



Tips for a Complete Submission in eIRB

Emory IRB Webinar – 8/12/2021

[Jackson Parker, CIP](#)

Senior Research Protocol Analyst

[Julie Martin, RN, MEd., CIP](#)

Assistant Director, Reliance Team



Topics to Cover

Website Resources

Initial Review

Modifications

Continuing Reviews

External IRBs

Grants for Multi-Site Studies

Q/A



Website Highlights

- About (IRB contact information)
- Policies and Procedures
- Forms & Guidance (Protocol and Consent form templates) and much more
- Education (CITI requirements)
- eIRB (page level help and videos for new eIRB system)

Submission Guidance

- Protocol templates
- Guidance documents
- Checklists for new study submissions (Device checklist, IND Exemption checklist...)
- Mobile Medical App worksheet

• ***IMPORTANT*** - Always download templates from website to ensure you are using current versions

The screenshot shows the eIRB website's 'Submission Guidance' page. The navigation bar at the top includes links for HOME, ABOUT, POLICIES, FORMS & GUIDANCE (which is highlighted), EDUCATION, EIRB, MEMBERS, and PARTICIPANTS. A left sidebar contains a list of links: Does My Project Need IRB Review?, Investigator Initiated? Start Here!, COVID-19 Guidance, Treating a Patient with an FDA Unapproved Drug or Device, Study Submission Guidance (highlighted), Consent Toolkit, Revised Common Rule at Emory, Waivers, Reportable New Information, Sponsor Investigator Studies, Sociobehavioral Research\Minimal Risk Studies, Clinical Study Initiation and Tools, International Research, Collaborative Research/Single IRBs/Reliance Agreements, Certificates of Confidentiality, Data Sharing Certifications (NIH), Frequently Asked Questions, and Atlanta VA Health Care System Studies. The main content area has a breadcrumb trail: Home » Forms & Guidance » Study Submission Guidance. Below this is the title 'Study Submission Guidance' in orange. The text reads: 'Ready to submit in eIRB? Make eIRB work for you! See detailed help on all smartform questions here: eIRB Smartform Help But first... Prepare using the required templates, tools, and guidance below.' A list of links follows, each in a grey box with blue text and a right-pointing arrow: Initial Submission Decision Charts », Lay Summary Requirements », Protocol Templates and Protocol Checklists - Required », Informed Consent Forms, Assents and HIPAA authorizations », Community Engagement for Subject Recruitment », Advertisement, Recruitment and Compensation », "Costs" and "In Case of Injury" Policies », DSMP, Site Monitoring and DSMB Guidance », Data Security and Mobile (Medical) Apps », Department of Defense, Department of Energy, and ICH-GCP Checklists », and Clinical Study Tools, Templates and Checklists ».

HOME ABOUT POLICIES FORMS & GUIDANCE EDUCATION EIRB MEMBERS PARTICIPANTS

Does My Project Need IRB Review?

Investigator Initiated? Start Here!

COVID-19 Guidance

Treating a Patient with an FDA Unapproved Drug or Device

Study Submission Guidance

Consent Toolkit

Revised Common Rule at Emory

Waivers

Reportable New Information

Sponsor Investigator Studies

Sociobehavioral Research\Minimal Risk Studies

Clinical Study Initiation and Tools

International Research

Collaborative Research/Single IRBs/Reliance Agreements

Certificates of Confidentiality

Data Sharing Certifications (NIH)

Frequently Asked Questions

Atlanta VA Health Care System Studies

Home » Forms & Guidance » Study Submission Guidance

Study Submission Guidance

Ready to submit in eIRB?

Make eIRB work for you! See detailed help on all smartform questions here:

[eIRB Smartform Help](#)

But first...

Prepare using the required templates, tools, and guidance below.

[Initial Submission Decision Charts »](#)

[Lay Summary Requirements »](#)

[Protocol Templates and Protocol Checklists - Required »](#)

[Informed Consent Forms, Assents and HIPAA authorizations »](#)

[Community Engagement for Subject Recruitment »](#)

[Advertisement, Recruitment and Compensation »](#)

["Costs" and "In Case of Injury" Policies »](#)

[DSMP, Site Monitoring and DSMB Guidance »](#)

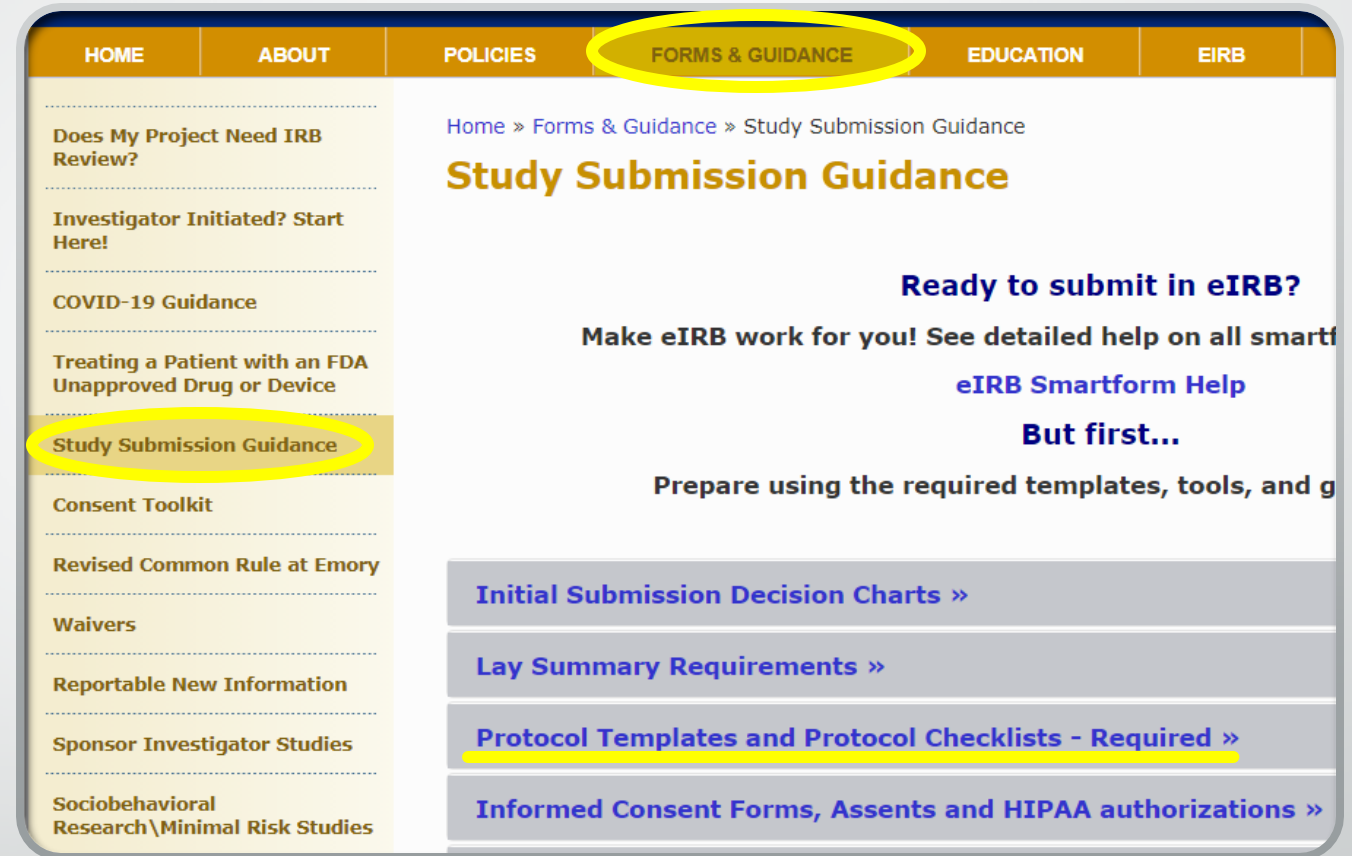
[Data Security and Mobile \(Medical\) Apps »](#)

[Department of Defense, Department of Energy, and ICH-GCP Checklists »](#)

[Clinical Study Tools, Templates and Checklists »](#)

Required Protocol Templates & Checklists

- Required for all new study submissions
- Templates specific to study type
 - Biomedical
 - Sociobehavioral
 - Chart Review
 - Registry, Repository, or Database
 - Secondary Data/Biospecimen Analysis
 - Supplement to Sponsor Protocol





Consent Toolkit

Informed Consent Form Templates

- Biomedical
- Sociobehavioral
- Verbal
- Assent
- Screening
- Modular language

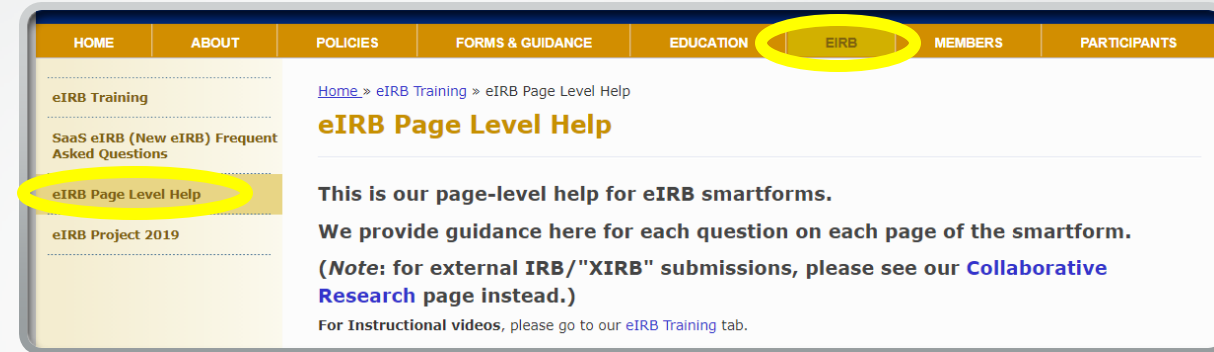
Guidance

- Documentation of informed consent
- e-Consent
- Short forms
- Interpreters
- Consent for screening

eIRB

Page Level Help

- The best way to ensure successful submissions
- Access through “eIRB” tab
- Specific guidance on every smartform question



For page level help select the links below for each application:

- [New Study Submission](#)
- [Continuing Review](#)
- [Modifications](#)
- [Reportable New Information \(RNI\)](#)
- [Study Closeout](#)

Required CITI Training

HOME ABOUT POLICIES FORMS & GUIDANCE **EDUCATION** EIRB

Training

Courses

HIPAA

Clinical Research Training (formerly Intro to Clinical Research/Key Concepts)

CITI Training

Past News and Email Blasts

Outreach & Help Clinics

Webinars

Home » Training » Courses » CITI Training

CITI Training


Latest News...

- eIRB can now display CITI training records for Emory research team members!
- This saves lots of time that IRB staff can use for other tasks, but only when it works

Are your or a team member's CITI records not displaying in eIRB? Here's what to do

Resources:

Type of study and role	SHB CITI	Biomed CITI	Either
1. Biomedical research: coordinators and investigators with active roles (recruitment, interventions)		X	
2. Clinical study: personnel not responsible for study conduct <u>nor</u> interacting or intervening with subjects (e.g. data entry, statistician), and <u>all</u> personnel when the study is in data analysis only			X
3. FDA-regulated clinical trial		Biomed CITI plus other requirements, including "Group 5" ICH-GCP module. See OCR Clinical Research Training page (need netID to access)	
4. Sociobehavioral study related to clinical care (e.g. only quality of life measures, or a study of novel consent methods...), with no physical interventions			X
5. Chart Reviews (a.k.a. medical record reviews)			X
6. Secondary data or specimen analyses, repositories, registry studies			X
7. Psychology studies, any socio-behavioral studies involving deception, or child behavior studies with no biomedical procedures	X		
8. Sociobehavioral studies that involve biomedical procedures, e.g. fMRI, or saliva collection to study cortisol levels	X	Not required but recommended	
9. Purely observational studies of any kind (<u>no</u> study-driven procedures)			X
10. Public Health Studies (when none of the above categories apply)			X
11. NIH-funded clinical trials (per NIH definition)		Per above, plus GCP training every three years for the duration of the award (CITI Group 5 GCP satisfies this)	



Requirements
for Complete
Submission

Initial Review

Modifications

Continuing Reviews



Initial Review

Complete lay summary

Protocol

Funding information including EPEX number

Study Team Members (current CITI training for all)

Drug and device information if applicable (IB, device manual, exemption form, FDA letters)

Study documents (recruitment materials, surveys, questionnaires, etc.)

Informed consent forms

Completed HIPAA Waiver and Applicability Worksheet

Modifications – Other Parts Of The Study

Modification / Continuing Review / Study Closure

* What is the purpose of this submission?

- ☐ Continuing Review
- ☒ **Modification / Update**
- ☐ Modification and Continuing Review

i To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

Other parts of the study

Active Modification For This Study

- Select the appropriate type of modification
- Provide a detailed summary of what is changing
- Include sponsor communication with all protocol amendments, revised Investigator Brochures (IB), and other study-wide updates
- When submitting revised IBs that have implications for changes to the consent form, submit the revised consent in the same modification or it will receive pending approval.







Modifications – Other Parts Of The Study

- When making updates to Word documents we no longer need redlined copies.
- Use the “Update” button to upload a clean version of the revised document. This will allow us to see the changes that are being made.

Local Site Documents

1. **Consent forms:** (attach local consent/assent documents) ?

[+ Add](#)

	Document	Category	Date Modified	Document History
 Update	 Assent Form.docx(8.11.2021)	Consent Form	8/11/2021	History 
 Update	 Informed Consent Form.docx(8.11.2021)	Consent Form	8/11/2021	History 

Changes in PI

Select “Other Parts of the
Study”

If the PI is leaving Emory – see
page level help for
Modifications and complete
Emory PI Transition Form



If making changes to the PI and
other study team members,
select both options (Other Parts
of the Study **AND** Study Team
Member Information)

Modification

Please see the sections below for information and instructions

Modification to add or remove study team members »

Study team changes can be done as a stand-alone modification, as a combined modification for "Other parts of the study" as well, and/or as part of a Modification/Continuing Review (Mod/CR) combination. You indicate your choice on the first page of the Mod or Mod/CR form.

You may submit one "Study team member information" Modification *simultaneously* with one "Other parts of the study" modification or with one Mod/CR.

If you chose to add or remove study team members as part of a Mod/CR, it will delay the approval of the study team changes. If urgent, it would be better to submit a separate modification for the study team changes.

PI Changes: you will need to select "Other parts of the study" to have access to the first page of the submission where this information resides. If you are changing the PI **and** other team members, select both options ("Study team member information" and "Other parts of the study").

- If the PI is leaving/coming from another institution, **fill out this form only** when 1) taking or bringing IRB approved studies to/from the other institution, or 2) will remain engaged in research (with the other institution) to be able to continue the study at Emory/Other Institution or 3) if they are taking/bringing the study grant with them. Attach this form with your submission. Your analyst will let you know if you require an institutional agreement in these cases.

Pre-Review

Entered IRB: 7/23/2021 7:08 PM

Last updated: 8/3/2021 2:30 PM

Next Steps

[View Modification/CR](#)

[Printer Version](#)

[Assign Coordinator](#)

[Add Comment](#)

[Add Private Comment](#)

[View CITI Training](#)

Modifications – Study Team Members Only

List

List study team members being added/removed in the modification summary (these will not be listed in the acknowledgment letters sent)

Click

Click View CITI Training button

Provide

If not current, provide copies of current CITI certificates

Adding External Collaborators

Only add if Emory IRB will be reviewing for the collaborator(s) under a *Reliance Agreement*—requires advance notice, and Emory IRB may decline

Provide a Word document listing name(s), contact information, role on the study, *specific* research activities

Provide CITI training certificate(s)

Collaborator may not begin research activities until agreement is final and modification is approved

Continuing Reviews (CR's)

Submit

- Submit at least 45 days prior to expiration date, but less than 90

Provide

- Provide the most recent Safety Monitoring reports, if applicable

Confirm

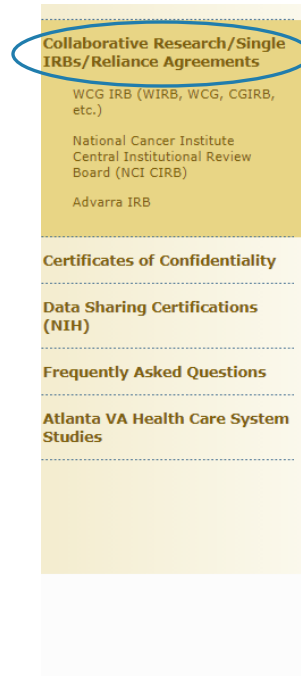
- Confirm CITI training in eIRB; provide CITI certificates if no data
- Confirm that site monitoring reports have been submitted to CTAC, if applicable

Check

- Review last year's continuing review (CR)
- Does information you are reporting (accrual numbers and milestones) align with previous CR? If not, RNI may be needed.

Using a Single IRB

- There is specific guidance for using WCG, Advarra, NCI CIRB IRBs
- Before asking the Emory IRB to rely on an external IRB other than these, review the guidance posted on our website under “The Reliance Process” tab.



While it is beneficial to use Single IRB Review for some studies, it does not mean that relying institutions no longer complete **any reviews** of the research when relying on a single IRB. It simply means the relying institution's IRB is not providing **approval** of the research. The work that would normally take place at the Emory IRB when reviewing and approving research for Emory study teams is simply replaced with **other** work by the Emory IRB to ensure all local requirements are met and execute reliance agreements.

For important guidance about the reliance process, click on the tabs below.

NOTE: For multisite, industry-sponsored trials, Emory uses commercial IRBs for review. See the left menu for submission guidance to Western IRB (WIRB) or Advarra IRB.

The Reliance Process »

To avoid delays in processing your submission, read the following information carefully.

- At this time the Emory IRB is not resourced to serve as the single IRB for multisite research studies, but we hope to be in the future.
 - We will agree to rely on AAHRPP accredited IRBs for non-exempt research when the use of a single IRB is required by the Revised Common Rule or the NIH Single IRB Mandate.
 - If you are planning to conduct research as a participating site in a multi-site federally funded study that has chosen to use a single IRB other than Emory, WIRB, Advarra or the NCI CIRB, **complete this document** and upload it in an XIRB submission.
1. Submit an XIRB study in eIRB once the study is approved by the reviewing IRB. **Use this guidance document** to complete the smart form

Reliance Tips

Collaborating on Federal Grants

Before submitting a grant that will require use of a single IRB, email Julie Martin to discuss IRB options.
Julie.t.martin@emory.edu



The Emory IRB is not yet resourced to serve as the single IRB for multiple enrolling sites.



If collaborating with researchers at other institutions and want to rely on another academic IRB, note that Emory primarily relies on AAHRPP-accredited IRBs.

Questions?
Thank you for
your time!

