Clinical Research Proposal Guidance

Go to the Key Personnel Tab, Compliance Questionnaire Sub Tab and review the Human Research Questions

|  |  |
| --- | --- |
| ***Human Research Question(s)*** | |
| *Question 1: "Do any of the activities proposed involve: Obtaining specimens or data through intervention or interaction with a living individual, or identifiable private information about a living individual, or Use of human tissue samples (including stem cells and their derivatives, fluids, or records, whether identifiable or not?* ***“If this question is answered "No,” the child questions below will not appear.”*** | |
| *Question 1a: Is this research covered by regulations for human subjects protection?* | |
| *Question 1b: Is this research covered by regulations for stem cell research?* | |
| *Question 1c: Is this project covered by the NIH Genomic Data Sharng policy?* | |
| *Question 1d: Does this project include a Clinical Trial?* | |
| *Question 1e: Has the external sponsor provided a study protocol for this project?* | |
| **Industry Funded:** | |
| Sponsor or Prime Sponsor (*if UCSD is a subrecipient*) is a for-profit entity (can check REMS for sponsor categorization if not sure) | |
| Question 1 - If YES **and if**: | **Activity Type = Clinical Research, 33% IDC rate is applicable** |
| Question 1a - is YES or NO and |  |
| Question 1d - is YES or NO and |  |
| Question 1e - is NO, then: | This should route to SPO. |
| **Industry Funded:** | |
| Sponsor or Prime Sponsor (*if UCSD is a subrecipient*) is a for-profit entity (can check REMS for sponsor categorization if not sure) | |
| Question 1 - If YES **and if**: | **Activity Type = Clinical Research, 33% IDC rate is applicable** |
| Question 1d - is YES or NO and |  |
| Question 1e is also YES, then: | [**This should route to OCTA (*However, review the protocol to see who "authored" it. If the external sponsor providing the study protocol is not a for-profit company, then this would route to SPO. OCTA only handles for-profit funded and for-profit authored clinical research studies.***](http://ct.gov/) |
| **Non-profit or Government Funded (even partially):** | |
| Sponsor or Prime Sponsor (*if UCSD is a subrecipient*) is a non-profit entity or a governmental entity (can check REMS for sponsor categorization if not sure) |  |
| Question 1 - If YES and if: | **Activity Type = Clinical Research, either the Federally negotiated rates or special State IDC rates or non-profit sponsor policy IDC rates apply depending on the sponsor type that is providing the funding** |
| Question 1a - is also YES or NO and |  |
| Question 1d - is also YES or NO and |  |
| Question 1e is YES or NO then: | This should route to SPO. |
| **Additional Background Guidance:** | |
| A study is considered a clinical trial/study when it contemplates the controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or diagnostics, or comparisons of approved drugs, devices, treatments, or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. | |
| A clinical trial/study is most often used in conjunction with obtaining new drug or device approval from the U.S. Food and Drug Administration, **although they can be designed with the sole purpose of collecting and analyzing data about an approved drug or device in order to contribute to medical knowledge about the treatment of a disease or medical conditions (non-interventional but relying on patient data).** | |
| ***Agreements for Industry-Initiated Industry-Funded clinical trials/studies are handled by OCTA (the company(ies) solely wrote the protocol and is funding the clinical study being conducted by a UCSD PI).*** | |
| ***All other awards/agreements for clinical trials/studies (regardless of who wrote the protocol) are handled by SPO.*** | |
| ***Quick Tip:*** *For most industry-sponsored agreements, KR PD records are after-the-fact "internal proposals - Noncompetitive Proposals" where no formal proposal is being submitted but rather an agreement is ready to be reviewed and should be uploaded in KR PD in the Attachments Tab.* | |

Resources:

<https://blink.ucsd.edu/research/preparing-proposals/clinical-research-trials/index.html>

<https://blink.ucsd.edu/research/preparing-proposals/clinical-research-trials/pi-vs-industry.html>