|  |
| --- |
| **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.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 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: | | | | |
|  | | | | | | |