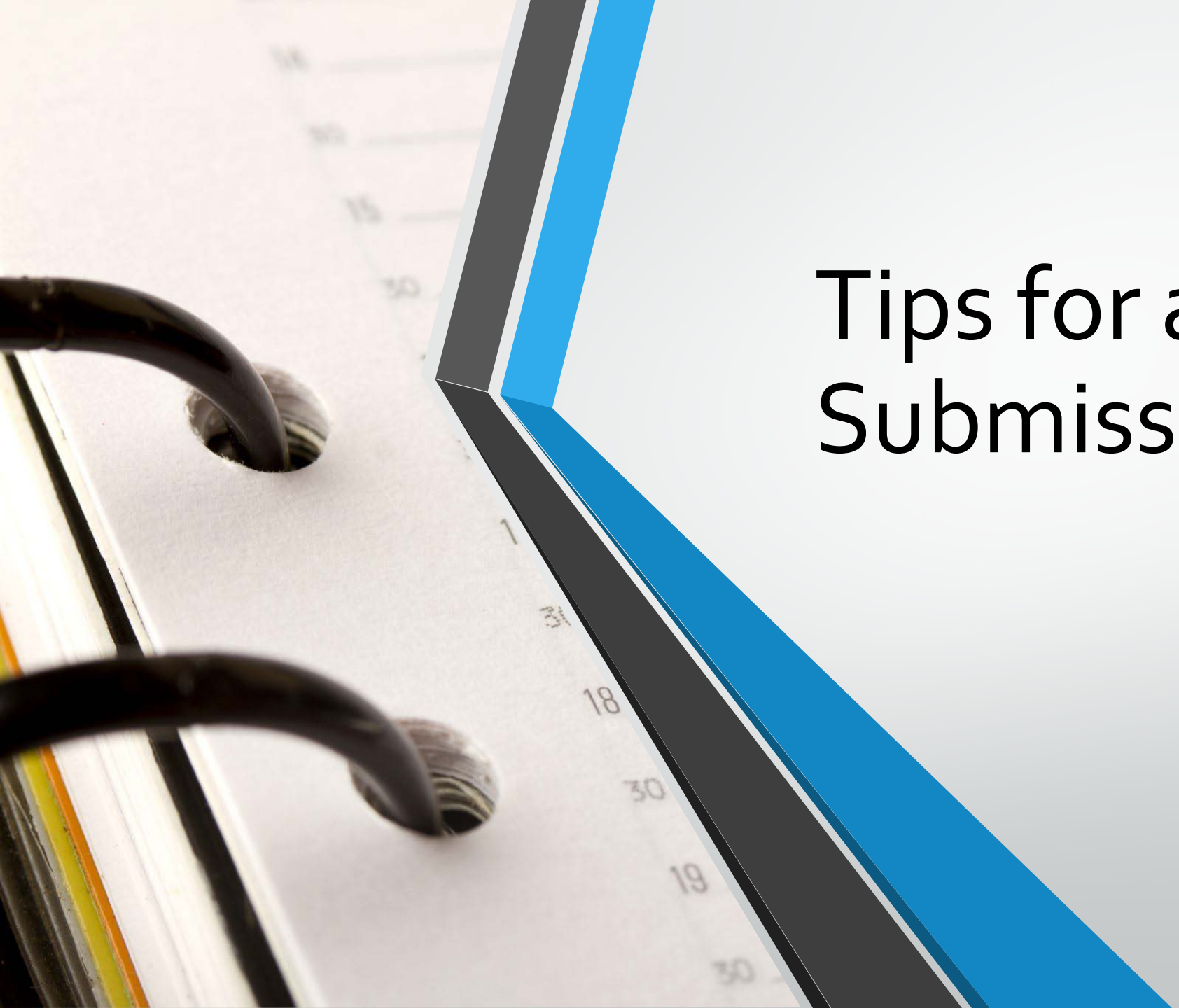


Tips for a Complete Submission in eIRB

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)

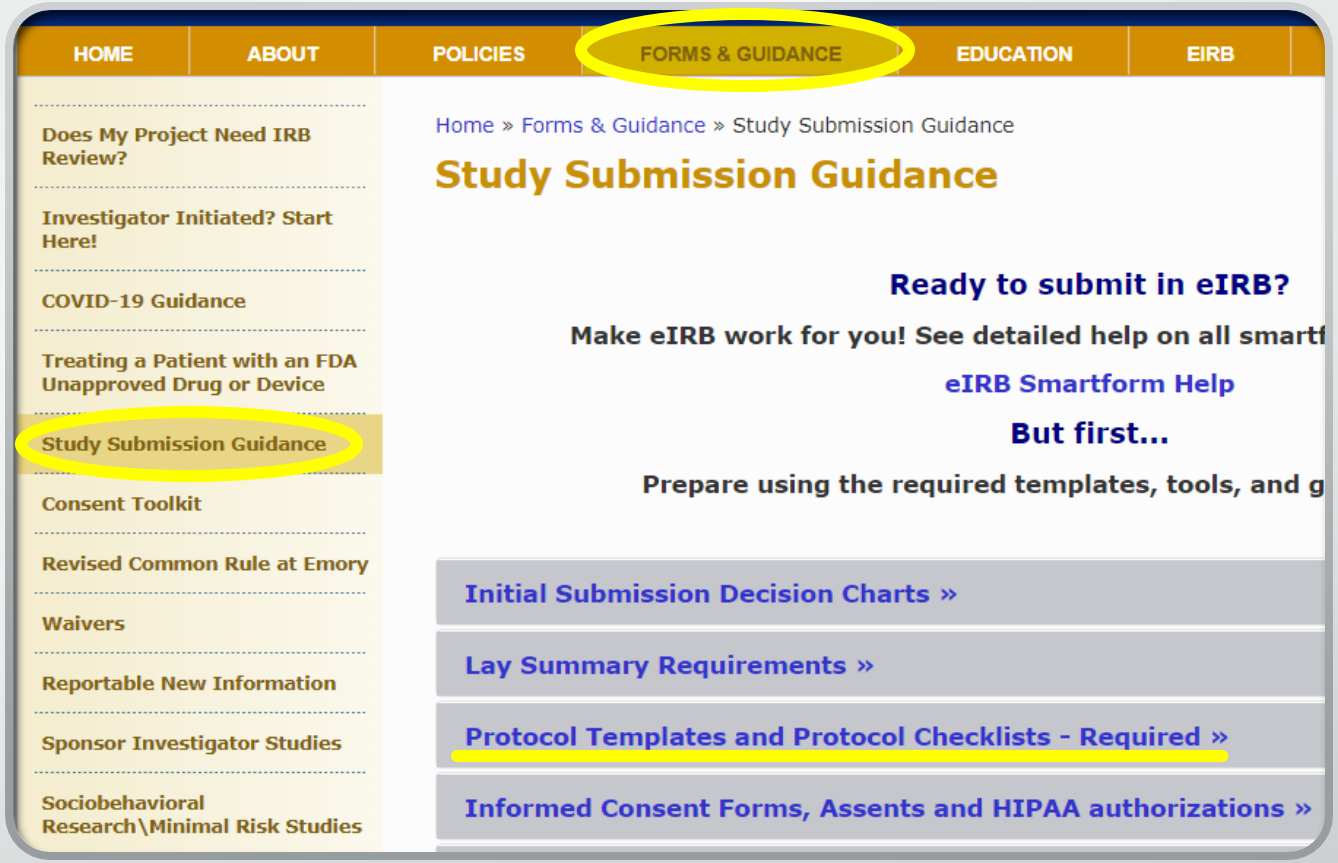
Submission Guidance

- 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

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

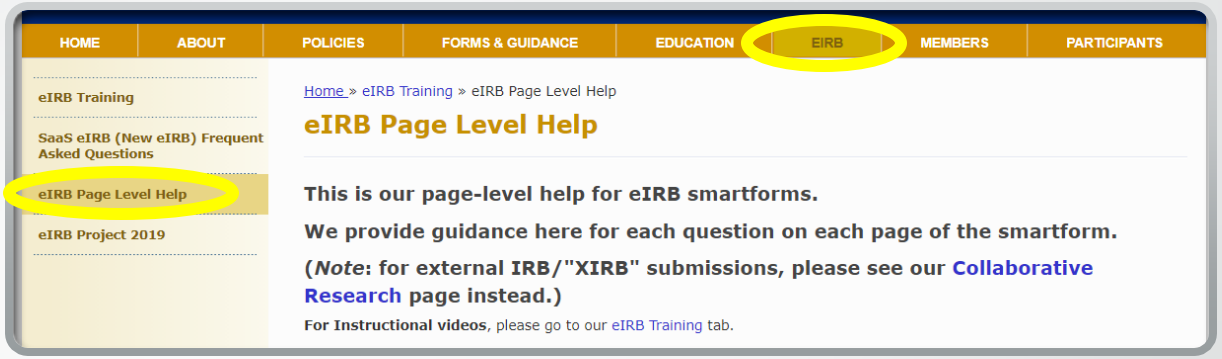
Informed Consent Form Templates

- 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

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 nor interacting or intervening with subjects (e.g. data entry, statistician), and all 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 (no 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)		

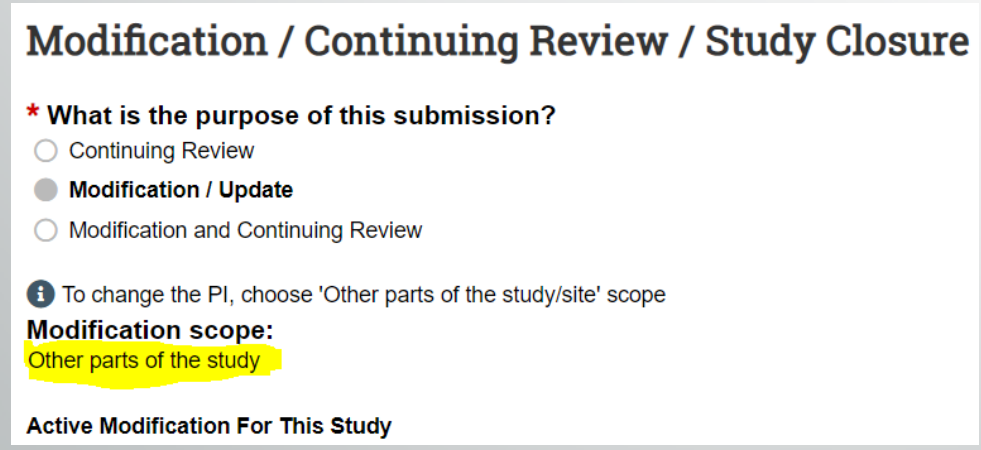
Requirements for Complete Submission

- 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

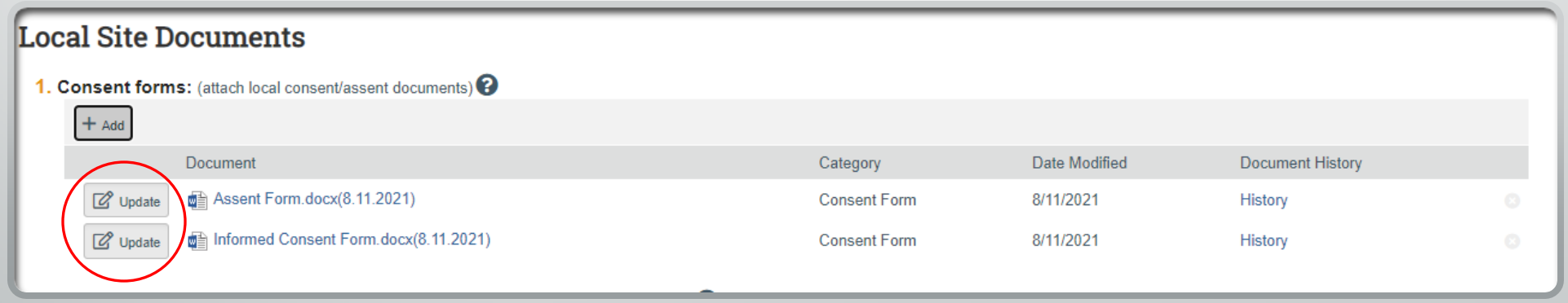
Modifications – Other Parts Of The Study



- 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.



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 »

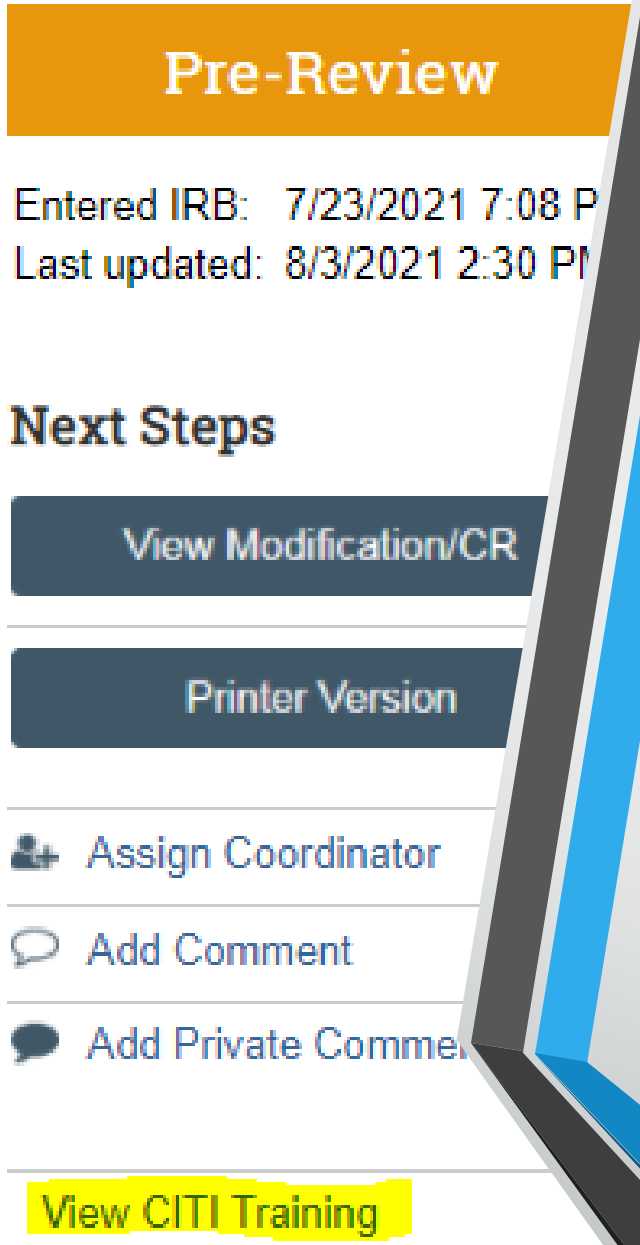
Study team changes can be done as a stand-alone modification, as a combined modification for "Other parts of the study" as well, and/or as part of a Modification/Continuing Review (Mod/CR) combination. You indicate your choice on the first page of the Mod or Mod/CR form.

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.



Modifications – Study Team Members Only

List	Click	Provide
List study team members being added/removed in the modification summary (these will not be listed in the acknowledgment letters sent)	Click View CITI Training button	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

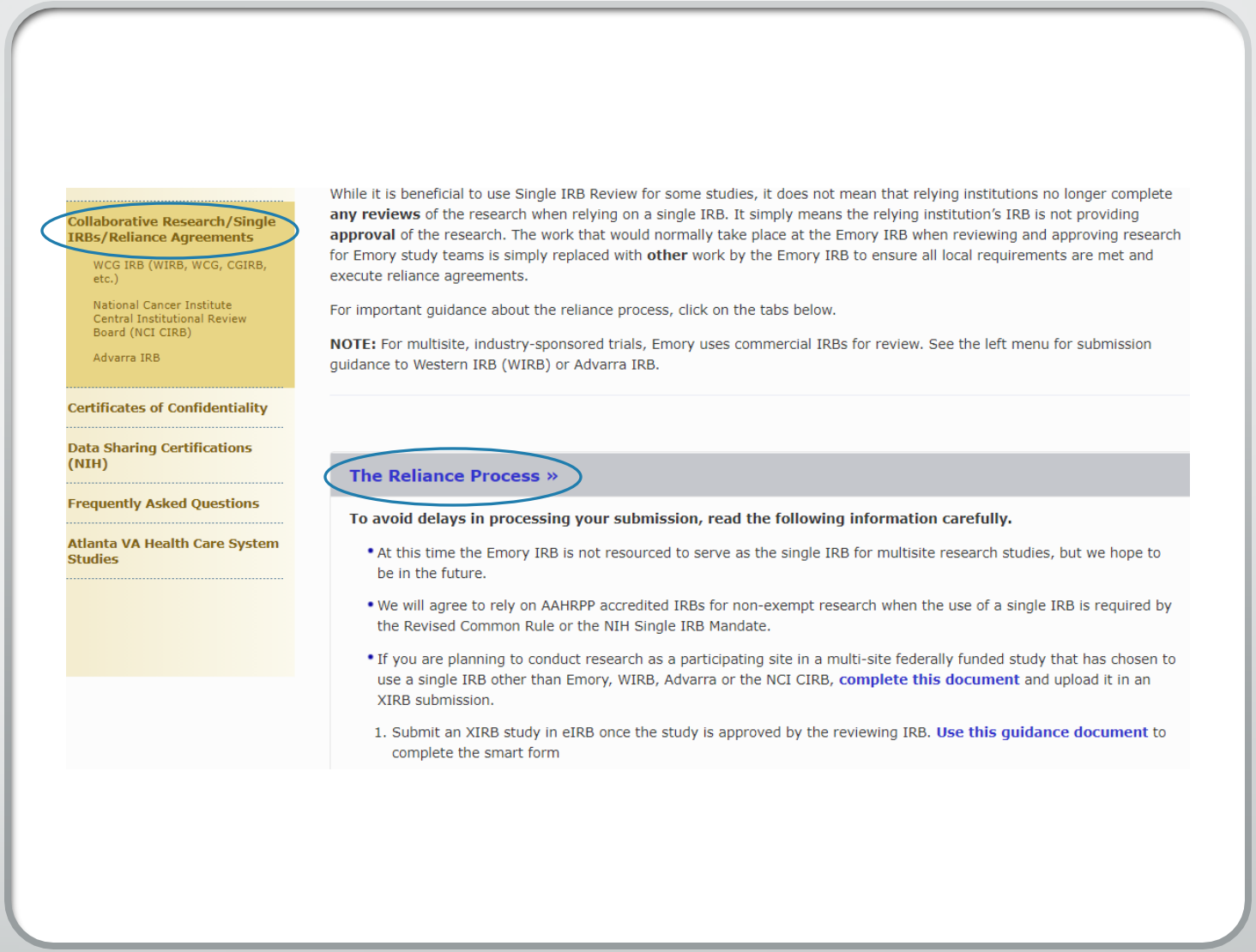
- Confirm CITI training in eIRB; provide CITI certificates if no data
- Confirm that site monitoring reports have been submitted to CTAC, if applicable

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
- <u>Before</u> 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.



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!