



# EMORY UNIVERSITY

## Institutional Review Board

### Research Administration

audio settings here.

Type all your questions in the Q&A space (not in the chat window). We will answer all your questions at the end of the webinar



Chat  Raise Hand  Q&A

An abstract graphic on the left side of the slide. It features a grid of squares, some of which contain arrows pointing to the right. The background is a gradient from dark blue at the top to bright orange at the bottom. A prominent white arrow is located in the upper left, and another white arrow is in the middle right. A large, glowing white arrow shape is also visible in the lower left area.

Emory IRB Webinar

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# Reportable New Information



What will be covered in this presentation?

- RNI Definitions
- Reporting Basics
- Timelines
- RNI submission steps
- Resources



# Why Report?

The IRB needs to review some types of events promptly, in case action is required to protect participants. These events may impact subject safety, confidentiality, or conduct of the study.

IRBs also have an obligation to notify federal oversight agencies (e.g.; FDA/OHRP as applicable) of reportable determinations:

- Serious/Continuing Noncompliance
- Unanticipated Problems



# Internal vs. External events

An *internal* event represents an event that happened to a participant who was enrolled at an Emory site or at a site in which the Emory IRB was the IRB of record.

For example, if a subject enrolled at Emory experienced an event at a different medical facility, the event will still be considered an internal event. In addition, if another site relied on the Emory IRB for review (under a reliance agreement), that site will be considered internal.

NOTE: External events involving an Emory sponsor-investigator (S-I, meaning the Emory investigator holds IND/IDE) should be reported as if it had occurred at an internal site.



# Reporting Timelines

**Promptly:** Reportable within 10 business days from study team's awareness

**Periodically:** Reportable at continuing review



# Noncompliance

Failure to follow the regulations, Emory P&Ps, or Emory IRB determinations, e.g.: IRB FB re-consent requirement was not followed

Info to include: What led to the noncompliance? (root cause analysis)

Substantive plan to correct (if possible) and prevent in the future (CAPA plan)

Reporting time: Promptly (10 business days)







# Protocol Deviations

*Reportable* protocol deviations are defined as substantive and negatively affecting at least one of the following:

- Rights, safety or welfare of participants
- Willingness to continue with study participation
- Integrity of research data

Info to include:

- An explanation of why one of the above referenced categories is impacted
- What led to the noncompliance? (root cause analysis)
- Substantive plan to correct (if possible) and prevent in the future (CAPA plan)

Reporting time: Promptly (10 business days)



# Reportable Deviations

The following deviations are ALWAYS reportable:

- Deviations involving errors during eligibility process that caused the enrollment of an ineligible subject
- Missed protocol-required labs or procedures indicated before study intervention, including pregnancy tests (even if harm did not occur)
- REMS requirements deviations
- Drug dosing errors **involving safety concerns** (for example, if a subject was dosed incorrectly at a lower or higher dose, or if the drug was not stored per manufacturer indications)
- Consent process errors (when subjects did not receive an adequate explanation of study, or there incorrect documentation of consent)
- Failures to maintain or submit FDA regulatory information (E.g.; DOA, 1572, IND or IDE annual reports, etc.)
- Study team delays in submitting documents that involve risk updates

# Unanticipated Problem

A Unanticipated Problem (UP) is an event that meets **all** the following criteria:

- Related to study participation
- Unanticipated (not described or not expected and/or observed previously)
- Poses an increased risk for participants or others (serious)

Info to include: PI assessment of why the event is considered a UP.

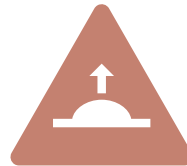
Reporting time: Promptly (10 business days)



# Examples of UPs



New SAE in a participant that is not expected and will be added to the ICF.



SAE previously described in the ICF but is occurring at an increased frequency, severity or duration



An event that doesn't involve safety but increases risk. E.g., a stolen laptop containing subjects' PHI

# Potential UPs:

**SUSARs:** Suspected Unexpected Serious Adverse Reactions. An adverse reaction that is both unexpected (not consistent with the applicable product information) and also meets the definition of a Serious Adverse Event/Reaction.

**UADEs:** Unanticipated adverse device effect is any serious adverse effect on health or safety, 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 application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.





# Death Related to Research

- Internal: Even if an internal death is considered anticipated, it should be reported promptly to the IRB if also considered related to study participation.
- Deaths assessed as not related should be reported periodically (at continuing review).
- External: External deaths are not reportable to the IRB unless also considered a UP, or unless at a site under the oversight of an Emory S-I.

# Serious Adverse Events



SAEs: An event resulting in death, a life-threatening experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect



Not promptly reportable unless they otherwise qualify ( UPs or a related, internal death)



Report SAEs at the time of continuing review via the “[Continuing Review Summary of Events](#)”

# Complaints

Complaints affecting subjects' rights, welfare, safety or willingness to continue with participation.

Rule of thumb, report the following:

- Participant does not want to participate anymore
- Participant expressed that research procedures were not what they expected Even if the event the subject is complaining about is on the ICF, still may be reportable





# Periodic Reporting

Some events are reportable at the time of continuing review (CR):

- Anticipated SAEs that are assessed as related to the research.
- Internal death assessed as NOT related to the research

NOTE: Protocol Deviations are NEVER reportable at the time of CR.

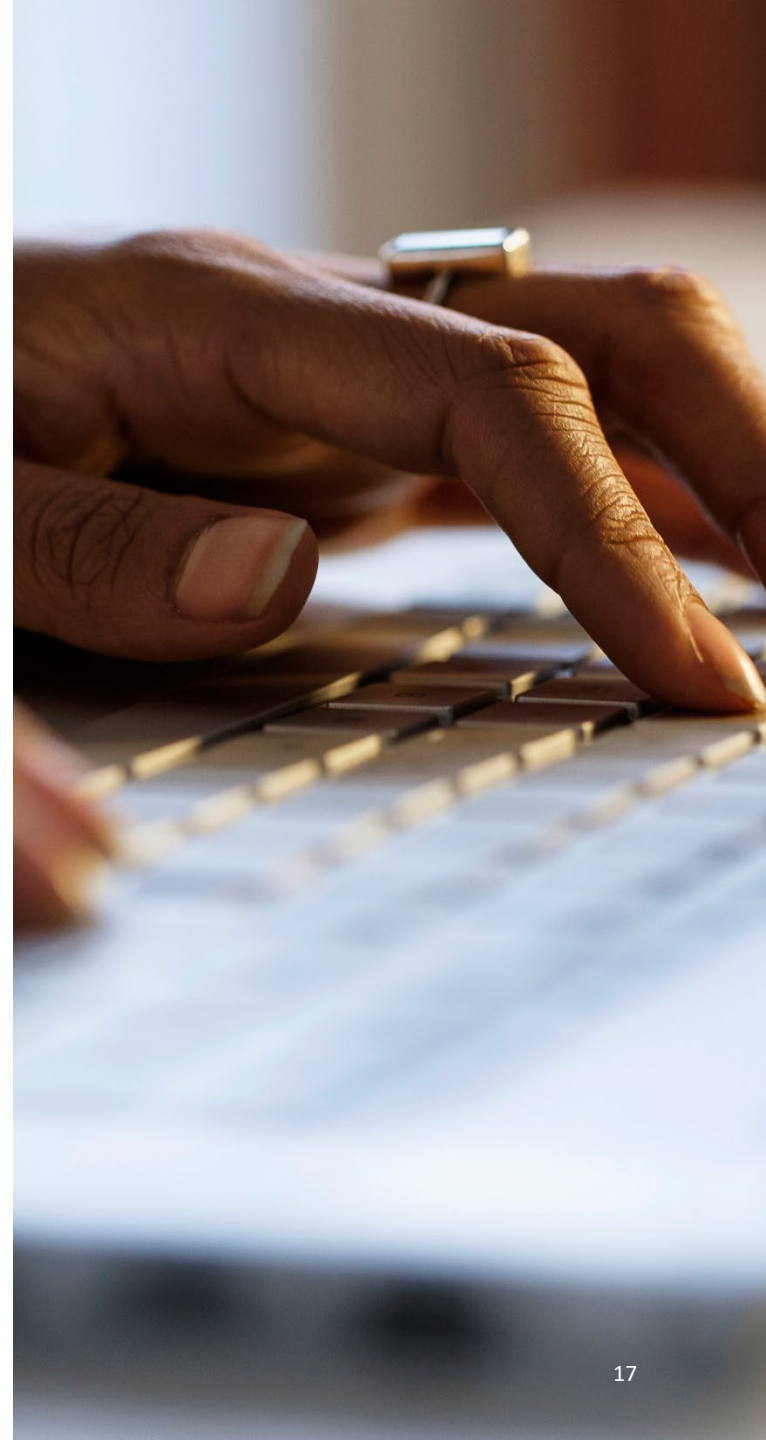


# External IRB Reporting Guidance

When assessing the need to report an RNI, please follow the external and the Emory IRB reporting requirement, whichever is more stringent.

All events should be reported to the external IRB as they are your IRB of record.

Follow the external IRB's SOP's for how to make the report (either directly, or via the lead study team or coordinating center).



# Reporting on XIRB Submissions

Teams are required to report the following “egregious” events promptly to the Emory IRB:

- Internal (at this site) death related or possibly related to the research
- Surgery on the wrong side
- Drug provided to the wrong patient, or a patient received the wrong drug
- Fabrication, plagiarism, or falsification of data
- HIPAA privacy matter (report any inadvertent data disclosure and we will help determine further actions)
- Study Suspension (related to compliance concerns)

**Note:** Some events will also require reporting to the [Emory Office of Research Integrity and Compliance](#) and the Emory Risk Management offices (Emory Healthcare).

The IRB can assist in determining what types of reports are required, so please reach out immediately in the above scenarios.

# Sponsor Reporting Requirements


Sponsors want to receive reports of deviations and SAEs, but it doesn't mean that you need to report these to the IRB.



Sometimes sponsors will want you to report to the IRB, even if it's not reportable

**What to do?** Check your protocol and contract. If required, you have to report

**What would the IRB do?** We will review it and acknowledge it for your records

A person wearing a light blue button-down shirt is sitting at a desk, typing on a silver laptop. The laptop is open and positioned on a wooden desk. To the right of the laptop, there is a glass of water and a small orange container. The background is a bright, out-of-focus office space. The text "RNI Submission Overview" is overlaid in the center of the image in a white, sans-serif font.

# RNI Submission Overview



Approved

Entered IRB: 2/21/2019 4:19 PM  
Initial approval: 2/21/2019  
Initial effective: 2/21/2019  
Effective: 2/21/2019  
Approval end: 2/20/2020  
Last updated: 3/1/2019 3:11 PM

### Next Steps

View Study

Printer Version


Create Modification/CR

Report New Information

Assign Primary Contact

## STUDY00000003: Re-Treatments with Ritumimab

**Principal investigator:** Wesley Becker (pi9)  
**Submission type:** Initial Study  
**Primary contact:** Wesley Becker (pi9)  
**PI proxies:** Rebecca Simms (pi)

**IRB office:** IRB Office 1  
**IRB coordinator:** Orlando Max (irbc)  
**Letter:**  Correspondence\_for\_STUDY00000003.pdf  
**Regulatory authority:** Pre-2018 Requirements



History

Funding

Contacts

Documents

Follow-on Submissions

Reviews

Snapshots

Filter by ?

Activity

Enter text to search for



+ Add Filter

× Clear All

Activity

Author

Activity Date

 Letter Sent

Max (irbc), Orlando

2/21/2019 4:21 PM

 Correspondence\_for\_STUDY00000003.pdf


You Are Here: \_IRBSubmission

## Creating New: IRB Submission


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### Reportable New Information

BEFORE REPORTING TO THE EMORY IRB PLEASE REVIEW OUR [REPORTING REQUIREMENTS](#).

1. **RNI short title:** (uniquely identify this new information report) 

2. \* **Date you became aware of the information:**

3. **Indicate if this event is internal (subject enrolled by Emory personnel or event is under Emory SI or IRB oversight) or external (if not). Check all that apply.**

Internal

External

4. Identify the categories that represent the new information: (check all that apply) ⓘ

Risk: Information that indicates a new or increased risk, or a safety issue. For example:

- a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
- b. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk.
- c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
- d. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.
- e. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.
- f. Any changes significantly affecting the conduct of the research.

Harm: Any harm experienced by a subject or other individual that, in the opinion of the investigator, is unexpected and at least probably related to the research procedures.

- a. A harm is “unexpected” when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
- b. A harm is “probably related” to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.
- Non-compliance:** Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
- Audit:** Audit, inspection, or inquiry by a federal agency.
- Report:** Written reports of study monitors that include findings that negatively affect subject’s rights, safety, welfare or their willingness to continue study participation, or that may affect the integrity of the research data. As a reminder, all monitoring reports should be forwarded via email to CTAC regardless of findings.
- Researcher error:** Failure to follow the protocol due to the action or inaction of the investigator or research staff.
- Confidentiality:** Breach of confidentiality.
- Unreviewed change:** Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
- Incarceration:** Incarceration of a subject in a study not approved by the IRB to involve prisoners in non-exempt research.
- Complaint:** Complaint of a subject that cannot be resolved by the research team. Such complaints generally affect the rights, welfare, safety of subjects or their willingness to continue with study participation.
- Suspension:** Premature suspension or termination of the research by the sponsor, investigator, or institution.
- Unanticipated adverse device effect:** 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.
- VA-SAE:** For Department of Veterans Affairs (VA) research, all local or internal serious adverse events (SAEs).
- ICF/HIPAA Deviations:** Deviations involving the consent signature(s), missing ICF/HIPAA forms, or using the wrong/expired forms to consent a subject.

5. \* Briefly describe the new information:

Make sure to include a concise summary with all relevant details!  
It's important to clarify what is being reported. If preferred, provide the details in an attached document in number 8.

6. In the submitter's opinion:

a. \* Does this information indicate a new or increased risk, or a safety issue?

Yes  No [Clear](#)

b. \* Does the study need revision?

Yes  No [Clear](#)

c. \* Does the consent document need revision?

Yes  No [Clear](#)

**i** If revisions are required, describe them above and submit a study modification for review.

7. Related studies and modifications:

ID	Short Title	Investigator	State	IRB Office
There are no items to display				

8. Attach files containing supporting information:

Name
There are no items to display

# Adding a Related Submission

## 7. Related studies and modifications: ?

ID	Short Title	Investigator	State	IRB Office	
STUDY00000002	Familial History of Carcinoid Cancer	Wesley Becker (pi9)	Closed	IRB Office 1	✕
STUDY00000003	Re-Treatments with Ritumimab	Wesley Becker (pi9)	Approved	IRB Office 1	✕



Pre-Submission

# RNI00000012: Sponsor Report

Last updated: 3/12/2019 8:13 PM

### Next Steps

Edit RNI

Printer Version

Submit RNI

Add Related Submission

Add Comment

Copy Submission

Discard

### Submit RNI

By signing below you are verifying that:

- The information you have submitted is complete and correct to the best of your knowledge.
- The information you have submitted has been done so in accordance with requirements in the [HRP-103 - Investigator Manual](#)

OK

Cancel

Review Complete

Reportable Information Opened

Becker (pi9), Wesley

3/12/2019 8:13 PM

# Important Reminders

- Redact any identifiers from the information provided.
- Make sure to “submit”. In many cases, teams “create” and don’t submit.
- If there is a question regarding whether something is reportable, reach out! Alternatively, go ahead and submit. The Team Q case manager will guide on next steps.



# What Comes Next...

The RNI may be “acknowledged”. In this case, we will not release a letter. Instead, teams can use this [memo](#) for your records or to show to your sponsors if needed, along with the RNI submission record.

Once the event moves to the “acknowledged” state, no additional action is required from the team.

# Compliance Review Process

If an event warrants further review, a Team Q staff member will review the event, gather details from the team, and route to CoRe.

The CoRe team is a designated group of the IRB Chair, Director, and qualified IRB staff that reviews reported 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.

If CoRe determines that the event is potential serious and/or continuing noncompliance and/or an unanticipated problem cases, the event will go to Committee Q.

# Contacts

- Call or email [your study analyst](#) directly, for specific study question.
- Call [any of our staff](#) for general questions.
- For Education/Outreach questions, Complaints from study participants, Compliance, and Adverse Event issues, please contact the [Education and Quality Assurance Team](#).
- General inquiries: [IRB@emory.edu](mailto:IRB@emory.edu)

