Existing Studies: Tips for Completing the Online Application

The existing study (previous paper-based forms) information that was loaded into the IRBIS system is limited to the following:

- Study number
- Research team - Investigator, Co-investigator, Research Assistant, Responsible Faculty (where applicable)
- Study Title
- Study Category (Exempt, Expedited, or Full)
- Current Approval Date

It is necessary at the time of renewal for Investigators to “build” their current protocol into the IRBIS system, given that there is limited information with the IRBIS system about existing studies. This essentially means that Investigators will need to complete the IRBIS online application.

Before getting started with this, ORC recommends that you gather or find the following information as it will help you as you build your online application.

- Current IRB approval letter (this was sent to you as a PDF attachment to an email notice of approval)
- Currently approved protocol application form

If you are submitting a renewal for an existing study, refer to the IRBIS Manual Existing Studies Renewal user guide for instructions in starting a renewal. If you are submitting a modification for an existing study, refer to the IRBIS Manual Existing Studies Modification user guide for instructions in starting a modification.

Once you have completed the renewal or modification information, the system will “open” the online application for you to input the information needed to build the application.

Application Sections

DO NOT copy directly from your paper-based protocol to IRBIS. The paper-based application form is highly formatted and copying and pasting may cause errors in your application and may corrupt the application. You may transfer text from your paper-based protocol to a new Word document and remove all formatting and then paste into the IRBIS application. Re-review the text first to remove any unusual or special characters that may appear (e.g., €, Û, A, Ñ, etc.) before you copy it to IRBIS. The best option is to type responses directly into the IRBIS application to avoid system error.

General Information:
- The Project Title information will be complete already.
- You only need to respond to the remaining questions in this section.

Project Personnel:
- The currently approved study personnel will be listed already.
• Refer to your current protocol application and/or current IRB approval letter (or a more recent amendment approval letter) to confirm for accuracy.
• If someone is missing from the team, you want to remove someone, or if you want to add someone to the research team you may make these changes to the personnel list.

Funding Sources:
If this project was funded at the time of initial approval, provide the funding information.

Screening Questions:
It is important that these questions be answered as applies to the study as it was initially approved.
• Question #1 – Answer “Yes”
• Question #2 and #3 – At least one of these must be “Yes.”
• Question #4 – This is only applicable if the study includes an IRB authorization agreement.

Exemptions:
• Review your current IRB approval letter. If the study is Exempt, the letter will state as such and will list the Exemption category.
• If the approval letter states that the study is Expedited or Full, answer “No” to the Exemption question.

Remaining Sections of the Application:
• Respond to all remaining application questions as applies to the study as currently approved.
• This may be different than the current state of the study.
  o For example, as you are submitting your renewal, your study may be closed to new participants. But you should still answer all the application questions about recruitment, even though recruitment is complete.
• Please upload any study materials you are using or will be using.
  o For example, if you will continue to consent new participants, upload the recruitment script you will use, the consent document, and any application study materials (e.g., surveys, interview protocols, etc.)

For additional resources including user guides, tips, and common questions:
http://research.uncc.edu/departments/office-research-compliance-orc/human-subjects/irbis