Read these instructions carefully before starting

* Complete this template if you are requesting the Emory IRB to rely on another academic IRB or a commercial IRB other than Western IRB (WIRB) or Advarra.
* Attach the entire sponsor’s main protocol with this document.
* Do **not** delete instructions in this document. Just add your text in black font where indicated.
* When you write a site-specific supplement, keep an electronic copy. You will need to modify this copy when making changes. You should **upload** the modified copy of your protocol instead of **adding a new version**.

**PROTOCOL TITLE**: Include the full protocol title. (Add your text)

**PRINCIPAL INVESTIGATOR:**

Name (Add your text)

Department (Add your text)

Telephone Number (Add your text)

Email Address (Add your text)

**VERSION**: **ADD** (Add your text)

**FUNDING SOURCE**: Include the information for the funding entity for this study. Please explain if this study is covered by a sub-award or other pertinent information. If Emory is not the prime awardee of a grant, indicate the awardee institution or organization. (Add your text)

**REVISION HISTORY**

No need to review this section if this is the first version of the protocol you are submitting to the IRB

|  |  |  |
| --- | --- | --- |
| Revision # | Version Date | Summary of Changes |
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# Emory’s Engagement in the Research

Review [OHRP Guidance on Engagement of Institutions in Human Subject Research](http://www.hhs.gov/ohrp/policy/engage08.html) and describe how Emory is engaged in the research.

***Note: Even if you are not conducting any research activities, and your only participation in the study is being the grant awardee, you are still considered “engaged” in research.***

(Add your text)

# Reason for Reliance

Describe the reason for requesting the Emory IRB rely on an external IRB. Include whether the use of a single IRB is required by the funding agency, regulation, or policy and provide details.

***Note: If the research has been determined to be exempt by the reviewing IRB, STOP. You will need to submit to the Emory IRB. Emory will not rely on an external IRB for exempt research.***

(Add your text)

# External IRB Information

In this section, provide information about the external IRB. **You may need to contact the IRB directly to obtain this information. Please provide:**

* Name of the external IRB
* External IRB’s reliance point of contact information
* If the external IRB is AAHRPP accredited
* If the external IRB has signed onto SMART IRB
* If the IRB has agreed to serve as the single IRB of record
* Link to the external IRB’s policies and procedures for Investigators
* External IRB study ID of the approved study
* Name of the PI at the reviewing IRB institution

If Emory agrees to rely on the IRB, you will need to know where to find the IRB’s policies and procedures because you will have to adhere to them in addition to Emory IRB’s policies and procedures.

***Note: Emory generally only relies on AAHRPP accredited IRBs.***

(Add your text)

# Communication Plan

Describe the plan for communicating:

* Reportable new information such as noncompliance, SAEs, participant complaints, etc. for your site to the IRB of record.
* Site-specific changes to the research to the IRB of record. For example, will changes to site-specific recruitment materials be submitted to the IRB directly by your site or will the lead study team, sponsor or coordinating center complete IRB submissions?
* Study-wide changes to the research (such as protocol amendments) to the IRB of record. For example, will the changes be submitted to the IRB directly by your site or will the lead study team, sponsor or coordinating center complete IRB submissions on behalf of your site?

(Add your text)

# Site Study Procedures

Describe the research activities that will be conducted by Emory personnel. **Note any differences in study procedures at your site compared to those outlined in the protocol**.

* If there are study procedures that are described in the protocol that your site will NOT be conducting, please list these.
* Describe any cohorts or arms of the study described in the protocol that your site **will** **not** enroll in the study.
* Describe any procedures that are considered standard of care and **not** considered research activities at other sites but are not considered the standard of care at your site.

(Add your text)

# Mobile Apps/Software Needing OIT Review

Describe if you are using any software or app that has not been vetted by [Emory Office of Information Technology](https://it.emory.edu/security/protecting-data/software_for_research.html). Be aware that you may need to submit an [OIT security review request](https://emory.service-now.com/sp?id=kb_article&sys_id=e5c2cd88f5cdf1c055c77bd8604896c2).

When submitting such request, include any security reviews already completed by the sponsor or lead study team.

(Add your text)

# Study Intervention/Investigational Agent

* If the research involves drugs or devices, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.
* If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., IDS SOP), reference that SOP.
* If using a drug for this study, explain if you are using IDS. If not using IDS, per Emory policy, explain why, and attach an IDS exemption form (approved by IDS) with your submission.
* If the drug is under an FDA [REMS](https://www.fda.gov/AboutFDA/Transparency/Basics/ucm325201.htm), plan to complete the [REMS checklist](http://irb.emory.edu/documents/REMS_checklist.docx) found here, on the Emory IRB website. If you are using a schedule I controlled substance, [fill out this checklist](http://compliance.emory.edu/documents/CS_checklist.docx).

(Add your text)

# Waiver or Alteration of HIPAA Authorization

Review the [Emory IRB waiver document](http://www.irb.emory.edu/documents/Combined_Waiver_Consent_HIPAA_Elements.docx) to ensure you have provided sufficient information for the IRB to make these determinations.

***Note: When ceding review to an external IRB, the Emory IRB will not grant study-wide waivers. Emory will grant a partial waiver of HIPAA authorization for recruitment purposes if applicable.***

If the research involves a waiver of the consent process for planned emergency research, please review the Emory P&Ps, Chapter 48, WAIVERS OF, AND EXCEPTIONS FROM, INFORMED CONSENT FOR PLANNED EMERGENCY RESEARCH to ensure you have provided sufficient information for the IRB to make these determinations.

(Add your text)

# Setting

List the local sites or locations where your research team will conduct the research.

***Note: If your research will take place at Grady, and Grady personnel will administer interventions or otherwise be engaged in the research, a separate reliance agreement may be needed between Grady and the external IRB. Contact Grady ROC as soon as possible to discuss if a separate reliance agreement is needed. The Emory IRB is not involved in this process.***