Investigator- Initiated Trial (IIT) Contracts Information Collection Form

Instructions
You have received this form because you have indicated that this study is Investigator Initiated by our local faculty and you are requesting funding or products (or both) from a company such as Merck, Pfizer, or another example Abbvie. We consider such studies to be IITs with “industry support.” Prior to completing your HSR Portal submission, this form must be completed and included with the HSR Portal submission.

This form is to collect information that will help us negotiate the agreement. In order to successfully negotiate such an agreement, the contracting team must understand the purpose of the study, how the support from the outside group will be used and whether the project is related to other agreements or existing 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 industry entity.

Example Answers
5(a) – I will be using ____________ which is approved for use in...
6(a) – This study was based off work I did in my lab...
7(a) – I am using an approved drug...
8 – I intend to collect biomarkers and the hope is...
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Protocol Title:

PI: 

IRB #: 

1. Who is the industry partner(s)?

2. What is being provided by each industry partner(s) (include who is providing what)?
   Drug(s)/Device(s) (please list):
   Funding
   Estimated Cost of Study:
   Estimated Funding Contribution:
   Other (e.g., sample analysis):

3. Are there other contracts related to this Study (not including confidentiality/non-disclosure agreements)? (e.g., pre-clinical agreement, sponsored research agreement)
   Yes __ No ___
   a. If yes, what are they? (Provide identifying information, such as a routing number, grant number, etc.)

4. Is each drug(s)/device(s) FDA approved? Yes ___ No ___

5. Is each drug(s)/device(s) being used for approved indication? (e.g., combination, biomarker)
   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? In vitro? In vivo?)
7. Do you anticipate any intellectual property resulting from this Study or do you anticipate any follow-up studies?
   Yes __  No __
   a. If no, please explain why.
   b. If yes, have you filed a disclosure with CU Innovations?
      Yes __  No __

8. 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)

9. Level of risk of the Study for the institution (select all that apply)
   a. Investigator held IND?  Yes __  No __
      i. If no, who is holding the IND? ________________________________
   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: ________________________________
(Should be hand-written: not electronic)

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