Joint 700U/IRB Projects (e.g., Industry Clinical Trials): Tips to Avoid Delays

Office of Research

News & Announcements

In September 2017, we implemented a new process to streamline the Conflict of Interest (COI) review for Joint 700U/IRB projects. Joint 700U/IRB Projects are projects which you know at proposal stage that have:

- 1. A non-governmental sponsor requiring the Form 700U (see list of exclusions);
- 2. Such sponsor funding the project through a research contract/subcontract or grant/subaward; AND
- 3. A new IRB application.

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To maximize the benefits and avoid delays, the individuals working on the funding proposal and the IRB application should coordinate as we all work together to process these projects efficiently. Below are some tips and clarifications about this new process:

General Tips

- This new Joint 700U/IRB process only applies to <u>new</u> studies NOT continuing protocol applications.
- Only Principal Investigators and Co-Principal Investigators are required to complete the Form 700U NOT all research personnel.
- If a contracted research organization (CRO) is signing the agreement, please upload Form 700Us for **both** the CRO and the sponsor.
- Create and save the KC Proposal **before** the new IRB application is created. Share the proposal number with the individual in your team working on the associated new IRB application to help link the forms with the appropriate projects.
- Respond accurately to the updated questions in the IRB application (Study Funding section) and KC Proposal (Conflict of Interest questions). The electronic systems have certain automatic procedures they follow based on your responses to these questions. If you are unsure how to answer the questions, see Non-Governmental Sponsor page or contact coioc@research.uci.edu before submitting the IRB application or KC proposal.
- Carefully follow the instructions regarding where and how to upload the completed Form 700U to avoid delays created by difficulties locating the Form 700U and/or having to request the Form 700U again.

• After notification from the electronic system or from the research team about the disclosures and/or Form 700U, COI will contact the researcher(s) if any additional forms are necessary.

New IRB Application Tips

- Answer the Study Funding section carefully in the IRB application. For Joint 700U/IRB projects ONLY, upload the Form 700U and include the KC proposal number. If you have any questions, contact coioc@research.uci.edu before submitting the IRB application, because the electronic system does not allow revisions to those responses after submission.
- Only upload the Form 700U with the corresponding "700 U Form" label. <u>Please do</u> <u>NOT label the attachment as "Other"</u> because the electronic system cannot send the file to COI without the proper label.
- If you answered the funding section questions incorrectly in your submitted new IRB application or forgot to upload the completed Form 700U with the new IRB application, please forward the Form 700U to COI at coioc@research.uci.edu with the IRB protocol number and KC proposal number as soon as possible to avoid further delays.

Thank you for your help in streamlining this process as we continue to find ways to improve our overall processes.

Questions? Contact Conflict of Interest at coioc@research.uci.edu. Visit Non-governmental Sponsor webpage.

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