
Other Helpful Tips

Converting a Paper Application to an Electronic Study

If your study was initially approved on paper, you are required to register (convert your paper study to an electronic, iMedRIS study) your study in iMedRIS prior to the submission of a renewal application or other study forms. Be sure to allow enough time for the registration to be reviewed and approved by the IRB office before you submit your renewal application or other study forms, such as revisions, adverse events, recruitment materials, etc.

Study Application

Section 2.0 Setup Department(s) Access:

In this section you are determining which departments have access to this study. If the study is distributed across more than one department, add each department that needs access.

Coordinators responsible for several departments need to note the main department associated with the study. The person completing the registration will have his/her department listed by default. If that department does not need access to the study, remove the department. The study personnel will have access to the study despite the departments listed.

Note: If any of the study procedures are taking place at Methodist Healthcare-Memphis Hospitals or at Le Bonheur Children's Medical Center, then Methodist should be added as a department. If any of the study procedures are taking place at a UT Medical Group, Inc. facility, then UT Medical Group, Inc. should be added as a department. If any study procedures are taking place at The Med, then The Med should be added as a department.

Section 3.0 Grant key study personnel (KSP) access to the study:

In this section of the study application you list all key study personnel associated with your research study. Be sure to list all study personnel and the roles of each of these individuals, not just those obtaining informed consent.

3.1 List the **principal investigator** associated with the research study

3.2 List all **protocol staff** including Co-PI, Co-Investigators, and/or Sub-Investigators, and research staff, such as research coordinators, research nurses, data analysts, research assistants, pharmacists, research nurse managers, etc. **Note:** The system does not automatically list the person completing the registration as study personnel, so the PI's and the Coordinator's (the coordinator should be listed under "Research Staff") name must be entered. If the person who is responsible for submitting study forms and responding to recommendations/provisos is not the PI or the co-investigator, he/she must

be listed as a research coordinator so that he/she has the appropriate access within iMedRIS to perform these tasks.

3.3 List the **Study Contact(s)** associated with your research study. The name(s) listed in this section will receive all the important notifications regarding your research study. Typically the study contact(s) are the research coordinators and/or principal investigator.

3.4 List **Faculty Advisor** in this section. Only complete this section if you are a student or resident and you have a faculty advisor from your department who is mentoring you for the study.

3.5 Designated Departmental Approval(s). In this section, list each individual who will need to provide departmental approval, such as Department Chair, Division Chief, Hospital Service Chief, and Program Chair. For example, if you are UT faculty/staff conducting an OB/GYN study at the Med, you will need to list the appropriate Hospital Service Chief in addition to the appropriate Department Chair(s). **Note:** Upon completing the new application, the names of the Hospital Service Chief at The Med and UTHSC Department Chair must be checked (i.e., check the checkbox beside the name) in the signature routing assignment list so that the application will be routed to them for their signature and approval *before* the IRB receives your application.

3.6 Select **Research Administrative Specialist.** In this section add the appropriate Research Administrative Specialist (see the bulleted list below) if any of your research activities will occur at the following institutions: CTSI, Methodist Le Bonheur Healthcare, the Med, and/or UT Medical Group, Inc. These activities include identification of subjects through review of their medical records; recruitment of subjects; consent of subjects; performance of screening procedures; interventions or interactions with subjects; or collection of private information about subjects. If none of the activities described will occur at any of these locations, you do not need to complete this section of the application.

- CTSI Clinical Research Unit- Risa Ramsey, PhD, MBA, RN **and** Kathleen A Pitts, RN
- Methodist Le Bonheur Healthcare - Rexann G. Pickering, PhD, RN
- The Med - Maria van Werkhoven, BVM, FACHE
- UT Medical Group, Inc. - Derita Bran, RN, CCRC

Responding to Recommendations / Provisos

When responding to recommendations or provisos from the IRB office, be sure to use the PI response form located under your 'Incomplete Tasks' tab on your iMedRIS home screen to address any queries or revision requests made by the IRB. **Do not** submit a new application or a Form 2 (Application for Revision) to respond to recommendations or provisos. And don't forget that you may contact the IRB office (448-4824) should you have any questions!

Revising Project Descriptors and Consent Forms

You can show changes in documents when responding to recommendations, provisos, or submitting a Form 2 in one of two ways now:

1. You can use iMedRIS to create a new version of project descriptors or of a consent form by “checking it out” of the system, changing that document on your desktop, saving the changes, and “checking it back in” to iMedRIS. Using this option, you do not have to highlight or track any changes; simply change the document and iMedRIS will remember the changes once it is uploaded back into the system. The important thing to remember here is that you have to make changes to the exact document that you check out and re-upload into the system. Using this option, you do not have to submit a highlighted/tracked copy and a clean copy every time you make a change.
2. You can choose to submit both a highlighted and a clean copy of project descriptors/consent forms in response to recommendations, provisos, or when submitting a Form 2. Please be aware that tracked changes must be visible on one of the documents so that they can be reviewed at the time the PI response, amendment, or revision is submitted for IRB review. The final approved version of the project descriptors and all approved, stamped consent forms must be free of tracked changes so that the IRB approval stamp may be applied, so remember to attach a clean copy of each revised document as well- you must accept all tracked changes throughout the document and save before attaching the clean copy. If you see “marked” versions of stamped documents in your approved studies, please contact the IRB Analyst promptly.

Required Signatures

Don’t forget that before you submit an application or response to the IRB you will have to route the submission to the appropriate key study personnel for them to apply their electronic signature before it is sent to the IRB. See table below for the required signatures.

<u>Type of Submission</u>	<u>Required Signature(s)</u>
Registrations (converting a paper study to an iMedRIS study)	Principal Investigator (PI) only
Response to recommendations/provisos for any submission form	PI only
New Application	PI, all Co/Sub-Investigators, Hospital Service Chief (for Med studies), & Dept. Chair if PI is a UT employee/faculty member
Revisions (Form 2), Continuation (Form 3), Adverse Events (Form 4x), etc.	PI or Co/Sub-investigator

