

First Steps – Intro to an IRB Submission

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IRB Training

All investigators and key personnel must complete CITI training and Conflict of Interest (COI) disclosure in COI-Smart before IRB submission

- **CITI Training**
- Training is completed online via the CITI website: www.citiprogram.org
- Enrolling in required courses:
 - Go to Question #1 Human Subjects Research Course Enrollment and select a Learners Group from the options provided. Depending on your area of research, select either Biomedical Research Certification or Social & Behavioral Certification
 - If you are completing Biomedical Certification, you must also select Good Clinical Practice (GCP) in Question #2. GCP is suggested, but not mandated, for Sociobehavioral research.
 - If you have completed CITI training at a different institution, log on and associate your profile with Thomas Jefferson University
- The Basic training is required only once; however, a refresher course is required every 3 years
 - Check the “IRB Training List (PDF)” for your certification status http://www.jefferson.edu/university/human_research/irb-reference-documents.html
- **Conflict of Interest (COI) Disclosure**
 - Jefferson students - contact JeffCOISmart@jefferson.edu. Explain that you are a SKMC student on a protocol and need to submit a COI disclosure. Provide your campus key. You will receive an email from the COI-SMART System with instructions.
 - Jefferson employees - submit your COI disclosure at <https://jefferson.coi-smart.com>. If you have not used COI-Smart before, contact JeffCOISmart@jefferson.edu to be registered.

Contact information: Adam Nester Phone: (215) 955-9050

IRB Submissions

IMPORTANT: The IRB process may take a few weeks, so start this process early. The Principal Investigator must sign IRB forms. CITI training and COI must be completed prior to submitting.

NEW STUDIES

- Determine which category your research falls in and what forms to use
 - An overview of necessary forms is available at http://www.jefferson.edu/university/human_research/forms.html under the heading “Guidance Documents” and subheading “OVERVIEW OF IRB SUBMISSIONS FOR NEW STUDIES”. Paperwork differs depending on whether studies are categorized as exempt, expedited, or full review as detailed in this form.
 - Most student studies are retrospective in nature and would be considered expedited, which would require Form OHR 1, OHR 4 and/or 15 (depending on whether data and/or tissue are to be collected), AND OHR 3 OR 5 (depending on whether Protected Health Information [PHI] is to be used).
- All studies require a faculty member to be principal investigator, unless the study is being conducted in a hospital department where the hospital employee may serve as PI. Students can be listed as key personnel.
- All submissions must be uploaded to the **IRB Portal** in order to be processed; select submissions may also require the creation of a **JeffTrial** record (see below for more details). The Portal and JeffTrial are behind the Jefferson firewall. This means that they may be accessed from a Jefferson computer that is inside the firewall or from an external computer via the remote access portal (RAP).
 - **Studies Requiring a JeffTrial Record:**
 - The following types of studies require a JeffTrial Record:
 - **All** trials with a **written** consent form
 - **Oncology trials** with **verbal consent**
 - Note: **Rothman** Institute trials have separate criteria. They are only required to be in JeffTrial, if there is EPIC-billable activity in the trial
 - JeffTrial Database may be accessed via: <https://jefftrial.tjh.tju.edu/login/>
 - For assistance with JeffTrial, contact JCRI@jefferson.edu
 - Create a transaction record in JeffTrial:
 - On the menu bar, select protocols and then PC console.
 - On the horizontal tab, click the drop down menu under “select protocol” if the protocol already exists.
 - Select “reviews” on the horizontal tab.
 - Click IRB on the vertical tab.
 - Add “submit date,” “review reason,” and add a brief note in the summary.
 - Click “submit and close.”
 - Note: Study team is responsible for entering ALL IRB review details

- **IRB Portal**
 - IRB Portal may be accessed via:
<https://black.kcc.tju.edu/legacytrialapps/esubmission/>
 - Submit electronic IRB forms through the Portal available on campus or through RAP.
 - Create IRB application. Select application type (new study, continuing review, amendment, etc.).
 - Enter the 4 digit protocol number or from JeffTrial (if applicable), or manually enter information as required.
 - Upload all required IRB forms. IRB forms are located on the OHR website:
http://www.jefferson.edu/university/human_research/forms.html

- **Paper Forms May Be Required**
 - Paper submissions are required for:
 - Full reviews: 3 collated packets of complete submission (please double-side copies)
 - OHR-12B (Adding study personnel): 1 copy
 - Paper submissions are NOT required for exempt and expedited IRB submissions
 - Deliver paper copies to the OHR office, JAH #M-34

ACTIVE STUDIES

- Adding personnel:
 - Submit an OHR-12B form to add new study personnel. This form must be dropped off at the IRB office
 - Note: Study team is responsible for documenting ALL staff additions and stop dates in JeffTrial

- Submitting an Amendment (any modification to an existing study):
 - Submit an OHR-12 form to add an amendment to research protocol
 - All submissions must be uploaded to the IRB Portal in order to be processed
 - Paper submissions are required in addition to portal uploads for studies considered in need of full review; drop off 1 paper copy to the Office of Human Research
 - Note: Study team is responsible for All JeffTrial updates (continuing reviews, amendments, final reports) must be entered with appropriate dates

IRB RESOURCES

- Please visit the OHR homepage for CITI training resources, additional submission guidance, and OHR personnel contact information:
http://www.jefferson.edu/university/human_research.html