

*OK! YOU NEED IRB APPROVAL.
HOW DO YOU GET IT?*

**10 steps
to get Emory IRB approval**

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1. Create eIRB^β account & take eIRB training:

(1) Create eIRB accounts

- Go to <https://www.app.emory.edu/helpdesk/>
- Login using your Emory NetID and password
- Click “New Support Request” in the center of the page
- In the “Summary” box, choose “eResearch”, then “ “eIRB – New Account”
- In the “Enter Details” box, provide the details of your request for an eIRB account.
- Click the “Submit” button to send in your request

(2) ALL Emory study staff members need an eIRB account.

(3) Under “Training”, please sign up for an eIRB training class:

<http://www.irb.emory.edu/researchers/eresearch/eresearch.cfm#train>

2. Get CITI^ω certificate:

(1) Go to www.citiprogram.org to take an online human subject protection education program and then get the certificate which is valid for 2yrs.

(2) Save the electronic CITI report in your folder for uploading in the eIRB application.

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

ω: CITI is hosted at the U. of Miami. If you have any difficulty access it, please contact CITI program.

Who should be the Principal Investigator (PI)?

Main Researcher		PI	CO-I	Require Review ^Ω
Emory Faculty		Faculty	NA	Department
Students/ Interns/ Residents/ Trainees	Emory College	Faculty Advisor	Students/ Interns/ Residents	Department
	SOM ^Σ			
	Grad. School	Graduate Student	Co-I= Faculty Advisor AND Faculty Advisor = Faculty Advisor	Faculty Advisor
not Grad. School A & S	Faculty Advisor = Faculty Advisor			

Ω: Please read step 8-2 for details.

Σ: Few departments in SOM allow Students/ Interns/ Residents to be PI. Please check with your dept. for details.

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3. Faculty Advisor:

- (1) If you are a student, find an Emory faculty to be your advisor.
- (2) Faculty advisor will be responsible and supervising the study.

4. Create your Protocol & Lay Summary:

- (1) Protocol & Lay Summary format can be found under “Other Researcher Tools” at: <http://www.irb.emory.edu/researchers/formstools/formstools.cfm#oth>
- (2) Some studies need to provide **consent** documents; consent-related information including [Sample SHB Consent Forms](#) can be found under “Consent Toolkit” at: <http://www.irb.emory.edu/researchers/formstools/formstools.cfm#consent>

5. Official site permission:

- (1) If the study will take place somewhere other than Emory, please contact **the study site** and obtain an official permission letter.
- (2) 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.

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6. Letter of cultural context :

- (1) If the study will take place outside the US, a letter of cultural context with proper signature is required.
- (2) It should confirm that the study procedures and process of informed consent are culturally appropriate for the study population.
- (3) This letter can be from the host agency or from an Emory or other investigator with experience in conducting research in the study site.
- (4) To prevent the conflict of interest, this letter should come from the third party who is not one of the study members or the faculty advisor.

7. Fill out the eIRB application:

This eIRB application needs to be completely filled and documents uploaded, such as protocol, consents, assents, questionnaires, flyers, site permissions, CITI certificates, etc.

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8. Submit application: Before the PI clicks the submit button, 8-1 & 8-2 should have been done.

8-1 co-investigators accept their roles:

The PI/ coordinators need to notify the co-Is to accept their roles through eIRB system. The eIRB system will NOT automatically do it for you.

8-2 Required review:

Please be sure the PI fill out this part correctly in the eIRB application

- (1) If PI is a student[#], the study needs to be reviewed **by the faculty advisor** in eIRB; then the system will make it available to the IRB for action.
- (2) If PI is faculty, the study needs to be reviewed **by the departmental approver** in eIRB; then the system will make it available to the IRB for action.

[#]: According to Emory University policy, undergraduate and SOM students cannot be the PI. A faculty needs to be the PI and the undergraduate or SOM student should be listed as a co-I.

Pay attention to the ROLES

<u>Requirements</u>	<u>Roles</u>
•eIRB account*	All EMORY personnel
•CITI certificate	ALL personnel (including non-Emory personnel)
•Create study protocol	PI/co-Is/ coordinator
•Obtain study site permission	PI/co-Is/ coordinator
•Fill eIRB application	PI/co-Is/ coordinator
•Obtain department/ faculty advisor approval	PI/co-Is/ coordinator
• <u>SUBMIT eIRB application*</u>	<u>PI</u>
•Respond to IRB requested changes	PI/co-Is/ coordinator
•Receive the IRB approval	PI/co-Is/ coordinator

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

*: Only PI is able to submit the application.

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9. Respond to changes requested by the IRB:

- (1) Less than 1% of the IRB reviewed studies are not requested any changes by the Emory IRB.
- (2) The faster the IRB receives your response the sooner the study can be approved.



10. Receive the IRB approval

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

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^Ψ, it may take even longer.

2. Take an eIRB training class:

(1) 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.

(2) Under "Training", please find the next available class at:

<http://www.irb.emory.edu/researchers/eresearch/eresearch.cfm#train>

3. Check eIRB account once a week:

If the application does not move for a while, CALL the IRB office at: 404-712- 0720.

Ψ: Full board review: studies involving with vulnerable populations (and more than observation/ survey), more than minimal risk, deception, or clinical trial, etc.

What the Emory IRB reviewers are looking for?

Three Main Documents:

1. Lay summary:

- Using non-technical language to explain to the reviewer the general purpose and method of the study and to describe the study justification, the data collection activities and the analytical methods.
- Emory IRB lay summary guidance can be found under :
<http://www.irb.emory.edu/researchers/formstools/formstools.cfm#oth>

2. Protocol:

- The purpose of the protocol is to inform the reviewer **EXACTLY** of the research method, especially parts related to human subjects.
- Please create the protocol using the Emory IRB format:
<http://www.irb.emory.edu/researchers/formstools/formstools.cfm#oth>

3. Subject Informed Consents:

- Certain language **MUST** be used for the consent documents. Please use Emory IRB consent template and Emory IRB consent samples to create the consents.
- Emory IRB consent template: <http://www.irb.emory.edu/researchers/formstools/formstools.cfm#consent>
- Emory IRB consent samples: http://www.irb.emory.edu/researchers/socio/socio_consents.cfm

Other Important Documents:

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

Emory IRB Contact Information I

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Efficient Ways to Reach the IRB Staff:

1st: e-mail

2nd: phone calls & voice message

3rd: in person **IRB Helpdesk**: Fri. 11 am - 1 pm @ the IRB office

in person **SHB DUC Helpdesk**: 2nd and 4th Fri ea. month, 11 am - 1 pm @
the "DUC" (Not held in May, June or July)

How to request an eIRB password reset

1. Go to <https://www.app.emory.edu/helpdesk/>
2. Login using your Emory NetID and password
3. If you do not know your Emory NetID and password, please contact the University Helpdesk at 404-727-7777
4. Click “New Support Request” in the center of the page
5. In the “Summary” box, choose “eResearch”, then “eIRB – Password Reset”
6. In the “Enter Details” box, provide the details of your request for a password reset
7. Click the “Submit” button to send in your request

How to request an eIRB account for Employees/Students

Emory employees/students with an Emory Account:

1. Go to <https://www.app.emory.edu/helpdesk/>
2. Login using your Emory NetID and password
3. Click “New Support Request” in the center of the page
4. In the “Summary” box, choose “eResearch”, then “eIRB – New Account”
5. In the “Enter Details” box, provide the details of your request for an eIRB account.
6. Click the “Submit” button to send in your request

Please note that it can take 2 business days to establish your eIRB account once your request has been received. When your account has been established you will be contacted with the login information.

Employees/students without an Emory Account:

After you attend employee orientation you can obtain an Emory NetID. Once you have an Emory NetID, follow the above steps for Emory employees/students with an Emory Account.