

Conflict of Interest Worksheet for IND/IDE Applications and Related Research.

Under the University of Arizona's ("UA") Institutional Conflict of Interest Policy, sponsorship of an Investigational New Drug ("IND") or an Investigational Device Exemption ("IDE") application by UA or UA personnel may create an Institutional Conflict of Interest.¹ Accordingly, all IND/IDE applications must be reviewed and approved by the Executive Review Committee ("ERC") prior to submission to the FDA. Please complete this form as far in advance of your anticipated IND/IDE submission date as possible, to minimize the risk of delays while awaiting ERC review.

Please send the completed form, along with a copy of the draft IND/IDE Application (if available), to coi@email.arizona.edu, with the Subject Line "IND (or IDE) Approval Request." Please know that the process of reviewing and approving your IND/IDE application can take up to 90 days.

Submitter:

Project:

IND/IDE Sponsor:

Purpose of IND/IDE:

Anticipated FDA Submission Date:

PROJECT DESCRIPTION

- Please provide an abstract of the project, including a description of the goals of the Research and its potential impact on your field, UA, and/or the public.

- Will the Research occur at UA facility? If so, where?

- Please identify any partner institutions collaborating on the Research and describe their role.

¹ The UA Institutional Conflict of Interest Policy is available here: <http://policy.arizona.edu/research/institutional-conflict-interest-policy>.

- Describe any anticipated future research related to the IND/IDE.

PROJECT PERSONNEL

- List all individuals who are responsible for the design, conduct, or reporting of Research for the project, including a description of their role on the project and whether they have oversight duties.

COI Disclosures: Please verify that all individuals listed above have submitted their individual COI disclosures here: <https://uavpr.arizona.edu/COI>.

- Provide a detailed description of your activities related to the Research.

- Please explain why you are uniquely qualified to serve as PI or IND/IDE-Sponsor for the Research. Please identify any other investigator who could serve as PI or IND/IDE-Sponsor for the Research.

FINANCIAL INTERESTS

- Which entity owns the drug or device being evaluated in the Research?

- Are any entities other than UA sponsoring the Research? If so, please identify those entities and explain how, if at all, those entities are related to the Research?

- Please explain how (if at all) UA would benefit financially from any of the possible outcomes of the Research.
- Please explain how (if at all) you would benefit financially from any of the possible outcomes of the Research.
- Please identify other entities, if any, that would benefit financially from any of the possible outcomes of the Research and explain how.
- Will this IND/IDE result in the development of patentable intellectual property?
- List all individuals and University units with expected future royalty or income streams and/or financial interests in IND/IDE or related Intellectual Property.
- If the Research is successful, will the IND/IDE result in the revisions to an FDA-approved label or a new label?

RISKS AND MITIGATION

- Describe the reasonably foreseeable risks to human subjects participating in the Research.

- Describe any steps that will be/have been put in place to mitigate the effects of a potential individual or institutional conflict of interest on the research.

- Identify any students or trainees (including undergraduate students, graduate students, and postdoctoral fellows) who are directly involved in the Research, and, for each, describe their role in the Research. Please specify if you are an academic advisor or graduate committee member for any of the students or trainees identified above.