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.

**Do not delete any sections of this supplement protocol.** If a section does not apply to the study, instead briefly indicate why the section is inapplicable or aligns completely with the sponsor protocol.

* **What template should I use?**
	+ Complete this template if you are participating in a sponsor-initiated study (to supplement the main study protocol).
	+ 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.
* 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**.

|  |
| --- |
| **Emory IRB Supplement to Sponsor Protocol**  |
| Protocol Title | [Title] |
| Version | **1.0** |
| Version Date | [Publish Date] |

|  |
| --- |
| Emory Principal Investigator Details |
| Name |  |
| Credentials |  |
| Title |  |
| Department |  |
| Phone |  |
| Email |  |

|  |
| --- |
| Funding Source |
| Insert information about the funding entity for this study. Explain if this study is covered by a sub-award or other pertinent information. |

**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 and Site Procedures

Complete the AI/ML Questionnaire and Summary below and **answer the questions based on the plans outlined in the Sponsor Protocol, not just plans for use of AI/ML at Emory.**

|  |
| --- |
| **Artificial Intelligence (AI) and Machine Learning (ML) Questionnaire and Summary** |
| **Question/Description** | **Response** |
| **1. Are any AI/ML tools developed, evaluated, or used within this research project?** *This includes clinical decision-making and algorithm-based tools, use of data to train or validate an AI/ML, etc.* | [ ]  Yes*🡪 Complete the questions 2-7 (do not leave any blanks)*[ ]  No *🡪 Delete questions 2-7 (the rest of the table, below)* |

|  |  |
| --- | --- |
| **2. Describe the source/development of the AI/ML tool** *(e.g., in-development at Emory, commercially available)* |  |
| **3. Describe any key characteristics of the AI/ML**, including:* Commercial prototype blackbox system
* Federated data system
* Adaptative or non-adaptive
 |  |
| **4. Will any data use agreements apply to the study or AI/ML tools?** *If yes, note status of OTT/OSP agreements* |  |
| **5. How will AI/ML tools in this protocol influence decisions affecting participants?** | [ ]  AI/ML has *no decision-making impact*[ ]  AI/ML *informs human-made decisions*[ ]  AI/ML *drives decisions,* with human oversight[ ]  AI/ML is *fully autonomous* (i.e., makes decisions without human oversight) |
| **6. Is there any intent to test the AI/ML tool clinically now, or in the future?** *(i.e., provide any output to healthcare providers or patients)* | [ ]  Yes, *the current study* intends to test the AI/ML clinically[ ]  *Yes,* there is intent totest the AI/ML clinically in a future IRB submission; however no *clinical testing will occur as part of the current submission.* [ ]  No, there is *no intent to ever test the AI/ML* clinically.  |
| **7.**  | **Confirm that this study will implement the latest best practices in building, testing, validation, and evaluation for each of the following:** |
| a. Representativeness of data sets | [ ]  Will be addressed [ ]  N/A |
| b. Reduction of bias | [ ]  Will be addressed [ ]  N/A |
| c. Minimize data leakage and model accuracy drift | [ ]  Will be addressed [ ]  N/A |
| d. Identify and address inaccurate output  | [ ]  Will be addressed [ ]  N/A |

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.

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?

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)

# 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.**

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.

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)

# 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)?

If your research questions involve race and/or ethnicity, please clarify the following:

(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 patients 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 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

**Complete the IRB-Defined Identifiers Questionnaire.** Note that if you respond *Yes* to any option listed below, these details should be address specifically in each of the Data and Specimen Banking Narrative sections, on the next page. To complete the questionnaire, respond to each question by using the following definitions:

* **Accessed**: The identifier is accessed, even if not recorded (e.g., seen in medical record but not saved)
* **Stored**: The identifier is saved in the local research records, including stored separately as a key
* **Shared:** The identifier is shared with others, outside the study team, such as in a repository
* **None**: The identifier will not be accessed, stored, or shared

|  |
| --- |
| **IRB-Defined Identifiers Questionnaire** |
| **1. For each of the IRB-defined Identifiers listed, indicate how the identifier will be used** |
|  | a. **Names**, including initials | [ ]  Accessed [ ]  Stored [ ]  Shared [ ]  Not used |
|  | b. **Address details**, including ZIP, county, etc. | [ ]  Accessed [ ]  Stored [ ]  Shared [ ]  Not used |
|  | c. **Age** in years for persons over 89 years old | [ ]  Accessed [ ]  Stored [ ]  Shared [ ]  Not used |
|  | d. **Dates**,including dates of birth, specimen collection, clinical events, more specific than year  | [ ]  Accessed [ ]  Stored [ ]  Shared [ ]  Not used |
|  | e. **Contact Information**, including phone, fax, email, mail address | [ ]  Accessed [ ]  Stored [ ]  Shared [ ]  Not used |
|  | f. **Personal or account identifiers**, including SSN, MRN, health plan IDs, username, license or serial numbers, IP address, etc. | [ ]  Accessed [ ]  Stored [ ]  Shared [ ]  Not used |
|  | g. **Biometric identifiers**, including fingerprints and full-face photographs | [ ]  Accessed [ ]  Stored [ ]  Shared [ ]  Not used |
|  | h. **Other** [**IRB-defined identifiers**](https://irb.emory.edu/_includes/documents/sections/phi_identifiers.pdf): *(list here)* | [ ]  Accessed [ ]  Stored [ ]  Shared [ ]  Not used |

**Complete the Information Security Questionnaire to determine if an** [**Emory Office of Information Technology (OIT) Security Review is required**](https://www.irb.emory.edu/_includes/documents/sections/guidance_when_lits_review_needed.pdf). Note that, in some cases, an OIT security review may be required, even if the questionnaire does not indicate a review is required.

|  |
| --- |
| **Information Security Questionnaire**  |
| 1. Will this study utilize any of the [applications or plug-ins not approved for use](https://it.emory.edu/security/protecting-data/not_approved_for_use.html) by OIT? | [ ]  Yes *🡪* *This is not permitted* [ ]  No *🡪* *Go to #2* |
| 2. Will any [IRB-defined identifiers](https://irb.emory.edu/_includes/documents/sections/phi_identifiers.pdf) be processed or stored in an application, plug-in, or software? | [ ]  Yes *🡪* *Go to #3*[ ]  No *🡪* *Move to next section* |
| 3. Will processing or storage of identifiers only occur with OIT-approved [applications, plug-ins, and software for research](https://it.emory.edu/security/protecting-data/software_for_research.html)? | [ ]  Yes *🡪* *Move to next section*[ ]  No *🡪* *Go to #4* |
| 4. Will any sensitive or health information be processed or stored alongside identifiers in any applications, plug-ins, or software?  | [ ]  Yes *🡪* *Go to #5*[ ]  No *🡪* *Move to next section* |
| 5. Will processing or storage of sensitive or health information only occur with OIT-approved [applications, plug-ins, and software for research](https://it.emory.edu/security/protecting-data/software_for_research.html)? | [ ]  Yes *🡪 Review not required*[ ]  No *🡪* [*Request an OIT Security Review*](https://it.emory.edu/security/services/reviews.html) |

**Add here a summary which describes the plans for storage and sharing of research data and specimens**. This narrative should include the following, by section:

1. **S*torage and access:*** Include the following details about the local study sites
	* **Storage locations for all data and specimens**, **including both physical and digital locations** and the locations of any key and data copies or backups
	* **How data and specimens will be accessed and who is able to access which data/specimens**
	* **The length of time in which data will be stored**, along with any plans to:
		+ **Permanently deidentify** data or specimens
		+ **Destroy or delete data** and specimens
	* **Indicate all software/platforms/programs that will be used to collect and store research data**
	* **If including data from the VA** (including data gathered from, or generated for VA repositories): confirm that the VA Data Repository SOP will be followed
2. ***Sharing:***
	* **Describe** **plans to make the data or specimens widely accessible**, such as adding the data to existing repositories, open-source data sites, alongside future publications, etc.
	* **Include details of NIH data sharing requirements**
	* **Indicate all software/platforms/programs that will be used to share research data**
	* **For Multisite or collaborative studies:** Describe what data and specimens are shared across sites. Including the following details about sharing:
		+ What group(s) will receive/store/manage data and specimens
		+ The identifiability of the data and specimens shared
		+ The length of time in which data and specimens will be stored at external locations
		+ Plans for data sharing and specimen transportation, including who is responsible for these activities at the local site (i.e., Emory)
	* **If specimens may be shared:** clearly describe what data will be linked to the specimens (e.g., specimen collection dates, patient diagnoses, patient demographics, etc.)
3. ***Banking:* Describe plans to bank data or specimens for future use**, including the procedures for releasing data or specimens in the future, such as**:**
	* **The process to request data/specimen access**
	* **Approvals required prior to the release** of any data/specimens (e.g., IRB review)
	* **Who is eligible to request or access** the data/specimens (e.g., only Emory-affiliated researcher, any researchers, etc.)
	* **Limitations to the data/specimens accessible for future use** (e.g., only deidentified data, limited identifiers, etc.)
	* **If specimens may be banked:** clearly describe what data will be linked to the banked specimens (e.g., specimen collection dates, patient diagnoses, patient demographics, etc.)

(Add your text)

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

**Complete the Data Monitoring Requirements Assessment below to determine which Data and Safety Monitoring Table or information should be provided to the Emory IRB.** If the below questionnaire does not capture the scope of your research activities or you have questions, send an email to irb@emory.edu to determine the appropriate monitoring plan table to be used.

*Note*: The IRB may request a different Monitoring Table be used, based on specific study details. Generally, clinical trials with INDs for radiotracers and dietary supplements are able to use Monitoring Table B, even if another table is indicated in the assessment, below.

|  |
| --- |
| **Data Monitoring Requirements Assessment**  |
| **1. Does this study use a Contract Research Organization (CRO) or a Data Coordinating Center?** | [ ]  Yes *🡪 Complete 1a. A DSM Table is not required in this supplement*[ ]  No *🡪 Go to #2* |
|  | a. **Indicate which document(s) provide information on the Data Safety Monitoring Plan** *(select all which apply).* Ensure the document is provided in the eIRB submission. | [ ]  Sponsor/Parent Protocol[ ]  Charter Document[ ]  Other: *(describe)* |
| **2. Do any of the below, highest-complexity categories apply to the research?** *(i.e., did you answer “yes” to 2a or 2b?)* | [ ]  Yes *🡪 This is a complexity cat. A study, insert table 1*[ ]  No *🡪 Go to #3* |
|  | a. **This a Phase I/II/III Clinical Trial with an IND or significant risk IDE** | [ ]  Yes[ ]  No |
|  | b. **The study or** **trial includes high-risk procedures**  | [ ]  Yes[ ]  No |
| **3. Do any of the below, high-complexity categories apply to the research?** *(i.e., did you answer “yes” to one of items listed in 3a-3d?)* | [ ]  Yes*🡪 This is a complexity cat. B study, insert table 1*[ ]  No*🡪 Go to #4* |
|  | a. **Study or** **trial is expected to be IND Exempt, IDE Exempt, or under an Abbreviated IDE/Non-Significant Risk Device** | [ ]  Yes[ ]  No |
|  | b. **Clinical trial of drugs or devices used under their FDA-approved indication** (e.g., comparative effectiveness trial of standard of care interventions) | [ ]  Yes[ ]  No |
|  | c. **Application of software or algorithm that will inform clinical care or direct care interventions** | [ ]  Yes[ ]  No |
|  | d. **Application of other novel** **clinical techniques or intervention** (e.g., nonstandard surgical step) | [ ]  Yes[ ]  No |
| **4. Do any of the below, medium-complexity categories apply to the research?** *(i.e., did you answer “yes” to one of the items listed in 4a-4d?)* | [ ]  Yes *🡪 This is a medium complexity study, insert table 2*[ ]  No *🡪 Go to #5* |
|  | a. **Protocol directs** **invasive sampling collection** (e.g., bone marrow, CSF, or biopsy collections) | [ ]  Yes [ ]  No |
|  | b. **Protocol directs** **imaging with contrast** (e.g., CTs or MRIs with contrast) | [ ]  Yes[ ]  No |
|  | c. **Protocol directs** **procedures that introduce energy into the body** (e.g., X-Rays, PET scans, microwaves, TMS, other electrode-based tools)  | [ ]  Yes[ ]  No |
|  | d. **Includes use of a wearable device that collects medical data** | [ ]  Yes[ ]  No |
| **5. If no categories above apply: What is the expected, overall risk level of the study?**  | [ ]  *More* than minimal risk *🡪 Contact the IRB to determine the appropriate table insert*[ ]  *No more* than minimal risk *🡪 No table is required* |

|  |
| --- |
| **Data and Safety Monitoring Table** |
| **1. What Data and Safety Monitoring type and table is required,** based on theData Monitoring Requirement Assessment, above? | [ ]  None, this study has a CRO or Coorinating Center[ ]  Complexity Category A, table 1[ ]  Complexity Category B, table 1[ ]  Medium Complexity, table 2[ ]  None, this study is minimal risk |
| **2. If you believe that the required Data Safety Monitoring Table is inappropriate and will deviate from this expectation, explain here:** |  |

**If a Data and Safety Monitoring Table is required**: Download the [Data and Safety Monitoring Table Document](https://irb.emory.edu/_includes/documents/sections/dsm-table-guidance.docx) and insert the appropriate DSM Table here. Follow the instructions of the Data and Safety Monitoring Table Document and complete all cells in the DSM Table.

***[Data and Safety Monitoring Table goes here]***

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 and not already described in the main protocol, please describe the composition of the board.** [Review this guidance](http://www.irb.emory.edu/documents/DSMB-Guidance.pdf) for more information.

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

* 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, if applicable)

# 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](https://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)

**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)