If “Yes”, provide the following: | | | | |
|  | | E-PCS number (submission number to SPS): |  | | | |
|  | | UO grant number (if known): |  | | | |
| * 1. Is UO the primary awardee for the funding/sponsorship? | | | | | | |
| Yes  No | | If “No”, list primary awardee: |  | | | |
| * 1. Are there subcontracts to institutions also participating in the human subjects research? | | | | | | |
| Yes  No | | If “Yes”, list sub-contractors: |  | | | |
| * 1. Does the study sponsor have any requirements or additional stipulations regarding IRB review (e.g., NIH requires single IRB review for some domestic, multi-site research studies conducting the same protocol)? | | | | | | |
| Yes  No | | If “Yes”, please explain in the textbox below: | | | | |
|  | | | | | | |
| * 1. Does the study sponsor have any additional review and approval requirements or additional stipulations regarding human subject research (e.g., Department of Defense requires agency review of any sponsored research involving human subjects)? | | | | | | |
| Yes  No | | If “yes”, please explain in the textbox below and provide a link to any agency specific policy(ies): | | | | |
|  | | | | | | |
| * 1. Are there any human subjects activities described in the funding/sponsorship that are not part of this IRB application? | | | | | | |
| Yes  No | | If “yes”, please explain in the textbox below: | | | | |
|  | | | | | | |
| * 1. Are there human subjects activities described as part of this protocol that are not covered under the funding/sponsorship? | | | | | | |
| Yes  No | | If “yes”, please explain in text box below: | | | | |
|  | | | | | | |
| * 1. If the study is NIH sponsored, does the study meet the NIH definition of clinical trial? | | | | | | |
| NIH Definition of Clinical Trial: A research study in which one or more human subjects are [prospectively assigned](https://grants.nih.gov/policy/clinical-trials/glossary-ct.htm#ProspectivelyAssigned) to one or more [interventions](https://grants.nih.gov/policy/clinical-trials/glossary-ct.htm#Intervention) (which may include placebo or other control) to evaluate the effects of those interventions on [health-related biomedical or behavioral outcomes.](https://grants.nih.gov/policy/clinical-trials/glossary-ct.htm#H) See NIH Website for more information on determining if the research is an [NIH Clinical Trial](https://grants.nih.gov/policy/clinical-trials.htm). | | | | | | |
| Yes  No N/A | |  | | | | |
| If yes, the following NIH Clinical Trials requirements apply to your research: | | | | | | |
| 1. **GCP training:** must be logged and tracked forclinical investigators and staff who are involved in the design, conduct, oversight, or management of the clinical trial. Recipients of GCP training are expected to retain documentation of their training. GCP training should be refreshed at least every three years in order to stay up to date with regulations, standards, and guidelines.   Describe how this requirement will be/has been fulfilled: | | | | | | |
| 1. **Registering & reporting of results at clinicaltrials.gov:** All NIH-funded clinical trials are expected to register and submit results information to [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/home), as per the "[NIH Policy on Dissemination of NIH-Funded Clinical Trial Information](https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm)" for competing applications and contract proposals submitted on or after 1/18/2017.   Describe how this requirement will be/has been fulfilled: | | | | | | |
| 1. **Single IRB Requirements:** For applicable domestic, multi-site clinical trials, the investigator must provide plans for use of a single Institutional Review Board (sIRB) to conduct the ethical review for human subjects in research.   Describe how this requirement will be/has been fulfilled or state if this requirement is not applicable: | | | | | | |
| 1. **Consent Form Requirements:**  * The following or similar information is provided to subjects or the subject LAR via the informed consent form:   “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”   * If the study also falls under the HHS 2018 Revised Common Rule, a copy of the consent form must be posted to clinicaltrials.gov within the timeframe outlined in the HHS regulations as noted above.   Describe how this requirement will be/has been fulfilled or state if this requirement is not applicable: | | | | | | |
| **NOTE: If you are conducting a clinical trial and/or clinical investigation that is supported by an entity other than NIH, you may have additional requirements to fulfill similar to those noted above for NIH. Check your sponsor requirements.** | | | | | | |