EMORY UNIVERSITY

Institutional Review Board

Emory University IRB

STANDARD OPERATING PROCEDURES

Contents

ADMINISTRATIVE 5
SOP Portfolio Modifications 5
Listserv Responsibilities 9
Mass Email Listerv Management 13
IRB Staff Study Checklists/Worksheets/Other documents Updates 17
Onboarding New IRB Staff 18
Evaluating IRB Staff Performance 20
Complaints About IRB Submissions 23
Reassigning Items From One Analyst to Another in Insight 24
COLLABORATIVE RESEARCH / SINGLE IRBS 25
Cede Review: WCG Listserv Duties 25
Cede Review: Initial Review When Emory Relying on An External IRB Other than the NCI CIRB 26
Cede Review: Processing NCI CIRB Studies 28
Cede Review: Issuing Partial HIPAA Waivers for Recruitment 30
Cede Review: Continuing Reviews and Closeouts 31
Cede Review: Amendments 32
Cede Review: Transitioning from Emory IRB to External IRB Review 33
Emory as sIRB: Initial Review for Multi-Site Study When Emory is the sIRB 34
Emory as sIRB: Amendments for Multi-Site Studies When Emory is the sIRB 36
Emory as sIRB: Continuing Reviews for Multi-Site Studies When Emory is the sIRB 37
Emory as sIRB: Closing Out One or More Sites in a Multi-Site Study Where Emory is the sIRB 38
IRB MEMBER MANAGEMENT 39
IRB Member Onboarding 39
QA AND EDUCATION 43
Acknowledgments & Noncompliance Determinations Made by Senior Team Q Staff 43
IRB Noncompliance 45
IRB Team Q CAPA Follow Up 48
Communication of Report of Internal Study Subject Death 51
Review of Single Use, Expanded Access of Unapproved Drugs or Devices 52
Informed Consent Monitoring SOP 57

Internal QA/QI review of documents before and after IRB Review 59
Letters after FB with PIs, OHRP and FDA after SNC, CNC and UP determinations 61
Other Event Submission Review Process 63
Review Process for Other Events for Cede Studies and Those Where Emory is the Reviewing IRB for External Study Teams 71
IRB Record Review of Studies 74
Review of Safety Reports submitted by sponsors holding an IDE 76
Routing External UPs (FDA Regulated) 77
S-I STUDY MANAGEMENT 80
New study screen process for S-I studies 81
CR screen process for S-I studies 83
Amendment screen process for S-I studies 84
Closeout submission screen process for S-I studies 87
STUDY MANAGEMENT 88
Not Research/ Not-Human-Subjects/Not-Human-Subjects-Research/Not-Engaged 88
NEW STUDIES 94
Processing of New Study Applications- Preliminary Analysis through Approval 94
RDRC Studies 98
Translation of Informed Consent Documents 100
Electronic documentation of informed consent via “electronic signature” or “digital signature”) 101
Data sharing certifications including genomic data sharing 105
Humanitarian Device Exemption (HDE) Studies 107
Processing Studies that will use Deception or Incomplete Disclosure 111
Emory Saint Joseph’s Hospital as a Study Site 114
REMS study review 115
Prisoner Studies: Handling of New/Amendments/Continuing Review Submissions when Prisoners are Subjects (Application of Subpart C) 117
VA Studies with non-VA Sites – IRB Submission Requirements 123
Determinations and Reviews by IRB Staff 125
Categories of Research Reviewable by IRB Staff as IRB Designated Members 126
DURING STUDY CONDUCT 129
Amendments - Processing from Preliminary Analysis Through Approval 129

Over-Enrollment Via Consent (No Research Activities including during Screening)..... 131
Continuing Reviews and Closeouts..... 133

ADMINISTRATIVE

SOP Title:	***SOP Portfolio Modifications***
SOP Category:	Administrative
Established:	08/29/2013
Last Revision:	12/01/2025

PURPOSE
The purpose of this document is to describe the process of adding or modifying approved SOPs, Guidance, and Policies and Procedures ('IRB documents') into the designated H drive folder.

SCOPE
This SOP applies to the SOPs, Guidance, and Policies and Procedures affecting the Emory IRB.

RESPONSIBILITIES
- **IRB Designated SOP Manager**: Add approved IRB documents to the designated H drive folder.
- **IRB Director**: Gives final approval of any new SOP.
- **IRB Revisions Working Group**: Identifies the need for the creation or modification of existing IRB documents.

PROCEDURES
Note: The official SOP Portfolio is a pdf document that is uploaded to our website documents folder. There's no link to it from our website itself to keep the document accessible only to the IRB staff. The direct link to the portfolio is:
http://www.irb.emory.edu/documents/SOP%20Portfolio.pdf

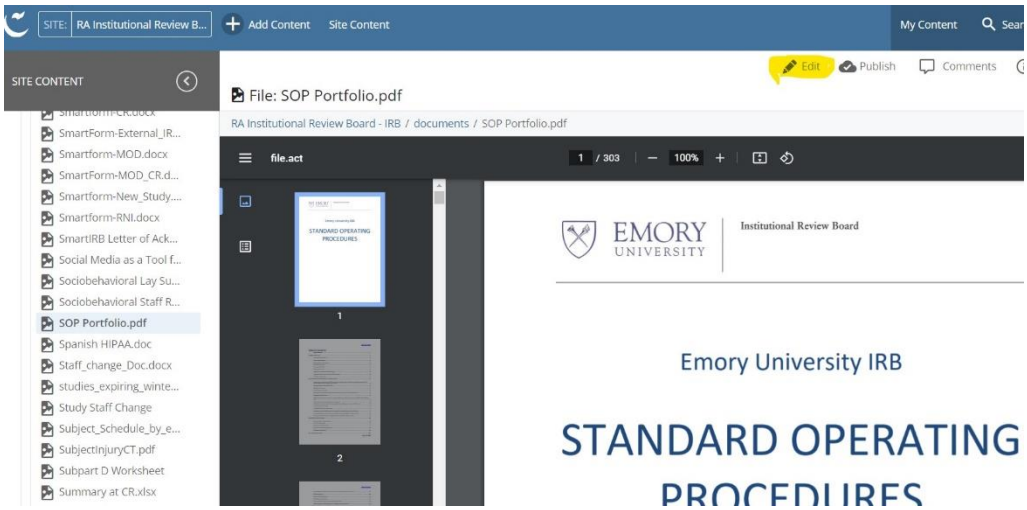
For SOP portfolio suggestions (staff)
1. To suggest changes to an SOP, copy the SOP from the SOP portfolio document in word.
2. Track changes and alert the IRB Designated SOP Manager. Save copy under H:\General\Admin IRB Documents\SOP Portfolio\SOPs in process Pre Approval Not Ready to Add in to the Portfolio Yet\In progress
3. Ask a member of the staff leadership team to review the change. For a new SOP, the IRB Director should approve it before adding it to the SOP portfolio.
4. After the Director or staff leadership member, as applicable, approve the new or changes to an existing SOP, move the document to the folder entitled H:\General\Admin IRB Documents\SOP Portfolio\SOP Portfolio Source Files & Where TLs track in ready to go live changes\Revised SOPs Already Approved and Ready to track in to the SOP and go live

Instructions for the Revisions Working Group
1. Track and make the approved changes to the Word document portfolio (H:\General\Admin IRB Documents\SOP Portfolio\SOP Portfolio Source Files\SOP Portfolio.docx)

a. Some changes could have been made to the clean copy, 'clean copy for future tracked changes' of the current portfolio located at H:\General\Admin IRB Documents\SOP Portfolio\SOP Portfolio Source Files
b. For other changes located under the "Ready for Add to Portfolio" folder, copy and paste just the body text of the new/revised SOP into the main portfolio; copying the header and the log of changes often led to formatting issues.
c. Add a new version date on the SOP that should be the date of the release of the SOP to the staff.
d. Under "Log of Significant changes" add the date of the portfolio revisions (same as the date on c) and describe the changes. Be as descriptive but succinct as possible.
e. After all the changes are made, remember to update the table of contents so that the page numbers are accurate. This is done automatically by simply right-clicking on the table of contents, click on "update field, and then on "Update entire table"

f. Review the table of contents and delete any subheaders.
g. Keep a copy of the tracked version, and create a new, clean version. PDF the clean version.

2. Update the online SOP portfolio with the revised, clean PDF version:
   a. Log in to Cascade: https://cascade.emory.edu
   b. Select "RE Institutional Review Board – IRB" from the dropdown menu at the very top of the first window
   c. From the left-hand menu, navigate to Base Folder/documents/SOP Portfolio.pdf
   d. Go to the "Edit" tab
   e. Select the revised PDF version of the portfolio, then click Submit.
   f. After replacing with the new version, click on "Publish."



3. After about a minute or so, check the online SOP link to make sure that the most recent version was successfully uploaded. You may need to press your browser's refresh button to clear the cache (force it to "forget" the old version)
4. Email or note in teams channel chat the IRB staff, letting them know about the changes, with a copy of the tracked SOP portfolio. Direct the Pod leaders to review these changes at their next meeting and add them to the next IRB staff meeting for in-depth review if needed.

See below an example of such an email/teams chat notification:

Subject: Changes to SOP Portfolio: November 1, 2018

Hi everyone,

Please, review the latest changes for the SOP portfolio, to keep up-to-date with new processes, as applicable.

Remember to refresh your browser in case you do not see the changes.

Sr. RPAs: PLEASE SAVE THIS IN THE IMPORTANT NEWS TAB OF YOUR POD REPORT TO REVIEW DURING THE NEXT POD MEETING. FEEL FREE TO REVIEW ONLY THE SOPS AFFECTING YOUR TEAM.

See the attached document for additional details on these changes. The following SOPs were modified, added, or deleted:

Changes to SOPs (see changes in attached tracked changes document)

- SOP Portfolio Modifications- Updating to reflect current practice
- Meeting Facilitation Responsibilities- Added that Meeting Materials be added as supporting documents to the Submit OE Committee Review activity for OEs.
- Modifications- Processing from Preliminary Analysis through Approval- Changes in the process to review contingency reviews.

- Processing of New Study Applications- Preliminary Analysis through Approval- Changes in the process to review contingency reviews.
- Certificate of Confidentiality Process in non-federal studies- Updated to follow new Online Certificate of Confidentiality System User Guide dated 06/25/2020.
- Continuing Review Processing-Preliminary Analysis through Approval- Changes in the contingency review process

New SOP

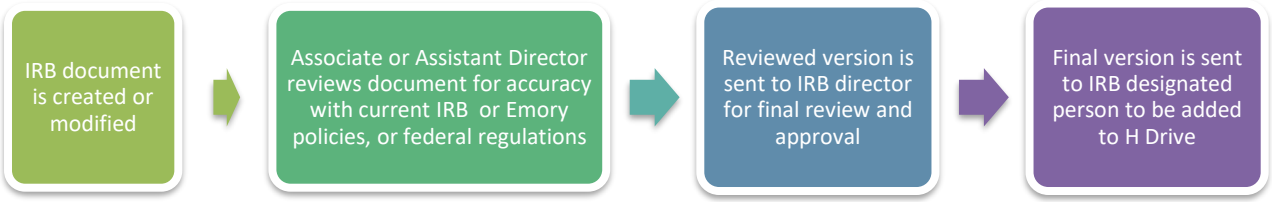
- Advarra Study Processing from Submission to Approval

Let me know if you have any questions,

NAME

5. Save a copy of the email or teams chat notification sent to the staff under H:\General\Admin IRB Documents\SOP Portfolio\Emails or Notifications sent to staff about portfolio changes
6. Save the tracked and PDF versions of the SOP in the archived portfolios folder located at H:\General\Admin IRB Documents\SOP Portfolio\Archived Portfolios

PROCESS FLOW



SOP Title:	***Listserv Responsibilities***
SOP Category:	Administrative
Established:	09/04/2013
Last Revision:	01/22/2026

PURPOSE

The purpose of this SOP is to provide guidance to analysts who are assigned to manage the IRB listserv email on a given day.

SCOPE

This SOP applies to IRB-L listserv (associated with irb@emory.edu) emails.

PROCEDURES

1. Respond to listserv emails on your assigned day or at the latest the next day, with no exceptions. If you can't fully respond, at least email to say that you are working on it (or have passed it on to someone, see "Required Procedures for Handling Listserv" below).
2. Listserv day starts at 4 pm the day before the assigned day. The shift ends at 3:59 pm on the assigned day. For example, for someone with a Wednesday assigned day, the shift will start at 4 pm on Tuesday and end at 3:59 pm on Wednesday.
3. Follow the instructions for specific types of emails as noted below. For any that fall outside of the scope addressed below, ask your supervisor for guidance. Propose what you think is the appropriate response/routing and ask your supervisor if that is correct.

Required Procedures for Handling Listserv	
If you send a response to a listserv email	Not required but preferred practice: Bcc yourself on the response and then save the blind copy to your "Listserv Duties" folder to more easily keep track of what you have done and can let other IRB staff know what has been done if they have questions. Alternatively, save the sent email into your Listerv duties folder.
If you forward the email to another analyst	ALWAYS do so by clicking "Reply" and CC'ing the analyst. The reply should let the sender know you've received their email and are sending it to [analyst] to handle it. That way the sender knows who's responsible for their inquiry. If there is an attached document, forward to assigned analyst in separate email.
If you cannot cover listserv due to illness or vacation	Communicate with another listserv staff member to ensure coverage (e.g., switch days for that week) and inform one of the Directors (or direct supervisor)

CITI Completion Reports	Just move to your "CITI Completion Reports" folder under inbox (best to set up a "Rule" so Outlook does this automatically)
If you handle listserv on a University Holiday	Complete tasks from your assigned day when you return to the office.
If designated person [see contact grid] from Emory Admin Assistant is unavailable during your listserv day	Complete Emory Admin Assistant Designated Person's tasks.

Types of Emails	**How to respond/Action taken**
Complaints from participants	Forward to Team Q (Shara Karlebach, Jackson Parker, Briana Rotterman); cc AVP for the HRPP
Compliance or safety event related	Send it to Team Q (Shara Karlebach, Jackson Parker, Briana Rotterman).
Corp_IRB_Options.xls from ORA-IT or OSP	No action required.
DSMC Plan approvals	No action required.
Insight account issues (e.g. account is "Inactive")	Direct them to submit an Insight Helpdesk request: (https://emory.service-now.com/sp?id=sc_cat_item_guide&sys_id=ea26109b1bf2a2501bbb86e1604bcbda&sysparm_category=38d0cff2331b22100cab10919e5c7bfa)
Insight "Department Chair cannot be found" error message	This means that there is no department chair (IRB Submission-Approver) affiliated with the users' organization in Insight for various reasons. If the inquirer or PI is: - an undergrad/graduate student – have them change PI to faculty advisor/mentor so that the study will route to organization with approver. - a medical resident/fellow – have them change the PI to faculty mentor so the study will route to organization with approver. - An EHC nurse, contact Carol Corkran so she can add the correct IRB Submission-Approver to the nurse's organization.
Insight IR routed to Incorrect organization for department chair approval	- User's Emory Online Directory Department does not align with where the PI thinks the IR should route for department chair approval. The most common situation is for a work-study student that works in one department but is completing their coursework/degree under a different department. Instruct them to change the PI to their faculty advisor/mentor

	so that the study will route to organization with correct department chair approver.
Emails containing identifiable health information, like the name of the study subject.	Delete the email from all folders (including the "Trash") and send an email to all IRB staff (do NOT include the PHI) OR post on IRB-Staff | General | Microsoft Teams and request that they do the same (identify the email by sender or subject). If an email from a study subject, forward to Team Q.
Fee/Cost Questions	Refer them to OCR's memo on research fees located here: https://ocr.emory.edu/secure/emory_university_standard_research_study_fees_signed-memo_7_18_2022_final-1.pdf (pull-down 'Research fees'). Direct study teams with research fee questions to contact OCR..
FWA, IRB registration questions	First check the IRB website for the answer (or direct the questioner):https://irb.emory.edu/about/index.html . If still unclear, forward to IRB Director.
IRB authorization agreements, collaborating with other institutions	Forward to reliance team at irb.reliance@emory.edu.
Membership List Requests/Roster Requests	The IRB does not provide rosters generally. Sponsors may use the compliance letter to confirm that no conflicted members take part in IRB reviews. Refer to Contact Us section on the IRB website for a partial roster (IRB Members): https://irb.emory.edu/about/contact/irb-members.html If a pdf is requested, they can copy and paste the information from the website into Word.
Cost Options	If the cost option is something other than default option 2, forward the email to the analyst assigned to the study.
Email from Dr. Nobles that includes "**Verification and submission of CoC Application**"	Forward to the IRB analyst assigned to the study. Ask them to confirm the following and if so, to let Dr. Nobles know he can sign it.: • the Project Description entered by team aligns with the applicable study • the consent form includes CoC language • the study has been approved by the IRB.
"O-day Closeout Notice for Your Award"	No action is needed.

Research Match emails	If the questions are about our SOP, refer them to the website. If the question is about the ResearchMatch website and posting/registration, then we should reply copying Mugisha Niyibizi at (Mugishamugisha.niyibizi@emory.edu) and the AVP of the HRPP to assist with this process.
Removal from or addition to IRB listserv ("blast") requests	Forward to Briana Rotterman (Team Q)
Request for consultation	Take the first one, and then email office about additional requests during the day. If the request is regarding reliance, send to the reliance Assistant Director.
Study-related questions	If a submission (initial review, amendment, continuing review) is in progress, forward to the analyst who is working on that submission. If no submission is in progress in Insight, the listserv manager should work directly with the team.
WCG IRB questions, notifications, and forms	Do nothing if they come directly from WCG IRB. If they are emails from a study team, please forward it to Reliance team.
Other	If unsure how to handle requests that are not noted in this chart, reach out to your supervisor for guidance. Depending on the situation, you may need to reply to the sender to acknowledge receipt and let them know you will get back to them with guidance.
Emails from OIT about security reviews	If it is a security report, upload as attachment in Insight. If there are issues with finding an IRB number, please contact Shara Karlebach for help. If the report indicates any critical issues, let the study team know the study cannot be approved if they are still planning to use the software or app.
Voicemails from IRB general number received via email	The person covering the Emory listserv is in charge of calling/emailing people back. The listserv may forward the message to another person as done for emails received in the listserv inbox, including inquiries about studies.
Reliance/Single IRB Questions	Provide them a link to the Collaborative Research page on our website and copy reliance team irb.reliance@emory.edu
Not Research/ Not-Human-Subjects/Not-Human-Subjects-Research/Not-Engaged	See the SOP, *Not Research/ Not-Human-Subjects/Not-Human-Subjects-Research/Not-Engaged*

(*) If the designated person is out of the office, the listserver is responsible for those tasks.

SOP Title:	***Mass Email Listerv Management***
SOP Category:	Administrative
Established:	11/06/2015
Last Revision:	10/14/2021

PURPOSE

Provides steps generate a list of recipients for a mass email from the IRB, formatting of the email, and management of the listserv online system.

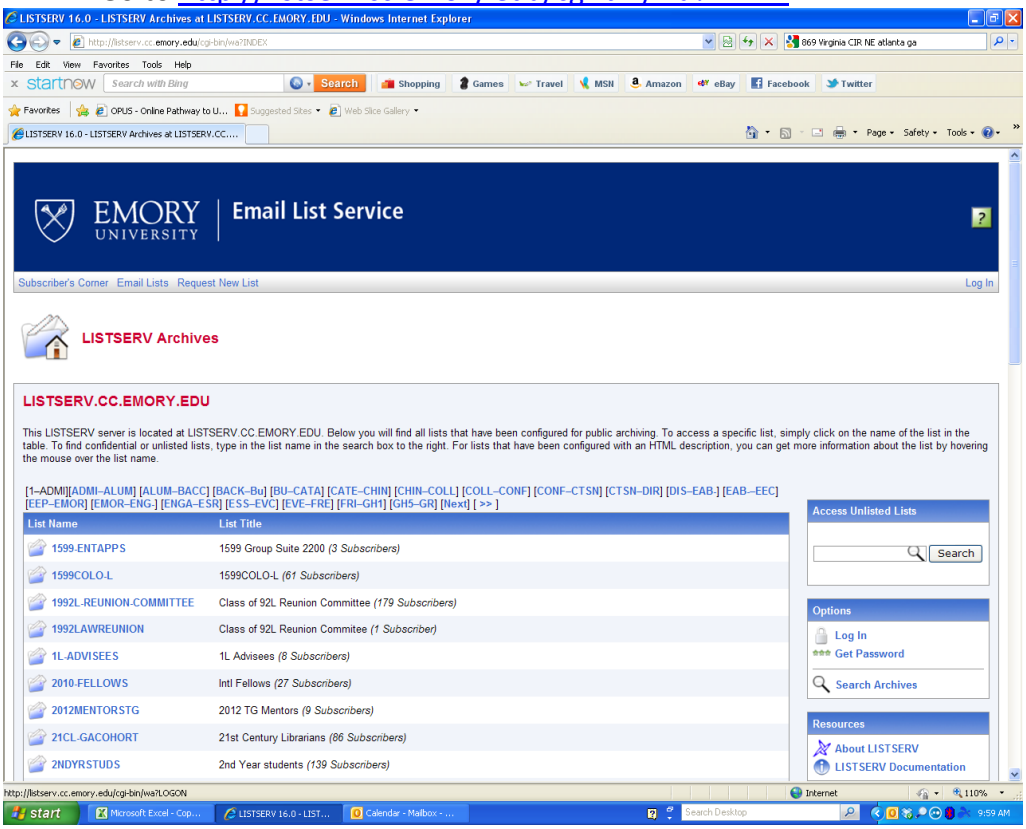
SCOPE

Applies only to IRBResearch-L listserv, not for IRB-L listserv (associated with irb@emory.edu).

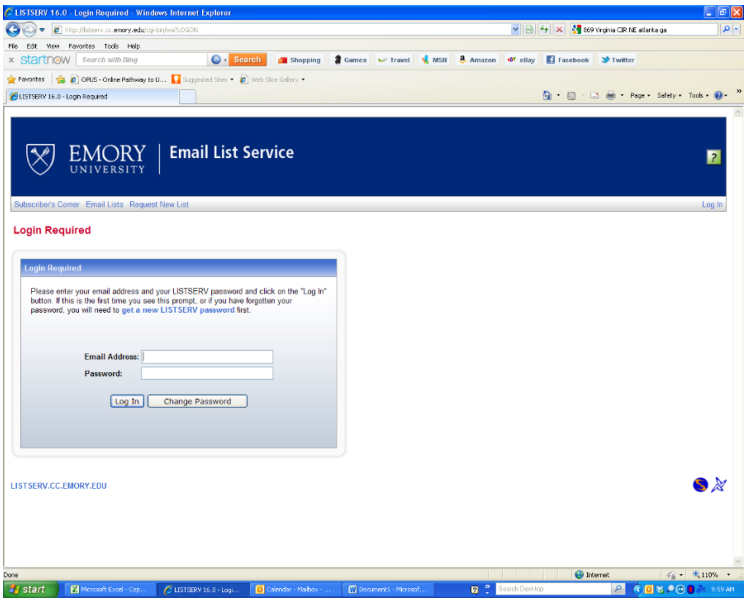
PROCEDURES

Logging in for the first time

1. Go to http://listserv.cc.emory.edu/cgi-bin/wa?INDEX

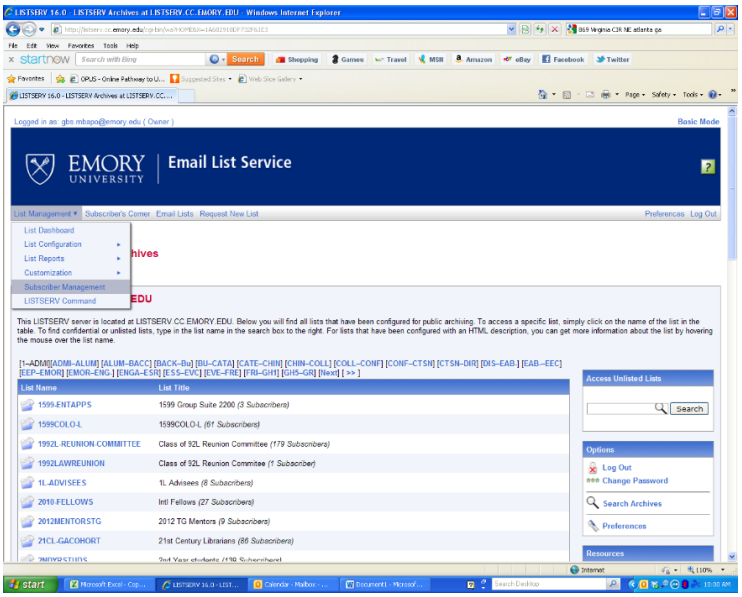


2. If this is your first time – click on the blue text: get a new LISTSERV password.



Creating Email List

1. Run the custom ORAIT_All emails for mass mailingand export results
    a. This pulls the emails of allIRB system accounts
2. Remove all columns except Emails
3. Save as Text (Tab delimited) to the E-mail blasts folder on H
    a. General/QA Working Files/E-mail blasts/YEAR/MONTH
4. Go to the Emory Email List Service website
    a. http://listserv.cc.emory.edu/
    b. You should use SSO log in
5. From the top-left drop-down menu, select Subscriber Management



6. Select the Bulk Operations tab
7. Select the Add/Do Not Remove option and choose the exported data as the Input File

8. Import the file, checking for any error messages
9. Open the Remove from listserv spreadsheet in the Email Blasts folder
10. Remove all columns except emails and save as Text (Tab delimited) in /YEAR/MONTH folder
11. Return to the listserv website and select the Remove/Do Not Add option and import the new Remove spreadsheet
12. Open the Add to listserv spreadsheet in the Email Blasts folder
13. Remove all columns except emails and save as Text (Tab delimited) in /YEAR/MONTH folder
14. Return to the listserv website and select the Add/Do Not Remove option and import the new Add spreadsheet

Writing the Blast

1. Solicit topics from IRB staff
2. Use a previous blast or the blast template as a guide
3. Draft the blast in a Word document so that revisions can be more easily tracked
    a. Formatting Components (for reference):
        i. Title: Emory IRB Update at Cambria 26, Date at Cambria 12
        ii. Table of Contents: Linking to individual sections; Title at Cambria 13 and Items at Calibri 11
        iii. Content: Titles linking back to TOC; Titles at Cambria 13, Body Text at Calibri 11
        iv. Contact us: Includes IRB email, phone number, website, and physical office; Title at Cambria 16, Body Text at Calibri 11
        v. Unsubscribe instructions: Send unsubscribe email to listserv or request to IRB email; Calibri Italic 10
    b. TOC title link to sections
        i. Highlight section title
        ii. Right-click and select Hyperlink…
        iii. Select Place in this Document
        iv. Select the appropriate Heading
4. Content headings link back to the TOC
    a. As above
    b. Select the Things to Know heading
    c. Repeat for each heading
5. To create new headings
    a. Go to the View Tab
    b. Select Outline view
    c. Add desired text
    d. Set as Level 2

6. Once the blast draft is ready, send it as an attachment to all the TLs for their input and revisions.

Unsubscribing instructions

1. Users can unsubscribe via two methods:
    a. Send an email to listserv@listserv.cc.emory.edu and type UNSUBSCRIBE IRBRESEARCH-L in the body of the email, the subject should be left blank
        i. This automatically removes them from the list and generates an email to irb@emory.edu and to the listserv manager(s)
    b. Send a request to irb@emory.edu. Please include the email address you wish to have removed
2. Add emails of individuals unsubscribing from listserv (via any method) to the master Remove from listserv spreadsheet
    a. If individuals still have accounts in the IRB sytem, their emails will be included in the original export file, even if they have unsubscribed. This is why you must continuously update this list, so that the unsubscription is saved.

Sending the Blast

1. Paste the drafted blast into an email. Make sure the banner image is centered in the email.
2. Ensure HTML is enabled
3. Double check that all links work correctly.
4. Send the email to irbresearch-l@listserv.emory.edu

Adding/Removing List Owners

1. Log in to the Emory Email List Service
2. From the List Management drop-down, select List Configuration, List Configuration Wizard. then the List Maintenance tab
3. Add/Remove the relevant email from an Owner line
    a. Be sure to use the netid@emory.edu email address
4. Save

Archiving the Blast* on the IRB Website

*Only for news-related blasts. Webinar or other education-related blasts don't need to be archived.

1. Log in to Cascade
2. Navigate to the Education, Past News and Email Blasts, Past Email Blasts page
3. Copy and paste the information in a new section of the page. You will have to adjust formatting a lot. You should remove all links except for links within blast news items to helpful documents.
4. You don't need to include the Helpful Links or Unsubscribe information.
5. Title the new section according to the blast title.

SOP Title:	***IRB Staff Study Checklists/Worksheets/Other documents Updates***
SOP Category:	Administrative
Established:	05/24/2021
Last Revision:	12/01/2025

PURPOSE

This SOP details the process of updating information in the IRB Staff study checklists and worksheets stored in the H drive folder H:\General\Admin IRB Documents\Checklists-Staff, Forms, and Templates\1. Staff Screening Checklists and Tip Sheets.

SCOPE

This SOP applies to documents provided to IRB staff in the H drive folder to aid in their review of IRB submissions.

PROCEDURES

- Changes can only be made by IRB leadership or the Revisions Working Group.
- Click on “Review” and then “Track Changes.” Update the document version in the footer and make all necessary changes.
- Save the tracked version of the document in the archive folder as a record of the changes.
- Click Accept all changes and stop tracking and save the clean version with the same name as the one in the one drive folder. Click Yes you want to replace the existing version.
- Announce the changes in Teams, under “IRB-Staff-To Remember”. Attach the tracked version of the document.
- Notify RWG of the changes made.

SOP Title:	***Onboarding New IRB Staff***
SOP Category:	Administrative
Established:	05/13/2015
Last Revision:	08/15/2024

PURPOSE

The purpose of this SOP is to document steps in the training of new employees. Resources for new hire training can be found in the Education folder located here on the H drive H:\General\Education\Staff Education New and Cont\New Staff Training and here http://www.irb.emory.edu/staff_training/.

SCOPE

This SOP applies to training for all new IRB staff.

PROCEDURES

IRB leadership will announce the name of the new employee and their start date prior to the new employee's start date.

Pre-Hire Preparations

- Before the start date of the new employee, the supervisor will confirm that ORA has arranged for computer equipment and monitors for the new employee and will obtain the new employee's email address.
- The supervisor will prepare the Go-To-Staff Training Sign-up Sheet and ask those who are assisting with training (leadership and Sr. RPAs) to sign-up for the specific days to complete their training.

New Employee Training Program

- The supervisor will send the new employee the welcome email template with important links and attachments including the training manual.
- The supervisor will meet with the new employee in person or on zoom and review the plan for the first week and for training.
- The supervisor will schedule time to take the new hire to lunch and will schedule a virtual meet and greet with other staff.
- Each day that training is scheduled, the trainer will send the zoom link for training and let the new employee know what materials should be reviewed prior to training. The trainer will find relevant IRB submissions to assign to the new employee for practice and will schedule time for follow up questions and review the new employee's work on the submissions.
- Sr. RPAs will schedule time to allow the new employee to shadow them performing reviews of submissions and will be points of contact for questions as will the Director and ADs.
- Once the new employee has demonstrated competence reviewing continuing reviews, amendments and new studies, a portfolio of studies will be assigned to the new employee.

- More complex training will be completed as specific questions/submissions warrant and as the employee's knowledge allows.

Title:	***Evaluating IRB Staff Performance***
Guidance	Administrative
Established:	08/27/2009
Last Revision:	08/21/2025

PURPOSE
The purpose of this SOP is to document steps for evaluating the performance of IRB staff.

SCOPE
This SOP applies to evaluating performance for all IRB staff.

PROCEDURES
Expected turnaround times are listed in business days. Study team contributions listed below are considered the best-case scenario; the IRB cannot control additional delays on their part. Therefore, the overall "total days" are also a best-case scenario. The IRB staff should stay within our targets each time the study team responds to our requests for clarification or changes.

Note: The times below should be decreased if needed due to urgency. Discuss with the Director or an AD if you are not sure we should act on the request for urgent handling.

Note: Staff are expected to respond to study team calls or emails within two business days.

Performance Quotient Expectations

New studies
130-150 new studies per year, ~32-38 per quarter: No more than 5% PQ

Amendments
90-110 Amendments per quarter: less than 1% PQ

Reportable new information submissions
36 to 40 cases per quarter: no more than 5% PQ

Turnaround times and performance quotients are based on getting ~35 new studies per quarter, and ~100 Amendments per quarter.
Variations from the above numbers due to understaffing or changes in submission volume will be considered when evaluating performance.
For reportable new information submissions, these numbers will not apply if team Q is assisting the office with other tasks or has not a full team to work on cases.

Type of Work	Initial Staff Screening	Omnibus Form Deadline and Pinging Schedule	F/up ltr out	Goal
FB New	Triage upon receipt or within 3-7 d of assignment depending on prioritization	Monday before the meeting (Friday for Tuesday meetings)	2 d of MTG	the aim is less than 1 calendar month or less
FB Mod	Triage upon receipt; 3-6 d depending on prioritization	Monday before the weekend (Friday for Tuesday meetings)	2 d of MTG	the aim is 3wks or less; **PRIORITIZE based on relevance to subject safety**
FB CR (once 45d or less pre-exp date)	Screen **no later** than 3 weeks from expiration (4 is better); **earlier** if Grady study; later if submitted less than 30 days before the expiration	Monday before the weekend (Friday for Tuesday meetings)	2 d of MTG but lower priority than New and Mod – UNLESS Grady, expiring, or study team needs for other reason	The ideal is IRB FB review at least 2 weeks prior to expiration, but 1 week if not possible
FB Post-Deferral Resubmission	3d – have Chair weigh in on adequacy of response before sending back to Full Board	Monday before the weekend (Friday for Tuesday meetings)	2 d of MTG	Send to the same panel if not urgent or submitted near that meeting; if urgent discuss with TL or Director as to whether we can send it to a different panel.
Post-Pending Response	2d of receipt		2 d of final approval	If the pending response is acceptable, aim for <6d; otherwise, the aim is 2wks or less
Type of Work	**Initial Staff Screening**	**Pinging schedule**	**F/up ltr out**	**Goal**
Simple Expedited New	Triage upon receipt or within 3-7 d of assignment depending on prioritization		2 d of decision	the aim is 3 wks or less
Complex Expedited New	Triage upon receipt or within 3-7 d of assignment depending on prioritization		2 d of decision	the aim is 4 wks or less: **USE PHONE OR EMAIL to resolve issues whenever possible to avoid delays (log notes in the study too)**
Expedited Mod by Staff	Triage upon receipt; 3-5 d depending on prioritization		same day as approval	the aim is 1wk or less
Expedited Mod by DR	Triage upon receipt; 3-6 d depending on prioritization		2 d of decision	the aim is 3wks or less

Expedited CR (once 45d or less pre-exp date)	Screen **no later** than 3 weeks from expiration (4 is better); **earlier** if Grady study; later if submitted less than 30 days before the expiration		2d of decision	The aim is IRB DR review no later than 1 week prior to expiration (more is better) when study team submits at least 30 days before the expiration
HSR Determination	Acknowledge immediately; 3d of assignment to screen. For each subsequent response, the IRB staff should reply within 2 days.		same day as determination	the aim is < 1wk (*) – we do not wish to hold up projects that do not require any IRB oversight.
Exempt	Triage upon receipt or within 3-7 d of assignment depending on prioritization		2 d of decision	the aim is 3 wks or less
RE case: SNC or CNC	Triage within 1 to 2 days. Sent to CoRE within one week or sooner if having all required case information (**)	If applicable, the omnibus form should be added one week before the meeting	If SCN or CNC: Friday or Monday after CMTE Q. If NC or not NC, 2 to 3 days	The aim is 4 weeks or less
OE case: UP	Associate or Assistant Director will log a comment indicating this is a potential UP case. Send to CoRe within 1 to 2 days	If going to Q, one week before the meeting. If going to other committees, follow meeting deadlines.	If the case went to FB, one day after meeting if involves a safety issue that needs to be addressed with an Mod. If not, 1 to 2 days	The aim is for 4 weeks or less
OE case: Not a UP, NC	Triage within 1 to 2 days. Sent to CoRE within one week or sooner if having all required case information, if applicable (**)	N/A	If expedited: 5 days If CoRE: 2 to 3 days	The aim is for 2 weeks or less

(*) There is often a lot of discussion with study teams so these determinations usually take longer to review, although we should aim to stay in our targets.

(**) Considering that there is some back and forth with the study team, it is acceptable to wait a week to send a case to CoRE. If the analyst has all the information, it is expected the case to be sent to CoRe sooner.

SOP Title:	***Complaints About IRB Submissions***
SOP Category:	Administrative
Established:	07/25/2018
Last Revision:	08/21/2025

PURPOSE

The purpose of this document is to explain the review process for complaints from study teams about studies that were processed or are being processed by an IRB analyst.

SCOPE

The SOP applies to complaints received by Associate or Assistant Directors, IRB Director, or other staff regarding items handled by an IRB analyst.

PROCEDURES

1. The recipient of the complaint will forward the email to the IRB leadership team (AVP and ADs). If there is enough information from the submission/emails to confirm that the IRB analyst has followed current procedures and turnaround times, the supervisor will respond directly to the study team.
2. If there is not enough information from the submission/emails to confirm the analyst has followed current procedures and turnaround times, the supervisor will investigate further to obtain the information needed to confirm whether the IRB analyst has followed current procedures and turnaround times.
3. The analyst's supervisor will follow up with the analyst until the matter is resolved and the study team has been informed.

SOP Title:	***Reassigning Items From One Analyst to Another in Insight***
SOP Category:	Administrative
Established:	08/21/2025
Last Revision:	12/01/2025

PURPOSE

This SOP details the process of reassigning an item from yourself to another analyst or to reassign a submission from one analyst to another in Insight. IRB submissions are assigned to specific IRB staff based on the type of submission.

SCOPE

This SOP applies to IRB submissions that need to be reassigned to a different IRB analyst than the one currently assigned to it.

PROCEDURES

1. To reassign a study from yourself to someone else:
    a. On right hand side click “forward activity.”
    b. Enter name of person you want to assign to (last name, first name)
    c. Enter a note to the new analyst in the box.
    d. Click Forward.
2. To reassign a study from any analyst to another analyst:
    a. Click “Administration” icon at the bottom of the left column.
    b. Click “Forward Activities”.
    c. Under Module Name, select IRB.
    d. Click search to see everything.
    e. In the field “Forward Activities to” select the analyst and mark the little box next to the studies you want to Forward.
    f. Click the forward button.
    g. You can also search by Assigned Name and get a smaller list of studies and then pick the ones you want to forward.

COLLABORATIVE RESEARCH / SINGLE IRBS

SOP Title:	***Cede Review: WCG Listserv Duties***
SOP Category:	Collaborative Research / Central IRBs
Established:	12/09/2014
Last Revision:	12/01/2025

PURPOSE
The purpose of this document is to outline the steps to address emails in the WCG Listserv.

SCOPE
This SOP applies to the IRB reliance analyst assigned to the WCG listserv duties.

PROCEDURES
1. Emails from WCG IRB Client Care with the following subject lines require no action:
   - [External] WIRB WCG IRB Reminder Notice
   - [External] New Submission
   - [External] Change in Research
   - [External] Report Form Transmission Notice
2. Emails from a specific WCG contact should be reviewed for what is needed. Although most are between the CRO, study team, and WCG, you may need to provide information.
3. Emails with subject line: [External] Documents Ready should be reviewed and require action as outlined below:
   - Study Closure Notice - Follow the “Cede Review Studies: Continuing Reviews and Closeouts” SOP.
   - Notice of Potential or Confirmed Noncompliance or Unanticipated Problems - Forward to QA/QI team and copy Reliance AD.

SOP Title:	***Cede Review: Initial Review When Emory Relying on An External IRB Other than the NCI CIRB***
SOP Category:	Collaborative Research / Central IRBs
Established:	01/03/2018
Last Revision:	10/29/2025

PURPOSE

The purpose of this SOP is to outline the steps IRB staff use to process submissions when Emory is relying on an external IRB (other than the NCI CIRB).

SCOPE

This SOP applies to any multi-site study where Emory is relying on an external IRB other than the NCI CIRB. It outlines steps for processing initial submissions as well as follow-on submissions.

PROCEDURES

1. Create new folder for the study: (H:\External IRB Relationships 6.3.2020\01. Current IAAs.
   - Right click and copy the folder "USE THIS TO CREATE NEW FOLDERS"
   - Double click on the "Emory Relying" folder
   - Paste the "USE THIS TO CREATE NEW FOLDERS" folder and then rename it with the following naming convention: NameofXIRB_PILastName_(short title)_studyID#.
   - Rename the study checklist to include the study number and save in the folder.
2. Use the XIRB study checklist to review external IRB studies. Complete the checklist and note on it any pending items and save in H drive folder when updates are made.
3. If changes are needed, create a comment on the form that needs to be modified. Click comment in the top right corner and describe the changes that are needed. Once all comments are added to the submission, click Require Modification under Actions in the lower right corner. Check the box and click the green Sign Off button.
4. When the submission comes back to the IRB, click Response to Review (on left menu – it has a comment icon next to it.) There will be links to each form that has comments. Click the link to the form, and then click the red comment button on the top right. Review the team's response to the comment and either click Reply or Resolve in the box. Once all items are addressed, resolve the comment. Otherwise ask for more changes. Once the comment is resolved, the comment box will be blue and the response to review will show there are no more unresolved comments.
5. If provided, complete the Local Context Review form provided by the reviewing IRB. If the form requests specific information regarding the study activities that will be conducted by Emory, forward the document to the Emory study team for completion of their portion of the form. Review completed form with reliance AD. If a LCR form is not provided in the smart form, use the Emory template found in this folder: H:\External IRB Relationships 6.3.2020\06. Forms and Checklists.

6. Once the local context review process is complete, look in the folder H:\External IRB Relationships 6.3.2020\03. Current Umbrella IAAs to see if there is an umbrella reliance agreement already in place. If in doubt, confirm with the Reliance AD or Sr. Reliance Analyst to confirm.
7. Click Attachments on the left menu to upload the executed reliance document (N/A for WCG or Advarra, CHOA, GT and other MOUs), the completed local context form, and COI management plan (if applicable and not provided by the study team) as Admin Attachments.
8. In the Attachments section, add a comment to the study team to upload the External IRB approval letter and stamped consent forms once they are provided by the external IRB.
9. Click Cede Request Approve under Actions in lower right corner. Check the box and click the green Sign Off button. The Institutional Signoff letter is automatically generated.
10. When the submission comes back to the IRB, ensure the study team uploaded the approval letter and stamped consents if applicable. Click Response to Review (on left menu – it has a comment icon next to it.) Click the link to the Attachments form, and then click the red comment button on the top right. Review the documents for accuracy (they are for the correct study and Emory's language has not been modified since signoff was issued.) If everything looks good, click Resolve. Otherwise click Reply and describe what needs to be changed.
11. Once you have confirmed the correct approval documents, click Approve under Actions in the lower right corner. Select the dates shown on the approval letter for the approval and expiration dates. Click Generate Review Letter. If the approval letter is in pdf format, save a copy of it in the study folder as a word document. You can drag and drop it into the field in generate review letter. Check the box and click the green Sign Off button. The study will now show it as active cede review.

SOP Title:	*Cede Review: Processing NCI CIRB Studies*
SOP Category:	Collaborative Research / Central IRBs
Established:	05/31/2016
Last Revision:	12/01/2025

PURPOSE

The purpose of this SOP is to outline the steps IRB staff uses to process studies reviewed by National Cancer Institute's Central IRB (CIRB), and to facilitate maintenance of the Emory investigator roster and institutional information for CIRB.

SCOPE

The SOP applies to all studies reviewed by NCI's CIRB with any Emory-affiliated study sites, including CHOA. The AVAMC may also use NCI CIRB, but their process may differ.

PROCEDURES

If study teams have questions as to how they access NCI CIRB Studies, please review and refer them to the guidance posted on the collaborative research section of our website.
If a study team member requests to be added to the NCI CIRB roster, please forward the request to the reliance AD or the Associate Director when the reliance AD is out of the office.

1. Create a new folder in the H drive folder for the external IRB and save a copy of the study checklist for the study. (H:\External IRB Relationships 6.3.2020\01. Current IAAs).
2. Use the following naming convention for the folder: NCI CIRB_PILastName_(short title)_studyID#
   Rename the study checklist to include the study number and save in the folder.
3. Confirm all required NCI CIRB documents are provided on the Attachments page of the submission:
   - NCI CIRB initial study-wide approval letter for our site
   - NCI CIRB most current continuing review approval if the study is past the expiration date in the NCI initial study approval
   - NCI CIRB approval letter for Emory as a site
   - NCI CIRB approved informed consent and assent (confirm it is same version noted in the NCI CIRB initial study-wide approval)
   - Emory Site Information and HIPAA Authorization form (must be uploaded as "stand alone HIPAA."
4. Click "Approve" under Actions on the lower right corner of the screen. Two new boxes open.
5. Enter the Approval Date from the NCI CIRB approval letter for Emory as a site
6. Enter the Expiration Date from the NCI CIRB initial study-wide approval or more current continuing review approval letter.
7. Outside of Insight, save the NCI CIRB approval letter for Emory as a site as a MS Word document.

8. Click “Generate Review Letter” under Actions on the lower right corner of the screen. This will open a section where you can upload a letter. Drag and drop the MS Word version of the NCI CIRB approval letter for Emory as a site.
9. Click the checkbox for “I have carefully reviewed the protocol and confirm my sign off.”
10. Click the green “Sign Off” button under Actions in the lower right corner.
11. The header of the study should now reflect under overall status “Active, Cede Review.”

REFERENCE

- NCI CIRB SOPs: https://www.ncicirb.org/about-cirb/sops

SOP Title:	*Cede Review: Issuing Partial HIPAA Waivers for Recruitment*
SOP Category:	Collaborative Research / Central IRBs
Established:	02/01/2019
Last Revision:	12/01/2025

PURPOSE

This SOP outlines the process for the Emory IRB to issue a partial HIPAA waiver for recruitment purposes to Emory study teams when Emory has ceded IRB review to an external IRB and that IRB does not issue such waivers.

SCOPE

This SOP only applies when Emory has been designated as the Privacy Board for the Emory study team under the reliance agreement. WCG IRB and Advarra IRB both serve as the Privacy Board as do most academic IRBs.

PROCEDURES

1. Confirm the study team has indicated in the external consent checklist that they are requesting a partial HIPAA waiver for recruitment purposes.
2. Review the information provided by the study team and request clarification if needed.
3. Send an email to the Emory IRB Asst or Associate Director requesting the partial HIPAA waiver for recruitment purposes. The IRB number should be included in the subject line of the email.
4. The authorized individual should review the waiver request within five (5) business days. (If not, send a reminder email.)
5. The authorized individual will add a summary note in the submission (in Insight indicating the waiver has been granted. For Type, select Administrative Update.

SOP Title:	***Cede Review: Continuing Reviews and Closeouts***
SOP Category:	Collaborative Research / Central IRBs
Established:	06/30/2025
Last Revision:	12/01/2025

PURPOSE

The purpose of this SOP is to outline the steps IRB staff use to update continuing review information for cede review studies.

SCOPE

This SOP applies to any multi-site study where Emory is relying on an external IRB.

PROCEDURES

1. Study team will send email to irb.reliance@emory.edu with the external IRB continuing review approval letter or study closeout letter.
2. On left menu, under Actions, click Create Administrative Action.
3. In the box, indicate if this is a CR or a closeout.
4. Click Yes to "Do you need to change the overall status" only if the study has been closed by the external IRB. Otherwise click No.
5. If the overall study is closing select "Inactive, Closed – Study Completed."
6. If the study is not closing, Click Yes to change expiration date. Otherwise click No.
7. Click No to "Do you want to change the protocol administrator."
8. Upload the CR approval or Closeout letter under Admin Attachments. Use file type "External IRB Approval Letter. If the approval letter is in pdf format, save a copy of it in the study folder as a word document.
9. Click Generate Review Letter. Drag and drop the MS word letter into the field.
10. Check the box and click the green Submit button.

SOP Title:	***Cede Review: Amendments***
SOP Category:	Collaborative Research / Central IRBs
Established:	06/30/2025
Last Revision:	12/01/2025

PURPOSE
The purpose of this SOP is to outline the steps IRB staff use to amend cede review protocol submissions.

SCOPE
This SOP applies to any multi-site study where Emory is ceding review to an external IRB.

PROCEDURES
1. Review the changes to make sure they meet the criteria for required Amendments for cede studies as posted on our website:

    - adding or removing drugs or devices used in the study
    - change of Emory PI
    - adding or removing Emory-affiliated study sites
    - changes in financial interests on the part of Emory investigators
    - new funding

If the proposed changes do not meet these criteria, add a comment on the amendment summary form telling the study team the changes are not ones that we need to review and to withdraw the Amendment.

2. Review the forms that were revised in the Amendment. Each form that was revised will have “MOD” next to it.
    - If changes are required, add a comment, and send back to submitter via “Require Modification.”
    - If no changes are required, click “acknowledge”, enter the current expiration date from the header of the study, check the box, and sign off on the Amendment.

SOP Title:	*Cede Review: Transitioning from Emory IRB to External IRB Review*
SOP Category:	Collaborative Research / Central IRBs
Established:	08/21/2020
Last Revision:	12/01/2025

PURPOSE

This SOP outlines how the IRB Analyst/Reliance RPA will process studies transitioning from Emory IRB to External IRB review when required by federal regulations.

SCOPE

This SOP applies to any study currently approved by the Emory IRB that is required to use an sIRB due to the NIH Single IRB Mandate or the Cooperative Research Component of the Revised Common Rule and must transition to the oversight of an external IRB.

PROCEDURES

1. Instruct the study team to submit a cede review study in Emory's IRB system and include the following documents:
    - Emory original IRB approval letter
    - all current documents from the previous IRB smart form
    - study-wide approval letter from the sIRB
    - local context review form and reliance document if provided by the sIRB
2. Instruct the study team to provide the following information in the lay summary of the cede review study.

   "This is a resubmission of Emory <enter study ID#>. This study is now required to transition to the [NAME] IRB that will serve as the single IRB of record for this study."
3. Follow the SOP titled "Cede Review Studies: Initial Review When Emory Relying on An External IRB Other than the NCI CIRB."
4. Instruct the study team to notify any offices at Emory who need the new IRB number.
5. Once the study team obtains IRB approval from the external IRB, notify the study team to submit a closeout to the IRB for the Emory-reviewed study.

SOP Title:	***Emory as sIRB: Initial Review for Multi-Site Study When Emory is the sIRB***
SOP Category:	Collaborative Research / Central IRBs
Established:	08/21/2020
Last Revision:	08/21/2025

PURPOSE

This SOP outlines the steps the reliance analyst follows to process studies when Emory IRB is serving as the sIRB for other enrolling sites.

SCOPE

This SOP applies to any new multi-site study for which Emory has previously agreed to serve as the sIRB for other sites that will enroll participants.

PROCEDURES

Initial Review

a. Confirm the study short title includes the prefix "sIRB - ". If the study is also an S-I study, instruct the study team to insert "S-I" after the short study title and review with your pod leader after you screen it to ensure all S-I requirements are completed.
1. Follow the SOP titled "Processing of New Study Applications – Preliminary Analysis Through Approval."
2. If the study is an S-I study (Emory PI holds IND or IDE), follow the S-I SOP.
3. Prepare the master consent form as a template for external sites to customize with their site-specific contact information and institution's required language.
    a. Insert placeholders in the header for PI, contact info, in the HIPAA Authorization section for revoking Authorization, and anywhere else Emory, CHOA or Grady are mentioned that are not already sections the study team should customize.
    b. Remove any Grady or CHOA-required language and if applicable the how will my study drug be provided language and Georgia Privilege language for studies with GINA.
    c. Add margin comments to the medical record, cost, in case of injury and HIPAA language (as applicable to the study) to indicate site can customize with their institution's required language.

    Note: The initial approval will be for the protocol and master consent form that will be distributed to the external sites as well as the approval for the Emory site.
3. Prepare the SMART IRB LOA or reliance agreement template if the relying institution has not yet signed onto SMART IRB's current version and local context review form for relying sites and save in the study folder.
4. Confirm the sIRB quote request form is included at an attachment and request the speedtype for the grant from the study team.

Relying Site Approval

1. Prepare the reliance instructions using the template located in this folder: H:\External IRB Relationships 6.3.2020\7. Templates. If the relying institution is not part of SMART IRB, use the standard reliance agreement template for that site. Prepare the template reliance documents with the study-specific information.
2. Send the following materials to the relying site PIs, coordinators, IRB points of contact and copy the Emory PI and point of contact as well as the reliance email address:
    i. Reliance instructions
    ii. Emory IRB approval letter
    iii. Emory IRB approved protocol
    iv. Emory IRB approved master consent form
    v. SMART IRB LOA (and/or standard reliance agreement if an institution is not part of SMART IRB)
    vi. Emory's LCR form
3. Remind the study team point of contact that they will need to follow up on the collection of documents until they are completed and upload them in the IRB submission once completed. As the partially executed SMART IRB LOAs or IAAs come back from relying institutions via email, route them for Emory signature. Provide to study team to include in the amendment once signed and save a copy in the study folder.
4. Review the submission for completeness and send back to submitted using the comment function if edits are needed. Confirm the study team has uploaded clean and tracked versions of the draft site-specific consent form in the relying site's section along with site-specific recruitment materials, executed reliance agreement, and signed local context review form.
5. Once the study team submits an amendment to add the external sites, process the amendment following the SOP "Emory as sIRB: Processing Amendments When Emory is the Single IRB of Record (sIRB) for a Multi-Site Study." When issuing the approval letter, confirm the letter includes the sites that were approved.
6. Add the sIRB fees into the spreadsheet which you can find here: H:\External IRB Relationships 6.3.2020\10. Emory as sIRB Materials\sIRB Fees Billing\2. Billing Spreadsheets

SOP Title:	***Emory as sIRB: Amendments for Multi-Site Studies When Emory is the sIRB***
SOP Category:	Collaborative Research / Central IRBs
Established:	01/20/2021
Last Revision:	08/21/2025

PURPOSE

This SOP outlines the steps to process amendments when Emory IRB is serving as the sIRB for external sites enrolling participants.

SCOPE

This SOP applies to multi-site studies for which Emory has agreed to serve as the sIRB.

PROCEDURES:

Changes in PI

1. For amendments to add or remove external site study personnel, the external study team is responsible for ensuring study team members maintain current CITI and credentials in accordance with their institution's policies and procedures. Emory IRB only reviews the PI for each external site. If the PI for the site changes, the relying IRB must complete a new local context review form or provide confirmation via email that the new PI has met all local training requirements and can be added as PI. If this is provided via email, the email must be uploaded in the amendment. The site's consent form must be updated with the change in PI and added to the amendment.
2. For amendments that require new ancillary reviews such as a new COI, change to radiation procedures, infectious agents, etc., a new local context review form must be obtained from each relying IRB and the completed forms must be uploaded in the amendment prior to approval. The local context review form is titled "Emory sIRB Relying Site LCR Form" and is located in the folder H:\External IRB Relationships 6.3.2020\06. Forms and Checklists.
3. If the study is an S-I study, follow the S-I SOP.
4. Add the sIRB fees into the spreadsheet which you can find here: H:\External IRB Relationships 6.3.2020\10. Emory as sIRB Materials\sIRB Fees Billing\2. Billing Spreadsheets

SOP Title:	***Emory as sIRB: Continuing Reviews for Multi-Site Studies When Emory is the sIRB***
SOP Category:	Collaborative Research / Central IRBs
Established:	01/20/2021
Last Revision:	08/21/2025

PURPOSE

This SOP outlines the steps to process CRs when Emory IRB is serving as the sIRB for external sites.

SCOPE

This SOP applies to multi-site studies for which Emory has agreed to serve as the sIRB.

PROCEDURES

1. The reliance analyst will use the Worksheet-Continuing Reviews document found here: H:\General\Admin IRB Documents\Checklists-Staff, Forms, and Templates\1. Staff Screening Checklists and Tip Sheets and follow the SOP titled "Continuing Review Processing-Preliminary Analysis through Approval" to process the continuing review.
2. Send an email to the Emory study coordinator with the "Emory IRB Relying Site Continuing Review Form" for each site to complete and return to the study coordinator as well as the "Cumulative Continuing Review Report for sIRB Study."
3. The Emory study coordinator will enter each site's information from their completed CR form into the spreadsheet. Once the spreadsheet is complete, the study coordinator will upload the spreadsheet in the attachments section. The forms and spreadsheet are in the folder H:\External IRB Relationships 6.3.2020\10. Emory as sIRB Materials\Relying Site Materials\03. Continuing ReviewMod.
4. Review the submission. If changes are needed, use the comment function to describe any changes needed. Under Actions, select Route to Submitter, check the box and click the green sign off button. If no changes are needed, determine if the CR needs expedited or full board review. If it requires full board review, select Scheduling under Actions. This will conclude your workflow. If it requires expedited review, select Expedited Review and select the designated reviewer from the drop down menu. Once the designated reviewer completes their review, they will route it back to you to issue the letter. Add the statement "This approval applies to the following relying sites: and list the names of the relying sites in the approval letter.
5. Add the sIRB fees into the spreadsheet which you can find here: H:\External IRB Relationships 6.3.2020\10. Emory as sIRB Materials\sIRB Fees Billing\2. Billing Spreadsheets

SOP Title:	***Emory as sIRB: Closing Out One or More Sites in a Multi-Site Study Where Emory is the sIRB***
SOP Category:	Collaborative Research / Central IRBs
Established:	03/30/2018
Last Revision:	08/21/2025

PURPOSE

This SOP details how to close out one or more sites that are relying on the oversight of the Emory IRB.

SCOPE

This SOP applies to multi-site studies where Emory is the sIRB and there are other enrolling sites external to Emory.

PROCEDURES

1. To close a site while the rest of the study remains open, the study team will submit an amendment to remove the site. Confirm the study team provided a description of why the site is closing in the summary of the amendment.
2. Follow the SOP "Amendments - Processing from Preliminary Analysis through Approval."
3. Confirm the letter states the name of the site that is closing.
4. Add the sIRB fees into the spreadsheet which you can find here: H:\External IRB Relationships 6.3.2020\10. Emory as sIRB Materials\sIRB Fees Billing\2. Billing Spreadsheets

IRB MEMBER MANAGEMENT

SOP Title:	***IRB Member Onboarding***
SOP Category:	Meeting and Member Support
Established:	02/25/2021
Last Revision:	08/21/2025

PURPOSE
The purpose of this document is to detail activities from the time an individual becomes a member candidate until appointment and first official IRB meeting.

SCOPE
The SOP applies to IRB staff working with the IRB Member Onboarding process.

PROCEDURES
IRB Director/Assoc/Asst Director:

1. Conduct an informal 3-5 minute phone call. Confirm the individual's interest in membership, prior IRB experience if any, expertise and availability. OR send the following recruitment email to potential candidate if no phone number is available:
    a. H:\General\CMTE\2. Members and Roster Docs\Recruitment - New Members\Application Materials for Membership\2. Email Templates\Community_ Member_UA-NS-Recruitment Email Text.docx
2. Once interest and eligibility is confirmed in consultation with the Director, send the relevant Emory IRB Membership email outlining the appointment process (either the one for Emory-affiliated members, or for Community members):
    a. Template: H:\General\CMTE\2. Members and Roster Docs\Recruitment - New Members\Application Materials for Membership\2. Email Templates

    Attach copies of the following to the email:
    - IRB Member Application Fillable Form (latest version date)
    - IRB Confidentiality Agreement Form
    - Instructions for completion of the CITI Member Module "What Every New IRB Member Needs To Know"* Or CITI IRB Community Member_New_Account_&_module_training_document
    - IRB New Member Pre-requisites document OR IRB New Member Pre-requisites-community members document
    - New Member Orientation-(latest version)
    - **Community Members only – Supplier_Individual_Information Form & Guidance for filling in vendor form for community members

    The above documents are attached to the email template or can be found here: H:\General\CMTE\2. Members and Roster Docs\Recruitment - New Members\Application Materials for Membership\3. Forms and Documents

3. Update a copy of the New Member Onboarding Checklist with date materials were returned or trainings completed.
4. Create folder for the member in the H: drive (H:\irb_shared\General\CMTE\2. Members and Roster Docs\Individual Member Files\01. Appt-Resig and CVs - by member) and store signed appointment letter, CV, and completed application, and copy of New Member Onboarding Checklist. You may wish to copy a shortcut to the checklist onto your Desktop until onboarding is complete.
5. Ask future Pod leader to set up a date and time for the candidate's orientation and training of the IRB system at the IRB offices or over Zoom. Email time, place and logistics to the candidate.

Relevant Pod Leader (*loop in Director re: all steps, so that Roster can be updated promptly*):

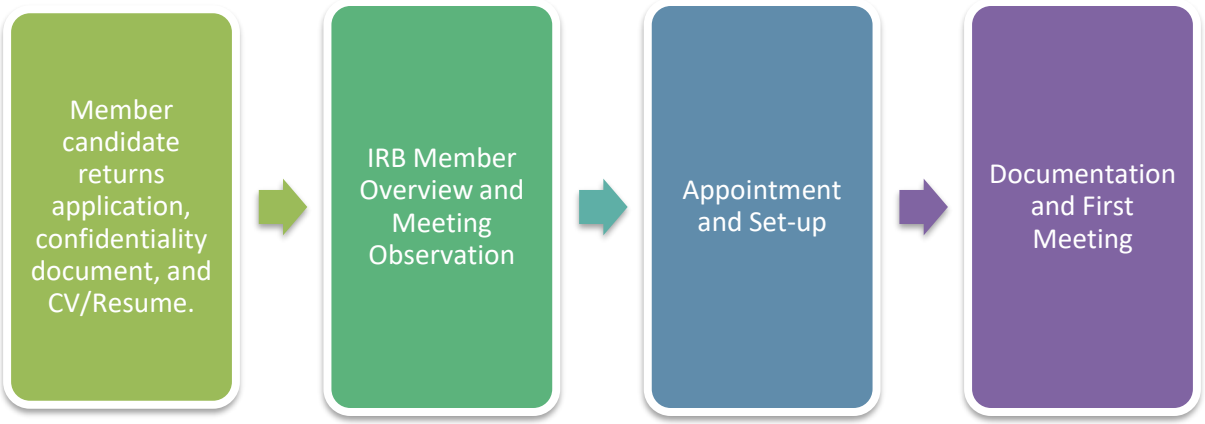
6. Update the New Member Onboarding Checklist with the scheduled training date.
7. Send a reminder email to the candidate before the scheduled training with review of the logistics.
8. Conduct the New Member orientation training using the New Member Power Point. H:\General\CMTE\2. Members and Roster Docs\Recruitment - New Members\Application Materials for Membership\4. Training Materials
   Key Points to include and/or emphasize:
   - Emory IRB Committee (A/B panels and Team C)
   - Meeting time and place
   - Meeting structure/presentations
   - Quorum
   - Member attendance once monthly and completion of assigned reviews in the IRB system
   - Review of a NEW study, CR and AM in the system
   - The schedule for Reviewer Assignments Completion
   - Member commitment to serve 2 years with option to renew for a third year
   - Role of Meeting Pod
   - Role of IRB Staff Analyst/Study Owner
   - Decide the panel assignment with the candidate.
   - Set up a meeting observation date.
   - Meet IRB Director if available.
   - Show conference room 5C when walking candidate out to the elevators
9. Update the Director and the New Member Onboarding Checklist with date of training completion and scheduled date for meeting observation.
10. Email candidate on what to expect after the observation. Confirm panel assignment.
11. Update the New Member Onboarding Checklist with observation completion date.
12. Draft appointment letter (template). Request review by the Director.
13. After Director review, email the appt letter to the office of the I.O. with a copy of the candidate's CV/Resume.

14. Update the New Member Onboarding Checklist with the date sent to the I.O.'s office.
15. Update the New Member Onboarding Checklist when the signed letter is returned to the IRB with the official appointment date (date on letter).
16. Email official welcome to the new member with appointment letter attachment and instructions for acknowledgment.
    Copy the following persons on the welcome email:
    IRB Director
    IRB Co-Chairs
    Meeting Chair
    Team Lead
    All Pod members
17. Confirm all documents (including fully signed appointment letter) have been stored in the member's folder on H: drive
18. If the new member is unaffiliated, request a sponsored account for her/him through IT Service Now.
19. Submit IT request for the user to receive the appropriate Role in the IRB system.
20. Update the IRB system to list new member on the appropriate panel. (Anyone in Pod can do this.)

IRB Director:

21. Update member roster per instructions on Roster's first sheet
22. Add new member to the Outlook member group email listing (new).
    a. Find list here: H:\General\CMTE\2. Members and Roster Docs\All Member Email List - update as needed.
    b. Open file – Click on "Add Members" and "Select Members: Offline Global Address List." Search by last name.
    c. Highlight the member you are adding, then click the "Members" button at the bottom of window. The members name will be added to field, then click "OK."
    d. Save & close mailing list.
    e. Open new message in your Outlook and copy the updated "IRB All Member Mailing Group – Updated _____(date)" to the email.
    f. Send email to the IRB Staff.
23. Confer with appropriate meeting pod on date of first official meeting and how the candidate faired.
24. Update member roster with first meeting date and any missing information to close out former candidate tracking.
25. Announce new member at next IRB staff meeting.

PROCESS FLOW


Member candidate returns application, confidentiality document, and CV/Resume.
IRB Member Overview and Meeting Observation
Appointment and Set-up
Documentation and First Meeting

QA AND EDUCATION

SOP Title:	*Acknowledgments & Noncompliance*
SOP Category:	QA and Education
Established:	10/19/2011
Last Revision:	08/21/2025

PURPOSE

The purpose of this document is to specify in which circumstances a designated senior Team Q staff may acknowledge reportable new information submission submitted to the Emory IRB.

SCOPE

The SOP applies to the reportable new information submissions submitted for studies reviewed by the Emory IRB.

PROCEDURES

The designated senior Team Q staff is allowed to acknowledge the events as detailed in this SOP. The designated senior Team Q staff may, at his/her discretion, send any of these events to an IRB vice-chair even if noted in this SOP to get confirmation of appropriate review. The designated senior Team Q staff may acknowledge the following events:

- Study staff not added to IRB submission, as long as staff was proper research (CITI and, if applies, Emory Clinical Research training) and protocol training before starting study activities
- ICF/HIPAA documentation issues where:
  - The form used was expired but it was the correct version approved by the IRB
  - The subject signing the consent forgot to time and date. A note to file is required to clarify this matter.
  - The study team member forgot to time and date the signature. A note to file is required to clarify this matter.
  - Discrepancies in signature/date/time by subject or study team unless there is a pattern of noncompliance.
  - ICF missing fields in the consent form that do not involve options made by the subject or signature, e.g. initials in pages.
- Lapses in approval for FDA trials where research activities did not take place during the lapse. Other studies do not need the submission of an OE.
- Errors in reporting enrollment numbers at continuing review (whichever is greater):
  - Gap difference in enrolment number is within 10, no matter sample size
  - No greater than 20 % of total enrolled.

- Over-enrollment in a NMTMR study, when subjects have undergone study procedures (not only signing consent), as long as it is the first occurrence for a study, if HIPAA does not apply.
- Any event caused by the subject's (not the study team's) lack of adherence to the protocol that, in the opinion of the principal investigator, does not affect the subject's safety, rights and welfare or willingness to continue with study participation, and is not an unanticipated problem.
- Adverse event (that is not an internal death) that is considered unanticipated by the principal investigator but for which the causal relationship to study participation is unknown, and no more information is or will be available. Such events will be acknowledged with directions to submit a new reportable new information submission if the cause of the event is determined as related at a later date.
- Adverse event reported to the IRB per sponsor requirements, that the principal investigator considers anticipated or unrelated to study participation. For VA studies, this will need to be acknowledged by a VA reviewer.
- Protocol deviation which the principal investigator considers not substantive and not affecting subjects' rights, welfare, safety, or willingness to continue with study participation, and not affecting integrity of the research data, reported per sponsor requirements.
- DSMB letter indicating that study can continue per the protocol without change, submitted per sponsor requirement only.
- Protocol deviation that may minimally affect the integrity of research data, but does not affect subjects' rights, welfare, or safety and which does not represent a pattern of noncompliance. Team Q staff should review prior reports and consult the vice-chairs when in doubt.

  Examples of such deviations are:
  - Visit occurred out of window.
  - Test done for research (not for safety) purposes which was not drawn or was drawn out of window, which does not reflect a pattern of noncompliance.
  - Missing data caused by subjects' noncompliance with protocol (specifically, missed data when not completing surveys not used for diagnosis or treatment) or missing data due to programming errors that do not affect subjects' safety.
  - Surveys or survey items completed in error, when the surveys or survey items' completion does not negatively affect subjects' rights, welfare or safety. For example, the completion of a survey asking for information that may upset the study participant should be sent to a vice-chair reviewer.

SOP Title:	***IRB Noncompliance***
SOP Category:	QA and Education
Established:	03/24/2015
Last Revision:	08/21/2025

PURPOSE

The purpose of this SOP is to describe the process of reviewing situations in which the IRB, either through the actions of the IRB Committee or its administrative office, may not have followed applicable regulations or its internal policies and procedures; this policy does not apply to instances of non-compliance by investigators or research team members. (NC). The Emory AVP of the HRPP, the Emory IO, and the ORA Office of Research Compliance and Regulatory Affairs (RCRA) are tasked with making sure the Emory IRB complies with the IRB policies and procedures and applicable federal regulations.

SCOPE

The SOP applies to all actions and determinations taken by the IRB.

DEFINITIONS

- IRB Noncompliance (NC): a failure of the IRB to follow IRB Policies and Procedures, IRB Internal Standard Operations Procedures or federal regulations during the review and oversight of study submissions.
- Minor IRB NC: IRB NC that does not significantly impact the rights, welfare, safety of participants, or the integrity of the research data.
- More than Minor IRB NC: IRB NC, or identification of a repeated pattern of Minor IRB NC, that could significantly impact the rights, welfare, safety of participants, or errors that cause a disruption for the study team that would take significant steps to resolve (for example, a large number of subjects will need to be reconsented)
- Findings: issues discovered during an IRB internal QA/QI process that may indicate an error during a study submission's review and approval by the IRB. A finding would not rise to the level of minor or more than minor noncompliance if it does not affect the rights, welfare, safety of participants, or the integrity of the research data.

RESPONSIBILITIES

- AVP for (RCRA) and Director of the Office of Research Integrity and Compliance (ORIC) – after the IRB identified trends, reviews information with the INS before routing to the IO.
- AVP of the HRPP – reviews IRB NC and makes a determination as to whether an event is minor or more than minor.
- IRB Q Team: Compiles information to be sent to the AVP of the HRPP or IRB NC Subcommittee (INS) or the AVP for RCRA and Director of ORIC as applicable.
- IRB NC Subcommittee (INS): reviews issues coming from the AVP of the HRPP (through a Team Q representative). The IRB INS is composed of the AVP of the HRPP, IRB Co-Chairs, and the AD who supervises the IRB analyst for the affected submission (if applicable). INS's role is to determine the CAPA is adequate for any IRB Noncompliance that is more than minor. They also determine whether a trend is more than minor IRB NC.

- AVP of the HRPP and Associate or Assistant Directors (ADs) – Utilizes IRB NC data to determine if there is a trend related to findings from routine record reviews, or other issues identified by IRB staff, researchers, or other members of the HRPP.
- IO: reviews more than minor IRB noncompliance to assess reporting requirements and adequacy of Corrective and Preventive Action (CAPA) plan.

PROCEDURES

1. IRB noncompliance issues may be identified during routine internal review or during incident-based reviews by IRB staff, researchers, or other members of the HRPP. An AD or Q team member will log all potential IRB NC in the IRB NC spreadsheet.
2. All potential IRB NC (that hasn't previously been determined to be no more than minor) should be elegantly summarized and sent via email to the AVP for the HRPP. Include links in the submission systems if relevant. The AVP for the HRPP will determine if findings constitute IRB NC and will determine which are minor and which are more than minor.
3. If the matter constitutes no more than minor (NMM)IRB NC, a CAPA will be instituted as applicable.
4. If the matter constitutes more than minor IRB NC, the AVP will email the Team Q representatives to route the matter to INS and the IO.
    - A root cause analysis and a CAPA plan must be drawn up for each matter that is potentially more than minor (MM) IRB NC. The Team Q representative should work with the parties involved to document this before sending to INS and the IO.

Cumulative Report Process for minor IRB NC

1. All minor IRB NC will be logged by an AD or Q team member in this spreadsheet located at OneDrive/IRB-Staff/Documents/H drive/General.
2. Team Q will review this spreadsheet routinely to identify trends.
    - **If a trend is identified,** a Team Q representative will provide a summary of the trend, the trend's impacts, and CAPA to INS via email. Reminder to copy: the AVP for (RCRA) and Director of the Office of Research Integrity and Compliance (ORIC)
        - The INS will make the determination of whether the trend is no more than minor or more than minor noncompliance and will determine whether the CAPA is adequate.
        - If more than minor, route to IO per SOP steps.
        - If no more than minor, close out per SOP steps.
    - **If no trends are identified,** document the absence of trends in the spreadsheet.

INS Review

The below process will be followed for identified trends during the review of the spreadsheet information.

- A summary with relevant details will be provided including trend information
- To close the case, the AVP for RCRA (or designee) must vote for no more than minor IRB NC, and at least two members of INS must agree.
- The event will be updated in the spreadsheet and the case will be considered closed when the CAPA plan is completed, if applicable.

- After receiving all required responses to close the email communication, the email thread should be saved under H:\General\QA Working Files\NC UP Complaints\IRB NC\Emails sent to INS with cumulative reports. The email thread should have the date of when this information was sent to the INS

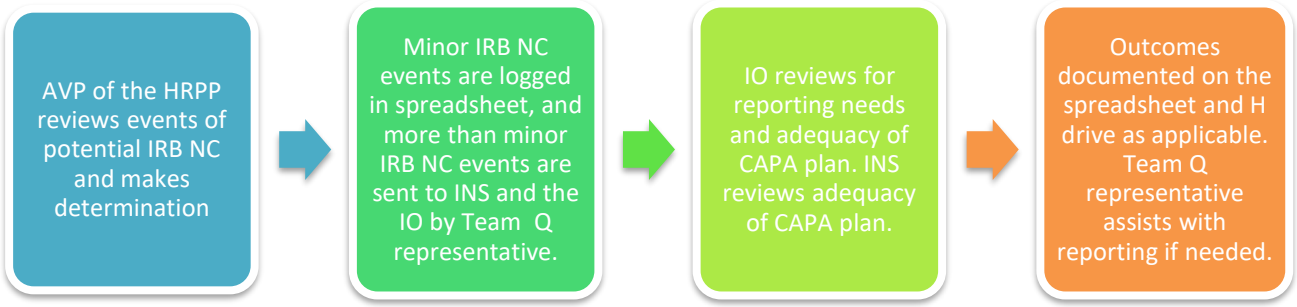
3. If the INS determines that the case constitute more than minor IRB noncompliance, follow the process under "IO Review".

IO Review

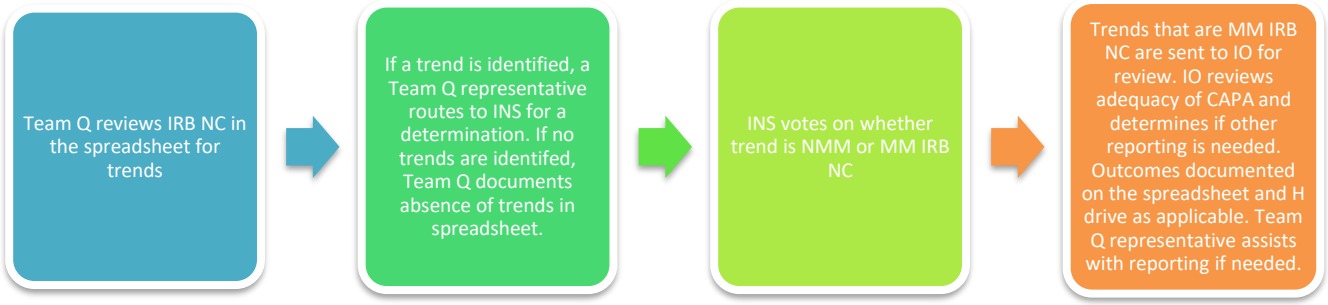
1. If the responses indicate that the cumulative report or case information needs to be sent to the IO, forward the INS email thread, and any other related information to the IO for their review. Copy the AVP of the HRPP, AVP for RCRA and ORIC Director in this communication. Specify in the email that you have sent this information to the INS and that you need them to decide if the noncompliance should be reported to the federal oversight agencies.
2. The IO will review the information to assess reporting requirements and adequacy of the CAPA plan.
   a) If the IO determines the case requires reporting, the Team Q representative will work with the AVP of the HRPP and IO in creating a letter to the oversight federal agencies, and AAHRPP, as applicable. Update the spreadsheet.
   b) If the case does not require reporting, update the spreadsheet and save the communication from the IO in this folder: H:\General\QA Working Files\NC UP Complaints\IRB NC\IO review.

PROCESS FLOW

Each individual incident of IRB NC:



Ongoing Trending



SOP Title:	***IRB Team Q CAPA Follow Up***
SOP Category:	QA and Education
Established:	02/14/2012
Last Revision:	01/10/2025

PURPOSE

The purpose of this document is to describe how the IRB Team Q will follow up on the IRB-approved Corrective and Preventive Action (CAPA) plans presented during Committee Q meetings. In addition, this SOP will cover the process of auditing CAPA plans for studies conducted at Emory and reviewed by External IRBs.

SCOPE

CAPA plans from studies reviewed by an External IRB or during Emory IRB Committee Q meetings for determinations of serious (SNC) and/or continuing non-compliance (CNC), and unanticipated problems (UP) resulting from study staff oversight or error. In cases where the status of the study does not warrant additional action based on enrollment or remaining study activities, team Q will use their discretion.

DEFINITIONS

- Corrective and Preventive Action Plan – a plan developed by an investigator, with or without the assistance and guidance of the HRPP, following a root cause analysis into an instance of noncompliance or other problems in the conduct of human subjects research. The CAPA must include measures designed to correct the immediate problem and prevent its recurrence or the recurrence of a similar type of problem. CAPA plans are reviewed and may be modified by the IRB before being approved. Investigators are responsible for implementing CAPAs in a timely manner.
- Committee Q – Full Board Committee that reviews cases of possible serious or continuing non-compliance and unanticipated problems.
- Team Q: IRB staff team specializes in Education and QA efforts including non-compliance, unanticipated problems and protocol deviation review, analysis, data-gathering and presentation.
- CoRe team: A designated group of the IRB Chair, Director, and qualified IRB staff to investigate cases of alleged non-compliance and UPs. Their findings are documented as part of the IRB record. All cases of non-compliance, UPs, and suspensions and terminations will be investigated and followed by the CoRe team. Additional investigations by other units or individuals may proceed concurrently or in sequence with those of the CoRe team.

RESPONSIBILITIES

- Committee Q –reviews, request changes in, approve or disapprove CAPA plans, and follows-up reports at Committee Q meetings.
- Team Q – Team Q designated member will compile CAPA updates. The follow-up report will be presented at the Committee Q meeting every month. Every Team Q case manager will email the designated person CAPA updates. The Team Q designated member will add the information to the follow-up report for the next available Committee Q meeting.

- Study Staff: Responsible to complete CAPA plan in the time allowed by the Committee Q members. This period is normally 30 calendar days from the date of the meeting unless specified otherwise.
- External IRB: Provides information about determinations of SNC, CNC, and UPs for studies conducted at Emory University/Healthcare.

PROCEDURES

Steps for Studies Reviewed by CMTE Q

- After Committee Q reviews and approves the CAPA plan for a specific case, the CAPA will be added by answering yes to question 2 (is further action required) under "Submit OE Committee Review". The person adding the notes will assign the OE Action to the OE case manager and will click ok. The OE Action Plan will be included in the determination letter sent to the principal investigator
- After the meeting and the OE will enter "Action Required" state.
- Responsible parties will follow up with the study team about the CAPA plan completion and the deadline.
- When the CAPA plan (OE Action Plan) is completed, the OE case manager will submit an Action Response in the IRB system. The case manager will review the action response. The case manager will complete the Required Actions Reviewed activity and will mark the action completed as required or not.
- If the action is completed, the case manager will prepare and send an OE Action Complete letter to move the OE to "Review Complete" status.
- If the CAPA plan has not been completed in the allowed period, the case manager will notify the study team that non-completion by this deadline is deemed non-compliance and will request an explanation of the delay to be submitted along with a notice of completion. This new NC will be reviewed by CoRe. The CoRe team will be notified about the delay for any additional determination. The Team Q designated member will create a report of incomplete CAPAs for the Full Board after CoRe review if this is considered reportable to FB.

Extension for CAPA Plan

The study team may request a deadline extension. This extension may be reviewed and granted or denied at the CoRe team discretion.

Steps for Studies Reviewed by an External IRB

- The reliance listserv is monitored for reports of determinations made by external IRBs of SNC, CNC, or UP for purposes.
- If the Emory IRB is informed via another method, it will be relayed to Team Q.
- Based on the nature of a reported event, Team Q may review the CAPA plan and schedule an audit to check the progress with the implementation of the CAPA
    - The audit can be conducted in person or via email correspondence, depending on the case and/or CAPA plan. For example, if the CAPA plan requires the creation of a document, Team Q can request a copy and examples of when it was used via email.

REFERENCES

- IRB QA Plan
- 45CFR 46.
- 21CFR 820.
- IRB policies and procedures

SOP Title:	*Communication of Report of Internal Study Subject Death*
SOP Category:	Administrative
Established:	07/17/2012
Last Revision:	12/01/2025

PURPOSE

The death of a subject who is an Emory Healthcare (EHC) Patient or University Employee or Student while in a study raises major institutional concerns if the death is deemed unanticipated, related to study participation, and potentially increasing the risk for participant s or others. This SOP is intended to guide the IRB in communicating with EHC and University Officials.

SCOPE

Deaths considered unanticipated problems in Emory study participants.

PROCEDURES

1. Assess whether we have enough information to notify others relevant parties. In most cases, we will need more information or clarification; in such case, the AVP, Education & QA Lead, or Co-Chair should communicate directly with the PI during this initial phase.
2. Recommend to the PI to inform their clinical chair of the event. The PI should also inform study staff since there may be immediate implications for other study subjects.
3. Confirm whether the participant's family has mentioned legal action or has expressed other serious concerns about the study's relatedness to the death. This information should be included in the notification to Risk Management and OGC.
4. Once we are aware of whether the PI considers the event to be a UP, Team Q takes the following action:
   a. Sent to CoRe for review.
   b. If CoRe considers the event to be a possible unanticipated problem, the people listed on the contact grid will be alerted via email, including the date when the full board will review the event.

SOP Title:	*Review of Single Use, Expanded Access of Unapproved Drugs or*
SOP Category:	QA and Education
Established:	07/27/2012
Last Revision:	08/21/2025

PURPOSE

The purpose of this document is to describe the review process of a new study for the use of an unapproved (or not approved for a specific indication) drug or device for Compassionate or Emergency use, from submission to approval. The FDA allows the use of an unapproved medical drug or device both for research and under what is known as expanded access or compassionate uses. This allows for the use of drugs or devices for treatment purposes outside a research protocol.

SCOPE

Compassionate/Emergency use of an unapproved drug or device in an Emory study participant or patient, done by an Emory affiliated physician. If the use is submitted from a doctor without an Emory affiliation, even if treating a patient in an Emory facility, it will likely require review by WIRB or another external IRB. There may be exceptions. Expanded access uses at CHOA should be routed to the CHOA IRB.

DEFINITIONS

- Sponsor: A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator
- Sponsor-Investigator (S-I): means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor

RESPONSIBILITIES

- IRB Team member: facilitates the submission of compassionate and emergency use request, verifying that the information provided is complete.
- IRB Co-Chair: reviews compassionate or emergency use requests before full-board review.
- Investigator: makes sure that the information submitted is complete and accurate, according to the information submitted to the FDA and/or the sponsor.
- Sponsor: submits an IND/IDE supplement to the FDA before use to obtain permission (for compassionate use only), and an IDE supplement after use as a follow-up report.

PROCEDURES

NOTE: Make sure to use our letter templates for IRB Chair concurrence, IRB acknowledgment of use or IRB approvals for these compassionate uses. The Team Q member should review the

submitted information, and assist investigators when possible, directing them to the Emory policies and procedures, FDA guidance or to the Research Integrity and Compliance for the submission of the IND/IDE supplement (in case of an Emory Sponsor-Investigator).

Emergency use of a device: does not require IRB or FDA approval before its use but the study team needs to contact the FDA to inform them of the use. In addition, the study team should submit an application to the IRB for acknowledgment of this use. This will be reviewed at Full Board for acknowledgment. The application should contain information about all the protection measures used before use and the following:

- A description of the circumstances that required the use.
- IDE protocol with a description of the device and name of IDE holder.
- Copy of uninvolved physician's assessment of use
- Copy of authorization from IDE holder if applicable
- Copy of consent document used for expanded access use (template use OK)

Before using the device, the physician should take as many of the following patient protection measures as possible, and provide the following information in the submission:

- Obtain a written independent assessment of the use of the device by an uninvolved physician
- Obtain documented informed consent from the patient or his/her Authorized Legal Representative
- Obtain documented authorization from the holder of the IDE for the Investigational Medical Device, if an IDE exists.
- Notify the Emory IRB by contacting the IRB Chair or his/her designee, and provide the Emory IRB with a written description of the circumstances necessitating the use of the device, along with copies of the uninvolved physician's assessment, informed consent and the IDE's holder's authorization.
- Notify any other institutional officials who require notice under institutional policies.
- If the patient did not consent before the use of the device, the physician should document this matter as described under the Emory IRB P&P, entitled Waiver or Alteration of Informed Consent for Research.

After the Emergency use submission has been initially reviewed, the Team Q member will contact the study team in case of any required changes, while alerting the IRB Chair via email about the Emergency use. Once ready for review by the full board, the Team Q member will place the study in the next available meeting agenda, notifying the meeting facilitator and meeting Vice-chair. The Team Q member should try to assign the review of the Emergency Use to Clinical Co/Vice chairs.
After the Emergency use is acknowledged, the IRB approval letter should be created using the applicable template.

Compassionate use of a device: should be approved by the FDA before the use. The use will also need IRB approval or, alternatively, IRB chair concurrence of use. If the IRB chair

determines that the use would benefit from full board review, the use would be routed that way, even if IRB chair concurrence was requested.

If the study team is seeking IRB Chair concurrence, the following information is required:

- A description of the circumstances necessitating the use.
- IDE protocol with a description of the device and name of IDE holder.
- Copy of uninvolved physician's assessment of use.
- Copy of authorization from IDE holder.
- Copy of consent document for expanded access use (using our current template)

The Team Q member is required to do the following:

- Create a folder with the information received from the treatment team. To document the use in the system, the study team will create a Single Pt Tx Use submission and will add all the documents required for the concurrence.
- Contact the study team in case of any required changes, while alerting the IRB Chair about the Compassionate use.
- Redact any identified information in the OE submission and upload revised copies to the submission.
- Send the concurrence to the study team after the IRB chair confirms it in the submission.

The physician should not use the drug or device unless and until FDA approval of the Compassionate Use and IRB concurrence (or Approval, in the case of a Compassionate Use for a group of patients) has been obtained. If the FDA approves the Compassionate Use and the IRB concurs, then the use may occur.
If the study team is submitting to the IRB instead of asking for IRB chair concurrence, or if the IRB chair decides the use should be reviewed via full board review, the Team Q member will assign the study to the IRB clinical chair or vice-chair and process as normal.
After the acknowledgement of the device use, the letter should be created using the applicable template.

Emergency use of unapproved drug: This use does not need to be approved by the IRB although requires authorization by the FDA. Authorization of the emergency use may be given by an FDA official by telephone, provided the physician explains how the expanded access use will meet the requirements and agrees to submit an expanded access application within 15 working days of FDA's initial authorization of the expanded access use. The physician may choose to use FDA Form 3926 for the expanded access application. The IRB will require a full submission within 5 working days of the use. This will be acknowledged by the Full Board. The submission should include:

- A copy of all information submitted to the FDA in connection with the Expanded Access use request.
- Informed consent form to be used or information demonstrating qualification for Emergency Use exception from informed consent. See the P&P entitled: Waiver or Alteration of Informed consent for Research, subsection entitled Emergency Medical Care

Exception – Exception to the Requirement to Obtain Informed Consent for the Use of a FDA-Regulated Item in Emergency Medical Care Situations.
- Documentation of FDA approval for the Expanded Access Use request

Compassionate use of unapproved drug: this use will require FDA and IRB approvals (or IRB chair concurrence as explained later) before use. The physician may use FDA Form 3926 for the FDA submission. A physician submitting an individual patient expanded access IND using Form FDA 3926 may select the appropriate box on that form to request authorization to obtain concurrence by the IRB chairperson or by a designated IRB member before the treatment use begins, in lieu of obtaining IRB review and approval. If the sponsor is submitting a Modification to an existing IND via Form FDA 1571, and because the form does not have a similar box, the information can be included in a separate request with the application.

If seeking IRB concurrence, the request should include the following:
- A copy of all information submitted to the FDA in connection with the Expanded Access use request
- Informed consent form to be used

If the FDA does not grant waiver of IRB approval or if the request was not made to the FDA via FDA Form 3926, the study team should submit an IRB application that would be routed to the Full Board per the regulations.
If the documentation received indicated the FDA has approved a waiver of IRB approval, the Team Q member will create a folder with the information received from the treatment team. To document the use in the system, the study team will create a Single Pt Tx Usesubmission and will add all the documents required for the concurrence. The Team Q member should redact any patient information in the submission and upload revised redacted copies of documents, if applicable.
The Team Q member will contact the study team in case of any required changes while alerting the IRB Chair about the Compassionate use. The IRB chair will confirm his/her concurrence with the use of the drug in the submission system or will otherwise notify the IRB staff. This concurrence will be sent to the study team. The use can only start after the FDA approves the Compassionate Use and the IRB concurs. The Q team member or the IRB chair processes the letter within Insight.
If the study team is submitting to the IRB instead of asking IRB chair concurrence, or if the IRB chair decides the use should be reviewed via Full Board, the study will be routed as usual via a new study submission.

REFERENCES
- FDA webpage: Expanded Access (Compassionate Use) at https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm#Investigational_Drugs
- FDA Guidance: Expanded Access to Investigational Drugs for Treatment Use — Questions and Answers at https://www.fda.gov/downloads/drugs/guidances/ucm351261.pdf

- FDA Expanded Access for Medical Devices Guidance at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm
- FDA Presentation: Emergency Use and Compassionate Use of Unapproved Devices at https://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf

SOP Title:	*Informed Consent Monitoring SOP*
SOP	QA and Education
Established:	02/24/2010
Last	08/21/2025

PURPOSE

The purpose of this SOP is to describe the process for the IRB to conduct consent form monitoring. The IRB members or staff) may conduct real-time informed consent observations as part of Emory's human research protection program. This is a valuable measure for providing constructive feedback to investigators and ensuring the highest quality experience for prospective research subjects.

SCOPE

This applies to all studies whether under the Emory IRB oversight or external IRB oversight.

PROCEDURES

- The IRB staff will give study teams advance notice of a proposed informed consent monitoring visit.
- The Emory IRB Informed Consent Monitoring Checklist should be used to capture relevant information for each session.
- The following procedure should be followed for consent observation:
  - In a private room or waiting area, the person obtaining informed consent should tell the prospective subject that a representative of the IRB is on site to observe the informed consent discussion. The IRB representative should then introduce him/herself to the prospective subject and ask for permission to observe the consent session. If the subject declines, the IRB representative will not observe that consent discussion.
  - The person obtaining informed consent will then conduct the informed consent discussion as usual, while the IRB representative observes silently, without taking notes or interjecting into the discussion.
  - The subject should be free to ask the IRB representative questions. If this happens, the IRB representative should answer them in a helpful manner.
  - At the conclusion of the discussion, the IRB representative will thank the subject and person obtaining informed consent and will leave the room. At that time, s/he should complete the checklist.
  - If the study team requests it, the IRB representative may give immediate feedback on the discussion and mention any deficiencies in the process.
  - The IRB representative will send the PI a letter in follow up describing the deficiencies from the observation, if any, within three business days. Recommendations for improvements should be included in this letter. Study teams are encouraged to discuss the findings with the IRB representative or IRB leadership.

- If deficiencies in the consent process are noted, the IRB staff member may refer those findings to the IRB Compliance Review team, require additional education on the consent process, or provide on-site informed consent training for the study staff.

REFERENCES

- 45 CFR 46.109(e)
- 21 CFR 56.109(f)

SOP Title:	*Internal QA/QI review of documents before and after IRB Review*
SOP Category:	QA and Education
Established:	06/01/2012
Last Revision:	12/01/2025

PURPOSE

The purpose of this document is to describe the process of auditing studies reviewed by Emory IRB members and staff.

SCOPE

The SOP will apply to human subject research studies reviewed by the Emory IRB.

PROCEDURES

On an ongoing basis, at least monthly, the QA team will review a sample of expedited and/or Full Board new studies submitted to the IRB. The review will encompass submissions across all analysts. The QA team member will populate a dedicated form for this purpose. The findings will be conveyed to the IRB analyst and their supervisor. If necessary, the analyst will follow up with the study team for any revisions needed.

During the review, the QA team will review the following documents, at a minimum:

- IRB submission
- Electronic study history
- Informed consent and HIPAA forms.
- Review of the correct review pathway, subparts (for vulnerable populations), consent waivers, and applicable regulations.

The QA team will determine if submissions contain all required information, such as applicable required templates, device risk determination, etc., and that the informed consent and HIPAA authorization has all required elements.

For Full Board studies, a designated person will review a set of full board minutes for compliance.

PROCESS FLOW

REFERENCES

- IRB policies and procedures
- 45 CFR 46.101
- 45 CFR 46.102
- 10 CFR 745
- 34 CFR 98.3
- 28 CFR part 46
- 28 CFR part 512
- 40 CFR 26 Subparts C and D

SOP Title:	***Letters after FB with PIs, OHRP and FDA after SNC, CNC and UP determinations***
SOP Category:	QA and Education
Established:	05/15/2013
Last Revision:	08/21/2025

PURPOSE

The purpose of this SOP is to describe the process for issuing letters after determinations of Serious Noncompliance (SNC), Continuing Noncompliance (CNC) and Unanticipated Problems (UPs) are made for research reviewed by the Emory IRB.

SCOPE

This SOP applies to studies reviewed by the Emory IRB for which determinations of SNC, CNC and UPs have been made.

PROCEDURES

- Letters to the PI and federal oversight agencies will be drafted by the case manager.
- Any letter to inform PIs about SNC, CNC or UP determinations should be reviewed by another member of Team Q for accuracy and readability before sending.
- Any letter to notify the FDA or OHRP about a SNC, CNC or UP determinations should be reviewed by the AVP of the HRPP or their delegate before sending.
- For notifications to the FDA, the letter should be signed by the IRB chair (who is a MD or clinician). In the case of an absence of the IRB chair, a MD vice-chair may sign on the IRB chair's behalf. For notifications to OHRP, the AVP of the HRPP or their delegate should review the content of the online submission. In case the AVP of the HRPP or their delegate is absent, the a co-chair or the Institutional Official could review the submission details.
- Once the letter has been signed, the letter should be scanned as a PDF document and saved in H:\irb_shared\General\QA Working Files\CMTE Q\YEAR\DATEofMTG\Letters to Feds
- All letters should be saved in their respective location for archiving purposes.
- The electronic copy of the letter to the PI should be emailed to the PI and Institutional officials, per our guidance document entitled: *Everything you need to know when writing letters to PIs, FDA and OHRP after a FB determination of SNC, CNC or UP*. A copy of this email should be kept under H:\irb_shared\General\QA Working Files\CMTE Q\YEAR\DATEofMTG\Letters to PIs.
- For letters to FDA/OHRP, use guidance document entitled: *Everything you need to know when writing letters to PIs, FDA and OHRP after a FB determination of SNC, CNC or UP*. See Contact Grid for IOs who should be copied and Fed (FDA, OHRP) contacts. When sending the email to the federal agencies:
  - Email the FDA by themselves
  - Forward that sent email to the PI, copying the IOs

  - Save a copy of the email to the PI (that also contained the information of the email to the federal agencies) under H:\irb_shared\General\QA Working Files\CMTE Q\YEAR\DATEofMTG\Letters to Feds
- If you receive an acknowledgment of receipt from OHRP or FDA, file it in the appropriate folder.

SOP Title:	*Other Event Submission Review Process*
SOP	QA and Education
Established:	07/29/2013
Last Revision:	08/21/2025

PURPOSE

The purpose of this document is to describe the review process of Other Events submitted to the Emory IRB office.

SCOPE

This SOP applies to all Other Events submitted to the Emory IRB.

SOP SECTIONS

Screening of OEs
Events sent to the CoRe team
Events sent to Committee Q
Cases involving a UP decision that affects multiple studies

DEFINITIONS

- IRB Team Q: Specialized IRB staff who reviews reportable events, work on fact-finding with study team, and submit events to a designated reviewer, Compliance Review (CoRe) team and/or Committee Q as applicable
- Designated Reviewer: A member who has been designated by the Chair to perform expedited reviews on a term basis, or as needed case by case, preferably in writing.
- CoRe Team: A designated group of the IRB Chair, Director, and qualified IRB staff that reviews other events (including alleged non-compliance, potential UPs, potentially serious or continuing non-compliance), suspensions, and terminations. The CoRe team triages cases to determine whether they need a review at a convened meeting of the Emory IRB. The CoRe may engage the assistance of ad hoc consultants.
- Committee Q: A Full board meeting that primarily reviews potential serious and/or continuing noncompliance and unanticipated problem cases.
- Non-reportable event: An event that is not reportable to the IRB per the IRB Policies and Procedures.

REPORTS TO AAHRPP

Within 48 hours but as soon as possible after the organization (or individual researcher) becomes aware, the IRB must report to AAHRPP:

- Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA WaOEng Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
- Any litigation, arbitration, or settlements initiated related to human research protections.

- Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

Work with the Team Q Lead or the IRB Director to assist with reporting.

PROCEDURES

Screening of Other Events

The Senior Q team member will screen the submission.

- If the case reported is potentially noncompliance, a reportable protocol deviation, or an unanticipated problem, it will be assigned to a Team Q member (see next section on CoRe Review).
- If the case is considered a minor protocol deviation, the Senior Q team member may send the Other Event to a designated reviewer. In some cases, the Other Event may be acknowledged by a designated member per SOP.
- Other cases sent for Acknowledgment: If there is precedent for a case, via CoRe and/or FB, that indicates that the Other Event is potentially noncompliance, but neither serious nor continuing, the Senior Q member may send the Other Event for expedited review. The following specific precedents are already in place for sending to expedited review:
  - Noncompliance involving the data collection from more charts than what was approved by the Emory IRB.
  - Over-enrollment of subjects, in cases where the study is expected to enroll a large number of subjects as, for example, in a multi-site trial. If the study is considered of higher risk (for example a Phase I study) or the study has over-enroll with more than 25% of the approved number, the Other Event should be sent instead to the CoRe Team.
- To send to a designated reviewer
  - Assign Other Event to Expedited Review.
  - The review can then be assigned to the designated reviewer for processing
  - If you are not sure if the case needs to go to CoRe, ask the designated reviewer to weigh in and determine if it should be acknowledged versus sent to CoRe. If they want to route the Other Event to CoRe, ask them to select Expedited Screening in the lower right hand section under Actions and select the IRB Q analyst in the drop down before attesting in the checkbox and clicking sign off.
  - If the reviewer would like to move forward with acknowledgement, they would click acknowledge, complete the OE Acknowledge Review Checklist, and then click Route to Final Results for the IRB Q analyst to complete the process.

Events sent to the CoRe team – **see contact grid for who should be included in CoRe email.**

- Create a folder on the H drive in the QA Working Files\Non-Compliance or UP folder with study title and PI name, using the following format (Study#, Other Event #PILASTNAME plus initials of case manager).
  - When the case is under review, it should be located under the Pending folder.
  - If closed, the case should be moved to the closed folder. It should be located at H:\General\QA Working Files\NC UP Complaints\NonCompliance\Closed\ OE

IRB/STUDY##PILASTNAME removing the case manager initials.

- The Team Q member should contact the PI and study team for the input and clarification of data, corrective and preventive action plan, or any other information if needed. Use current SOP Ed & QA Team Mission and Process.
- The information obtained is added to the worksheet. The form can be located at: H:\General\QA Working Files\Forms, templates and Guidance\ Forms for OE review, but you can also download the PDF of the Other Event form and utilize the CoRe screening checklist to generate the information needed for CoRe routing.
- The team Q member emails the worksheet information to the CoRe team. The information from the form should contain information from the title of the study to the CAPA plan. Other appropriate documents may be attached as well.
- The CoRe team as of June 14, 2021, , is composed of Carlton Dampier, Cliff Gunthel, Shara Karlebach, Julie Martin, Rebecca Rousselle, Aryeh Stein, and Larry Tune.
- The CoRe team should "Reply All" via email with the recommendations. If anyone on the CoRe team thinks the case could represent serious or continuing noncompliance (SNC/CNC) or an unanticipated problem (UP), refer the case to the next Com. Q meeting. If three CoRe members think the case is not SNC, CNC, or UP, including at least one clinician, or at least one Vice-chair or Co-Chair, the case can be closed and you can prepare the letter. Also, if any member of the CoRe has a conflict, they should recuse him/herself from the review of the Other Event.
- The cases will be divided into Clinical CoRe cases and Procedural CoRe cases.
    - Clinical CoRe cases may be those involving clinical care or participant safety such as a missing clinical test or dosing issues.
    - The Procedural CoRe cases may be those that are nonclinical in nature such as HIPAA issues, protocol deviations, noncompliance and unanticipated problems not involving a clinical matter.
    - Team Q may decide at their discretion to whom to send a case, but members will be selected according to their area of expertise. In cases that involve both clinical and nonclinical issues, route it to clinical CoRe. Only 5 CoRe members will be selected for each case, always including a Co-Chair and the three staff members.
- If the CoRe team determines that the Other Event represents no noncompliance, not serious or continuing noncompliance or not an unanticipated problem, the Other Event will be closed. The Other Event worksheet should be completed and non- applicable sections should be deleted.
    - The Other should be closed in Insight by the Q analyst assigning themselves to Expedited Review of the Other Event. After navigating back to pull the item from Actions Required, the analyst can continue by clicking CoRe Determination in Insight in the lower right hand Actions menu. Then, the OE CoRE Determination Checklist should be completed. After clicking next after completing the checklist, select Complete, click the attestation check box, and click sign off.
- If CoRe has determined that a safety report submitted in an Other Event is not a UP, additional studies reporting the same safety event can be sent in an abbreviated form to the CoRe, with information about the study, to confirm that applies to this new study. The email should be saved in the folder on the shared drive in lieu of a worksheet. The Other

Event letter should also be saved in the same folder.

- If the case is closed after a CoRe determination, the folder should contain the following:
  - Letter to the PI: study number, PI last name, Letter to PI, date of issue (example 123 Smith Ltr to PI 11-5-12
  - CoRe correspondence
  - Completed Other Event worksheet

Events sent to Committee Q

- If the CoRe assesses the Other Event as potentially SNC or CNC, the Other should be forwarded to committee Q for review
- If the CoRe assessed the information as a potential UP, the Other Event should be sent to the next available full board meeting or CMTE Q if the Other Event does not represent an immediate safety issue for subjects.
- The following actions should be completed:
  - Click Scheduling in the lower right hand Actions menu, attest, sign off.
  - Navigate to scheduling, and find the item, click on it and assign it to the relevant meeting on the right hand side.
  - The case manager is also required to inform and forward the invite CHOA or VA colleagues as per the contact grid of any cases going to CMTE Q involving CHOA or VA facilities via email. VA cases are required to be reviewed within 30 days.
  - Save the materials in the appropriate CMTE Q folder (do not include CoRe emails).
  - Contact the PI to schedule the SNC/CNC/UP review for a Committee Q meeting. The PI must be invited to attend by zoom. Attendance is only required for compliance reviews. If the PI or a PI representative cannot attend, the study team may submit a response in writing. Schedule the case for an agenda based on the PI's availability. If the PI cannot come to the meeting, consult with CoRe about moving the case to the next available meeting. In the case of UPs, the case should be reviewed at the next available meeting if it represents imminent harm to subjects, despite PI availability.
- If the board determines that an Other Event constitutes an unanticipated problem or serious or continuing noncompliance, some or all of the following actions could be required:
  - Suspension of the research
  - Termination of the research.
  - Notification of current participants when such information might relate to participants' willingness to continue to take part in the research.
  - Modification of the protocol.
  - Modification of the information disclosed during the consent process.
  - Providing additional information to past participants.
  - Requiring current participants to re-consent to participation.
  - Modification of the continuing review schedule.
  - Monitoring of the research.
  - Monitoring of the consent process.
  - Referral to other organizational entities.

<u>After the meeting</u>

- Team Q will meet to review findings from the meeting and submit committee reviews using the Insight Meeting Process outlined in the Facilitator Checklist here, H:\General\CMTE\1. Meetings\1-Meeting Facilitation Prep Kit. During this time, the CAPA plan will be added as well per the IRB Team Q CAPA Follow Up SOP, if applicable.
- The PI should receive a determination letter within 2 business days. Follow available templates and make sure institutional officials are copied per the contact grid if the issue was determined to represent an UP, SNC or CNC by the convened IRB. For external UPs, follow the contact grid for who should be copied.
- If applicable (after a UP, SNC or CNC determination), a letter to OHRP and FDA should be drafted and sent to the AVP for the HRPP for review (refer to SOP). Specifically:
  - For studies funded with federal funds: report to OHRP
  - For studies using an FDA regulated product: report to FDA
  - If both of the above apply, report to both. You may be able use a PDF of the OHRP online submission to the FDA.
- Once the FDA/OHRP letters/online submission have been reviewed by the AVP for the HRPP, they can be reported to the applicable Fed agencies. Once that reporting is complete, email the PDF of the online submission or forward the FDA email to the study PI and university officials as per the contact grid.
- The letters to OHRP and FDA should be saved in the Other Event folder. These letters should also be saved under the CMTE meeting folder entitled "Letter to Feds."
- The Other Event is closed in Insight after the letter is sent to the PI. Once the case is considered closed, the Other Event folder should be archived in the closed folder.
- Save a copy of the sent email correspondence under "Letter to Feds" folder
- If the case is closed after a FB determination, the folder should contain the following:
  - Letter to the PI: study number, PI last name, Letter to PI, date of issue (example 123 Smith Ltr to PI 11-5-12
  - CoRe correspondence: CoRe determination on DATE
  - Copy of worksheet
  - Copy of Letter to Feds: study number, PI last name, Letter to FDA or OHRP, date of issue (example 123 Smith Ltr to FDA 11-5-12)
- If the case has a CAPA pending item, the case should be moved from the "pending" folder to the "working on CAPA" folder. When the CAPA issue is completed, the case can be moved to the "closed" folder.

For AVAMC Research:

- If the convened IRB or the IRB reviewer/CoRe determines that the problem or event was serious, unanticipated, and related to the research, a simultaneous determination is required regarding the need for any action (e.g., suspension of activities; notification of participants) necessary to prevent an immediate hazard to participants in accordance with VA regulations.
  - All determinations of the IRB reviewer (regardless of outcome) must be reported to the IRB at its next convened meeting.

- The VA medical center director must report the problem or event to the appropriate VA Office of Research Oversight research officer within five business days after receiving such notification.
- If it was determined that the problem or event is serious, unanticipated, and related to the research, the convened IRB must determine and document whether a protocol or consent document modification is warranted.
- If the convened IRB determines that a protocol or consent document modification is warranted, the IRB must also determine and document:
  - Whether previously enrolled participants must be notified of the modification.
  - When such notification must take place and how such notification must be documented.

Cases involving an UP decision that affects multiple studies

- During the meeting, the board may make a UP determination. If the determination affects studies using the same drug or device, the board should make a note on the meeting minutes stating one or more of the following options:
  - IRB case manager informs other study teams that are using that drug or device. Study teams should review the information for the UP, and assess if an Other Event and a MOD if applicable, is needed to add the new risk to their study documents.
    - The study team may disagree, and if so, they should document why this UP does not affect their study.
    - The Other Event and MOD submission can be reviewed via the expedited process as a risk/benefit ratio analysis was done during the convened IRB meeting.
- After the meeting, the case manager will send an email to the IRB staff, letting them know that this UP may affect several studies, and that the Other and MOD can be reviewed expedited, if applies. The email should contain the list of the studies.
- In addition, the case manager will log comments to each study, asking the study team to submit an Other Event and a MOD as applicable. If the original Other Event had letters from the sponsor explaining the issue, they should be added to the comment. Here is an example for this comment:

  Dear study team,

  The IRB received the attached letter in an Other Eventsubmission involving a different IRB study using the same investigational agent than your study. The Other Event was reviewed at an IRB convened meeting on DATE, and determined that the event of NAME OF EVENT, represents an unanticipated problem.

  The Board determined that this UP determination may affect your study. As such, you are may be required to submit an Other Event. Please review the attached document, and submit an Other Event with your assessment of this risk. If you do not agree with the submission of the Other Event,please let us know why this event does not apply to your study population. If you agree with the UP determination, you may also be

required to submit an amendment to add the risk to the informed consent form. If this risk is already in your consent form, you may disregard.

Your Other Event and amendment will be reviewed via expedited process, as approved by the full board meeting on DATE. You have 10 business days to submit the Other Event and AM or provide your assessment of why this event does not apply to your study. If your study is reviewed by an external IRB, please report to them directly.

Let us know if you have any questions,

- The case manager is responsible to check that the Other Events and MODs have been submitted if required. The MODs will be processed by the study owner. If the study team does not take action in the allowed time, the case manager needs to escalate emailing the study team and the Senior Q member with the following information:

  Dear Dr. X,

  On DATE, you were notified of an unanticipated problem determination that may affect your study. You were required to get back to us and indicate if this determination negatively impacts your study. Please, respond to this email with your assessment by close of business on DATE *(Friday of this week)*. Failure to respond by this dateline represents noncompliance.

  If you have any questions, please let us know,

  NAME
- When the Other Event is submitted, the information can be sent to a designated reviewer (DR) for expedited process. The DR should be a member of CMTE Q members who is a medical doctor. The message to the DR should include this information:
  - Determination was made during CMTE X on DATE
  - Assess if the UP determination also affects this study
  - Attach copy of the meeting materials and determination letter
  - Here is an example of the information for DRs:

    Dear Dr. X,

    This same event was reviewed by CMTE X on DATE for another study (IRB 123456). The event, NAME OF EVENT, was considered an UP. This same event is being reported for several studies. We need your help assessing if this event also applies for this study. If so, we will acknowledge this event as an UP for this study as well. Please submit an Other Event to document the event. If you feel this event may affect this study differently and needs to be assessed again, let me know and I will send to the CoRe team.

    Looking forward to hearing from you,

NAME of TEAM MEMBER

PS: See attached documents from the Q meeting for your reference

- After the DR reviews the Other Event, the Other Event may be acknowledged or sent to CoRe for new review (if the DR does not think the UP determination affects this study). If the latter, the Other Event will follow the CoRe review process as outlined before.
- If the Other Event was confirmed as an Unanticipated Problem by the DR, the case manager will close the Other Event in Insight with indicating the determination using the actions as indicated above.

REFERENCES

- IRB policies and procedures
- Emory SOP: Acknowledgments & Noncompliance Determinations Made by Senior Team Q Staff
- Emory SOP: Letters after FB with PIs, OHRP and FDA after SNC, CNC and UP determinations

SOP Title:	***Review Process for Other Events for Cede Studies and Those Where Emory is the Reviewing IRB for External Study Teams***
SOP Category:	QA and Education
Established:	12/09/2015
Last Revision:	08/21/2025

PURPOSE

This SOP details the process the QA team uses when reviewing Other Events for studies that include reliance.

SCOPE

This SOP applies to Other Events reported to the Emory IRB for cede review studies and for studies where Emory is serving as the reviewing IRB for external sites.

PROCEDURES

Cede Review Studies

Emory study teams are responsible for submitting Other Events to the external IRB as required by the external IRB's reporting policies but should follow our reporting requirements if the external IRB's requirements are less stringent. If an external IRB determines an event represents an unanticipated problem, serious noncompliance, or continuing noncompliance, the external IRB will forward the determination letter to the Emory IRB. Study teams conducting research under the oversight of an external IRB are responsible for reporting **internal** events to the Emory IRB as described on the IRB website under Collaborative Research.

1. Upon receipt of the Other Event and no later than within two business days of receipt, the QA Director/Team Lead reviews it to determine if it meets reporting criteria. If it does not meet reporting criteria, the QA Director/Team Lead will return to submitter with a comment that the event does not meet reporting criteria and ask them to discard the OE.
2. If it does meet reporting criteria, the QA Director/Team Lead delegate the case to a member of Team Q for Institutional notification.
    a. Complete the internal notification as noted below.
    b. Enter the information of the reported event in this spreadsheet located at OneDrive/IRB-Staff/Documents/H drive/General.
3. If it is a reportable determination, the external IRB should send notice of its determination and the determination letter to the Emory IRB. Alternatively, the study team can upload the determination letter in the Other Event if it is not already provided.
4. Once all reporting is complete and any federal letters have been filed in the QA folders, the Q team member should update the spreadsheet and should self-review the Other Event submission. The Q team member should not check any determination boxes, since these determinations were not made by our IRB. The Q team member should instead enter the

reviewing IRB's determination in the Notes field and submit the review. The final state is "acknowledged." There is no need to write a letter.

5. Follow the post determination notification procedure noted below.
6. Once the external IRB determination is in, follow the 'external IRB determination' notification process below for SNC, CNC, UP, suspension as applicable.

Institutional Notification (pre-IRB-determination)

1. While awaiting a determination from the reviewing IRB, a member of Team Q will draft an email to the appropriate parties and will copy and paste the lay summary into the body of the email. They will attach a pdf copy of the Other Event report and any relevant attachments. Include a link to the Other Event submission in the body of the email as well.

See contact grid for who to copy in the notifications.

REPORTS RECEIVED DIRECTLY FROM EXTERNAL IRBs

2. For external IRB determinations of serious noncompliance, continuing noncompliance or unanticipated problems received directly from external IRBs, the Emory IRB person who was notified will forward the email to the AVP for the HRPP, Reliance AD and Team Q with the information with the Other Event number (if applicable).
   2.1. Upload a copy of the letter under the Other Event submission (as applicable).
   2.2. If an Other Event does not exist, Team Q will review the information to determine if the submission was needed (in case it was not submitted).
   2.3. Follow the procedure under "Notification to Internal IOs" as appropriate. These notifications are only required for determinations of SNC, CNC, or *internal* (at Emory sites) UPs.
3. For external IRB determinations that an event was **not** SNC/CNC/internal UP, proceed to EGREGIOUS EVENT OTHER EVENT CLOSURE IN EMORY'S IRB SYSTEM.

PROCEDURE AFTER DETERMINATION IS MADE

IRB DETERMINATION NOTIFICATION TO INTERNAL IOs

For egregious events or events the external IRB determined to be SNC, CNC, UP, update the External IRB reporting spreadsheet. The Q team member drafts an email to the Emory PI with the IRB # and Study Short Title in the subject line stating the following:

i. Dear Dr. _____:
We have received notification that the [Reviewing IRB] determined that a reportable new information submission during the course of the above-referenced study constitutes a [type of determination]. Attached, please find the determination letter from [Reviewing IRB]. This determination may be reported to the sponsor and federal oversight agencies, as applicable.
It is imperative that you follow your CAPA Plan as written. If you find that there are any inaccuracies in this letter, please notify your point of contact at [Reviewing IRB].

Please let me know if you have any other questions. Thank you for your cooperation.

2. CC based on the contact grid. Once sent, save a copy of the determination letter and the email in the study folder under QA Working Files.
3. Note: If you receive copies of external reports from agencies or notices of receipt of external reports from agencies, scan and/or save them under QA Working Files in the appropriate study folder. If the report produces any results, save the contents in the same manner, and email it to the IOs using the same process described above.
4. Save letters to federal agencies in the folder in QA working files, but there is no need to send the letters to the IOs.

EGREGIOUS EVENT OTHER EVENT CLOSURE IN EMORY'S IRB SYSTEM

Once all reporting is complete and any fed letters have been filed in the QA folders, the Q team member should update the spreadsheet and should self-review the Other Event submission. There is no need to write a letter.

SOP Title:	*IRB Record Review of Studies*
SOP Category:	QA and Education
Established:	08/30/2011
Last Revision:	08/21/2025

PURPOSE

The purpose of this document is to describe how the IRB Team Q conducts record reviews of studies approved at the Emory University IRB, whether in person or virtually. The Emory IRB is committed to helping the research community maintain a high standard of compliance through education and guidance. Record Reviews will play an integral role in achieving this goal as it will allow the identification of problems offering opportunities for education.

SCOPE

Record Reviews conducted in human subjects' research overseen by the Emory University IRB and studies conducted at Emory under external IRBs.

DEFINITIONS

- Not-For-Cause Compliance reviews – Periodic compliance reviews are conducted using a systematic method to review IRB-approved research or IRB records and activities on a regular basis. The IRB aims to perform 10 routine record reviews per year.
- Directed Reviews – Assigned to Team Q from the IRB, ORA offices, or Emory affiliates to address a concern or previously identified potential for noncompliance.
- For-Cause Compliance Reviews: Designed to assess the Investigator's compliance with federal regulations, state laws, and Emory IRB P&Ps. These reviews of IRB-approved research studies are in response to credible evidence of identified concerns or alleged noncompliance.

PROCEDURES

The process will start by communicating with the research staff and coordinator about the record review visit. The notice for the record review may vary according to review type. For Not-For-Cause compliance reviews, the study team will have two-week (10 business days) notice from the date of the initial communication to the date of the record review unless there is a compelling reason for a delay. For-cause compliance reviews should be conducted within 2 business days of the IRB's initial contact with the study team. The study team should respond within 24 hours to schedule the record review. Directed record reviews will be conducted according to study team needs or as mandated by the IRB.

1. The IRB will contact the study team to schedule the meeting. The study team generally has from 1 to 5 business days to respond to this request, depending on the record review type.
2. The IRB will conduct the record review on the scheduled date. The minimum documents needed for review are the study regulatory binder (for clinical research), protocol (all

versions), informed consent and HIPAA consent forms (all versions), correspondence with the IRB, IRB submission records and individual study subject information. The IRB reviewers may give real-time feedback and answer questions about the information that is being reviewed. The IRB reviewer may also ask questions to the PI and study staff in case of doubts when performing the record review. The IRB reviewer may not communicate expected actions of the IRB.

3. The IRB reviewer aims to send the record review report within 10 business days of the record review's completion. The PI will review the findings and CAPA, and determine if the findings are accurate and if they accept the CAPA as is, or if they would like to modify it.
4. The PI has 5 business days to respond to the reviewer findings.
5. If desired by the study team, the IRB reviewers will meet the following week to discuss the findings and next course of action including CAPA implementation and education opportunities.
6. The IRB reviewers will send the report and accepted CAPA plan to CoRe team for review or to the full board meeting, if needed.
7. If findings required CoRe review, the study team should submit a OE in 10 business days. If the study team do not comply with the request, the Team Q member will create the OE for them and ask a super user for submission, documenting the communication with the study team about this requirement.

APPLICABLE REFERENCES

- IRB QA Plan 12.15. 08
- 45CFR 46.
- IRB policies and procedures

SOP Title:	***Review of Safety Reports submitted by sponsors holding an IDE***
SOP Category:	QA and Education
Established:	06/08/2012
Last Revision:	08/21/2025

PURPOSE

The purpose of this document is to describe the process of reviewing progress reports received under 21 CFR 812.150 (b) (5).

SCOPE

The SOP will apply to Emory human subject research working under an IDE.

DEFINITIONS

- Investigational Device**:** means a device, including a transitional device that is the object of an investigation. An investigational device is permitted by the FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.
- Investigational Device Exemption (IDE): An IDE allows an Investigational Device to be used in a clinical study in order to collect the safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification submission to the Food and Drug Administration.
- Sponsor: A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator

PROCEDURES

Once the IRB receives a progress report (different from the annual report that should be submitted at continuing review), IRB leadership will review the report to verify that it does not contain any new information that should be reported promptly to the board. If the progress report contains new safety information, it will be sent to Team Q for processing.
Any reports may be destroyed after required steps are completed.

REFERENCES

- 21 CFR § 312
- 21 CFR § 812
- IRB policies and procedures

SOP Title:	***Routing External UPs (FDA Regulated)***
SOP Category:	QA and Education
Established:	07/17/2012
Last Revision:	08/21/2025

PURPOSE

The purpose of this document is to describe how the IRB Team Q will route external unanticipated problems from studies considered FDA regulated.

SCOPE

FDA regulated trials conducted in human subjects' research overseen by the Emory University IRB.

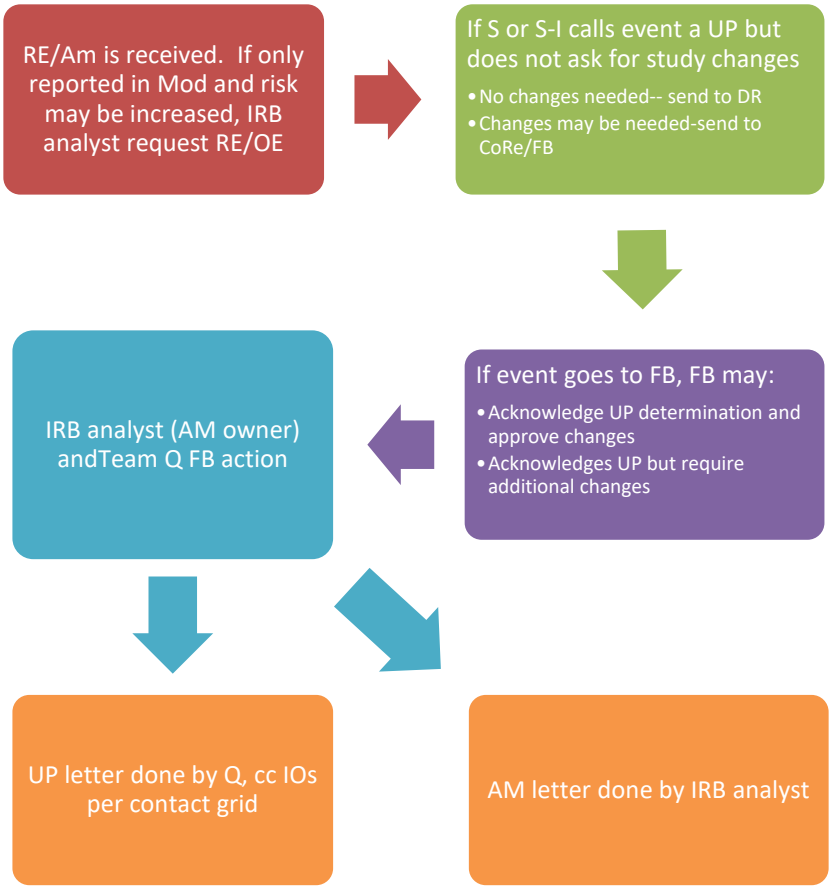
DEFINITIONS

- Investigational Device**:** means a device, including a transitional device that is the object of an investigation. An investigational device is permitted by the FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.
- Investigational Drug or Investigational New Drug: An Investigational Drug or Investigational New Drug means a new drug or biological drug that is used in a clinical investigations or a biological product that is used in vitro for diagnostic purposes.
- Investigational Device Exemption (IDE): An IDE allows an Investigational Device to be used in a clinical study in order to collect the safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification submission to the Food and Drug Administration.
- Investigational New Drug (IND) Application**:** An application that must be submitted to the FDA before a drug can be studied in humans. This application includes results of previous experiments; how, where, and by whom the new studies will be conducted; the chemical structure of the compound; how it is thought to work in the body; any toxic effects found in animal studies; and how the compound is manufactured.
- Sponsor: A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator
- Sponsor-Investigator (S-I): means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor
- Unanticipated Problem: any unexpected problem related to the Research, including any unexpected adverse experience, whether serious or not, that affects the rights, safety or welfare of subject or others or that significantly impacts the integrity of the research data.

OHRP considers unanticipated problems, in general, to include any incident, experience, or outcome that meets all of the following criteria:
  - Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
  - Related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
  - Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
- Unanticipated Adverse Device Effect (UADE): any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects

PROCEDURES
- If an external event is called an unanticipated problem by the sponsor (or S-I), then the event will be reported via OE (and Mod if necessary).
  - If event does not merit changes via Mod (e.g. study is closed for enrollment without active subjects), Associate or Assistant Director will send event to DR.
  - If the sponsor has not requested changes in the study but the event may merit changes, (e.g. study is still enrolling or have active subjects) the event will be reviewed by CoRe. CoRe may acknowledge the event/no changes in study or may recommend FB to review the CoRe suggested changes to study.
  - If sponsor or S-I reports events as unexpected and related but does not call it a UP, the event will go through CoRe/FB as normal.
- If the event is reported only as an amendment, the IRB analyst will request the submission of a OE/Other Event as well.
- The IRB analyst will contact Team Q lead to notify about the amendment. Team Q only needs to know about amendments involving increased risk (e.g. changes to the ICF involving new adverse event).
- Team Q lead will assign the OE to a Team Q member who will be in close communication with the IRB analyst.
- When the RE/Other Event goes to FB, the FB should make one of these two determinations:
  - The IRB acknowledges the UP determination and determines that changes as submitted are appropriate.
  - The IRB acknowledges the S or S-I determination, but thinks additional changes are necessary.

- After the FB meeting, The Team Q member will send FB determination letter to the PI, copying IOs per contact grid.



REFERENCES

- IRB QA Plan 12.15. 08
- 45 CFR 46.103
- IRB policies and procedures
- 21 CFR 812.3

S-I STUDY MANAGEMENT

Definition for the SOPs on this Section

- Investigational New Drug (IND) Application**:** a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans which must be secured prior to administration of any new drug, biological product that is not the subject of an approved New Drug Application, or Biologics/Product License Application. An IND may be required for a clinical investigation using a marketed drug for a use other than the indications in the approved labeling. [21 CFR § 312.3].
- Investigational Device Exemption (IDE): An IDE allows an Investigational Device to be used in a clinical study in order to collect the safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification submission to the FDA. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE (either abbreviated or issued by the FDA) before the study is initiated. [21 CFR § 812.3].
- Sponsor: A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. [21 CFR § 312.3, 812.3].
- Sponsor-Investigator: an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor. [21 CFR § 312.3, 812.3].
- Annual or Progress Report Submission: A report submitted to the FDA by the IND or significant risk IDE holder within 60 days of the anniversary date that the IND went into effect or at regular intervals and at least yearly for an IDE for a significant risk device. The report contains the study progress information, general investigational plan for the following year, and other applicable information. [21 CFR § 312.33, 812.150].

SCOPE

FDA regulated studies, involving an Emory faculty member holding an IDE for a significant risk device or an IND.

References for SOPs in this Section

- 21 CFR § 312
- 21 CFR § 812
- IRB policies and procedures

Emory Sponsor Responsibilities Checklist Continuing Review Update=

SOP Title:	***New study screen process for S-I studies***
SOP	S-I Submission Management
Established:	07/26/2012
Last	08/21/2025

PURPOSE

The purpose of this document is to describe the review process of new study submissions by the IRB analyst and when the study involves an Emory Sponsor or an Emory Sponsor-Investigator (S-I) holding an IDE for a significant risk device or IND.

PROCEDURES

- The IRB analyst will direct the study team to add "S-I" to the beginning of the short title (if not already added).
- The IRB analyst will notify the Sponsor/S-I to complete the required S-I training and ask Sponsor/S-I to provide additional information about the study IND/IDE (e.g. IND/IDE submission date, FDA correspondence, Study May Proceed letter etc.)
    - If the investigator is applying for a new IND/IDE, a study cannot be placed on a Full Board agenda until we receive either FDA "study may proceed" correspondence or more than 30 days have passed since the date of IND/IDE submission. If the team pushes back, the analyst will contact the Associate Director for additional steps.
- If the investigator is submitting an IND Amendment to add a study under an existing IND, a study cannot be placed on a FB agenda until documentation that the IND amendment has been submitted is received. If available, the team should provide FDA correspondence related to the review of the IND amendment; however, the submission package sent to FDA should be provided. There may be situations where the IRB requires feedback from the FDA before moving forward with review.
- If the study team received an IND or IDE letter stating that it is *pending some contingencies* before proceeding, the IRB analyst will ask the team for the information received from the FDA (via email, for example) and the changes to the protocol and consent forms sent to the FDA to address said contingencies. The FDA correspondence should be uploaded in Attachments. When the FDA has issued non-clinical hold comments, the IRB analyst will request a response from the team on how they will address the comments (a copy of correspondence with the FDA is not required).
- When the study is ready for FB, the IRB analyst will add the study to the next available meeting agenda.
- If the study team adds a site not previously listed in the IDE or IND protocol, they should submit a new amendment to update the protocol with the new site information (see SOP 'Amendment submission screen process for S-I studies' for more details).
- If the non-Emory sites include an international site, the Emory sponsor should provide:
    - Analysis from Emory's General Counsel review.
    - Approval letters from the international site IRB/EC review.

- Include the use of a CRO with expertise in the rules and laws of the international site in the protocol's site monitoring plan section

SOP Title:	*CR screen process for S-I studies*
SOP	S-I Submission Management
Established:	07/26/2012
Last	12/01/2025

PURPOSE

The purpose of this document is to describe the review process of continuing review (CR) submissions by the IRB analyst when the study involves an Emory Sponsor or an Emory Sponsor-Investigator (S-I) holding an IDE for a significant risk device or IND.

PROCEDURES

- The IRB analyst will request that the Emory Sponsor/S-I complete the Emory Sponsor Responsibilities Checklist Continuing Review Update and place it in the submission.
- Once the Emory Sponsor Responsibilities Checklist Continuing Review Update is complete and information provided confirmed, you can move forward with review.
- If the study is in data analysis only or if the IND is withdrawn (inactive), the Emory Sponsor Responsibilities Checklist is not required.
- The IRB analyst will ensure that the IND or IDE annual or progress report submission to FDA is included in the Attachments.
    - If the annual report submission is not included in the application, the IRB analyst will determine from the anniversary date that the IND or IDE went into effect by reviewing the date of the 'Study May Proceed' correspondence.
    - If the date occurs in the future, the IRB analyst will remind the team to submit the annual report at the next continuing review.
    - If the anniversary date has already passed, the IRB analyst will request a copy of the annual report submission.
    - If the annual report submission is not provided and the annual reporting date has passed (within 60 days of the IND Effective date) the IRB analyst will notify the team to submit an OE.
    - The continuing review can still be assigned to a Full Board committee meeting without the IND or IDE annual report; however, this might be deemed a pending issue by the committee.
- When the continuing review is ready for Full Board review, the IRB analyst will add a note the status of the IND/IDE annual report submission and route it for scheduling.

SOP Title:	*Amendment screen process for S-I studies*
SOP Category:	S-I Submission Management
Established:	07/26/2012
Last Revision:	12/01/2025

PURPOSE

The purpose of this document is to describe the review process of amendments by the IRB analyst when the study involves an Emory Sponsor or an Emory Sponsor-Investigator (S-I) holding an IDE for a significant risk device or IND.

PROCEDURES

Note for any change to the protocol/IB/IC: *if there are any delays in the submission of these documents (check cover letter or dates on the documents), please check with Team Q as the study team may require the submission of an OE.*

CHANGE SPONSOR

- The IRB analyst will confirm that the Sponsor submitted an IND amendment or IDE supplement to the FDA to change sponsor. If the FDA issues correspondence for the transfer of sponsor this should be provided as well.
- The IRB analyst will verify that the FDA amendment/supplement was submitted and that the protocol and ICF have been changed accordingly.

CHANGE OF PRINCIPAL INVESTIGATOR

If the study changes the study PI, without changing the Emory Sponsor, the Emory Sponsor is required to submit an IND amendment or IDE supplement to the FDA. The change must be submitted by the current PI or Department Approval is required (can be in the form of an email accepting the change for department leadership). PI Changes require ODP ancillary review before final approval can be issued. The study analyst will verify that the FDA amendment/supplement was submitted and that the protocol and ICF have been changed accordingly.

TEMPORARY CHANGE OF PI OR S-I STATUS

For studies that are not in data analysis only: If there is a situation that requires the PI or S-I to temporarily relinquish their role on the study due to a leave of absence (e.g. mateOEty leave, sabbatical) for a period of ≥3 months, a new faculty member should be appointed to fulfill this role in their absence. The study team must submit an amendment to update the record in the IRB submission, protocol, and consent form.

S-I MOVES TO ADJUNCT STATUS

In situations where an Emory S-I leaves the institution remains the S-I and maintains an adjunct status role, the study will no longer be considered a S-I study when the following criteria are met:

- The faculty member has a primary affiliation with another institution.
- A different faculty member has been appointed as the Emory PI.

CHANGES THAT MODIFY THE PROTOCOL

If the Emory Sponsor/S-I holding an IND or significant risk IDE is making modifications to the protocol required to be submitted to FDA as defined by 21 CFR 312.30 / 812.35, the Emory Sponsor/S-I holding an IND or significant risk IDE will need to either (1) include documentation that they have submitted the change to the FDA, (2) add a date for when they will submit to the FDA, or (3) confirm the changes do not require FDA submission. If the FDA submission date is a future date, the study team is also responsible for logging a comment in the study, confirming that they have notified the FDA of the change; this will not be a pending issue for the review and approval of an amendment. The following language should be included in the approval of the amendment:

"The protocol amendment cannot be implemented until the FDA has been notified of the protocol amendment. If FDA responds with any concerns with the protocol amendment, the IRB should be notified via a new amendment."

If there is any indication that the FDA has concerns with the proposed amendment, the IRB should be provided with these details.

Studies where the Emory Sponsor/S-I holds an IND

Substantial modifications to the protocol must be submitted to the FDA and IRB. Substantial modifications include any change in a Phase 1 protocol that significantly affects the safety of subjects or any change in Phase 2 or 3 protocol that significantly affects the safety of subjects, the scope of the investigation, or the scientific quality of the study. If the IRB analyst is unsure whether the change would be considered substantial requiring FDA notification the team should be asked to clarify their plans for notifying FDA and why the change does or does not meet the definition of substantial. Examples of changes requiring an amendment under this paragraph include:

- Any increase in drug dosage or duration of exposure of individual subjects to the drug beyond that in the current protocol, or any significant increase in the number of subjects under study.
- Any significant change in the design of a protocol (such as the addition or dropping of a control group).
- (The addition of a new test or procedure that is intended to improve monitoring for, or reduce the risk of, a side effect or adverse event; or the dropping of a test intended to monitor safety.

Studies where the Emory Sponsor/S-I holds a significant risk IDE

A sponsor must obtain (FDA and IRB) approval before implementing a change to an investigational plan unless the change does not affect:

- The validity of the data or information resulting from the completion of the approved protocol, or the relationship of likely patient risk to benefit relied upon to approve the protocol;
- The scientific soundness of the investigational plan; or
- The rights, safety, or welfare of the human subjects involved in the investigation.

CHANGES ADDING SITES TO THE PROTOCOL

If the study team adds a site (not previously listed) to the IDE or IND protocol, the study team should submit an amendment to update the protocol. For IDE studies IRB approval is required before the FDA will approve the addition of sites.

SOP Title:	***Closeout submission screen process for S-I studies***
SOP Category:	S-I Submission Management
Established:	07/26/2012
Last Revision:	08/15/2024

PURPOSE

The purpose of this document is to describe the review process of closeout submissions by the IRB analyst when the study involves an Emory Sponsor or an Emory Sponsor-Investigator (S-I) holding an IDE for a significant risk device or IND.

PROCEDURES

Studies where the Emory Sponsor/S-I holds a significant risk IDE

- Once a close-out request is submitted, the IRB analyst will ensure that the Emory Sponsor/S-I holding a *significant risk IDE* provides: 1) a copy of the final IDE report (which is due to the IRB & FDA within 6 months after the completion or termination of the investigation) and 2) confirmation that they have submitted the report to the FDA.
- If a final IDE report is not available, then the study must be kept open until the step above is complete.
- *If the study approval lapses*, even if a close-out is submitted before expiration, the study will be considered to have lapsed, and an OE will also be required for completion of the close-out.
- Once all supporting documentation is submitted (final FDA report, OE if necessary), then the study can be closed-out using normal close-out procedures.

Studies where the Emory Sponsor/S-I holds an IND

Once a close-out is submitted, the IRB analyst will ensure that the Emory Sponsor/S-I holding an IND provided a timely annual report to the FDA (if one is required) or submitted an IND withdrawal.

STUDY MANAGEMENT

SOP Title:	***Not Research/ Not-Human-Subjects/Not-Human-Subjects-Research/Not-Engaged***
SOP Category:	Study Management
Established:	06/28/2013
Last Revision:	08/21/2025

PURPOSE

Outline the necessary steps for processing a determination of not research (NR), not-human-subjects (NHS), not-human-subjects research (NHSR), or not-engaged. Determinations are made in response to:

- Requests for a determination via MS Form **NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM**
- Requests for a determination via email (typically after using the form on the website but have been instructed to contact the IRB)
- Insight submissions which upon initial review are determined NR/NHSR/NE

SCOPE

This applies to all IRB staff, particularly those who manage listserv and analysts who conduct initial review of new Insight submissions.

PROCEDURES

REVIEW OF NR/NHSR/NE DETERMINATIONS

NR/NHSR/NE determinations are typically made in response to either MS Forms NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM requests, email requests after the determination form refers requestor to IRB, or upon initial review of Insight submission. These scenarios are separated into respective sections below:

Email Requests for NR/NHSR/NE Determinations – No prior MS Forms submission

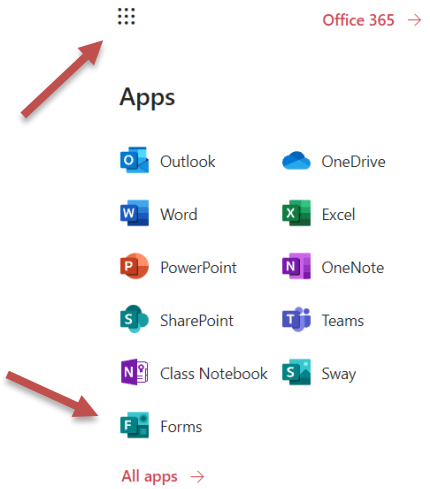
If not clearly HSR, request that the person use the MS Forms NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM tool first and come back if the tool determines IRB consultation is needed. If requestor has been told a formal letter is required, skip to "Email Requests for Formal NR/NHSR/NE Determinations – MS Forms not accepted by third party," section below.

Email Requests for NR/NHSR/NE Determinations – Requestor has already used MS Forms

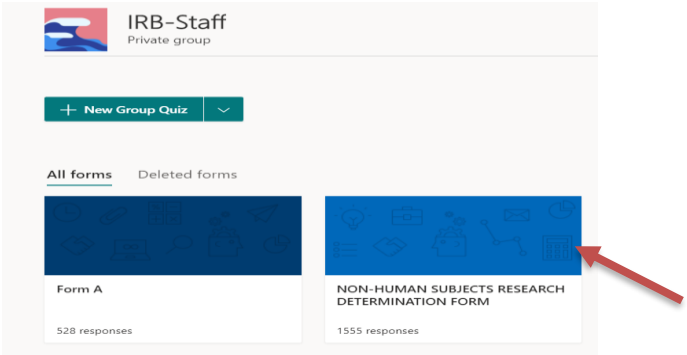
1. If the investigator has not provided any attachments that may include their NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM request responses, you will first need to

locate the investigator's NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM responses.

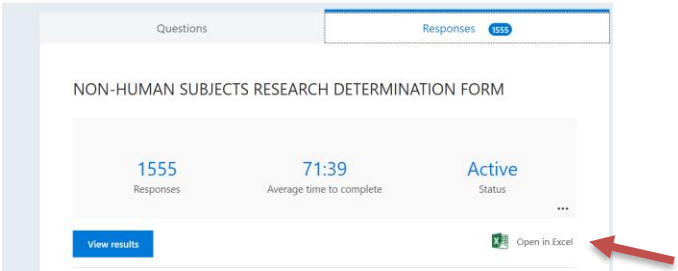
a. Ensure that you are logged into Emory Office 365.
b. Click on the "waffle" in the upper left-hand corner of the display and navigate to the Office 365 App Forms.



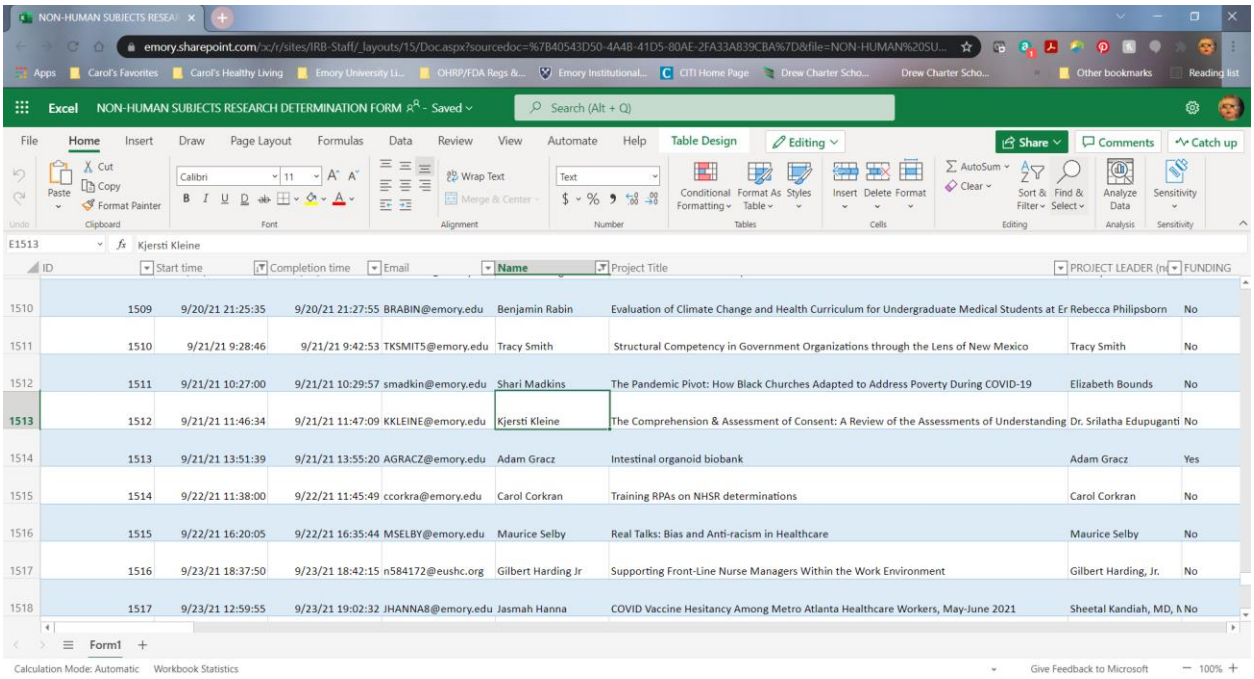
c. When you first navigate to Forms, you may not see any Forms to choose from. Scroll down until you see "My Groups" and click on IRB-Staff. The view may look like this:



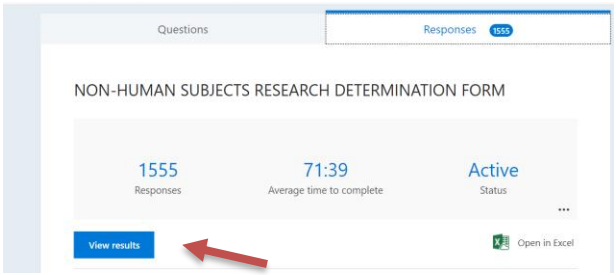
d. Click on NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM – there will be two tabs, Questions and Responses, click on Responses. Click on the "Open in Excel" icon.



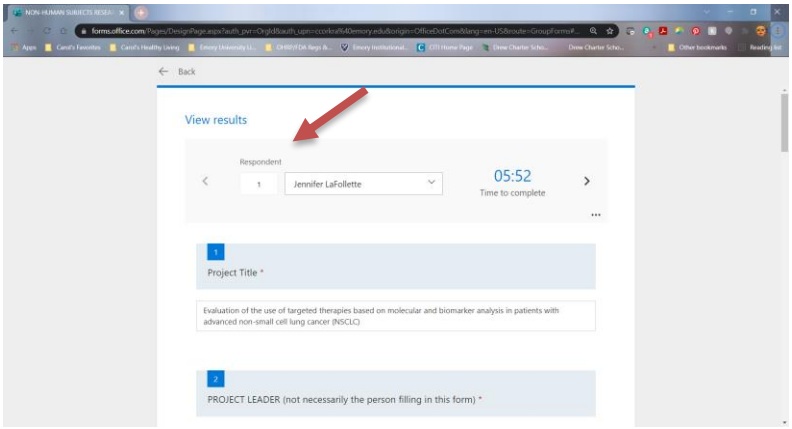
e. Search the Responses Excel spreadsheet for the investigator's name or email address



f. If you want to review their actual responses in the Form layout, you can click on the blue "View results" button



g. If you have already found the Respondent ID number from the spreadsheet you can enter it here:



h. Review the investigator's responses to determine which item on the form recommended that they submit their project proposal to the IRB for review and confirmation that their project does not constitute human subjects research at Emory. You will also need to read the project proposal.

i. Either ask the study team to correct the MS Form if they made an error and it should have resulted in a "no IRB required" determination or confirm that they need to submit in Insight.

Email Requests for Formal NR/NHSR/NE Determinations – MS Forms not accepted by third party.

1. Take a preliminary review of the information submitted about the project; determine whether additional information is required.
   a. The NON-HUMAN SUBJECTS RESEARCH DETERMINATION FORM requires most basic information to be included (emails directly to the listserv may be lacking)
   b. Typically it is necessary to have a copy of the protocol summary along with information about objectives, procedures, funding and data source.
2. If the project involves the VA in any way (study site, affiliation of researchers, data source, etc.), send the determination request to the Emory/VA liaison. Copy the person who made the request when you forward the email to the liaison to let the person know that the request has been received and it is being rerouted.
3. After receiving all the necessary information, consider whether the project qualifies as human subjects research.
   a. Is it a "systematic investigation designed to contribute to generalizable knowledge?" Does it involve human subjects with whom an investigator has interaction or intervention, or about whom an investigator receives identifiable private information? (See 45 CFR 46.101)
      1) Remember that the FDA has a different interpretation of human subjects; even if using only de-identified samples, clinical investigations that support applications for research or marketing permits for products regulated by the FDA require IRB review.
   b. There are several resources to aid your determination; refer to the guidance folder and consult with colleagues for assistance.
      4. Reply by email to the investigator with an official determination
         a. The email should state that the IRB has reviewed the provided information and determined that the project does not require IRB review because it (a) does not meet the definition of "research" or (b) does not involve "human subjects" or (c) Emory is not "engaged" in the human subjects research. (Refer to the letter template for guidance on the language to include in the email: "H:\General\Admin IRB Documents\Checklists, Forms, and Templates\Letter templates and suggested language\NHS NR Letter Template.doc" and "\Not Engaged Template Letter")
         b. The more specific the better, remember that we may need to refer back to this determination in the event that a concern arises later.

Cite specific regulations if possible, and explain any possible points of confusion. For example, "…not research because this is a quality improvement/case report/educational initiative designed to…"

c. At the end, explain that the email is sufficient documentation of the IRB's determination but if a more formal letter of determination is necessary in the future, please let us know.

5. Document the determination on the H: Drive
    a. Create a new folder under H:\General\NR-NHS Letters\[Last Name, First]
    b. Add to the new folder:
        a. Submitted documents (e.g. protocol, survey, etc.);
        b. PDF of all email correspondence;
        c. The formal letter of determination, if drafted.
    c. *Remember: this documentation is the only proof that the IRB will have in the future. If, for example, an academic journal requests our reasoning for not requiring IRB oversight, we need to have this documentation. It's also necessary for internal record reviews, and possibly external audits.*

Insight Submissions Determined NR/NHSR or "Not Engaged"

1. Review the Insight submission and determine whether the project constitutes human subjects research, and if so, is the Emory team "engaged" in the research
    a. Is it a "systematic investigation designed to contribute to generalizable knowledge?" Does it involve human subjects with whom an investigator has interaction or intervention, or about whom an investigator receives identifiable private information? If a multisite study *does* involve HSR, is Emory actually *doing* any of it (i.e. are we "engaged")? (See 45 CFR 46.101)
        1) Remember that the FDA has a different interpretation of human subjects; even if using only de-identified samples, clinical investigations that support applications for research or marketing permits for products regulated by the FDA require IRB review.
        2) Also remember that if Emory is the prime awardee of a federal grant where the grant proposal was submitted as human subjects research, we are still considered "engaged" in the research, even if we're farming out the human subjects research activities.
    b. There are several resources to aid your determination; refer to the guidance folder and consult with colleagues for assistance.
2. If determined NR/NHSR or "Not Engaged,"
3. Assign yourself as a designated reviewer and conduct the review, noting that the project is not research with human subjects by selecting as applicable

'Not engaged in Human Subjects Research" or "Not Human Subjects Research"

4. complete the applicable checklist
5. attest, and sign off
6. Then preview letter and process.

Note: some scenarios may warrant a withdrawal versus taking it through the above steps

NEW STUDIES

SOP Title:	***Processing of New Study Applications- Preliminary Analysis through Approval***
SOP Category:	Study Management
Established:	03/12/2015
Last Revision:	09/04/2025

PURPOSE
This SOP outlines the steps IRB staff take to complete the initial review of new studies.

SCOPE
This SOP applies to any new studies submitted to the Emory IRB that have been assigned to IRB staff for review. These studies will appear first in the "triage" state.

PROCEDURES
Triage:
While in Triage state, do a quick ***daily screen*** for the following to determine if reassignment is required. If you need to reassign, see the SOP "Reassigning Items from One Analyst to Another in Insight."

Categories	If you see	Assign for screening to
VA	Form: Research Locations: Atlanta VA Health Care System	Brianna Wong
Single IRB	Form: Study Overview Selection: Is this submission for a multisite study where Emory IRB is being asked to serve as the Reviewing/Single IRB for other participating sites? Yes **AND** Form: Funding Selection: Federal **AND** Attachments: Protocol Indicates external site is enrolling participants	Beth Poplaski (who will reassign within the reliance team)
Emergency Use	Form: Study Overview	Jackson Parker (who will reassign within the Q team)

	Selection: Use of a drug or device in a single patient (either emergency, or non-emergency where alternate IRB review/concurrence was not requested) - Skip to next question if this is selected.	
Chart Review with a complete waiver	Form: Study Overview Selection: Is your project limited to secondary use of data and/or specimens/tissue? (Includes "chart review" projects, and can be retrospective or prospective, as long as there are no research-driven interactions or interventions.) Yes **AND** Form: Informed consent – requesting complete waiver	Tracy Cermak

Does this study require review by a different IRB?

What to check:	**What to tell study team:**
• Study will be conducted at CHOA **and** ○ Is sponsored by COG **OR** ○ involves review of solely Children's patient records and surveys, interviews, questionnaires, or other data collection of non-clinical interventions (no blood draws) of Children's patients and/or their families	Withdraw and submit to the CHOA IRB.

• Is an industry sponsored drug and/or device trial.	Withdraw and submit a cede review submission. These studies go to WCG IRB or the IRB used by the sponsor. Follow the guidance posted here on our website.

If none of the above apply, assign to yourself for "expedited screening" and continue to procedures below. You can always change from "Expedited Screening" to "Full Board Screening" or vice versa.

Screening:

Note: All checklists related to this SOP are in this folder: H:\General\Admin IRB Documents\Checklists-Staff, Forms, and Templates\1. Staff Screening Checklists and Tip Sheets.

1. When reviewing a study that meets one or more of the special study considerations listed below, confirm the study short title includes any applicable prefixes or suffixes. If more than one designation applies, list multiple designations in alphabetic order.
   Prefixes:
   Cede Review – [XIRB: <name of the external IRB>]
   NCI Central IRB – [XIRB: NCI CIRB]
   Emory as Single IRB [sIRB]
   Suffixes
   Emory Sponsor Investigator study – [S-I]
   Department of Defense – [DoD]
   Veteran Affairs – [VA]
   REMS- [REMS]
2. Review all forms shown in the panel on the left for accuracy and completeness using the appropriate review checklist from the H drive (exempt or non-exempt). Click “Next” in the bottom right of the form to move from one form to the next form.
3. If changes are needed by the study team, navigate to the form that needs to be changed and click the blue “comment” link in the top right of the form. A text box will open. Describe all of the changes that are needed for that form in one comment box. Click “comment” in the bottom right. Do this for each form that needs to be changed in the submission. Under Reviewer Actions in the right lower corner, click Route to Submitter. Check the box and click the green Sign Off button.
4. Each comment must be addressed by the study team before the study team can submit back to the IRB. Once the study is submitted back, click Response to Review on the left menu. Click the hyperlink to each form that is listed. Once the form opens, click the red comment bubble which opens the response from the study team. Review each of the responses and confirm the changes requested have been made to the forms or documents. Click the blue “Reply or Resolve” button. If the changes have been made correctly, click Resolved at the bottom of the comment box. If the requested changes were not made, add text to describe the changes still needed and then click Reply. Do this for each comment.

5. Use the Note function to add a note with a description of the study for the reviewers.
6. If there are ancillary reviews that are managed by IRB staff (such as CHOA security or device reviews-see Overview and Ancillary Reviews accordion under New Study Application for more information), and documentation has been provided by the study team indicating the ancillary is not required or has been completed, resolve the ancillary. Click Action Required and select the study title in the row for the ancillary review. Under Actions in the blue box on the lower right corner, click Approve or Review Not Needed.
7. Once all necessary changes have been made and the study is ready to be routed for review, under Actions in the lower right corner, click Expedited Review if it meets the criteria for expedited review or Scheduling if it requires full board review. If Scheduling for full board review, this will conclude your workflow for the study. If study will route for expedited review, select the reviewer. Check the box and click the green Sign Off button.
8. The expedited reviewer will either send comments back to the study team or will complete their review. They will select "Route to Final Results" and select the analyst who assigned them to the review.
9. Click on the blue study ID number (IR will be in gold to the right of it) on the left side panel. A screen will open in the center of the screen. Under Review Letters there will be a pdf icon. Click that icon to review any specific comments or determinations made by the reviewer.
10. Under Actions in the lower right corner, select "complete" and select "Generate Review Letter." Open the download to review the letter. If any changes are needed, edit the letter and drag and drop it in the green area. See template letter language document in this folder: Confirm list of reviewed documents is correct and relevant dates are accurate. Check the box and click the green Sign Off button.

SOP Title:	***RDRC Studies***
SOP Category:	Study Management
Established:	12/09/2015
Last Revision:	12/09/2015

PURPOSE

The purpose of this document is to describe the procedures for the coordination between the Institutional Review Board (IRB) and the Emory Radioactive Drug Research Committee (RDRC) on protocols involving the use of radioactive drugs for research projects designed to obtain basic information regarding metabolism (e.g., kinetics, distribution, and localization) or human physiology, pathophysiology, or biochemistry.

BACKGROUND

The Radioactive Drug Research Committee (RDRC) program under 21 CFR 361.1 permits certain basic research using radioactive drugs in humans without an IND. The RDRC is the body charged with classifying all radioactive drugs as either new drugs requiring an Investigational New Drug Application (IND) for investigational use (21 CFR 312), or as generally recognized as safe and effective when administered under the conditions specified in the RDRC regulations. Key requirements include that 1) number of subjects should not exceed 30, 2) only adults with legal capacity be enrolled, 3) all females of childbearing potential either confirm they are not pregnant on the basis of a pregnancy test or state in writing they are not pregnant, and 4) the investigator shall immediately report to the RDRC all adverse effects associated with the use of the radioactive drug.

RESPONSIBILITIES

- RDRC- Review and approve the use of research-related administration of radioactive material to subjects. RDRC is also tasked with reviewing all adverse effects associated with the use of the radioactive drug in research and immediately reporting to the FDA all adverse reactions probably attributed to the use of the radioactive drug in research.
- IRB – Ensure human research protocols involving the research-related administration of radioactive material to subjects have prior RDRC approval and that the study protocol include the required reporting to RDRC. In addition, alert RDRC and study team of need for IND if study team requests increase in enrollment to over 30 subjects obtaining the radioactive agent.

PROCEDURES

1. When a study is submitted that involves a radioactive tracer not approved by the FDA for the indication described in the study, the IRB analyst will review whether the study has an IND or RDRC approval for the use of the tracer.
    a. If the study does have an IND, than the study falls outside the scope of this SOP.
2. For studies that meet the qualification for RDRC IND exemption, the IRB analyst will ensure that:
    a. RDRC approval has been granted before the IRB grants final approval.

b. The authorized investigators in the RDRC approval letter are listed as study staff, including the "Authorized User"
c. The radioactive tracer is listed in the drug section of the IRB submission.
d. The protocol and DSMP include that the investigator shall immediately report to the RDRC all "adverse effects" associated with the use of the radioactive drug in the research study.
e. The protocol and consent note that only adults (18 and older) with legal capacity will be enrolled.
f. The protocol and consent note that all females of childbearing potential confirm they are not pregnant.

3. Once all of the above requirements have been verified, the IRB analyst should assign the study to an IRB Committee meeting – these studies do not qualify for expedited review under F(1) due to the possibility of allergic reaction.

4. After the initial IRB approval, IRB analyst should note whether future amendments that substantially change the protocol may require additional review by the RDRC or, alternatively, an IND application. Analyst should consult with RDRC if needed.

SOP Title:	*Translation of Informed Consent Documents*
SOP Category:	Study Management
Established:	11/17/2016
Last Revision:	08/21/2025

PURPOSE

The purpose of this SOP is to describe process for IRB analysts to review submissions that include IRB approved consent forms that have been translated into languages other than English.

SCOPE

Applies to all non-exempt studies that have translated consent forms because they expect to enroll non-English speakers.

PROCEDURES

1. Confirm documentation of one of the following translation methods have been provided along with the translated consent form(s).
   - Certified Translation: Current, valid certification of translator's credentials along with an invoice or memo stating the specific document that was translated. The translation certification should reflect the file names and version dates of the documents that were translated.
   - Back Translation: This is a two-step process where one individual including a member of the study team, translates the English version of the approved informed consent form into the foreign language and then a different person translates that consent form back into English.
2. If documentation hasn't been provided, request it from the study team.

Note: For studies that will enroll participants in a foreign country, a local Ethics Committee or IRB may require changes to translated informed consent documents that are submitted for their approval. For this reason, study teams may want to wait to submit their translated documents to the Emory IRB until after the local approval is in place.

Revisions to Approved Translated Consent Forms:

When only administrative changes (such as contact information) are made to already approved translated consent forms, they can be approved without further translation quality documentation as long as the change can be verified in the revised document. If more extensive changes are made, new documentation of translation must be provided.

SOP Title:	***Electronic documentation of informed consent via "electronic signature" or "digital signature")***
SOP Category:	Study Management
Established:	12/20/2016
Last Revision:	08/21/2025

PURPOSE

The purpose of this document is to explain the use and IRB requirements for the currently available options Emory researchers have to use electronic informed consent documentation (eICD) after consenting a subject into a study using (or not) an electronic informed consent method.

This SOP is **not** applicable for cases where the IRB can waive written signature/documentation of consent (e.g. online survey studies) or for studies done at the VA or CHOA, as they do not need to obtain signature after online consent.

Note: HIPAA authorization may be obtained via electronic signature as well, when in compliance with the below SOP and federal guidance. OIT will not review requests of eICF if the study does not involve IIHI, PHI, or sensitive information but the IRB will need to verify that the app or software. For FDA studies, the IRB needs to ensure that capturing the subjects' signature after consent complies with the requirements in Part 11.

SCOPE

The SOP applies to all studies submitted to the Emory IRB and when the Emory IRB provides local context information to external IRBs.

RESPONSIBILITIES

- IRB analyst – responsible for letting the study team know about the currently available options for the use of eICD, making sure the use aligns with previously approved parameters given to us by LITS
- OIT representative - reviews proposals to implement eICD outside the currently approved options
- Team Q- facilitates the discussion with OIT representatives and investigators

FEDERAL GUIDANCE (OHRP and FDA)

- http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm436811.pdf

PROCEDURES

- Review our guidance document (When is an OIT security review needed?) to verify if the current software needs LITS review.

  - Electronic documentation of consent is not permitted the AVAMC (though they do allow online consent with a waiver of the signature when regulatory criteria are met). Please verify with the IRB Directors if this is still the case when reviewing your study as exceptions may have been allowed due to public health needs.
  - Electronic documentation of consent is allowed at CHOA only if using REDCap. For other platforms, the study team will need to put a request for security review by the CHOA IT group.

- The protocol and/or smartform should include a plan for providing copies of the signed consent to participants. (HHS and FDA regulations require that the person signing the informed consent be given a copy of the written informed consent form (45 CFR 46.117(a) and 21 CFR 50.27(a)) unless the requirement for documentation of informed consent has been waived under 45 CFR 46.117(c) and 21 CFR 56.109(c)).
  - Although FDA regulations do not require that the subject's copy include a signature, FDA recommends that a copy of the signed informed consent form that includes the date when the eIC was signed be provided to the subject.)
  - The copy provided to the subject can be paper or electronic (i.e. be provided on an electronic storage device, not via email unless encrypted). If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and information should be accessible until study completion (if a paper version is provided, it should contain the necessary content from any hyperlinks).
- The protocol and/or smartform must include a plan for verifying the identity of the subjects that will be electronically signing the Informed Consent, for FDA-regulated investigations.
  - FDA regulations do not specify any particular method for verifying the identity of an individual and accept many different methods. For example, verifying someone's identity can be done by using information from some form of official identification, such as a birth certificate, government-issued passport, or a driver's license. Also, the use of security questions to confirm an individual's identity can be considered.

<u>Redcap</u>

- Besides adding the intention of using Redcap in the study protocol, the study team should submit to the IRB copies of all forms (electronic and paper forms) and informational materials, including any videos and Web-based presentations, which the subject will receive and view during the eIC process.
- The study team should submit an MS Word version of the informed consent language that will be signed electronically by subjects
- Once IRB-approved, the study team should <u>not</u> send the consent form to subjects via email, unless encrypted. If not using the encrypted email they should explain in the submission that the form will be sent via a link to an email previously provided by the study subject or LAR.
- The signature area could be drafted the same as the ICF/HIPAA template or could allow for documentation of the signature of the person obtaining consent at a later time. Here is an example:

Name of Person Conducting IC discussion	Date when IC discussion took place
Signature of Person Conducting IC discussion	Date when IC was signed by person obtaining consent

- The Redcap system must capture the signature of the subject in a way that it can be electronically audited. The ideal format is as follows:

DocuSign

- Because DocuSign only adds signature lines to current documents, the study team can obtain approval of their documents with initial approval of the consent. The study team should add to their protocol there are using DocuSign for eIC. If the study is using DocuSign for an FDA regulated study, the team should say in the protocol that the DocuSign they are using is part 11 compliant. Send this link with information about the process to obtain the account to the team when asking about this. This information includes instructions of how to transmit to the FDA directly but the relevant part about obtaining a Part 11 compliant account if found here:

Logging in to DocuSign

- Go to docusign.emory.edu
- Log in through the Emory Login page
- If you are working remotely, you may be required to authenticate using Duo.
- If you do not yet have Duo installed, follow the setup prompts to do so.
  If you have an account in both the general purpose and FDA CFR Part 11 account, you will need to switch accounts. To do so, click on your initials or profile in the upper right-hand corner. Select "Switch Account" or verify you are in the FDA account. Under your name and email, you should see an account name of "Emory CFR 21 Part 11 Compliant".

Unapproved OIT software

- If the study team is not using an approved eConsent method, they should submit a ticket for an OIT security review of the app/software they want to use for eConsent.
- After asking the team to submit an OIT ticket, add the information to this spreadsheet.

- The study team should go to this link: https://emory.service-now.com/sp?id=kb_article&sys_id=e5c2cd88f5cdf1c055c77bd8604896c2 to place a ticket for this review.
- The form has the information to provide under "more information"
- The study team should be advised that this process may take time, and to work with OIT and let the IRB know if their eICF platform was approved.
    - If the study is funded, let OSP know (at osp@emory.edu) that the study will be reviewed by OIT for a security review as this may affect contract negotiations or require additional actions such as a Business Associate Agreement.
- For more information about the OIT security review report, and how to address its findings, see guidance found in this folder.

SOP Title:	*Data sharing certifications including genomic data sharing*
SOP Category:	Study Management
Established:	10/31/2018
Last Revision:	08/21/2025

PURPOSE

The purpose of this document is to explain the steps to follow if reviewing a study under a data sharing requirement, including genomic data sharing.

DEFINITIONS

- Genomic data sharing repository (e.g. dbGap): public repository for individual-level phenotype, exposure, genotype, and sequence data, and the associations between them. dbGaP assigns stable, unique identifiers to studies and subsets of information from those studies, including documents, individual phenotypic variables, tables of trait data, sets of genotype data, computed phenotype-genotype associations and groups of study subjects who have given similar consents for use of their data.
- Institutional Certifications: Institutions are responsible for assuring, through an Institutional Certification, that plans for the submission of large-scale human genomic data to the NIH meet the expectations of the Genomic Data Sharing Policy (examples of research within the scope of the GDS Policy can be found in the Supplemental Information to the Policy). An Institutional Certification must accompany the submission of all large-scale human data to the NIH Database of Genotypes and Phenotypes (dbGaP). The Institutional Certification (for sharing human data), should also be provided to the funding NIH Institute or Center prior to award, along with any other Just in Time information (for extramural researchers) or at the time of scientific review (for intramural researchers).
- Provisional Institutional Certification: to be used in a situation such as for a prospective study where the IRB has not completed its review of the protocol and therefore the institution cannot attest to all of the elements of the formal Institutional Certification

We have a guidance for investigators in our website at
http://www.irb.emory.edu/forms/Data_Sharing.html
Study teams should fill these forms as appropriate:
Institutional Certification Request form for Emory submitting data
Institutional Certification Request form for Emory not submitting data

PROCEDURES

- If this is a urgent, very tight-turnaround request, strongly recommend to OSP analyst that OSP instead sign the "Provisional Institutional Certification" – state that IRB believes this is an appropriate use of the Provisional version. This form can be found under the NIH Institutional Certifications page.
- Request comes into IRB from OSP and/or Study team

- Refer study team to IRB form to fill out and await it
- The IRB analyst reviews as follows:
    - Does the Consent Describe Sharing? Y/N
        - If sharing is described if it is optional? Y/N or N/A
    - Genetic or Genomic Research Described? Y/N
    - If Genetic or Genomic Research Described is it optional? Y/N or N/A
    - Data Use Specifications:
    - Appropriate for DbGaP submission (if applies): Y/N
    - Unrestricted or restricted areas: Y/N
    - Controlled access: Y/N
    - If study in question was approved by the IRB before January 23, 2015, ICF will only need to make reference to sharing data or samples, but not as explicit as above
    - If the study wants to access a database or repository approved after January 23, 2015, a waiver of consent will not be valid for this purpose.
- After this process was completed, forward the information the study team sent and what was reviewed to the IRB Director or designee.
- The IRB Director or designee will determine if this information is consistent with the approved study and protocol, and forward letter to IRB chair for signature
    - If the IRB Director or designee finds that the study did not allow for this use, she will communicate with study team
- After the Chair signs the letter, the IRB Director will forward to IRB analyst to communicate with study team and to upload in the study as an administrative attachment.

REFERENCES

- NIH webpage: Institutional Certifications.
- dbGAP submission process: chart
- NIH Guidance: Expectations for Non-NIH-funded Submission Requests
- NIH Institutes and Centers Genomic Program Administrators
- Provisional Institutional Certification form

SOP Title:	***Humanitarian Device Exemption (HDE) Studies***
SOP Category:	Study Management
Established:	08/08/2013
Last Revision:	11/03/2020

PURPOSE

The purpose of this document is to describe the IRB process for reviewing studies under a Humanitarian Device Exemption.

SCOPE

The SOP will apply to Emory human subject research working under an HDE.

DEFINITIONS

- Investigational Medical Device**:** means a device, including a transitional device that is the object of an investigation. An investigational device is permitted by the FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.
- Humanitarian Use Device (HUD): medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year – *21 CFR 814.3(n)*. To obtain approval for an HUD, a humanitarian device exemption (HDE) application is submitted to the FDA.
- Humanitarian Device Exemptions (HDE): allows use of an HUD; the HDE application is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market.
- Sponsor: A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator

RESPONSIBILITIES

- IRB analyst- initially screens application before sending it to IRB Full Board or the IRB Chair.
- IRB Chair or Co-Chair – reviews the progress reports submitted by the sponsor or sponsor-investigator. The Chair or Co-Chair must be a clinician

PROCEDURES

Initial Review Submission

The Emory IRB cannot be the IRB of record for community physicians who want to use a HUD for non-research purposes. We can only serve as the IRB of record for Emory physicians using HUDs at Grady or Emory. If the HUD is being used at St. Joseph's Hospital, CHOA, etc., their IRB (or a commercial IRB) should review the HUD submission.

Non-research HUD

Screen the study using the HUD NS checklist. When adding this to the FB agenda, make sure to attach the FB section to your notes.

The study team should provide the following documents with the submission (forward this checklist to the treating physician for their information):

- A copy of the HDE approval order
- A description of the device
- The product labeling
- An ICF is not required if used under the FDA HDE-approved use, but the study team should submit an information sheet for the patient. The information sheet should describe a general definition of the FDA's HDE program, a brief description of the device and related procedures, risk/benefit ratio, and physician contact information if the patient experiences a device-related adverse event.
    - If the HDE holder has developed a patient information packet, this packet always should be distributed to patients prior to receiving their HUDs. Labeling for the HUD may also be made available to the patient to provide further information regarding the device's HUD status and possible risks/benefits packet for the patient. See here for the Emory IRB template.
- A summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient monitoring with follow-up visits, tests, or procedures. Refer here for a protocol outline.
- The IRB reviewer also may request that the physician submit documentation that he/she is qualified through training and expertise to use the HUD.
  The staff should confirm the approval status of the HUD. The information can be found at
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm.Letter template information can be found at H:\General\QA Working Files\Forms, templates and Guidance\Letter templates & guidelines.
- Ancillary reviews required: Department Review, Biosafety/Radiation Safety, and Clinical Research Key Points Summary.
- Requires Full Board initial review- most criteria in the worksheet don't apply since the project isn't research
- Treating staff are not required to have CITI certification.

Research HUD

Even though HUD's are "approved" devices, the sponsor may still want to gather data from the uses of the device in order to support a premarket approval. If this is the case, then the PI should provide a research protocol and research informed consent and HIPAA Authorization. The use in the study may require an IDE. This information should be reviewed and approved by the IRB, and all regular IRB P&Ps should apply. Refer to the SOP "Processing of New Study Applications- Preliminary Analysis through Approval" for next steps.

Note: Off-label use of an HUD for *research* purposes requires an IDE. And unless it is an emergency, before an HUD is used off-label *treatment*, the FDA recommends that the HDE holder obtain FDA approval of the use following the compassionate use policy for unapproved devices. IRB approval is also required per our policies and procedures.

Continuing Review Submission

Non- research HUD

- When a continuing review application is submitted to the Emory IRB, the IRB analyst will screen the information.
- As a part of Continuing Review, the IRB reviewer may request the HDE holder to provide safety information on the HUD provided to the FDA in periodic reports required under 21 CFR Section 814.126(b)(1).
- It is mandatory for the PI to provide a detailed list of each use of the HUD within the previous approval period. Summaries should include a brief description of the patient's condition (with no identifiers), how the device was used, whether or not an information sheet was provided to the patient, and the patient's outcome.
    - The analyst will route the continuing review, as permitted by the FDA regulations, to the clinician IRB Co-Chair for expedited review. The chair will make the decision if the HDE should be reviewed at Full Board instead of expedited review for any reason.
    - The IRB analyst and reviewer should compare the uses made of the device to the approved scope of the HDE/indication.
    - If there is a case where the PI appears to have used the device off-label, without informing the IRB in advance or within 5 days of the use, the analyst in charge of the continuing review should alert the Q team of possible non-compliance (NC).

Reportable new information submission for NC/UPs and Emergency/Compassionate Use

- Research or non-research HUD
    - The study team should follow Emory IRB's usual reporting P&P for reporting protocol deviations, noncompliance, and unanticipated problems.
    - If the protocol deviation involves an emergency use or compassionate use in a single patient:
        - If the device user is or can be added to the HUD submission, study team should submit an OE to report this matter. Team Q will send the event to FB using the appropriate emergency use omnibus form.

- If the device user is not and cannot be on the HUD submission (per the PI choice), the device user must submit a new submission. Please make Team Q aware so they may follow up and take ownership of that submission.
- A study team can add the new device user to an approved study to avoid a new submission.

*Note: The Emory IRB will not review HUD compassionate/emergency use request for community doctors. A non-research HUD PI can **add** a community physician to the submission.*

Close-Outs

- If the treating physician has use the device in new patients since the last CR approval (to the close-out), he/she should include a detailed list of each use of the HUD within this period. Summaries should include a brief description of the patient's condition (with no identifiers), how the device was used, and the patient's outcome. The close out should be reviewed by a medical vice-chair.
- If the close-out is submitted and the treating physician has not used the device in new patients since the last CR, the close-out can be processed by an analyst.

REFERENCES

- 21 CFR Part 812 (investigational devices)
- 21 CFR Part 814 (premarket approval of medical devices)
- 21 CFR Part 860 (device classification procedures);
- 21 CFR Parts 862 –892 (device type classifications)
- IRB policies and procedures

SOP Title:	***Processing Studies that will use Deception or Incomplete Disclosure***
SOP Category:	Study Management
Established:	05/17/2018
Last Revision:	08/21/2025

PURPOSE

The purpose of this document is to outline special considerations when processing studies that will utilize deception or incomplete disclosure. The IRB will determine when certain restrictions apply and consider the extent to which the deception in a given study interferes with the subject's ability to give informed consent. The IRB will need to distinguish whether "deception" or only "incomplete disclosure" (without deception) is involved, whether there is sufficient justification for use of such measures, and whether there is an appropriate consent and debriefing process in place.

SCOPE

The SOP applies to any study that will utilize deception or incomplete disclosure.

DEFINITIONS

Deception - occurs when an investigator gives false information to subjects or intentionally misleads them about some key aspect of the research. Examples include:

- The subject is given a "cover story" which falsely describes the purpose of the study, but provides a feasible account of the researcher's objective.
- Participants complete a quiz and are falsely told that they did poorly, regardless of their performance.
- Participants who don't know they are in a research study are observed to see how they behave when they find valuables (e.g., wallet, laptop) unattended in a public location.
- The study includes a researcher's "confederate," an individual who poses as a participant, but whose behavior in the study is actually part of the researcher's experimental design.

Incomplete disclosure -occurs when an investigator withholds information about the specific purpose, nature, or other aspect of the research. Withholding information may or may not be considered deception. Examples include:

- Participants are asked to take a quiz for research, but they are not told the research question involves how background noise affects their ability to concentrate.
- Participants are told they are completing a survey to evaluate customer service when the true purpose of the study is to correlate psychological responses with patient care satisfaction.

Incomplete disclosure that is also deception. An example:

- The study involves audiotaping or videotaping of subjects without their knowledge or prior consent.

PROCEDURES

Considerations when triaging studies:

In keeping with federal regulations and ethical codes established by the Belmont Report and the American Psychological Association, the IRB will consider the following criteria when reviewing research involving the use of deception or incomplete disclosure:

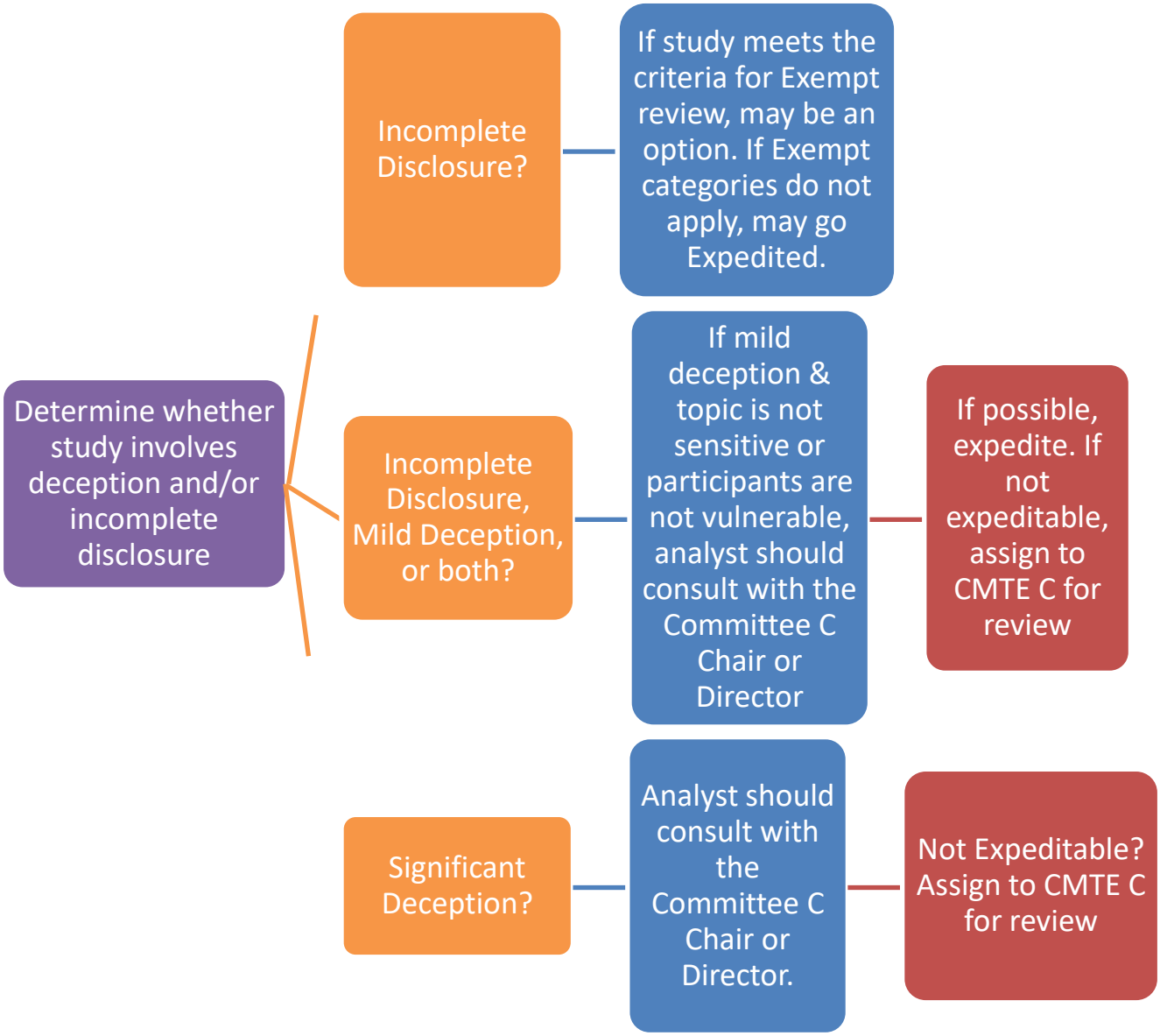
- The study must not involve any more than minimal risk to the subjects.
- The use of deceptive techniques must be justified by the study's prospective value AND there should be no reasonable alternative method that would be equally effective (i.e., the researcher must demonstrate that the deception is necessary to conduct the study).
- Prospective subjects must not be deceived about any physical or psychological risks, discomforts, or unpleasant emotional experiences of the study.
- If the study design allows, subjects should be told during the original consent process that some information is being withheld or is incomplete, and that they will receive more information after the research is over. This is sometimes known as "authorized deception" because it provides participants with an opportunity to decide whether or not to participate, knowing that they aren't receiving complete information. However, researchers often believe that even vague references to hidden purposes will affect subjects' behavior and make the study impracticable. Investigators should either add such language to their consent forms when it is possible or note in their protocols why it is not feasible to do so.
- In addition, the research must meet the criteria for a waiver of one or more elements of informed consent.
- Whenever appropriate, researchers should debrief participants. The debriefing should occur as early in the study as the design permits, preferably at the conclusion of a subject's participation, but no later than the conclusion of the research.

Please note: Research involving incomplete disclosure but no deception may be reviewed as Exempt. Research employing deception **may not** be reviewed as Exempt under the Pre-2018 Common Rule. Under the Post-2018 Common Rule, such research may be reviewed as Exempt if it otherwise meets the Exemption criteria and the deception is authorized (see [§ 46.104 (d)(3)(iii)]).

Research that involves incomplete disclosure, or that involves mild deception where the topic is not sensitive and the participants are not vulnerable, may be reviewed as Expedited with the discretion of the designated reviewer. Research that involves deception where the topic may be sensitive and/or the participants may be vulnerable should be referred to full board for review,

in parallel with consultation with the Committee C Chair in case she determines that the study may receive expedited review. The IRB Analyst should also consult with the Associate or Assistant Director or IRB Director to determine whether Full Board review is appropriate.

PROCESS FLOW



*Adapted from University of North Dakota IRB's 'Guidance on the Use of Deception or Incomplete Disclosure in Research"

SOP Title:	***Emory Saint Joseph's Hospital as a Study Site***
SOP Category:	Study Management
Established:	11/27/2013
Last Revision:	08/21/2025

PURPOSE

The purpose of this SOP is to describe steps for reviewing a study submission including or adding Emory Saint Joseph Hospital (ESJH) as a study site in order to ensure compliance with institutional requirements and ethical and religious directives (ERDs).

SCOPE

The SOP applies to all new studies with ESJH as a site or amendments adding it as a site.

PROCEDURES

1) Review the research locations in the IRB submission to confirm ESJH is listed.
2) Determine if ESJH local context (ERD's and credentialing) review is required. If not, the rest of this SOP does not apply
   a. Chart reviews do not require ERD review.
   b. Clinical trials/research conducted at other Emory sites (e.g. EUH) but isolated diagnostic services performed at ESJH for research purposes due to patient convenience or equipment availability do not require ERD review, though the informed consent should include information about where study procedures will or may take place.

   All other studies taking place at ESJH require ERD review.
3) Ensure that the correct terminology for "birth control" is used, per our template, and that no specific birth control methods other than abstinence are listed (e.g. no mention of birth control pills, condoms, etc).
4) Email Rebecca Heitkam (rebecca.heitkam@emoryhealthcare.org) a copy of the study protocol and consent forms and copy the study PI and primary contact. A response is not needed.

SOP Title:	*REMS study review*
SOP Category:	Study Management
Established:	01/31/2018
Last Revision:	08/21/2025

PURPOSE

The purpose of this document is to explain the process an IRB analyst will follow when reviewing a study under Approved Risk Evaluation and Mitigation Strategies (REMS) requirements.

SCOPE

The SOP applies to studies under REMS requirements that are reviewed by the Emory IRB by an external IRB.

PROCEDURES

NEW STUDIES REVIEWED BY THE EMORY IRB

1. The drug form will indicate if the study is under REMS if the team has selected yes to the question, "Does this project involve administration of drug under the FDA REMS program.
2. The analyst will contact the ODP and direct the study team to fill out the REMS Investigator Checklist.
3. The ODP will verify that the study protocol and informed consent include all the requirements for that drug under REMS. That information can be found at this FDA website
4. When the information is complete, the ODP will log a comment under the study history indicating that the REMS requirements are met in the submitted protocol and informed consent
5. The IRB analyst may send the study to full board (FB), before this process is completed. If the ODP review has not been completed before the IRB meeting, the analyst should complete omnibus form accordingly.
6. When forwarding the study for FB review, the analyst will add to the agenda items notes that the study is under REMS requirements.
7. After the study is approved, the approval letter should include the following language:
   "This study utilizes a drug(s) under FDA required REMS. You must ensure your study remains compliant with current requirements as listed in the "REMS Document" and the protocol/informed consent document"

STUDIES REVIEWED BY AN EXTERNAL IRB

- Follow same steps from 1 to 4 as above.
- The study will not be given an institutional signoff until the REMS requirements are verified.

AMENDMENTS REVIEWED BY THE EMORY IRB

1. If the AME adds a new drug under REMS requirements, follow steps as detailed before, letting the ODP know, and making sure the ODP has reviewed the checklist. The AME may

be placed on FB agenda prior to completion, making sure the notes reflect that this process is still pending.

SOP Title:	***Prisoner Studies: Handling of New/Amendments/Continuing Review Submissions when Prisoners are Subjects (Application of Subpart C)***
SOP Category:	Study Management
Established:	10/17/2016
Last Revision:	12/01/2025

PURPOSE

An institution that intends to conduct HHS-supported research involving prisoners as subjects must certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a), including the finding that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a)(2) or meets the criteria for the Epidemiological Waiver. The purpose of this SOP is to describe the steps the IRB uses to process new study submissions, continuing reviews, and amendments when research includes Prisoners as a study population.

SCOPE

This applies to all IRB submissions for studies involving prisoners as a study population.

DEFINITIONS

Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons or may be untried persons who are detained pending judicial action, for example, arraignment, trial or sentencing (45 CFR46.303). Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners. Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Institutions may consult with OHRP when questions arise about research involving these populations.

Minimal Risk: The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons (45 CFR 46.303(d)).

Prisoner Representative: An IRB member who has appropriate background and experience that includes a close working knowledge, understanding and appreciation of prison conditions from the Prisoner's perspective.

Important Notes:

- Research involving prisoners **cannot be reviewed as exempt**, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
- Expedited studies that pose no more than minimal risk and **do not involve interactions with prisoners** (i.e. involve only existing data or record reviews) do not require review by the prisoner representative per OHRP, AARHPP, and Emory IRB P&Ps.
- For research involving prisoners as subjects, the IRB must meet the special composition requirements of 45 CFR 46.304 for all types of review of the protocol, including initial review, continuing review, review of protocol amendments, and review of reports of unanticipated problems involving risks to subjects. Minutes from full board meeting where research involving prisoners was reviewed must document the fact that the Emory IRB meets the compositional requirements for the review of a Research protocol involving Prisoners.
- One member of the Emory IRB shall be a Prisoner or a Prisoner Representative.
- When a prisoner representative completes a review (either for an expedited study or at a full board meeting), contact Carol Corkran so she can process the payment to the prisoner rep.

PROCEDURES

Initial Reviews:

1. If the study is federally funded, OHRP certification of subpart C findings must be obtained before the IRB can issue final approval. If the study will also enroll non-prisoners, suggest to the study team that they omit prisoners as a study population in the initial submission, and add prisoners via an amendment after initial IRB approval is in place. This would enable them to begin enrolling non-prisoners as soon as the study is approved.
2. Screen the study following the SOP "Processing of New Study Applications- Preliminary Analysis through Approval" and the non-exempt new study checklist.
3. Prepare the top portion of the Subpart C worksheet.

Expedited Review:

1. Send an email to the prisoner representative with the following: Subpart C worksheet, protocol and consent form(s) and other relevant attachments, and ask them to review. If there is no separate protocol attachment, provide the PDF of the Insight submission forms.
   - Remind the prisoner representative to complete the remaining section of the Subpart C worksheet and return to the IRB as an attachment to an email that includes their recommendations.
   - If the prisoner representative's review includes concerns about the study, discuss with your team lead.
   - Upload a pdf of the email and the worksheet into the study as an administrative attachment.
2. Under Actions in the lower right corner, click Expedited Review and select the reviewer. Check the box and click the green Sign Off button.

3. The expedited reviewer will either send back to the submitter for changes or will complete their review.
4. If the reviewer requests changes, forward the revised information to the Prisoner Representative for review in the event the changes impact the prisoner representative's findings.
5. The expedited reviewer will select "Route to Final Results" and select the analyst who assigned them to the review.
6. **If the study is NOT federally funded, follow these steps:**
   - Click on the blue study ID number (IR will be in gold to the right of it) on the left side panel. A screen will open in the center of the screen. Under Review Letters there will be a pdf icon under "Reviewer Checklist." Click that icon to review any specific comments or determinations made by the reviewer, for use when drafting the approval letter.
   - Under Actions in the lower right corner, select "Complete" and select "Generate Review Letter." Open the downloaded files and review the letter. If any changes are needed, edit the letter, save, and drag and drop it into the green area. See template letter language document in this folder: H:\General\Admin IRB Documents\Checklists-Staff, Forms, and Templates\2. Letter templates and suggested language. Confirm list of reviewed documents is correct and relevant dates are accurate. Check the attestation box and click the green Sign Off button. Finish remaining Post-Review steps noted in the SOP "Processing of New Study Applications- Preliminary Analysis through Approval" and your initial review process is complete.
5. **If the study IS federally funded, follow these steps:**
   - Continue to Subpart C Certification steps below.
   - Do not send the final approval letter until the Subpart C Certification is received (following letter-drafting steps as in the section above).

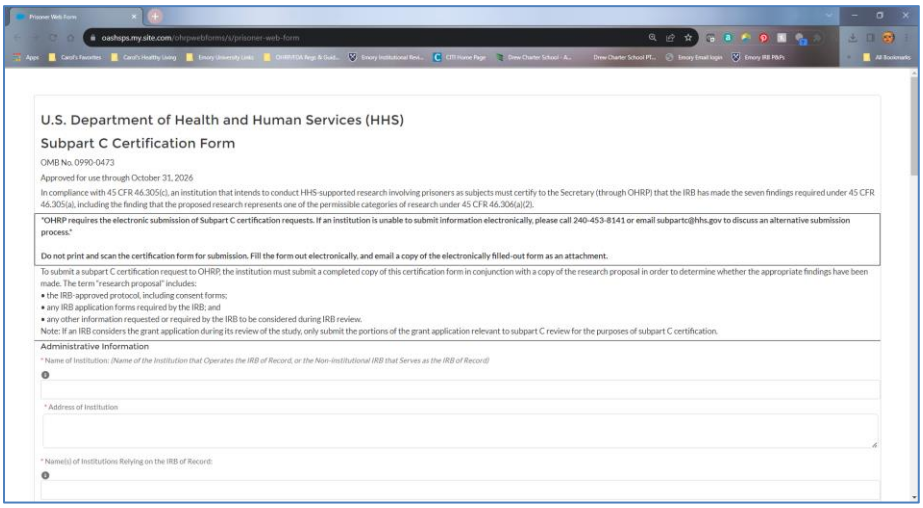
Full Board Review:

1. Send an email to the prisoner representative with the Subpart C worksheet, protocol and consent form and ask them to review. Let the prisoner representative know this study will require full board review and they will need to have their recommendations ready to discuss with the committee.
2. Add to the Notes that the prisoner representative will need to attend the meeting. If the study is federally funded, also include in the Notes that the Subpart C certification must be obtained from OHRP before the final approval letter can be issued.
3. Assign to scheduling. If the study is NOT federally funded, this concludes your steps for this study.
4. If the study is federally funded, it will be assigned back to you after the full board review. Continue to Subpart C Certification steps below.

Subpart C Certification (required for federally funded studies)

1. Draft a letter certifying the Subpart C Category findings to OHRP.

2. To send a subpart C certification request to OHRP, you will need the grant number, the program officer's name and email address, the Emory IRB's FWA and IRB registration numbers as well as the following documents:
   - PDF versions of the IRB-approved protocol
   - PDF versions of the IRB-approved consent form(s)
   - Any IRB application forms required by the IRB; and
   - A PDF version of the IRB application. To save a copy from Insight, click "Download" at the top right of the study space and select View Full Application and save as a PDF.
   - PDF versions of any other information requested or required by the IRB to be considered during IRB review (e.g. completed Subpart C checklist, recruitment materials, data collection instruments, other documents submitted for review, etc.)
   - Only include portions of the grant application that are relevant to the Subpart C review.
3. Complete this e-form https://oashsps.my.site.com/ohrpwebforms/s/prisoner-web-form and attach the documents listed above.



4. Once you receive the email response from subpartc@hhs.gov in about 7-14 business days, upload a copy of the OHRP authorization as an administrative attachment.
5. Finish remaining Post-Review steps noted in the SOP "Processing of New Study Applications- Preliminary Analysis through Approval."

Continuing Reviews:

1. Continuing reviews for studies that required a prisoner representative at initial review must be reviewed by a prisoner representative.
2. Email the prisoner representative a pdf of the continuing review form in Insight along with the protocol (or PDF of Insight forms, if no protocol) and other relevant attachments.
   - If the CR is expeditable, ask them to relay if they have any concerns or if they think it should proceed to final review. Upload the prisoner representative's email review as an administrative attachment then send to the faculty/staff reviewer.
   - If the CR requires full board review, the prisoner representative must attend the meeting for review of that item instead of providing their review via email.

Amendments:

Prisoner representatives must review all amendments to the research unless the changes are purely administrative in nature. Email the documents as in the above sections. If the Amendment requires full board review, the prisoner rep must attend the meeting for review of that item.

Incidental Enrollment of a Prisoner:

1. If a participant becomes a prisoner while enrolled in a research study that has not been reviewed according to Subpart C, the study team must immediately notify the IRB (via amendment or other communication) that a participant has become a prisoner.
2. The IRB shall confirm that the participant meets the definition of a "Prisoner."
3. If the participant is a prisoner, the IRB shall ensure that either:
   - The PI terminates enrollment of the subject **OR**
   - If it is feasible for the participant to remain in the study, cease any research activities until the IRB reviews the research under Subpart C (following the steps outlined above) or not if it meets the "Non-DHHS" criteria per the P&Ps. **OR**
   - Determine if the incarceration is temporary and will end before the participant would undergo any further procedures for the research, including secondary data collection. If so, no further determinations or action must be taken.
4. If a formal review is required, an amendment is needed. The designated reviewer will make one of the following findings:
   - The study is neither DHHS-funded nor considered VA Research, and the "Non-DHHS" criteria below are met, OR
   - The research meets the criteria set forth in Subpart C of the Common Rule. The PI must provide written documentation if he/she feels there are special circumstances that justify why research activities should continue while the IRB reviews the research under Subpart C. The special circumstance should be reviewed by a Vice-Chair.

Non-DHHS Criteria:

- The research is NOT conducted or funded by DHHS or Veterans Administration (VA).
- The subject was not incarcerated at the time of enrollment, and subsequent incarceration was unexpected.
- The incarceration does not put the rights and wellbeing of the subject in jeopardy with respect to the study.
- The prisoner representative has been consulted.
- The terms of the subject's confinement do not inhibit the ethical conduct of the research.
- There are no other significant issues preventing the research from continuing as approved.
- This approval is limited to the individual subject and does not allow the recruitment of prisoners.
- One of the following is true:

- The subject will be at increased risk of harm if withdrawn from the research
- The research presents no more than Minimal Risk and no more than an inconvenience to the subjects

For DHHS-Regulated Research:
The research shall be reviewed per Subpart C

- If some requirements of Subpart C cannot be met:
  - If it is in the best interests of the subject to remain in the study, the subject shall remain enrolled and the IRB shall inform OHRP of the decision along with the justification.
  - Otherwise, the IRB shall advise the PI to remove the participant from the study and to keep the participant on the study intervention under an alternate mechanism as necessary.

- When considering whether to terminate enrollment, the IRB/PI should consider the risks associated with termination of the subject in the study.
  - If the participant cannot be terminated for health or safety reasons, the IRB should advise the PI to keep the subject enrolled in the study and it shall review the research under Subpart C.
  - If some requirements of Subpart C can't be met, but it's in the best interest of subject to remain in the study, the subject shall remain enrolled and IRB shall inform OHRP of the decision along with the justification.
  - The IRB shall advise the PI to remove the participant from the study and to keep the participant on the study intervention under an alternate mechanism as necessary.
  - If a participant is incarcerated temporarily while enrolled in a study, and if that incarceration has no effect on the study, the participant shall remain enrolled.
  - If the temporary incarceration has an effect on the study, the IRB shall handle the case according to the case set forth above.
  - Note: An adolescent (e.g., age 14) detained in a juvenile detention facility is a prisoner; therefore, the IRB would need to comply with Subpart C and Subpart D – Children.

SOP Title:	*VA Studies with non-VA Sites – IRB Submission Requirements*
SOP Category:	Study Management
Established:	04/11/2019
Last Revision:	08/21/2025

PURPOSE

The purpose of this document is to describe the additional IRB submission requirements for study where the sites include both the Atlanta VA and Emory University or its affiliates, without a PI credentialed at both sites.

SCOPE

The SOP applies to studies with both a site at the Atlanta VA and a site at Emory University or its affiliates, without a PI credentialed at both sites.

PROCEDURES

- If consulted before approval, the VA liaison will let study teams know that the PI of a study taking place at the Atlanta VA must be credentialed at the VA. If the overall study PI is not so credentialed at VA, there must be a separate VA credentialed PI (local site investigator) for the VA site. In general a separate IRB submission is preferred for that PI/site; however, if the VA credentialed PI is listed on the grant application and the data is to be combined as part of a collaborative project, an exception can be requested through the VA Research Office and the IRB Director.
- If the VA liaison is assigned a study that, despite the above, takes place at both VA and non-VA sites, and indicates that there two separate PI's, (for example, via listing different PI names in the consent forms) or has a single PI who is not credentialed to serve at the Atlanta VA, he will log the following as a comment in the study history:
    - "Dear study team: My name is X and I will be conducting the initial review of your study. I noticed that this study has [non-VA site(s)] and the Atlanta VA as sites, but does not have a PI credentialed to conduct research at both sites. If this is correct, we require that you submit separate submissions for each site, as the Atlanta VA requires a PI with valid VA credentials. Please confirm if this is your case, and provide the name of the person serving as PI at the VA, and a research coordinator. To prevent additional work on your part, we will clone the study and provide it to you in "pre-submission" status so it can be submitted to the correct department head right away. Make sure you specify in the protocol the work that will be done at each site, so it is clear for both submissions. In the event that this is a collaborative study and you wish to continue with one IRB submission, you will need to request a consult with the VA Human Research Protection Group. The Group will discuss with the IRB you request and make a determination if the systems are in place to properly manage this as one IRB submission. Let us know if you have any questions".

- In the event that the study requires two submissions, and after obtaining the names for the PI and coordinator for the VA site, the VA liaison will instruct the study team to create another submission.
-
- The RPA will let the VA liaison know the Emory study has been submitted, and to ask then which meeting will review the VA study, if already known, and attempt to assign it to the same meeting. If not already assigned, RPA and VA Liaison should work together to have the studies reviewed at the same future meeting, with Agenda Notes indicating that they are the same protocol at two different sites.

SOP Title:	***Determinations and Reviews by IRB Staff***
SOP Category:	Study Management
Established:	06/26/2012
Last Revision:	08/21/2025

PURPOSE

The purpose of this SOP is to describe the type of determinations and reviews that can be made by an IRB analyst. The IRB Director shall decide when IRB staff are qualified, based on length of experience and demonstrated expertise.

SCOPE

This applies to new studies, continuing reviews, and amendments.

PROCEDURES

Reviews Permitted by IRB Staff (without involving an IRB member):

1. Determining whether a study qualifies as research involving human subjects (NR/NHSR).
2. Approving Exempt reviews that do not involve HIPAA Privacy Rule waivers or authorizations. Only staff authorized by the IRB Director to approve exempt studies can do so. For more information about exempt research that can be reviewed by staff or staff designated reviewers, review this guidance.
3. Amendments submitted for exempt studies can be reviewed only by staff authorized by the IRB Director to approve exempt studies.
4. Approving certain minor administrative changes.

Minor Administrative Changes: Some minor administrative changes may be approved by qualified IRB staff. These changes are exclusively limited to the following:

- Change of contact information
- Title change that does not reflect a change in study
- Corrections of typographical errors
- Reformatting of unchanged text
- Errors in completion of the IRB application, as confirmed with study staff as appropriate (as long as the study was initially reviewed with the correct impression)
- Removal of study sites that were never activated

REFERENCES

- Emory IRB P&Ps, chapter 28 (IRB Protocol Triage and Assignment of Review Category)
- Emory IRB P&Ps, chapter 30 (Exempt Research)
- Emory IRB P&Ps, chapter 40 [Protocol Modifications (Modifications)}

SOP Title:	***Categories of Research Reviewable by IRB Staff as IRB Designated Members***
SOP Category:	Study Management
Established:	03/29/2013
Last Revision:	08/21/2025

PURPOSE
The purpose of this SOP is to describe the research that are reviewable by IRB Staff as designated reviewers.

SCOPE
This SOP applies to IRB submissions reviewed by the Emory IRB.

PROCEDURES
Note that all IRB staff, including those appointed as IRB members, can review minor administrative changes as described in the IRB Policies and Procedures, "Modifications" chapter, and the SOP entitled "Determinations and Reviews by IRB Staff." IRB staff can perform reviews within the scope described below only if they are appointed as IRB members and have been designated by an IRB Chair as authorized to perform expedited reviews.

A. NEW STUDIES

1. Minimal risk expeditable studies involving only the following:
    a. F (5) (e.g chart reviews or specimen analyses, whether retrospective or prospective)
    b. F (7), but only as a last resort when faculty DRs are particularly busy or unavailable. Before such an assignment can occur, the study analyst should consult a TL or Director to make sure there are no other available reviewers to help. In addition, the staff DR should have enough expertise to be comfortable with such reviews.

   If staff IRB member is not comfortable with children populations or sensitive studies, forward to faculty DR.
2. Exempt Studies: Staff DRs can review all exempt categories. If a DR is uncomfortable reviewing any category of research, the staff DR can reassign to faculty.
    a. Remember: Do not use D4 for chart reviews because our HIPAA policy does not cover these type of studies. Use F (5) instead. Also, For more information about exempt research that can be reviewed by staff non-DRs or staff designated reviewers, review the 'Guidance – Non-Committee Reviewers' document in H:\General\Admin IRB Documents\Checklists-Staff, Forms, and Templates\1. Staff Screening Checklists and Tip Sheets.
3. Contingency reviews (full board and expedited studies):
    a. ICF revisions as specifically requested by IRB Committee
    b. Revisions to the submission as specifically requested by IRB Committee

c. Confirmation of full board's stated assumption (i.e. not new information from study staff)

Note that all IRB staff can do contingency reviews for Cost and In Case of Injury options, as well as ancillary committee approvals where no changes were required.

B. AMENDMENTS

1. Changes of any kind to studies that Staff DR could have approved at initial review (see the section above), unless the changes move the study outside that scope. For example, F5 studies, moving to other review categories due to the addition of procedures.
2. Changes to informed consent that are made solely to update template language.
3. Changes to PI *on minimal risk studies where the PI is NOT the IND/IDE holder.*
4. Updates of other documents insofar as they are needed to reflect changes above.
5. Change to ICF, protocol, or other study documents that are limited to corrections or factual updates (i.e. no changes to protocol risk, benefit, design; not clarifications to parts of the protocol that were not clear); simplification for lay-friendlier language, or reflecting completion of a pending issue the IRB knew was in process (such as Cert of Confidentiality, funding). (See "Minor Administrative Changes" list in Emory IRB P&Ps for a subset of corrections/factual/administrative updates that all IRB staff may review.)
6. Use of electronic informed consent when:
    a. Obtaining an electronic signature using an Emory OIT approved method, if the consent content was already approved by a faculty designated reviewer or the IRB Full board.
    b. Obtaining verbal consent, when the verbal consent content and verbal consent process has been already approved by a faculty designated reviewer
7. Adding funding sources (but not delete them)
8. Adding Emory-affiliated sites (includes EHC, CHOA if not also adding minors for the first time, Grady)
9. Expeditable increase or decrease of N if the same type of population already approved, OR to allow more consents/screen failures - both on MIN RISK studies only (P&Ps say what levels of increase are expeditable). If new population or more than min risk, send to faculty.
10. Changes in data collection instruments (questionnaires, surveys, chart abstraction forms, CRFs) as long as expertise is not needed to assess risk-level change
11. Advertisements and other recruiting materials
12. Retention materials, newsletters, blasts, reminder cards, health tips related to the disease being studied, participant alert cards, other miscellaneous items that do not involve changes to compensation
13. Sensitive study determination requests, if not done when the application was initially submitted
14. Translated versions of approved documents, requests to enroll non-English speaking subjects, and the addition of Short Form consents in other languages if the population to be studied (for example, patients with leukemia) are the same.

C. CONTINUING REVIEWS

1. All chart reviews, secondary data analyses, and research on existing specimens - F(5)
2. All F(7)
3. Data analysis only (DAO):
    a. For full board studies (i.e. F8c) – but not the first year that study has entered DAO stage. Those should go to faculty reviewer because there may have been significant new information in the past year before subject interaction ended.
    b. For all other categories of expedited studies with no restriction on how long the study has been in DAO.

D. OTHER EVENTS

1. Acknowledgments per Associate or Assistant Director review (based on Emory IRB P&Ps)
2. Finalizing decisions made by Compliance Review team or chairs (document)

STAFF DRS REVIEWING THEIR OWN ITEMS:

- **CAN review their own:**
    - Continuing Reviews and amendments that would fall under "minor administrative changes" per P&Ps
    - Truly retrospective F(5) new studies
- **CANNOT review their own:**
    - Exempt studies (need to obtain a second opinion on exempt status)
    - Prospective F(5) new studies (need to get a second opinion on consent/HIPAA waivers)

DURING STUDY CONDUCT

SOP Title:	***Amendments - Processing from Preliminary Analysis Through Approval***
SOP Category:	Study Management
Established:	08/09/2013
Last Revision:	01/22/2026

PURPOSE
The purpose of this SOP is to outline the step-by-step procedures for processing an amendment from submission to approval.

SCOPE
This SOP applies to amendments that need both expedited and full board review.

PROCEDURES
Note: Find all the checklists on this SOP in this folder H:\General\Admin IRB Documents\Checklists-Staff, Forms, and Templates\1. Staff Screening Checklists and Tip Sheets.

1. Use the AME screening guide found here H:\General\Admin IRB Documents\Checklists, Forms, and Templates while reviewing the amendment. For more information about pre-review and ancillary review information, review our SOP.
2. If the amendment includes a 483 report after an FDA inspection to the study or sponsor, ask the study to remove this report and to submit as an Other Event.
3. Review the changes made to the study and confirm they are described in the text box where indicated in the amendment. The forms that have been changed will appear on the left panel with "MOD" next to them.
4. If changes are needed, use the comment function on each applicable form to request all of the changes or clarifications needed for that form from the study team. Under Actions in the lower right corner, click Route to Submitter, check the box and click the green sign off button.
5. Each comment must be addressed by the study team before the study team can submit back to the IRB. Once the study is submitted back, click Response to Review on the left menu. Click the hyperlink to each form that is listed. Once the form opens, click the red comment bubble which opens the response from the study team. Review each of the responses and confirm the changes requested have been made to the forms or documents. Click the blue "Reply or Resolve" button. If the changes have been made correctly, click Resolved at the bottom of the comment box. If the requested changes were not made, add text to describe the changes still needed and then click Reply. Do this for each comment.
6. Once no further changes are needed, click Notes on the right panel. Click Add Notes and enter the description of the changes included in the amendment, select the type, select Internal for the indicator and click Add.

7. "Check for any outstanding Ancillary reviews. If any, do not route to Expedited review (you still may route for Scheduling)."
8. Determine if the submission must go to full board, or if it can be routed for expedited review. Review OHRP Expedited Categories. Click Expedited Review if it meets the criteria for expedited review or Scheduling if it requires full board review. If assigning to Scheduling for full board review, this will conclude your workflow for the Amendment. If routing for expedited review, select the reviewer and follow the steps below. If routing for expedited review, select a reviewer whose specialty is most closely related to the study. Reference the following SOPs and guidance documents to determine the appropriate route and reviewer assignment:
    - Guidance-Non-Committee Reviewers in this folder: H:\General\Admin IRB Documents\Checklists-Staff, Forms, and Templates\1. Staff Screening Checklists and Tip Sheets
    - *Determinations and Reviews by IRB Staff:* for minor administrative changes that can be approved by the analyst assigned to review the amendment
    - *Categories of research reviewable by IRB staff as IRB designated members*: for selected amendments that could be reviewed by Associate or Assistant Directors or other Sr. RPAs.
    - *Amendments Indicating Increased Risk:* for an amendment that may require Full Board review
9. The expedited reviewer will either send comments back to the study team or will complete their review. They will select “Route to Final Results” and select the analyst who assigned them to the review.
10. Click on the blue study ID number on the left side panel. A screen will open in the center of the screen. Under Review Letters there will be a pdf icon. Click that icon to review any specific comments or determinations made by the reviewer.
11. Under Actions in the lower right corner, select “complete” and select “Generate Review Letter.” Open the download to review the letter. If any changes are needed, edit the letter and drag and drop it in the green area. Check the box and click the green Sign Off button.

SOP Title:	***Over-Enrollment Via Consent (No Research Activities including during Screening)***
SOP Category:	Study Management
Established:	05/15/2012
Last Revision:	08/21/2025

PURPOSE

The purpose of this SOP is to explain the process to follow if over-enrollment took place in a study, when the subjects enrolled beyond informed consent (hereafter referred to as "over-enrollment via consent"). It may also be used if researchers also did basic screening with those subjects, i.e. reviewed those subjects' charts or asked them for private information.

SCOPE

This SOP only applies when over-enrollment was due to consenting more subjects than had been approved by the IRB. It does not apply to cases in which the over-enrollment included subjects who completed any study-driven interventions (even if done for screening or if the activities are considered minimal risk), or post-screening study activities. These activities may include fasting for blood test and medication withdrawal before informed consent was obtained.

PROCEDURES:

Cases should be maintained in a running record sorted by PI. No need for CoRe to review individually unless there is evidence of continuing noncompliance. Team Q is responsible for reviewing records to identify trends of persistent over-enrollment. Persistence of over-enrollment after the issue has already been identified and pointed out to the PI could be continuing noncompliance and should be sent to CoRe. Team Q will review the spreadsheet monthly and report all instances of potential continuing noncompliance to the CoRe team. Other general trends (e.g., departmental patterns) will be reported to the CoRe team and the Associate or Assistant Directors.

Analyst

If enrollment is close to the cap, but not over it, analyst should recommend a review and, perhaps, an increase in enrollment cap. If an analyst identified a case (e.g. at continuing review), he/she will contact the PI providing:

- A description of the noncompliance (the number approved vs. the number consented
- A corrective and preventive action plan that includes:
    - The submission of a Modification to increase enrollment (if the study is closed to enrollment, the NC should be acknowledged, but no Modification is necessary).
    - Portfolio-wide audit of enrollment numbers (*See Guidance to PIs Regarding Self-Audits*)
    - Education by the analyst about the issue with references to IRB P&Ps (p. 155 defines enrollment in Chapter 43, Informed Consent, under Procedures)

The analyst should follow up to make sure the Modification is submitted (using Outlook calendar or other ticklers). If it is not submitted by the time of review, it becomes a pending issue. The analyst should enter the issue into the over-enrollment tracking sheet. The tracking sheet is in the QA working files main folder. H:\IRB\General\QA Working Files

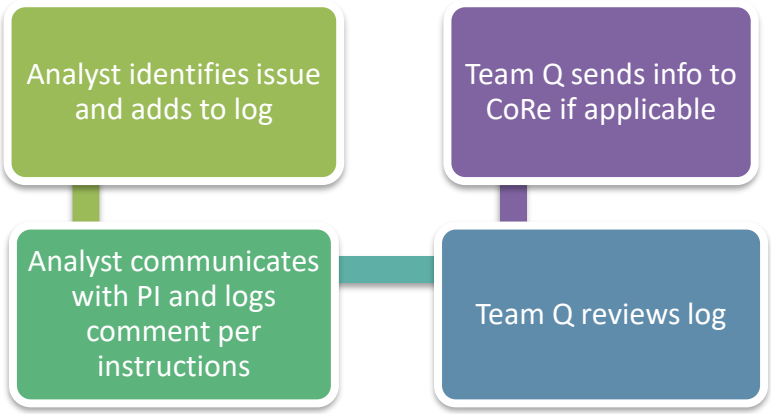
Guidance to PIs Regarding Self-Audits

Paste as a Logged Comment:

- If over-enrollment via consent is not present in any other studies, there is no need to report this.
- If over-enrollment via consent is discovered in other active studies, please submit an amendment to increase enrollment and explain why (i.e. discovered as part of audit).
- If over-enrollment is found that was not due to solely to consenting more subjects than had been approved but included exposing subjects to screening or procedures beyond the consent, report the over-enrollment as an other event.

-

PROCESS FLOW



SOP Title:	*Continuing Reviews and Closeouts*
SOP Category:	Study Management
Established:	06/28/2011
Last Revision:	01/22/2026

PURPOSE

The purpose of this SOP is to describe the process that research protocol analysts follow when processing continuing reviews (CRs) including CRs with Amendments and closeouts.

SCOPE

This SOP applies to CRs and closeouts for single-site studies.

PROCEDURES

1. If the short title includes sIRB, this indicates it is a multi-site study where Emory is the single IRB of record. For those submissions, forward to the Sr. Reliance Analyst. In the lower right corner, click Forward Activity. Enter the Sr. Reliance Analyst's name and enter a note in the comment box.

Continuing Reviews

2. Use this SOP and the Continuing Review Worksheet together when reviewing CRs. The worksheet is in this folder H:\General\Admin IRB Documents\Checklists-Staff, Forms, and Templates\1. Staff Screening Checklists and Tip Sheets. If the CR includes an Amendment, follow the SOP "Amendment Processing – Preliminary Review through Approval."
3. Screen CRs as soon as they are assigned to make sure studies don't expire and teams are able to meet the Grady ROC deadlines when applicable. Do not hold CRs until they are closer to expiration.
4. If the study has lapsed and the team needs to continue research activities, follow the steps listed in page 151 of the P&Ps.
   - Ask the study team to provide a summary regarding the subjects who could be harmed by the cessation of study procedures with rationale
   - Forward the summary to an IRB Chair
   - Forward the IRB Chair's determination to the study team
   - Attach a PDF of the email thread in a private comment to the submission page.
5. CRs assigned to you will show in your dashboard under Action Required Items on the top left corner. CRs will be in the triage state when assigned to you. Click the hyperlink and under Actions, select "Route to Expedited Screening." Select your name from the drop-down list.
6. Review the information provided in the CR form. If changes are needed by the study team, click the blue "comment" link in the top right of the form. A text box will open. Describe all of the changes that are needed for that form in one comment box. Click "comment" in the bottom right. Under Reviewer Actions in the right lower corner, click Route to Submitter. Check the box and click the green Sign Off button.

7. If the study team submits a spreadsheet with mixed information (SAEs reportable at CR and events that are not reportable), ask them to remove the events that are not required and submit in a reportable new information submission.
8. If any of the following have been included in the CR, instruct the study team to remove and report using an OE:
   - 483 reports (FDA inspection findings)
   - Any event/death/protocol deviation/noncompliance report that met the criteria for being promptly reportable:
     - Unanticipated problems (including external deaths that are considered a UP)
     - Reportable protocol deviations
     - Internal deaths considered related to the research
     - Noncompliance
     - Any report that indicates an increase in risk for the rights, welfare or safety of subjects
9. If the study is close to expiration, remove the promptly reportable items from the submission. Email the study team and copy the QTL, asking the team to submit an OE within 2 weeks. Continue processing the CR.
10. If the study is not close to expiration (e.g. more than three weeks for expedited, or longer for full board studies) send the CR back to the study team asking them to submit the list in an OE instead of in the CR and submit the CR back after they have submitted their OE. Email the QTL to make them aware. If the study team does not respond and the study may expire, check with the QTL for next steps.
11. If any of the following have been included the CR, instruct study team to remove. If they require a letter, tell them they must submit an OE.
    - Any items that are not periodically or promptly reportable
    - Minor protocol deviations (per the study team)
    - External deaths so long as they are not UPs (per the study team)
    - Site Monitor's Report (This is not the same thing as a DMC/DSMB report). Monitoring reports should be submitted to CTAC, not the IRB. Tell the study team to email the monitoring report(s) to CTAC at ctcompliance@emory.edu.
12. Once all changes have been made, determine if the CR must go to full board, or if it can be routed for expedited review. See "Categories reviewable by Staff DR" SOP. Review *both* the Continuing Review Worksheet and OHRP Expedited Categories. Click Expedited Review if it meets the criteria for expedited review or Scheduling if it requires full board review.

    Full Board Review

    Click Scheduling on the lower right panel if the CR requires full board review. This will conclude your workflow for the CR.

    Expedited Review

    If study will route for expedited review, first confirm there are no outstanding Ancillary reviews (if so, wait for those to be completed). Then click Expedited Review and select the reviewer.

13. The expedited reviewer will either send comments back to the study team or will complete their review. They will select "Route to Final Results" and select the analyst who assigned them to the review.
14. Click on the blue study ID number on the left side panel. A screen will open in the center of the screen. Under Review Letters there will be a pdf icon. Click that icon to review any specific comments or determinations made by the reviewer.
15. Under Actions in the lower right corner, select "complete" and select "Generate Review Letter." Open the download to review the letter. If any changes are needed, edit the letter and drag and drop it in the green area. Check the box and click the green Sign Off button.

Closeouts

1. The status of the research should be marked "Completed/Closed (no longer using/accessing identifiable data)" if the team is requesting a close-out.
2. Reviewing the submission for accuracy:
   - Are the study numbers correct?
   - Did they provide any DSMB reports, etc.? If applicable we will need to see the latest DSMB report, unless the study has been in data analysis since the last approval period. Review the DSMB document, and if it says anything other than no issues or continue as planned, then consult w/an AD to determine if it needs to be reviewed by faculty.
   - Has the study team marked that all other events have been submitted or that there were none?
3. If any details are inaccurate or clarification needed from the team, add a comment using the comment bubble next to the item that needs correction/clarification and "Route to:" Submitter.
4. Once the submission is ready to be assigned to a reviewer, "Route to:" Expedited Review and select yourself under "select reviewer" if there is no new information presented in this close-out. If the team selected any of the options other than "None of the above" in the "Other Events" section this will require an OE transaction and the close-out submission should be placed on hold. If there is new information presented in the close-out transaction related to the investigator's assessment of risks and benefits or concerns noted in the latest monitoring report or publication (if applicable), the close-out should be assigned to a faculty designated reviewer.
5. If the close-out will be processed by staff you will locate the transaction in the "Actions Required" tab and the action required with be categorized as "Expedited review".
6. Open the transaction and once reviewed and confirmed the study can be closed select "NOTE" under the "Actions" tab. This will populate the checklist to be completed titled, "Study Closeout NW". Complete this checklist and save.
7. Select "Complete" is selected under the "Actions" tab below the link to the checklist. From here the option to "SIGN OFF" is highlighted green. Select "SIGN OFF" to complete the transaction and issue the close-out letter.