TIPS/TRICKS

The following list consists of a few tips and tricks to use when navigating eIRB.

GENERAL

Submitting applications – Only the PI can submit applications. However, the Study Coordinator can submit Continuing Reviews, Amendments, Reportable Events, and Requested Revisions. The Co-Investigator will have the ability to create and edit study applications and subprojects; however, he/she cannot submit new applications to the USF IRB.

It is important to note that selecting "Finish" at the end of an application does not submit it for review. In order to submit the initial application, continuing review, amendment or reportable event, you must select "Submit" on the respective workspace page. To verify your application submission, please check the current state, which you can find by looking at the red rectangle in the top left corner of the workspace screen. If the red rectangle still says "Pre-Submission" or "Changes Requested by…," your application has not been submitted for review to the USF IRB. You can also check your history tab, which will indicate the date and time an application has been submitted, as well as by whom.

Withdrawing applications – Only the PI or USF IRB has the ability to withdraw applications. After an application has been created, the PI has the ability to withdraw the application during the Pre-Submission stage. Withdrawal by the PI can also take place at the Department Review and/or Affiliate Review stages (as long as the application is in the study staff's inbox). Once the application reaches the IRB, he/she will need to notify the assigned IRB Staff Reviewer to withdraw the application.

Back button on application form – When completing the study application in eIRB, you will use the Continue and the Back buttons, to navigate the application. One thing to note is the back button within the eIRB application takes you back to the previous page visited, not the previous application page. Also, make certain to Save before clicking the Back button, or all information added and changes made to that particular page will be lost.

Required Reviews (section 2.2 of Study Application) – If the H. Lee Moffitt Cancer Center & Research Institute (MCC) is selected as a USF affiliate Site on question 1.8.2, it will not appear on section 2.2 for Required Reviews however Tampa General Hospital (TGH) and James A. Haley Veterans Hospital (VA) will. This is okay and you will not be asked to correct it.

If you are a student and do not have a specific department affiliation, choose the department to which your faculty advisor is assigned.

CV/Team Member Education Certification – Everyone on the study team, regardless of assigned tasks, should have current Human Subjects Protections Certification and a CV/resume uploaded to the arc system.

If the study team uploads education into eIRB, the account will continue to show the education as "*certification not current"* until the IRB Staff verifies and enters the dates during the IRB Staff Review. The "*certification not current"* education status will not prevent you from submitting an application, nor will it prevent the study from being reviewed. Just keep in mind, the study will not be approved by IRB until it all study team member have current education.

Amendments – After a study has been approved, any changes made to the study must be submitted via an Amendment.

It is helpful if the study team provides as much detail and justification as possible as to what is being amended. In addition to uploading the new "clean" documents (i.e. protocol and consent forms) adding a track change version of the amended documents or a summary description of the changes is also helpful. Without track changes or a summary description of the changes, the IRB Staff reviewer does not know what the revisions are.

When informed consent documents are revised and approved via an Amendment, you can find the approved Consent forms either by clicking the links in the Amendment approval letter or under the "Attachments" tab on the study's main workspace.

Continuing Reviews – When submitting a continuing review application, PI's are asked to provide copies of the 2 most recently signed informed consent documents, unless they are not obtaining signed informed consent because they were granted a waiver of documentation. When submitting the consent documents, please redact any identifiable information related to the subject from the signed forms.

Converting to eIRB (submitting final reports) – Only convert from paper to eIRB if your study will be active beyond January 1, 2013. If you are only completing a final report, do not convert your study to do so. Submit your final report on paper forms which can be found at http://www.research.usf.edu/cs/irb_forms.htm.

Requested Revisions - When receiving requested revisions from a reviewer (Department, Affiliate, or the IRB), in addition to making all the necessary revisions requested by the reviewer, you must also respond to all reviewer notes. The revisions should <u>not</u> be placed in the "Response Required" comment box, but instead directly in the application. Doing so will result in the application being returned to you to put in the appropriate section, thus prolonging the review process.

Responding to concerns is a three-step process. First you must respond to the concerns within the application and make relevant changes on the applicable forms. Second, you must click "submit revisions" in order for the reviewer to receive your responses. If you are unsure whether your application has been submitted, check the state of the study and the history tab. As long as the current state says, "Changes requested by…," your study is still in your inbox and has not been sent back to the reviewer for further review.

Department Review - A member of the study team <u>cannot</u> issue department approval (or affiliate approval) for their own study, due to the conflict of interest this presents. If department approval has been issued by a member of the study team, the IRB cannot review the application until it has been reviewed by an alternate department approver who is not on the study.

If your department is designated as a department (or affiliate) approver (question 2.2.2 or 2.2.3) in error, please send the application back to the study team, by choosing the "submit requested revisions or information" activity. Make certain to include a reviewer note, asking the study team to remove your department as an approver.

If you are study staff and realize you have you made errors or need to add information to the application after it has been submitted, please contact the department approver (outside of eIRB) and request that they send the application back to you to make the necessary changes. After you have made your revisions, make certain to Submit to route your application back through the review process.

Email addresses – Email addresses are one way that the IRB ensures each person has only one eIRB account (a unique ID). When registering, it is imperative that you do not list anyone else's email address, and that both the primary and secondary email address belong to you, the registrant. If you list another person's email address and that person decides to create his or her own account using the same email address, s/he may experience a delay in the registration process, as we determine which email address belongs to whom. We may also need to obtain alternate email addresses, reset the password, and/or deactivate the existing account, all of which take time to process.

Inbox vs. IRB tabs (determining if the study requires your attention) – If you are unsure whether a study requires your attention, make note of where the study is located. If the study is in your "INBOX", then it means the study requires that the study team work on the application and Submit. If you find the application is under the IRB tab, it is an application you are listed on as a study team member. This does not mean you are required to act on anything. If the study is not in the study team's "INBOX", then you will not be able to make any revisions to the application at that time. However, you can make revisions to an application, submit a continuing review, and process reportable events to studies appearing in your IRB tab.

COMPLETING THE STUDY APPLICATION

- If you are presented with a question in the application, that question should be answered. If you feel it does not apply to your particular research, explain why the question does not apply (i.e. N/A – this is a records review study where subjects will not be recruited). With an N/A, RCA's will request less revisions or clarification, thus shortening the length of the review process.

- Be consistent with your application (protocol should match application, consents, flyers and other material).

- Spell out acronyms (i.e. MRI, CT) and explain medical terms in lay terms, especially in the informed consent document.

- Question 1.1 - Please only list one role per study team member. If you are the PI on the study, it is not necessary to list yourself as Co Investigator or Study Coordinator.

- Question 1.2.2 **-** All study personnel must have a current Resume/CV and Human Subjects Protections Education certification uploaded.

- Question 1.8 – A Letter of Support is required if you are using a Non-USF or Non-Affiliate Site to conduct research.

- Question 2.1.1 **–** Please include a clearly stated hypothesis.

- Question 2.1.3 – Please upload an appropriate protocol. It is strongly advised to write protocols in accordance with the IRB Protocol Guidelines. If you need assistance, please visit http://www.research.usf.edu/cs/irb_Guidance.htm and click on "Protocol Guidelines."

- Sections 3 and 4 –Although this information may already be included in the protocol, please write detailed responses in these sections or copy and paste the information from your protocol.

  If you copy and paste information from Protocols or Investigator's Brochures into the application, please be sure the information is relevant to what is being asked and proofread what you paste to ensure it is understandable as a response and covers all questions asked.

- Question 3.5.1 **-** Upload survey instrument(s) if included in your research.

- Section 5 – All research data must be kept for a minimum of 5 years after the Final Report is approved by the IRB. If collected research data is on tape, you can destroy the tapes if the information has been transcribed, still ensuring the transcriptions are kept for the minimum timeframe.

- Section 6 – If you are using any form of recruitment script, email, invitation, etc., attach in Section 6.1c.3 as this must be reviewed and approved by the USF IRB.

- Section 7 – It is strongly advised that Informed Consent documents are based off the IRB templates and contain all required elements in the IRB consent templates (Exceptions to this include templates created by – MCC and VA).

- If requesting a waiver of Informed Consent, do not put the consent form in section 7.2.2 (this is only for researchers obtaining a signed consent form). Instead, attach the document(s) in section 7.3.3.

- Question 7.2.1. - Studies with non-English speaking subjects must have the translated informed consent document and verification that the document has been back-translated uploaded into eIRB. In this document, please have the person translating the non-English informed consent document state that they take responsibility for the document's accurate translation. You may also wait until the English version of the informed consent document is approved to translate the form into another language. Once this is completed, the translated version of the form must be submitted to the USF IRB for review and approval via an amendment.

- Question 7.2.3 - This section addresses the participants' understanding of the research. In this section, indicate if the participant will be asked open-ended questions that will require them to respond in such a way that the study personnel will be able to judge the participant's comprehension of the research study. If the potential participants will have legally authorized representative (LAR) who will be consenting for the subject's participation in the research, please indicate if this individual will be asked open-ended questions that will require them to respond in such a way that study personnel will be able to judge their comprehension of the research study.

- Section 9 – State who will have access to the participants' confidential and private information, as well as where and how this information will be stored.

  "Privacy" responses should be different from "Confidentiality" responses. "Privacy" refers to participants and their interests in controlling the access of others to themselves and to information about themselves. "Privacy" also refers to how the study is presented to individuals (e.g. in private rooms), and should address the ways in which study data are collected (e.g. is study data collected in a private place). "Confidentiality" responses, on the other hand, should address how the data, source documents, and informed consent documents will be kept confidential and secure during data collection, analysis and storage.

- If any member of the study team is going to have access to Protected Health Information (PHI) then you must answer "yes" to question 9.1.6. If medical records are being reviewed, then PHI is being accessed. The PI or Coordinator will need to respond to all HIPAA questions and in most cases apply for a HIPAA waiver if the Informed Consent process or documentation is being waived (applicable only to covered entities).

- Question 9.1b.2 -Data that includes medical record numbers and/or dates associated with a procedure or illness ***are*** considered identifiers according to the HIPAA Privacy Rule. Therefore, datasets that include this information would not be considered "de-identified."

- Question 10.1.1 **-** Data Safety Monitoring refers to your plan for ensuring the integrity of the data collected, including how often you plan to monitor the data. (e.g. "We will review the data, as it becomes available, with the PI to assure that the data is accurate. All data will be reviewed and initialed by the PI. All data will be compared to the participant's record and to their diary to ensure data was recorded accurately. Data integrity is monitored by the PI, the study staff members and the sponsor by verifying that study documents/data entry with the source and patient's medical charts.")