



RNI00000034

View: Emory SF: New Information

Reportable New Information

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

Fill these questions as highlighted. If you see questions left unanswered please do the same on your submission

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

Concurrence for a single use expanded access

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

Today's date.

- 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

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

There are no items to display

Don't answer

i Important! Information that does not fit into one of the categories above does not need to be reported to the IRB as new information.

- 5. * Briefly describe the new information:**

We are seeking the IRB chair concurrence for the use of DRUG/DEVICE. See attached documents for more information.

- 6. In the submitter's opinion:**

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

Yes No

b. * Does the study need revision?

Yes No

c. * Does the consent document need revision?

Yes No

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

7. Related studies and modifications:

Don't answer

ID	Short Title	Investigator	State	IRB Office
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None

8. Attach files containing supporting information:



Do not attach documents here. Please email them as attachments to members of the IRB Education and QA Team via encrypted email. Please include the RNI number your email. IRB staff will ensure the documents are fully redacted before uploading them on your behalf. You will just need to submit changes back to the IRB at the end of this process.

If using a drug, remember to check box 10b when submitting form 3926 to the FDA. If this isn't done, a full new study submission is required in order to obtain IRB approval for the use.