USF Research Integrity and Compliance
Step by Step: Submitting to the IRB

Step 1: If you do not already have one, you will need to obtain an account to use the ARC on-line submission system. Go to the ARC Web Site https://ARC.research.usf.edu/prod/ and click "Register Here" on the right side of the page. Your new account will be activated within two business days and you will receive an email containing your account information.

Step 2: All study team members must complete the required human subject protection education. The courses may be accessed at: https://www.citiprogram.org/

Acceptable online courses include:

- Biomedical Investigators and Key Personnel
- Social/Behavioral Investigators and Key Personnel
- IRB Member
- Spanish Language Biomedical Modules
- VA Human Subjects Protection and Good Clinical Practices

The ARC system does not prohibit you from submitting an application if education is not complete, however, final approval will not be issued until all study team members have current education.

Step 3: Log in to the ARC system and complete your application.

- Upload appropriate supporting documentation as requested (protocol document, survey instruments, informed consents, etc.). If you are a student and are unsure how to respond to a particular question, you should first consult with your faculty advisor. Sample consent forms may be found at: https://eirb.research.usf.edu/Prod/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5BOID%5BEC93D33F0BFE684E9BABF4F231A0A81F%5D%5D
- Make sure that you select the appropriate department in section 2.2.2 of the application which will provide the approval to proceed. If you are a student and do not have a specific department affiliation, choose the department to which your faculty advisor is assigned.
- Remember, if someone on the study team is also a designated approver for your department, he or she cannot issue approval for your study. Most departments have an alternate approver. The ARC Help Desk can help identify an alternate, if needed.
- You must upload a protocol document in section 2.1.3. The Protocol Guidelines document linked in question 2.1.3 of the application provides additional guidance.
- Ensure that the information in your protocol, consent and application are consistent.
- Once your application is complete, formally submit it by clicking "Submit Study" under "My Activities" on the left side of your main study workspace.

Step 4: The study is automatically routed to the appropriate Department and/or Affiliate reviewer.

Step 5: Once the study is approved by the Department/Affiliate reviewer, it will be automatically routed to the IRB for review. An IRB staff member will complete a pre-review of your submission and send a request for revisions or information via the application. You will receive an email notifying you if further action is needed.

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Step 6: Respond to all staff comments and update the application as necessary. The system will not let you submit the application unless you type something in response to the comment box. If a revision to the application is requested, make sure that you update the actual application, in addition to responding to the comment, so that your regulatory file is accurate.

Step 7: Once you have responded to all requested revisions, be sure to formally submit the submission to the IRB. This is a two-step process. You will first click "Save" (be sure to do so before you exit the system), and then you must go back to the main study page and click "Submit Requested Revisions or Information" under "My Activities" on the left side of your main study workspace.

Study 8: Once all revisions are completed, the IRB staff member will forward the submission to the IRB Chairperson (Expedited or Exempt review) or assign it to the next full committee meeting agenda (Full Board review). The Chairperson or Board may request additional information or revisions.

Step 9: Once your study is approved by the Chairperson or Board, you will receive a formal approval letter accessible to view or print from the main study page. You are now able to begin your research. The official IRB stamped informed consent/assent document(s) may be accessed under the "Attachments" tab on the main study page. Please note, these consent/assent document(s) are only valid during the approval period indicated at the top of the form(s). If your study was reviewed as Expedited or Full Board, it will be approved for one year unless otherwise noted. If your study was determined exempt, the approval is for five years.

Important to note after initial approval:

- Make sure that you submit an amendment via ARC *before* changing any approved study activities or staff.
- If your study was reviewed as Expedited or Full Board and you wish to continue study activities after your initial approval period (typically one year), you **must** submit a continuing review application 45 days prior to the study expiration date. If you submit the continuing review too close to the expiration date, your study may not be reviewed on time and will expire, causing research activity to be suspended until the study may be approved and issued new approval dates.
- Once you have completed all study activities, you must submit a final review to formally close the study with the IRB.

Useful Links and Information

ARC Help Desk Contact: RSCH-arc@usf.edu or 813-974-2880

ARC Home Page: https://eirb.research.usf.edu/Prod
(select "ARC training materials" on the left side of the page for more training documents)

USF Human Research Protection Program (IRB) Contact: 813-974-5638
Web Site: http://www.research.usf.edu/dric/hrpp/default.asp

IRB Policies and Procedures: http://www.research.usf.edu/dric/hrpp/policy-procedure.asp

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