DELETE All INSTRUCTIONS AND COMMENTS

Read these instructions carefully before starting

Before submitting to the IRB, **remove these instructions**, and delete all the template language (in dark orange).

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?**
	+ This template is for studies involving clinical procedures or tests (except for behavioral studies where the only collected sample is obtained via a non-invasive method, for example saliva for cortisol tests).
	+ If unsure whether IRB review is required for your project, please start by [using our website tool](http://irb.emory.edu/forms/review/index.html) under “Does My Project Need IRB Review?”
	+ For studies involving interviews, surveys, focus groups, or behavioral interventions, please use the [Sociobehavioral](http://www.irb.emory.edu/forms/Study%20Submission.html) template instead.
	+ For studies involving secondary data analysis only, please use the “[Secondary Analysis Protocol](http://www.irb.emory.edu/forms/Study%20Submission.html)**”** templateinstead**.**
	+ For studies involving solely a review of medical charts, please see the “[Retrospective Chart Review Protocol](http://www.irb.emory.edu/forms/Study%20Submission.html)” template instead.
	+ Use our [Supplement to Sponsor Protocol](http://www.irb.emory.edu/forms/Study%20Submission.html)and for studies that are industry-sponsored and industry-initiated, or when we are one of the sites in a multisite study we are not leading. You will be required to attach these forms plus the main consent from the sponsor to the submission
* **You must complete the** [**Biomedical Protocol Checklist**](#_Protocol_Checklist)at the end of this document to attest that you have considered all the required sections in this template. This can be found at the end of this document.
* Grant applications normally **may** **not** be submitted to the IRB instead of a protocol document
* When you write this document, 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)

**EXTERNAL (NON-EMORY) COLLABORATORS**

Name, Title(s), Institution, and Department of External Collaborators

(For each entry, please indicate whether that institution’s IRB will review (or has already reviewed) that individual’s engagement in human participants research activities)

(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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# Study Summary

|  |  |
| --- | --- |
| **Project Title** |  |
| **Project Design** |  |
| **Primary Objective** |  |
| **Secondary Objective(s)** |  |
| **Research Intervention(s)/Interactions** |  |
| **Study Population** |  |
| **Sample Size** |  |
| **Study Duration for individual participants** |  |
| **Study Specific Abbreviations/ Definitions**  |  |
| **Funding Source (if any)** |  |

# Objectives

Describe the purpose, specific aims, or objectives and state the hypotheses to be tested.

The following must be addressed when study involves developing/evaluating an algorithm/clinical decision tool/artificial intelligence/machine learning tool(s)):

* Whether data will or may be submitted to FDA
* Whether there is a plan to test the model clinically (i.e., providing any output to healthcare provider(s) or patients at this stage) in the current submission. If there are no plans to test the model clinically in this protocol, note that a new IRB submission will be required if it will be tested clinically in the future.
* Whether the Algorithm/Product/Software is intended to become proprietary, and can/will it be commercialized outside of Emory?

(Add your text)

# Background

Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data.

Provide the scientific or scholarly background for, the rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

(Add your text)

# Study Endpoints

Describe the primary and secondary study endpoints. Describe any primary or secondary safety endpoints.

(Add your text)

# Study Intervention/Investigational Agent

Description: Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.

Drug/Device Handling: 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).
* If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:
	+ Identify the holder of the IND/IDE/Abbreviated IDE. An Emory investigator who holds an IND or IDE is considered to be a Sponsor-Investigator. If this applies to this study, please [review this section of our website](http://irb.emory.edu/forms/SI_Studies.html).
	+ Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:

|  |  |
| --- | --- |
|  | Applicable to: |
| FDA Regulation | IND Studies | IDE studies | Abbreviated IDE studies |
| 21 CFR 11 | X | X |  |
| 21 CFR 54 | X | X |  |
| 21 CFR 210 | X |  |  |
| 21 CFR 211 | X |  |  |
| 21 CFR 312 | X |  |  |
| 21 CFR 812 |  | X | X |
| 21 CFR 820 |  | X |  |

(Add your text)

# Procedures Involved

Describe and explain the study design and include a study schema, if possible.

Describe all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or minimize risks.

Describe:

* Procedures performed to lessen the probability or magnitude of risks.
* All drugs and devices used in the research, the purpose of their use, their regulatory approval status, and if they are being used solely within their approved indications/labeling, if applicable.
* The source records that will be used to collect data about participants. (Attach all surveys, scripts, and data collection forms to the eIRB Smartform.)
* What data will be collected during the study and how that data will be obtained.
* If there are plans for long-term follow-up (once all research-related procedures are complete), what data will be collected during this period.
* Detail whether any of the following are brought to an Emory research laboratory for further experimentation: microorganisms or infectious materials; nanomaterials; genetically modified primary cells or cell lines; genetically modified live or live-attenuated microbes (e.g., bacteria, fungi, virus, etc.); arthropods; plant products; toxins; environmental samples; human cells, cell lines, stool samples, or other human source materials; and human blood, blood products or tissue. (Note: If yes, then EHSO Biosafety ancillary review is required.)

(Add your text)

# Statistical Analysis Plan

Describe the data analysis plan, including any statistical procedures or power analysis.

(Add your text)

# Data and/or Specimen Banking

If data or specimens will be banked 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). The VA Data Repository SOP is required if the study is creating a data repository at the Atlanta VA

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

Describe the procedures to release 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 participants or others (e.g., the participant’s primary care physicians) and if so, describe how the results will be shared If applicable (e.g. for studies involving scans and/or panels of exploratory testing on specimens)
* 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: include language in the consent form to let the participants know your plans for returning results and for handing incidental findings – see [Modular Language for Informed Consent Forms](http://irb.emory.edu/documents/modular-consent-language.docx) on IRB website)

(Add your text)

# Study Timelines

Describe:

* The duration of an individual participant’s participation in the study.
* The duration anticipated enrolling all study participants.
* The estimated date for the investigators to complete this study (complete primary analyses)

(Add your text)

# Inclusion and Exclusion Criteria

* Describe how individuals will be screened for eligibility.
* Describe the criteria that define who will be included or excluded in your final study sample.
* Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as participants in your research unless you indicate this in your inclusion criteria.)

(Add your text)

# Population

Indicate specifically whether you will include or exclude any of the following special populations: (You may not include members of these populations as participants in your research unless you include them in the description of your subject population.)

* Adults unable to consent
* Individuals who are not yet adults (infants, children, teenagers)
* Pregnant women
* Prisoners
* Cognitively impaired or Individuals with Impaired Decision-Making Capacity
* Individuals who are not able to clearly understand English (If you indicated you will exclude, please provide reasoning.)

Community Participation (if applicable)

For studies aimed at addressing issues that affect a certain community or group, how, if at all, will this study involve people from the target community in the design of the study? Conduct of the study? How will the results of the research be shared with the participants and/or the target community(ies)?

(1) Describe the definition you are using for “Race” and/or “Ethnicity” in this study (examples here (link to [JAMA](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fjamanetwork.com%2Fjournals%2Fjama%2Ffullarticle%2F2776936&data=04%7C01%7Crebecca.rousselle%40emory.edu%7C98fd1abfb9004c48e8fb08d9a583cf9f%7Ce004fb9cb0a4424fbcd0322606d5df38%7C0%7C0%7C637722807820672228%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=lEegCWT0%2Byid8HZ%2FBk%2FuP1rTaABQlAiGQW%2FIyoKBawU%3D&reserved=0), [JHM](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.journalofhospitalmedicine.com%2Fjhospmed%2Farticle%2F235223%2Fhospital-medicine%2Fnew-author-guidelines-addressing-race-and-racism-journal&data=04%7C01%7Crebecca.rousselle%40emory.edu%7C98fd1abfb9004c48e8fb08d9a583cf9f%7Ce004fb9cb0a4424fbcd0322606d5df38%7C0%7C0%7C637722807820682221%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=aCTdniEe5lj%2F8cHWWhNKweykajcbqk7kUYjxZi4wf2s%3D&reserved=0), [AHA](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ahajournals.org%2Fdisparities-research-guidelines&data=04%7C01%7Crebecca.rousselle%40emory.edu%7C98fd1abfb9004c48e8fb08d9a583cf9f%7Ce004fb9cb0a4424fbcd0322606d5df38%7C0%7C0%7C637722807820682221%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=SFwpaswIRrcefX0z3eE0vj5GUo4shR60EIiTiQUCl90%3D&reserved=0), and [Health Affairs](https://nam11.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.healthaffairs.org%2Fdo%2F10.1377%2Fhblog20200630.939347%2Ffull%2F&data=04%7C01%7Crebecca.rousselle%40emory.edu%7C98fd1abfb9004c48e8fb08d9a583cf9f%7Ce004fb9cb0a4424fbcd0322606d5df38%7C0%7C0%7C637722807820692211%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=UIPb8XoHu6Xj1hKNSfb2XBBzcw3BnaExQvOKCooG06Q%3D&reserved=0) guidance). (2) State whether you are using racial and ethnic classification of subjects for descriptive statistics or within an explanatory model (as a covariate). (3) If you are using race and/or ethnicity as a variable to explain differences between patients (as a covariate), please describe the proposed mechanism of action (what is race being used as a proxy for?).

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 Number of Participants

Indicate the total number of participants to be accrued locally.

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)

# Recruitment Methods

* Describe when, where, and how potential participants will be recruited, who will make initial contact and how, and if physicians or staff refer participants.
* 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 in Smartform on the “Study-Related Documents” page under “Recruitment material templates.” 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.)
* How will eligibility be determined? Provide a detailed description of any eligibility screening done before enrolling the subject (including whether any identifiers will be recorded – note that IP address is an identifier)
* If recruiting online, describe how potential participants would be directed to your recruitment information and study description.
* If using contests or raffles as incentive, you must offer entry to all potential participants, not just those who enroll in the study/complete study-related procedures, per Georgia State Law.
* 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 anticipated circumstances under which participants will be withdrawn from the research without their consent.

Describe any procedures for orderly termination.

Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.

(Add your text)

# Risk to Participants

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related to the participant's participation in the research. Include as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.

If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable.

If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

If applicable, describe risks to others who are not participants.

(Add your text)

# Potential Benefits to Participants

Describe the potential benefits that individual participants may experience from taking part in the research. Include as may be useful for the IRB’s consideration, the probability, magnitude, and duration of the potential benefits.

Indicate if there is no direct benefit. Do not include benefits to society or others.

(Add your text)

# Compensation to Participants

Describe if/how subjects will be compensated for participation in this study. Indicate what method compensation will be delivered (e.g. cash, gift card, school credit). Describe the amount and timing of any payments to participants. How much? What kind? Is tax information required? (if so, must be reflected in the informed consent form). Will payments be pro-rated if a participant withdraws early?

(Add your text)

# Data Management and Confidentiality

Describe the data/biospecimens management plan. Describe the steps that will be taken to secure the data and specimens (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission. Describe any procedures that will be used for the quality control of collected data.

Describe how data/biospecimens will be handled study-wide:

* What information will be included in the data/biospecimens?
* Where and how will the data/biospecimens be stored?
* How long will the data/biospecimens be stored?
* Who, in general, will have access to the data/biospecimens (to be described in further detail in section 18)?
* Will any data be shared with an external entity or non-Emory collaborator? If so, clarify what identifiers will be included with the data.
* Will any identifiable data be shared via a platform/software/eConsent/app? If not a [vetted option](https://it.emory.edu/security/protecting-data/software_for_research.html), please note [Emory OIT security review](https://emory.service-now.com/sp?id=kb_article&sys_id=e5c2cd88f5cdf1c055c77bd8604896c2) may be required.
* Who is responsible for receipt or transmission of the data/biospecimens?
* How will data/biospecimens be transported?
* Explain what would take place if a participant declines participation. For example: “If a participant declines to participate in all portions of the study, the participant will not be assigned a study ID number and the study coordinators/data collects will refrain from collecting any data on the participant. If the participant agrees to participate in some portions of the study by not others, the participant will be assigned a study ID number and the study coordinators/data collectors will be instructed to collect data only on those aspects of the study to which the participant has agreed to participate. These procedures will help prevent unauthorized inclusion of the patient’s data in the database.”

(Add your text)

# Plans to Monitor the Data to Ensure Safety of Participants and Data Integrity

**Check the box for the study’s risk level:**

[ ]  **No more than minimal risk** - Study not required to follow DSMP guidance, may delete the rest of this section. (Non-invasive sampling or imaging, blood draws, etc. are likely minimal risk if all procedures fall [clearly within these categories](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html). If all study procedures do not fall into these categories, and you still believe your study is minimal risk, consult with IRB staff.)

**☐ More than minimal risk** – Continue below.

Review our [Data and Safety Monitoring Questionnaire](http://www.irb.emory.edu/documents/DSMP%20Questionnaire%20and%20Monitoring%20Tables.docx) and insert the relevant monitoring table at the end of this section. Also upload the completed questionnaire in the “Basic Study Information” smartform section in eIRB, question #8, as a separate document.

Mark the risk categorization, as determined by the Data and Safety Monitoring Questionnaire, that applies to your study below:

|  |
| --- |
| Select one of the following (do not delete this table; review the guidance document for definitions): |
| [ ]  Medium Complexity |
| [ ]  High Complexity Category A |
| [ ]  High Complexity Category BIf choosing this category for a study under an IND or IDE because you believe the study intervention does not significantly impact morbidity or mortality, please provide your rationale: |

Review the [Data and Safety Monitoring plan guidance](http://www.irb.emory.edu/documents/DSMP_requirements.pdf) document for additional details about this section.

If a DSMB is needed, please describe the composition of the board here. [Review this guidance](http://www.irb.emory.edu/documents/DSMB-Guidance.pdf) for more information.

Please address the other 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)
* 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.

 (Add your text and monitoring table)

# Provisions to Protect the Privacy Interest 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.

(Add your text)

# Informed Consent

In general, informed consent cannot be waived for these protocols. Indicate whether you will be obtaining informed consent and if so, describe:

* Where will the consent process take place?
* Will there be any waiting period between informing the prospective participant and obtaining the consent?
* Will there be a 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)

**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)

**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](https://www.irb.emory.edu/forms/consent/shortforms.html).

(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)

# Setting

Describe the sites or locations where your research team will conduct the research.

* Identify where your research team will identify and recruit potential participants.
* Identify where research procedures will be performed.
* Describe the composition and involvement of any community advisory board.
* For research conducted outside of the organization and its affiliates describe:
	+ Site-specific regulations or customs affecting the research for research outside the organization.
	+ Local scientific and ethical review structure outside the organization

(Add your text)

# Resources Available

Describe the resources available to conduct the research: For example, as appropriate:

* Justify the feasibility of recruiting the required number of suitable participants within the agreed recruitment period. For example, how many potential participants do you have access to? What percentage of those potential participants do you need to recruit?
* Describe the time that you will devote to conducting and completing the research.
* Describe your facilities.
* Describe the availability of medical or psychological resources that participants might need as a result of anticipated consequences of the human research.
* Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

(Add your text)

# Multi-Site or Collaborative Research

List external collaborators on the first page of this protocol including whether external collaborators are seeking IRB approval from Emory IRB or their own IRBs. If there are any external collaborators seeking approval from Emory IRB, please reach out to the reliance team at irb.reliance@emory.edu. Please see our [collaborative page](https://www.irb.emory.edu/guidance/research-types/collaborative.html) for more information.

Study -Wide Number of Participants

If this is a multicenter study, indicate the total number of participants to be accrued across all sites.

Study-Wide Recruitment Methods

* If this is a multicenter study and participants will be recruited by methods, not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described later in the protocol.
* Describe when, where, and how potential participants will be recruited.
* 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 processes to ensure communication among sites. All sites have the most current version of the protocol, consent document, and HIPAA authorization. All required approvals (initial, continuing review, and modifications) have been obtained at each site (including approval by the site’s IRB of record).
* All modifications have been communicated to sites and approved (including approval by the site’s IRB of record) before the modification is implemented.
* All engaged participating sites will safeguard data, including the secure transmission of data, as required by local information security policies.
* All local site investigators conduct the study following applicable federal regulations and local laws.
* All non-compliance with the study protocol or applicable requirements will be reported following local policy

Describe the method for communicating to engaged participating sites:

* Problems (inclusive of reportable events).
* Interim results.
* The closure of a study

If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality.

* Where and how data or specimens will be stored locally?
* How long the data or specimens will 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 data and specimens will be transported locally?

(Add your text)

# References

Add references.

(Add your text)

# Protocol Checklist

**Please note that protocol sections with an asterisk (\*)should always be included in the protocol; if the section does not have an asterisk, and you have not included the section in the protocol, the IRB will consider it your attestation that the section does not apply to your study.**

|  |  |
| --- | --- |
| **Protocol Section** | **Added to the protocol?** |
| **External Collaborators**- if applicable, add each external collaborator information and indicate whether that institution’s IRB will review (or has already reviewed) that individual’s engagement in human participants research activities)  | [ ]  **Yes** |
| **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. Say “department” if you do not have any other funding. | [ ]  **Yes** |
| **Objectives*\**:** Describe the purpose, specific aims, or objectives and state the hypotheses to be tested | [ ]  **Yes** |
| **Background*\**:** Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data. Provide the scientific or scholarly background for, the rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge | [ ]  **Yes** |
| **Study Endpoints\*:** Describe the primary and secondary study endpoints. Describe any primary or secondary safety endpoints.  | [ ]  **Yes** |
| **Study Intervention/Investigational Agent\*:** Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.  | [ ]  **Yes** |
| **Drug/Device Handling:** 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 participants and be used only by authorized investigators.If using a drug, explain if the control of the drug is managed by IDS (or VA/Grady/CHOA research pharmacies). If not, provide IDS exemption document.If a device, explain how the device is being stored and managed. | [ ]  **Yes** |
| 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 IRB website. | [ ]  **Yes** |
| If the drug is considered a controlled substance, make sure [you have filled out this form](http://compliance.emory.edu/documents/CS_checklist.docx). | [ ]  **Yes** |
| If applicable, identify the holder of the IND/IDE/Abbreviated IDE. An Emory investigator who holds an IND or IDE is considered to be a Sponsor-Investigator (S-I). If the study is under an S-I, [review this section of our website](http://irb.emory.edu/forms/SI_Studies.html) for additional requirements. | [ ]  **Yes** |
| **Procedures involved\***: Describe and explain the study design and include a study schema. Describe all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or minimize risks | [ ]  **Yes** |
| **Procedures-Minimizing risk\*:** describe the procedures performed to lessen the probability or magnitude of risks. | [ ]  **Yes** |
| **Procedures- Drug/Device Use:** describe all drugs and devices used in the research and the purpose of their use and their regulatory approval status | [ ]  **Yes** |
| **Procedures-Source Records\*:** describe source records that will be used to collect data about participants. Attach all surveys, scripts, and data collection forms to the submission. | [ ]  **Yes** |
| **Procedures-Data collection\*:** describewhat data will be collected during the study and how that data will be obtained | [ ]  **Yes** |
| **Procedures- Long Term Follow Up\*:** once all research-related procedures are complete, what data will be collected during this period. If no data is collected after procedures are completed, please state in the submission. | [ ]  **Yes** |
| **Data and Specimen Banking:** 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. Depending on the volume and nature of the collection, this may require a separate repository-specific IRB submission. The VA Data Repository SOP is required if the study is creating a data repository at the Atlanta VA.List the data to be stored or associated with each specimen.Describe the procedures to release 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. | [ ]  **Yes** |
| **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 participants or others (e.g., the participant’s primary care physicians) and if so, describe how the results will be shared If applicable (e.g. for studies involving scans and/or panels of exploratory testing on specimens)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) | [ ]  **Yes** |
| **Study timelines\*:** describe the duration of an individual participant’s participation in the study; anticipated time to enroll all study participants and the estimated date for the investigators to complete this study (complete primary analyses) | [ ]  **Yes** |
| **Inclusion and Exclusion Criteria\*:** describe how individuals will be screened for eligibility and the criteria that define who will be included or excluded in your final study sample | [ ]  **Yes** |
| **Population\*:** describe the study popualation and indicate specifically whether you will include or exclude each of the following special populations: * Adults unable to consent
* Individuals who are not yet adults (infants, children, teenagers)
* Pregnant women
* Prisoners

Note: you cannot exclude people with limited English proficiency unless you can demonstrate the scientific need for such exclusion.Community Participation: For studies aimed at addressing issues that affect a certain community or group: How, if at all, will this study involve people from the target community in the design of the study? Conduct of the study? How will the results of the research be shared with the participants and/or the target community/ies?**If studying Race or Ethnicity, have you defined these terms, and explained their proposed mechanism of action if these characteristics will be used in an explanatory model?** | [ ]  **Yes** |
| **Research with pregnant women, fetuses, or neonates:** review [this checklist](http://irb.emory.edu/documents/Emory%20Subpart%20B%20Worksheet.doc) to verify you have provided enough information to ensure the safety and well-being of this population. | [ ]  **Yes** |
| **Research with neonates of uncertain viability:** review [this checklist](http://irb.emory.edu/documents/Emory%20Subpart%20B%20Worksheet.doc) to verify you have provided enough information to ensure the safety and well-being of this population. | [ ]  **Yes** |
| **Research involving prisoners:** review [this checklist](http://irb.emory.edu/documents/Emory%20Subpart%20C%20Worksheet.doc) to verify you have provided enough information to ensure the safety and well-being of this population. | [ ]  **Yes** |
| **Research involving children:** review [this checklist](http://irb.emory.edu/documents/Emory%20Subpart%20D%20Worksheet.doc) to verify you have provided enough information to ensure the safety and well-being of this population. | [ ]  **Yes** |
| **Research involving cognitively impaired adults:** review [this checklist](http://irb.emory.edu/documents/CHECKLIST-Cognitively_Impaired_Adults.docx) to verify you have provided enough information to ensure the safety and well-being of this population. | [ ]  **Yes** |
| **Research involving economically or educationally disadvantaged persons:** describe the additional safeguards that have been included in the study to protect the rights and welfare of these subjects | [ ]  **Yes** |
| **Local Number of Participants\*:** Indicate the total number of participants to be accrued locally. 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.  | [ ]  **Yes** |
| **Recruitment Methods\*:** 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. If including advertisements, attach the final copy of them. 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. Reimbursement for expenses/travel?If using contests or raffles as incentive, you must offer entry to all potential participants, not just those who enroll in the study/complete study-related procedures, per Georgia State Law.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. | [ ]  **Yes** |
| **Withdrawal of Participants\*:** Describe anticipated circumstances under which participants will be withdrawn from the research without their consent. Describe any procedures for orderly termination. Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection. | [ ]  **Yes** |
| **Risk to Participants\*:** List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related to the participant's participation in the research. Include as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable.If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.If applicable, describe risks to others who are not participants. | [ ]  **Yes** |
| **Potential Benefits to Participants\*:** Describe the potential benefits that individual participants may experience from taking part in the research. Include as may be useful for the IRB’s consideration, the probability, magnitude, and duration of the potential benefits.Indicate if there is no direct benefit. Do not include benefits to society or others. | [ ]  **Yes** |
| **Compensation to Participants\*:** Describe if/how subjects will be compensated for participation in this study. Indicate what method compensation will be delivered (e.g. cash, gift card, school credit). Describe the amount and timing of any payments to participants. How much? What kind? Is tax information required? (if so, must be reflected in the informed consent form). Will payments be pro-rated if a participant withdraws early? | [ ]  **Yes** |
| **Data Management and Confidentiality\*:** Describe the data analysis plan, including any statistical procedures or power analysis. Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission. Describe any procedures that will be used for the quality control of collected data.  | [ ]  **Yes** |
| **Describe how data or specimens will be handled study-wide\*:** What information will be included in that data or associated with the specimens?* Where and how data or specimens will be stored?
* How long the data or specimens will be stored?
* Who will have access to the data or specimens?
* Who is responsible for receipt or transmission of the data or specimens?
* How data or specimens will be transported?
 | [ ]  **Yes** |
| **Data Monitoring and Participants Safety (if this study is more than minimal risk, this section is required):** Ensure that you review our [Data and Safety Monitoring plan guidance](http://irb.emory.edu/documents/DSMP_requirements.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. Include the appropriate completed monitoring table, if applicable. 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
 | [ ]  **Yes** |
| **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 participant 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.
 | [ ]  **Yes** |
| **Economic Burden to Participants\*:** Describe any costs that participants may be responsible for because of participation in the research. | [ ]  **Yes** |
| **Consent Process\*:** Describe where the consent process will take place, any waiting period available between informing the prospective subject and obtaining the consent; and the process to ensure ongoing consent.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; and 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). | [ ]  **Yes** |
| **Consent Process-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](https://www.irb.emory.edu/forms/consent/shortforms.html). | [ ]  **Yes** |
| **Consent Process-Children:** After determining if the subject is a child per GA law (or if enrolled outside GA, per state/country law), please 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.When assent of children is obtained describe whether and how it will be documented per Emory Policies and Procedures | [ ]  **Yes** |
| **Consent Process-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. | [ ]  **Yes** |
| **Consent Process-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 “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 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 | [ ]  **Yes** |
| **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 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 “CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)” to ensure you have provided sufficient information for the IRB to make these determinations. | [ ]  **Yes** |
| **Setting\*:** Describe the sites or locations where your research team will conduct the research including where the subject will be identified and recruited, where the research procedures will be performed, and if you will involve a community advisory board. For research conducted outside the organization and its affiliates describe the site-specific regulations or customs affecting the research outside the organization and the local scientific and ethical review structure outside the organization. | [ ]  **Yes** |
| **Resources Available\*:** Describe the resources available to conduct the research such us the feasibility of recruiting the required number of suitable participants within the agreed recruitment period; describe the time that you will devote to conducting and completing the research; describe the availability of medical or psychological resources that participants might need as a result of an anticipated consequences of the human research; describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions. | [ ]  **Yes** |
| **Multi-Site Research when Emory is the Lead Site:**Study -Wide Number of Participants: indicate the total number of participants to be accrued across all sites.Study-Wide Recruitment Methods: If this is a multicenter study and participants will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Describe when, where, and how potential participants will be recruited.Describe the methods that will be used to identify potential participants.Describe materials that will be used to recruit participants. Describe the processes to ensure communication among sites. See “WORKSHEET: Communication and Responsibilities (HRP-830).” All sites have the most current version of the protocol, consent document, and HIPAA authorization.All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site’s IRB of record).All modifications have been communicated to sites and approved (including approval by the site’s IRB of record) before the modification is implemented.All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.All local site investigators conduct the study in accordance with applicable federal regulations and local laws. All non-compliance with the study protocol or applicable requirements will reported in accordance with local policyDescribe the method for communicating to engaged participating sites (see “WORKSHEET: Communication and Responsibilities (HRP-830)”):* Problems (inclusive of reportable events).
* Interim results.
* The closure of a study

If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality. (See “WORKSHEET: Communication and Responsibilities (HRP-830).”)* Where and how data or specimens will be stored locally?
* How long the data or specimens will 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 data and specimens will be transported locally?
 | [ ]  **Yes** |