REPORTING OBLIGATIONS FOR EXTERNAL STUDIES

When and how to report to the IRB

Topics to Cover

- What events should be reported
- Who should receive the report(s)
- How to report
- Timing of reports
- Review website resources for studies under reliance agreements
- Q/A

What Requires Reporting?

Report events/information to the **REVIEWING IRB** according to the Reviewing IRB's policies and process.

If in doubt: report anything that Emory IRB would require to be reported, and if the Reviewing IRB's rules go beyond our requirements,
you must follow their policies.

Note: You do not have to create an RNI in eIRB if you only need to report it to the external IRB.

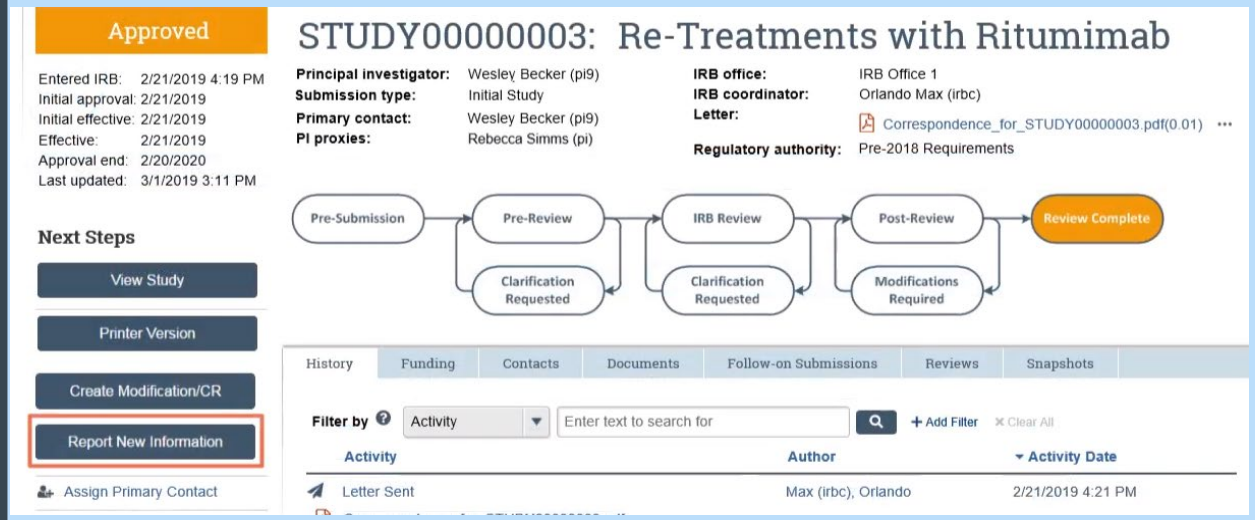
Prompt Reports to Emory

- Report "egregious" reportable events promptly to Emory office of Compliance, Risk Management Office, and Emory IRB *IN ADDITION to* the Reviewing IRB.

Examples of Egregious Events

- wrong side surgery
- wrong drug, wrong patient
- fabrication or falsification of data
- HIPAA privacy matter (report any inadvertent data disclosure and we will help determine further actions)

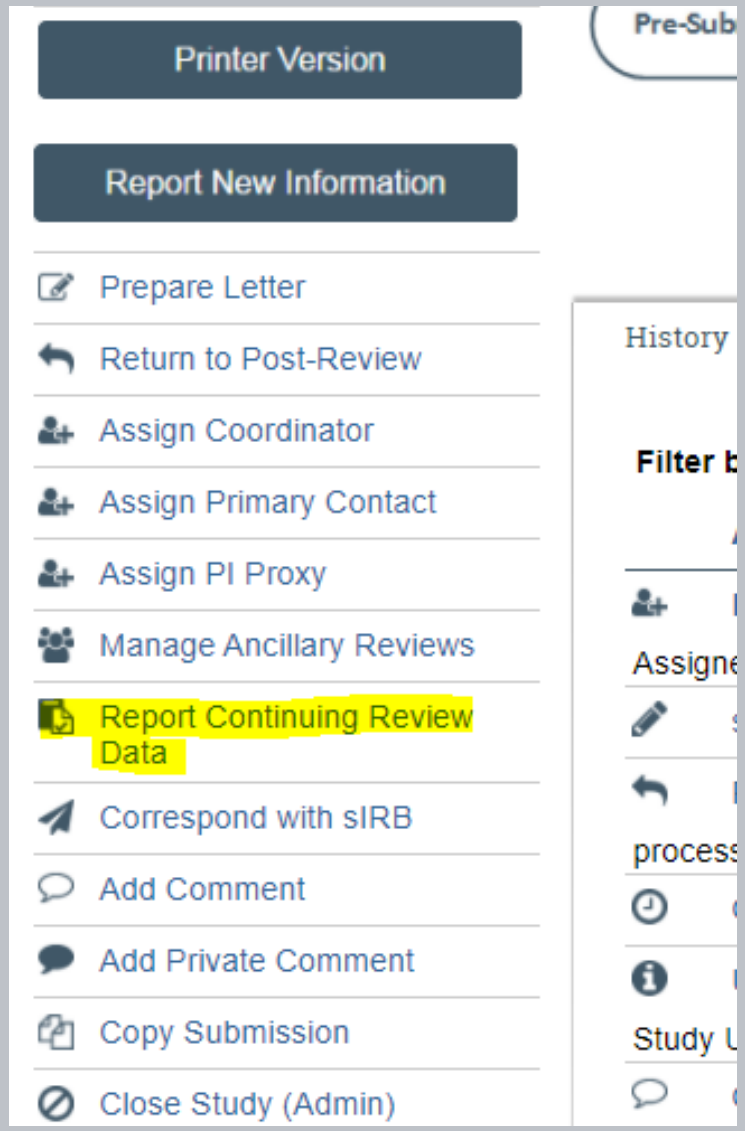
Reporting Egregious Events



- Select "Report New Information"
- Upload a copy of the report(s) made to the reviewing IRB, and any correspondence from the reviewing IRB
- No need to wait for their determination

Periodic Reporting Requirements

Teams have an obligation to report CR data to the Emory IRB. The report should be made upon receipt of the CR approval letter provided by the reviewing IRB.



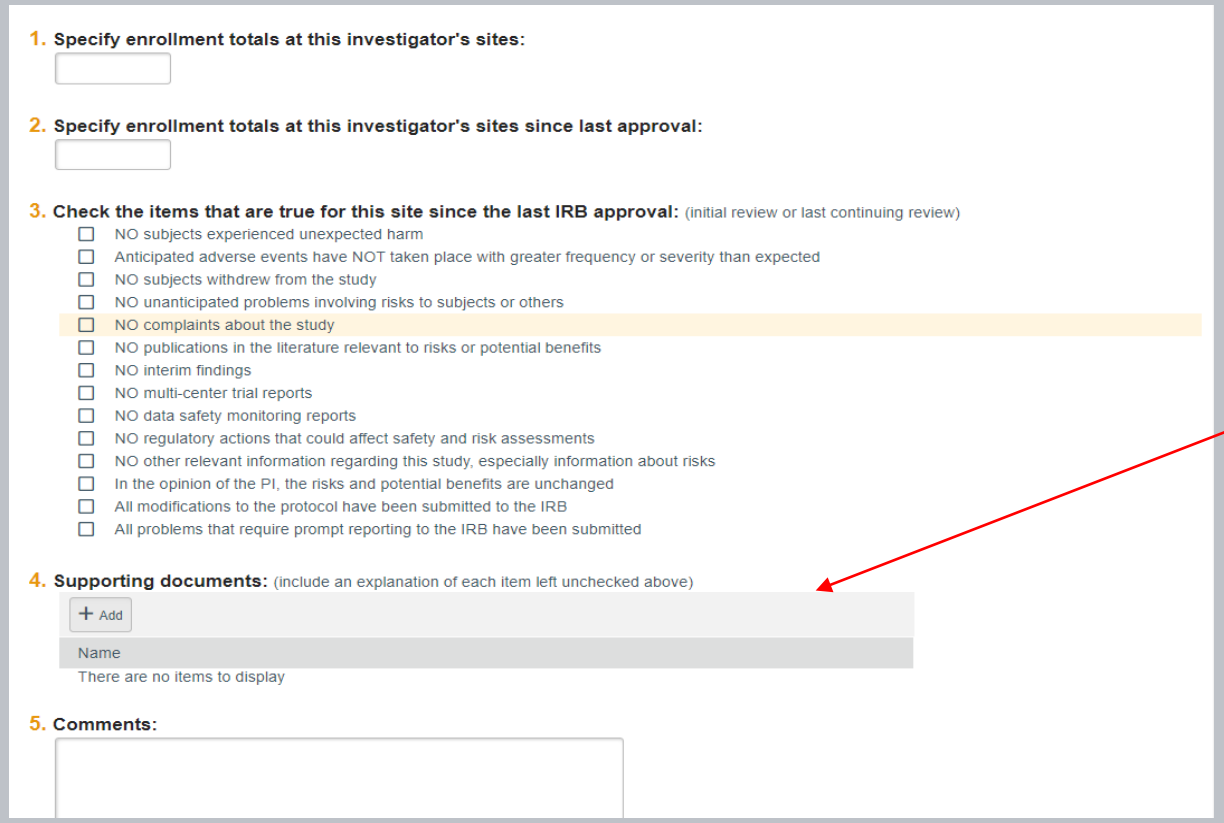
Periodic Reporting Requirements

The Emory IRB would like a summary of events reported to the External IRB during the past approval period.

The PI can select "Report Continuing Review Data" from the main study workspace.

Again, these do not need an RNI submission

CR Workbook



1. **Specify enrollment totals at this investigator's sites:**

2. **Specify enrollment totals at this investigator's sites since last approval:**

3. **Check the items that are true for this site since the last IRB approval:** (initial review or last continuing review)
   - ☐ NO subjects experienced unexpected harm
   - ☐ Anticipated adverse events have NOT taken place with greater frequency or severity than expected
   - ☐ NO subjects withdrew from the study
   - ☐ NO unanticipated problems involving risks to subjects or others
   - ☐ NO complaints about the study
   - ☐ NO publications in the literature relevant to risks or potential benefits
   - ☐ NO interim findings
   - ☐ NO multi-center trial reports
   - ☐ NO data safety monitoring reports
   - ☐ NO regulatory actions that could affect safety and risk assessments
   - ☐ NO other relevant information regarding this study, especially information about risks
   - ☐ In the opinion of the PI, the risks and potential benefits are unchanged
   - ☐ All modifications to the protocol have been submitted to the IRB
   - ☐ All problems that require prompt reporting to the IRB have been submitted

4. **Supporting documents:** (include an explanation of each item left unchecked above)

   + Add

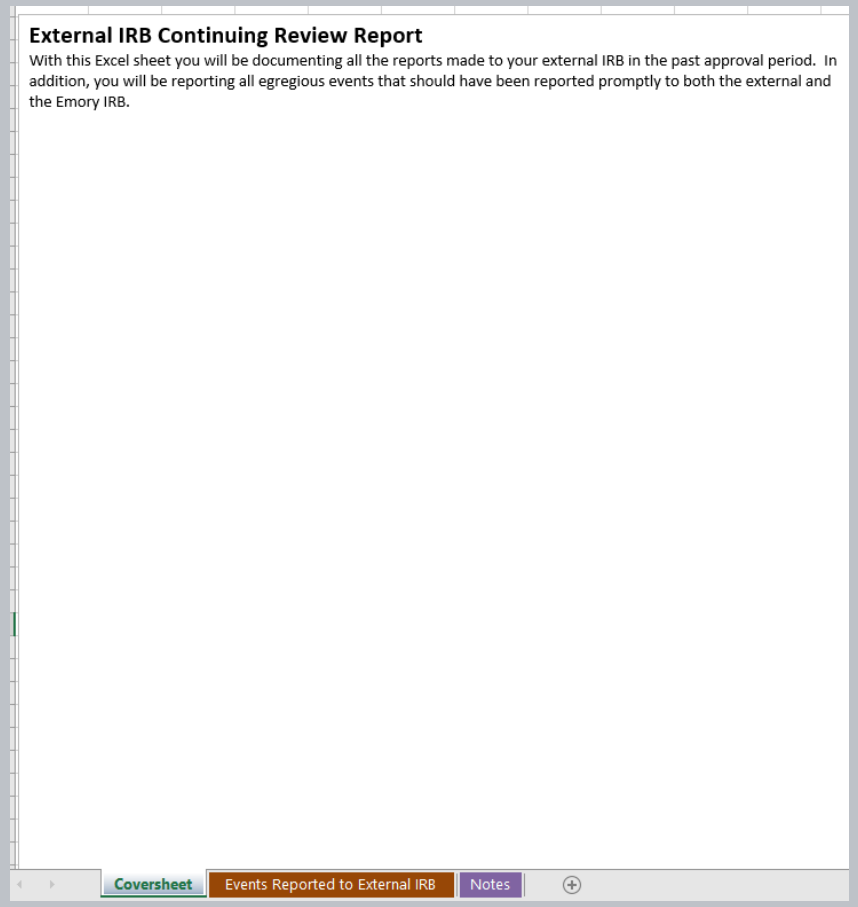
   Name

   There are no items to display

5. **Comments:**

- Under question #4, attach the completed "CR Workbook" as well as the renewal letter from the reviewing IRB.

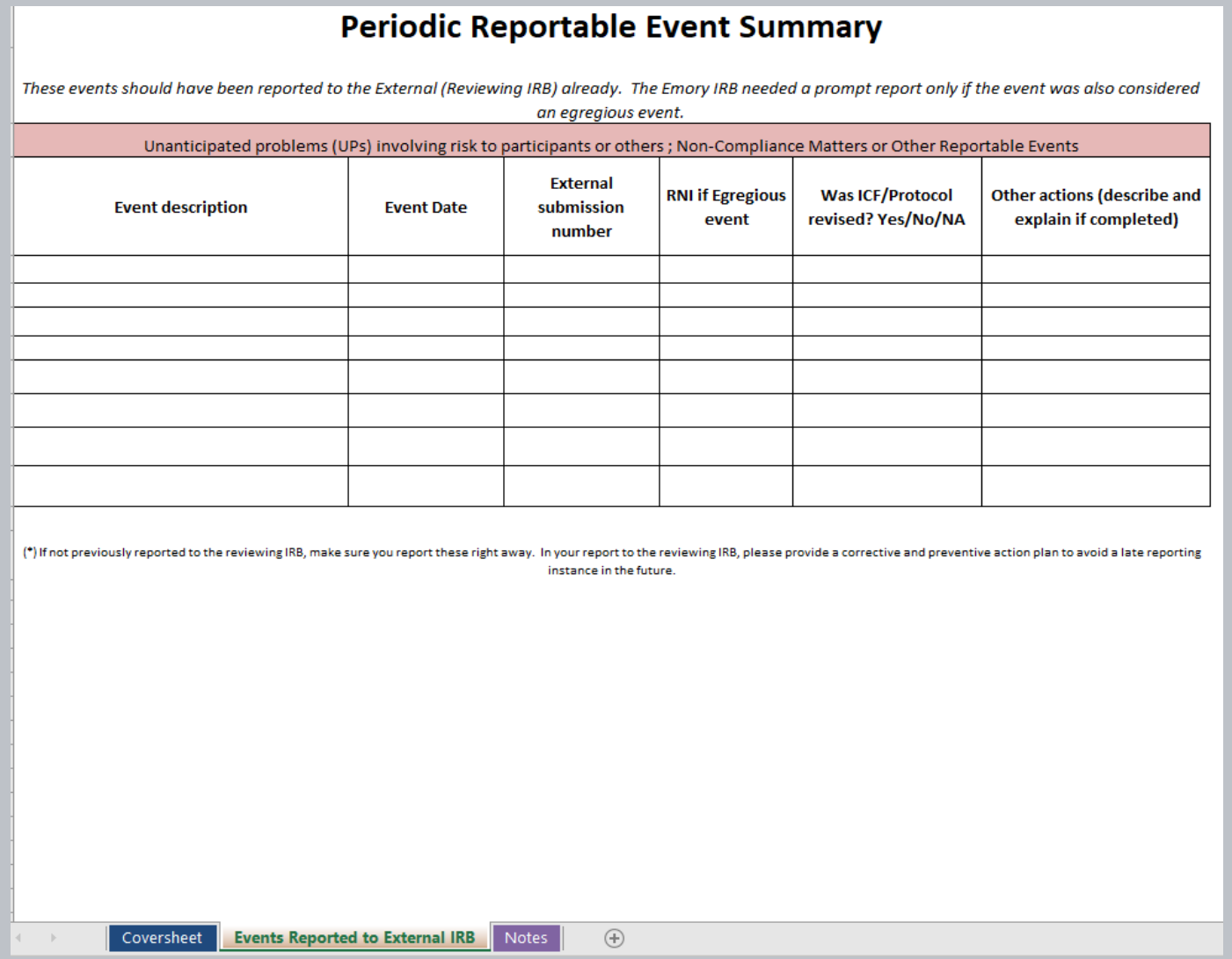
CR Workbook



External IRB Continuing Review Report

With this Excel sheet you will be documenting all the reports made to your external IRB in the past approval period. In addition, you will be reporting all egregious events that should have been reported promptly to both the external and the Emory IRB.

Coversheet | Events Reported to External IRB | Notes



Periodic Reportable Event Summary

These events should have been reported to the External (Reviewing IRB) already. The Emory IRB needed a prompt report only if the event was also considered an egregious event.

Unanticipated problems (UPs) involving risk to participants or others ; Non-Compliance Matters or Other Reportable Events

Event description	Event Date	External submission number	RNI if Egregious event	Was ICF/Protocol revised? Yes/No/NA	Other actions (describe and explain if completed)

(*) If not previously reported to the reviewing IRB, make sure you report these right away. In your report to the reviewing IRB, please provide a corrective and preventive action plan to avoid a late reporting instance in the future.

Coversheet | Events Reported to External IRB | Notes

Alternative process for CR data reports

- If the PI is unavailable to submit the CR data, the team can log a can log a comment along with the CR approval letter and CR workbook.
- The analyst will manage the technical process within the system

Reportable Changes in Research

- changes to drugs or devices used in the study
- changes to local study personnel
- changes to Emory-affiliated study sites
- changes in financial interests on the part of Emory investigators
- new funding mechanisms
- No other changes need to be submitted locally to us at this time (subject to change)

How To Report Changes

- Depending on the state of your approved study, do the following:
  - "Active" status- submit via 'Create Site Modification" (for Emory-specific information changes) or "Update Study Details" (for study-wide changes).
  - "External IRB" status- you need to submit an "Update" to the submission.


Navigating the IRB Website

Questions?