Investigator- Initiated Trial (IIT) Contracts Information Collection Form

Instructions

You have indicated that this study is designed by UCD faculty and the study will receive support in the form of funding or products (or both) from a commercial entity. To successfully negotiate such an agreement, the CRAO contracting team must understand the purpose and scope of the study, how the support from the commercial entity will be used and whether the project is related to other agreements, existing intellectual property, and whether it has the potential to generate new intellectual property.
We strongly recommend that this form be completed **by the Principal Investigator** because the PI has the most knowledge about the intent of the study and the support requested from the commercial entity.

Investigator- Initiated Trial (IIT) Contracts Info Form

Protocol Title:

PI: _____
IRB #: _____

1. Name of the commercial entity(ies):_____
2. What specifically is being provided by each commercial entity?

   Drug(s)/Device(s) (please list): _____
   Funding
   Estimated Cost of Study: _____
   Estimated Funding Contribution: _____
   Other (e.g., sample analysis): _____

3. Are there other contracts (e.g., pre-clinical agreement, grant funding agreement) related to this Study (**not** including confidentiality/non-disclosure agreements)?
   Yes __ No __
   a. If yes, what are they? (Include InfoEd routing number, IRB number, as applicable)

4. If a drug/device is being provided, is each drug/device= FDA approved?
   Yes __ No __
5. Is each drug/device being used for approved indication?
   Yes __ No __
   a. If no, describe how study design differs from approved indication. Include a description of how close or far study design is to current FDA approval (e.g., population)

6. Is this study based on data/technology/methodology developed by PI and collaborators at CU Anschutz?
   Yes __ No __
   a. If yes, briefly describe (has prior work, including pre-clinical work, related to this Study been published or preserved?)

7. Do you anticipate any intellectual property resulting from this Study?
   Yes __ No __
   a. If no, please explain why.

   b. If yes, have you filed a disclosure with CU Innovations?
      Yes __ No __
8. What data and information from the Study do you plan to share with the commercial entity? (be as specific as possible)

9. Will the study include sample collection intended for use in future research?
   Yes __ No __
   a. If yes, is future research known at this time? (Describe the area of potential research)

10. Logistical information (select all that apply)
    a. Investigator held IND/IDE? Yes __ No __
       i. If no, who is holding the IND/DE? _____
    b. Multicenter coordination, including North/South (# centers: _____)?
       Yes __ No __
       i. If the Study is multicenter, who is the coordinating Site?
          _____
       ii. Is a CRO being utilized? Yes __ No __
    c. Phase: I __ II __ III __ N/A __

Completed By: _____

Assessment: (To be completed by Contracts Associate, CU Innovations, etc., as necessary)

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