10 Steps To Get Emory IRB Approval

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Overview

Step 1: Request an eIRB Account (online eIRB Training highly recommended)
Step 2: Get CITI Certified
Step 3: Find a Faculty Advisor*
Step 4: Create Protocol & Consents
Step 5: Obtain Official Site Permission*
Step 6: Obtain a Letter of Cultural Context*
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*if applicable

Step 1. Request an eIRB* Account & Take eIRB Training

- ALL Emory study staff members need an eIRB account.
- Request a New eIRB account following the instructions on the "How To's" page at: http://www.irb.emory.edu/eirb/index.html
- A series of recommended instructional videos can be found on the IRB's website at: http://www.irb.emory.edu/eirb/index.html

*eIRB is the online electronic IRB application system used by the Emory IRB.

Step 2. Get CITI* Certified

- Go to www.citiprogram.org to take an online human subjects protection course
- Certification is valid for 2 years
- Choose either the Biomedical or Social-Behavioral course, whichever best matches your research field

Step 3. Find a Faculty Advisor:

- Undergraduate and non-faculty SOM investigators (including residents and fellows) cannot serve as Principal Investigators
- Faculty advisor will be ultimately be responsible for supervising the conduct of the study

*CITI is hosted at the U. of Miami. If you have any difficulty accessing it, please contact CITI program.

Step 4. Create your Protocol & Consents:

Templates for both can be found on the Emory Forms page:
http://www.irb.emory.edu/forms/index.html

- Protocol & Lay Summary format can be found under "New Study Guidance: http://www.irb.emory.edu/forms/new.html
- Consent templates and consent-related information found under "Consent Toolkit": http://www.irb.emory.edu/forms/index.html

Step 5. Official site or data permission:

- If the study will take place somewhere other than Emory, but the site is not itself engaged in the research, please contact **the study site** and obtain an official permission letter to conduct research there.
- If the PI will access a **database which is NOT publicly available**, please contact **the owner of the database** and obtain an official permission letter.

Step 6. Letter of cultural context:

- Only required if the study will take place outside the US
- Should confirm the study procedures consent are culturally appropriate for the study population
- Can be from the host agency, or from an Emory or other investigator with experience in conducting research in the study site
- Ideally, the letter should come from a third party, not a member of the study staff or the faculty advisor

Step 7. Complete the eIRB application:

- The SmartForm will guide you through the required sections for your study depending
- Using the “Continue” button will automatically save your work as you move to the next page
- Required questions are marked like so*
- Make sure to upload all study documents, such as protocol, consents, assents, questionnaires, flyers, site permissions, etc.
- Contact the IRB if you unsure about a question

Step 8. Submit Your Application:

Before the *PI* clicks the *submit* button, check the Required Reviews page.

1. **Departmental/Faculty Advisor Review:**
   Please be sure the PI fills out this part correctly in the eIRB application
   - If PI is a student, the study will need to be reviewed and approved **by the faculty advisor** before the IRB can review the study.
     - If you cannot find your advisor's name in eIRB, send an email to irb@emory.edu to have them added to the system
   - If PI is faculty, this review will be performed by a designated Departmental Reviewer
2. **Ancillary Committees**

   Other groups, such as the Radiation Safety Committee, may need to review certain aspects of the study before the IRB grants final approval. This can be done concurrently with IRB review.

Step 9. Respond to Changes Requested by the IRB:

- 99% of submitted studies require changes before final approval, sometimes a few rounds of changes
- The faster the IRB receives your response the sooner the study can be approved.

Step 10. Receive IRB Approval

Once your study receives IRB approval, the PI, co-Is, and coordinators will receive an e-mail notification through eIRB.

Who Should be the Principal Investigator (PI)?

<table>
<tr><th colspan="3">Main Researcher</th><th>PI</th><th>CO-I</th><th>Required Review</th></tr>
<tr><td colspan="3">Emory Faculty</td><td>Self</td><td>Whoever is working with you</td><td>Dept.</td></tr>
<tr><td rowspan="4">Student/ Intern/ Resident/ Trainee</td><td colspan="2">Emory College</td><td rowspan="2">Faculty Advisor</td><td rowspan="2">Self</td><td rowspan="2">Dept.</td></tr>
<tr><td colspan="2">SOM</td></tr>
<tr><td rowspan="2">Grad. School</td><td>Arts & Sciences</td><td rowspan="2">Self</td><td>Faculty Advisor</td><td rowspan="2">Faculty Advisor</td></tr>
<tr><td>School of Public Health</td><td>Whoever is working with you (need not be Faculty Advisor)</td></tr>
</table>

Pay Attention to the ROLES

Requirements	Roles
•eIRB account	All EMORY personnel
•Emory CITI training	ALL personnel (including non-Emory personnel)
•Create study protocol	PI/co-Is/ coordinators
•Obtain study site permission	PI/co-Is/ coordinators
•Fill in eIRB application	PI/co-Is/ coordinators
•SUBMIT eIRB application*	PI
•Respond to and submit IRB requested changes	PI/co-Is/ coordinators
•Receive the IRB approval	PI/co-Is/ coordinators

*: Only PI is able to submit the application. PI, co-Is, and coordinators will be able to **edit** the application. The other study staff can only **view** the application

Where to Find Samples or Templates ?

The IRB Forms Page: http://www.irb.emory.edu/forms/index.html

What Is the IRB Looking for?

Two Main Documents:

1. **Protocol:**
   - The purpose of the protocol is to inform the reviewer **EXACTLY** of the research method, especially parts related to human subjects.
   - Use the Emory IRB template on the "New Study Guidance" page at: http://www.irb.emory.edu/forms/new.html

2. **Subject Informed Consents:**
   - Certain language **MUST** be used for the consent documents. Please use the Emory IRB templates to create the consents.
   - Emory IRB consent templates are located on the Consent Toolkit page at: http://www.irb.emory.edu/forms/index.html

Other Important Documents:

eIRB application, funding documents, questionnaires, flyers, site permissions, CITI cert. etc.

Emory IRB's Top 3 Suggestions

1. Start early:

Studies are reviewed on the rolling basis. It takes **AT LEAST 3 wks**, **and on average 7 wks** to get IRB approval. If the study needs full board review*, it may take even longer.

2. Watch the eIRB training videos:

- In the IRB world, we can't help using IRB language. Therefore, it is a very important class to help you know the basic IRB language and navigate the eIRB system.

- The videos can be found on the IRB's website at: http://www.irb.emory.edu/eirb/index.html

3. Check your eIRB account after a few business days:

If the account has not activated within a week, call the Emory Helpdesk at 404-727-7777 or contact the IRB at 404-712-0720 or irb@emory.edu.

*Required for more than minimal risk studies such clinical trials, interventional projects with vulnerable populations, psychological studies using deception, etc.