DELETE All INSTRUCTIONS AND COMMENTS

Read these instructions carefully before starting

As you are finishing this document, **remove these instructions**, delete all the template language (in dark orange) so that they are not contained in the final version of your protocol.

Delete sections that do not apply to your study. **If removing sections of this protocol**, update the table of contents by right-clicking on it and selecting “update field”.

* **What template should I use?**
  + Complete this template if you are participating in a sponsor-initiated study (to supplement the main study protocol) or when Emory is ceding their review to another IRB in a multi-site study.
  + If you are initiating this study (even if you have an industry sponsor) [use our other templates](http://irb.emory.edu/forms/Study%20Submission.html) as applicable.
* You must submit the Supplement to [Sponsor Protocol Checklist](http://irb.emory.edu/documents/Protocol_Checklist-Supplement_Protocol_Sponsor.docx) with your protocol, to attest that you have considered all the required sections in this template.
* Attach the entire sponsor’s main protocol with this document.
* Unless otherwise specified, provide only site-specific information below.
* 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. (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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# Site Study Procedures

In this section, describe any differences in study procedures at your site compared to those outlined in the protocol. For example, if there are study procedures that are described in the protocol that your site will NOT be conducting, please list these.

Please 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)

# Communication Plan

**Delete this section if this is a multisite study where each site is doing its own IRB review, i.e. Emory is not in any reliance agreements.**

In this section, describe the plan for communicating reportable events such as noncompliance, SAEs, participant complaints, etc. for your site to the IRB of record.

Describe the plan for communicating site-specific changes to the research to the IRB of record. For example, will the changes such as staffing changes and changes to site-specific recruitment materials be submitted to the IRB directly by your site or will a sponsor or coordinating center complete IRB submissions on behalf of your site?

If the Emory IRB is not the IRB of record, describe the plan for communicating 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 is there a sponsor or coordinating center that will complete IRB submissions on behalf of your site?

If your site is considered the lead site and the Emory IRB is the IRB of record, describe the processes to ensure communication among sites:

* Describe the plan to ensure that all sites have the most current version of the protocol, consent document, and HIPAA authorization.
* Describe the plan to ensure that all required approvals (initial, continuing review, and modifications) have been obtained at each site (including approval by the site’s IRB of record).
* Describe the plan for disseminating IRB approval letters and stamped consent forms to non-Emory sites.

(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), please reference that SOP in this section.

If using a drug for this study, explain if you are using IDS. If not using IDS, per Emory policy, explain why.

If the drug is under an FDA [REMS](https://www.fda.gov/AboutFDA/Transparency/Basics/ucm325201.htm), please also 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)

# Site-Specific Data and Specimen Banking

The sponsor’s protocol may require banking data or specimens for future use and both storage and use will be determined by the sponsor. However, if additional data or specimens will be banked locally for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens. (may require a separate repository-specific IRB submission).

List the data to be stored or associated with each specimen banked locally.

Describe the procedures to release locally banked data or specimens, including the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

(Add your text)

# Sharing of Results with Participants

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how it will be shared.

If applicable (e.g. for studies involving scans and/or panels of exploratory testing on specimens): Incidental Findings –

Plan for managing the types of findings that might arise. This should include any secondary findings that are being sought actively, findings that might be anticipatable, and findings that might be un-anticipatable.

Plan for recognizing, analyzing, and handling incidental findings and how incidental findings will be communicated to participants during the consent process. If the plan is not to disclose any findings, then this should be included. This plan might include the option for participants to opt-out of receiving incidental findings.

Description of the research team’s responsibilities following disclosure of a finding. This should detail educational information about the nature of the finding, how to seek care from a clinician or specialist, obtaining health insurance to secure treatment, and/or referral to a clinical specialist, if one is required.

Reminder to include language in the consent form to let the participants know your plans for this – see Modular Language for Informed Consent Forms on IRB website.

(Add your text)

# Site-Specific Inclusion and Exclusion Criteria

Describe any inclusion or exclusion criteria that will differ for your local site compared to the criteria listed in the sponsor’s protocol. For example, if the sponsor’s protocol allows the enrollment of children but your site will not enroll children, indicate that here.

(Add your text)

# Vulnerable Populations

If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

If the research involves pregnant women, human fetuses, or neonates of uncertain viability or non-viable neonates review the “[Pregnant Women, Fetuses, and Neonates Checklist”](http://irb.emory.edu/documents/Emory%20Subpart%20B%20Worksheet.doc) to ensure that you have provided enough information.

If the research involves prisoners, review the “[Prisoner Subjects Checklist”](http://irb.emory.edu/documents/Emory%20Subpart%20C%20Worksheet.doc) to ensure that you have provided enough information.

If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the “[Minor/Children Subjects Checklist](http://irb.emory.edu/documents/Emory%20Subpart%20D%20Worksheet.doc)” to ensure that you have provided enough information.

If the research involves cognitively impaired adults, review the “[Cognitively Impaired Checklist”](http://irb.emory.edu/documents/CHECKLIST-Cognitively_Impaired_Adults.docx) to ensure that you have provided enough information.

(Add your text)

# Local Accrual Goal

Indicate the total number of participants to be accrued locally. Please note this includes all participants who will sign a consent form, not just those who are eligible after screening.

If applicable, distinguish between the number of participants who are expected to be enrolled and screened, and the number of participants needed to complete the research procedures (i.e., numbers of participants excluding screen failures.)

Provide your projected enrolling goals, including the percentage of participants according to sex and race.

(Add your text)

# Local Recruitment Methods

This section is for recruitment methods under the control of the local site ONLY.

Describe when, where, and how potential participants will be recruited.

Describe the source of participants.

Describe the methods that will be used to identify potential participants.

Describe materials that will be used to recruit participants. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/videotape. You may submit the wording of the advertisement before taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/videotape.)

Describe the amount and timing of any payments to participants.

Describe how you will ensure that the study enrollment targets underrepresented populations and women.

All research recruitment through social media needs to follow [this guidance](http://irb.emory.edu/documents/Guidance-Using_Social_Media_Recruit_participants.pdf), which does not allow the use of personal social media accounts for some recruitment activities.

(Add your text)

# Withdrawal of Participants

Describe procedures that will be followed locally, if different than the sponsor’s protocol, when participants withdraw from the research.

(Add your text)

# Data Management and Confidentiality

Describe your local plan to ensure that the data you are collecting is complete and obtained adequately. For example, when obtaining consent from a participant, the person obtaining consent should check the consent document to ensure the participant has signed in the right place(s) and the documentation of the consent process is adequate.

* Describe the local procedures for maintenance of confidentiality.
* Where and how will data or specimens will be stored locally?
* How long will the data or specimens be stored locally?
* Who will have access to the data or specimens locally?
* Who is responsible for receipt or transmission of the data or specimens locally?
* How will data and specimens be transported locally?

(Add your text)

# Provisions to Monitor the Data to Ensure the Safety of Participants

This section is required when research involves more than Minimal Risk to participants.

Ensure that you review our [Data and Safety Monitoring plan guidance](http://irb.emory.edu/documents/DSMP_requirements_ver_2-2-2021.pdf) for specific details about this section, and examples of what the IRB will be requiring according to the level of risk.

If a DSMB is needed, please describe the composition of the board (if not already detailed in the protocol). [Review this guidance](http://irb.emory.edu/documents/DSMB-DSMPGuidance.pdf) for more information. If the sponsor protocol does not contain all required information, please in this section.

Describe the plan to periodically monitor the data at the site level, according to risk level and if you hold, IND/IDE sponsorship, and if you have international sites.

Description of the plan for notifying the IRB of reportable events; whether the sponsor requires reporting above and beyond the Emory IRB reporting requirements, and if so, a description of the requirements and plan for meeting them.

Please address the specific details below. If deemed not applicable, please provide rationale:

Subject safety:

* Specific subject safety parameters
* Frequency of subject safety observations
* Individual responsible for safety monitoring
* Subject stopping rules – under what conditions will a subject be removed from study participation and who will make the decision?
* Study stopping rules - under what conditions will the study be modified or stopped and who will make the decision?
* Reporting mechanisms (i.e. Deviations, adverse events, UPs)

Data Integrity:

* Specific data elements to be reviewed
* Frequency of monitoring data, points in time, or after a specific number of participants
* Individual responsible for data monitoring

Additional considerations for FDA regulated trials

Depending on the procedures affecting risks to participants, the site monitoring plan should specify:

* Categorization of activities done centrally and those on-site if applicable
* Monitoring methods (may include centralized/remote, on-site, and self-monitoring)
* Reference to any tools used (i.e. checklists)
* Identification of events that may trigger changes
* Identification of deviations or failures that would be critical to study integrity

(Add your text)

# Provisions to Protect the Privacy Interests of Participants

Describe the steps that will be taken to protect participants’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact with or whom they provide personal information.

Describe what steps you will take to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Indicate how the research team is permitted to access any sources of information about the participants.

(Add your text)

# Economic Burden to Participants

Describe any costs that participants may be responsible for because of participation in the research, e.g., fuel, parking, childcare, or any procedures considered standard of care at other sites but not at your site.

(Add your text)

# Informed Consent

Indicate whether you will be obtaining consent and if so describe:

* Where will the consent process take place?
* Any waiting period available between informing the prospective subject and obtaining the consent.
* Any process to ensure ongoing consent.
* Please describe:
* The role of the individuals listed in the application as being involved in the consent process.
* The time that will be devoted to the consent discussion.
* Steps that will be taken to minimize the possibility of coercion or undue influence.
* Steps that will be taken to ensure the participants’ understanding.

Note: If you are planning to obtain consent via electronic signature, please review [this document](http://www.irb.emory.edu/documents/guidance-eICF_use.pdf). Additional guidance on consent documentation and process can be found on our website, under the [consent toolkit](http://www.irb.emory.edu/forms/consent_toolkit/guidance.html).

(Add your text)

**Non-English-Speaking Participants**

* Indicate what language(s) other than English are understood by prospective participants or representatives.
* If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent.
* If you checked N/A, please provide reasoning of why subjects with limited English proficiency are excluded.

Note: if you stated that subjects with LEP will be enrolled, you are approved for the use of the Emory IRB short forms. Please read the guidance about the use of short forms here.

(Add your text)

**Participants who are not yet adults (infants, children, teenagers)**

* Describe the criteria that will be used to determine whether a prospective participant has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)
* For research conducted in Georgia, review “Emory IRB Policies and Procedures: 53 RESEARCH INVOLVING CHILDREN – ADDITIONAL PROTECTIONS” and “46 LEGALLY AUTHORIZED REPRESENTATIVES AND SURROGATE CONSENT” to be aware of which individuals in the state meet the definition of “children.”
* For research conducted outside of Georgia, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. Please reference Emory IRB Policies and Procedures chapters 53 RESEARCH INVOLVING CHILDREN – ADDITIONAL PROTECTIONS and 46 LEGALLY AUTHORIZED REPRESENTATIVES AND SURROGATE CONSENT.

Describe whether parental permission will be obtained from:

* Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
* One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.

When assent of children is obtained describe whether and how it will be documented.

(Add your text)

**Cognitively Impaired Adults**

Describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require children to sign assent documents.

(Add your text)

**Adults Unable to Consent**

* List the individuals from whom permission will be obtained in the order of priority. (E.g., durable power of attorney for health care, a court-appointed guardian for health care decisions, spouse, and adult child.)
* For research conducted in the state, review Chapter 46 LEGALLY AUTHORIZED REPRESENTATIVES AND SURROGATE CONSENT to be aware of which individuals in the state meet the definition of “legally authorized representative.”
* For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research.

Describe the process for the assent of the participants. Indicate whether:

* Assent will be required of all, some, or none of the participants. If some, indicated, which participants will be required to provide assent, and which will not.
* If assent will not be obtained from some or all participants, an explanation of why not.
* Describe whether the assent of the participants will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require participants to sign assent documents.

(Add your text)

**Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)**

* 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.
* 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

* This section pertains to the local sites or locations where your research team will conduct the research.
* Identify where research procedures will be performed.
* Describe the composition and involvement of any community advisory board.

For research conducted outside of Emory and its affiliates describe:

* Site-specific regulations or customs affecting the research for research outside the organization.
* Local scientific and ethical review structure outside Emory.

(Add your text)

# References

Add references.

(Add your text)