Protocol Template Instructions

**Read these instructions carefully before starting. Delete these instructions prior to uploading your completed protocol in the IRB system.**

**Before using this template:**

1. [Use this IRB webpage](https://irb.emory.edu/guidance/getting-started/review.html) to determine if IRB review is required for your project.
2. **If IRB review is required, review the** [**Protocol Template webpage**](https://irb.emory.edu/forms/protocol-templates.html) to identify the correct protocol template for your project.

**About this template:**

* **This template is for biomedical/health-related research studies that include clinical procedures, drugs, devices, or tests.**
	+ *Social and behavioral* studies that also involve procedures limited to minimal, non-invasive sampling methods (e.g., saliva tests, (f)MRI, eye tracking) or simple blood draw/venipuncture, should use the socio/behavioral template instead.
* Do notuse this protocol template if any of the following sub-bullets apply. Instead, see the [Protocol Template webpage](https://irb.emory.edu/forms/protocol-templates.html) for the correct template.
	+ The proposed activities are to develop a registry, repository, or database for future research, even when the protocol includes invasive sampling methods
	+ Research activities are limited to the following: educational tests, interviews, surveys, focus groups, social/behavioral interventions, analysis of secondary data or specimens, abstraction, or analysis of medical records
	+ This is a multi-site study where Emory is not the lead site for the research
	+ The protocol is for a Winship Cancer Institute study or treatment use of a Humanitarian Use Device

**Template instructions:**

* **Instructional text is formatted in dark orange**. Delete all instructional text from the document, before uploading the protocol in the IRB system.
* **Protocol sections and key tables highlighted in dark blue**. If you believe a section does not apply to this study, enter a statement indicating why this section does not apply. Do not delete any sections of the protocol.
* **Complete all tables, questionnaires, and checklists** as instructed throughout the protocol.
* **Use lay-friendly terminology** throughout and ensure that all relevant elements of each protocol section are addressed.
* **Do not copy text directly from funding applications**.
* **Once you have completed your protocol**, make sure that the protocol header, footer, and table of contents are up-to-date and accurate.

|  |
| --- |
| **Emory IRB Biomedical Study Protocol**  |
| Protocol Title | [Title] |
| Version | **1.0** |
| Version Date | [Publish Date] |

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

**List all the study sites and associated study activities at each site**

|  |
| --- |
| Study Locations |
| **Location/Setting** | **Recruiting**  | **Consenting**  | **Conducting Procedures** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Select all of funding types that apply to this research and follow the instructions for each**

|  |
| --- |
| Research Funding Sources |
| [ ]   | **Non-Federal funding** | List all non-federal funding sources here |
| [ ]   | **Federal funding** | *Complete the Federal Funding Information table, on the next page* |
| [ ]   | **No funding sources** | *Move to the next section* |

**Describe each federal funding source on a separate line in the table below.** If your study is not federally funded, leave the table blank.

* **Only list funding sources that are either in the Just-in-Time (JIT) stage or already funded**.
* **If the funding source lists multiple institutions or performance sites***:* Contact the reliance team at irb.reliance@emory.edu to discuss reliance requirements before submitting your protocol to the Emory IRB.
* For each federal funding source listed, upload the *complete grant application* in the “Study Funding Sources” section of eIRB.

|  |
| --- |
| Federal Funding Information |
| **Federal funding source** | **Award number**(JIT or already funded) | **Emory’s awardee role** | Are other performance sites in the funding application conducting activities for the current IRB protocol?  | **Award scope**  | **Aims linked to this protocol** (list) |
| [ ]  CDC [ ]  DOD [ ]  FDA[ ]  NIH [ ]  Other: *List* |  | [ ]  Prime[ ]  Sub | [ ]  Yes[ ]  No  | [ ]  Applies to this protocol only[ ]  Extends to other protocols |  |
| [ ]  CDC [ ]  DOD [ ]  FDA[ ]  NIH [ ]  Other: *List* |  | [ ]  Prime[ ]  Sub | [ ]  Yes[ ]  No | [ ]  Applies to this protocol only[ ]  Extends to other protocols |  |
| [ ]  CDC [ ]  DOD [ ]  FDA[ ]  NIH [ ]  Other: *List* |  | [ ]  Prime[ ]  Sub | [ ]  Yes[ ]  No | [ ]  Applies to this protocol only[ ]  Extends to other protocols |  |
| [ ]  CDC [ ]  DOD [ ]  FDA[ ]  NIH [ ]  Other: *List* |  | [ ]  Prime[ ]  Sub | [ ]  Yes[ ]  No | [ ]  Applies to this protocol only[ ]  Extends to other protocols |  |

*Add additional rows to this table, as needed*

**Do not update this section until the protocol has been reviewed and approved by the IRB.**

|  |
| --- |
| Protocol Revision History |
| **Version Update** | **Version Date** | **Summary of Changes** |
| *1.1* | *YY-MM-DD* |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

***Add a new entry to the Protocol Revision History table each time a new modification is submitted to the IRB.*** *If revisions are made to an ongoing submission, ensure the Summary of Changes describes all changes since the last, approved version of the protocol.*

*Note: The latest version and date listed above should align with the version number and date of the protocol footer.*

|  |
| --- |
| Table of Contents |

[1. Study Summary 6](#_Toc174624487)

[2. Objectives 7](#_Toc174624488)

[3. Background 7](#_Toc174624489)

[4. External Collaborators 8](#_Toc174624490)

[5. Study Endpoints 9](#_Toc174624491)

[6. Study Drugs, Devices, and Interventional Agent Details 9](#_Toc174624492)

[7. Procedures Involved 11](#_Toc174624493)

[8. Study Timeline 12](#_Toc174624494)

[9. Analysis Plan 15](#_Toc174624495)

[10. Data and Specimen Identifiability, Storage, and Sharing 15](#_Toc174624496)

[11. Population 18](#_Toc174624497)

[12. Inclusion and Exclusion Criteria 19](#_Toc174624498)

[13. Projected Enrollment 21](#_Toc174624499)

[14. Advertising, Recruitment, and Screening 21](#_Toc174624500)

[15. Informed Consent 25](#_Toc174624501)

[16. Reporting Results and Incidental Findings 29](#_Toc174624502)

[17. Withdrawal of Participants 31](#_Toc174624503)

[18. Risks and Burdens 31](#_Toc174624504)

[19. Privacy Interests of Participants 32](#_Toc174624505)

[20. Potential Benefits to Participants 33](#_Toc174624506)

[21. Compensation to Participants 33](#_Toc174624507)

[22. Data and Safety Monitoring 34](#_Toc174624508)

[23. References 38](#_Toc174624509)

# Study Summary

|  |
| --- |
| **Study Summary Table** |
| **Project Title** |  [Title] |
| [**Objectives** (brief overview)](#_Toc17190175) |  |
| [**Study collaboration**](#_External_Collaborators) | [ ]  Single-site [ ]  Multi-site[ ]  Collaborative [ ]  Other (describe): |
| [**Interventions and research interactions**](#_Procedures_Involved)(list) |  |
| [**Length of involvement for individual participants**](#_Study_Timeline) |  |
| [**Research design**](#_Analysis_Plan) |  |
| [**Study populations**](#_Population) |  |
| [**Maximum number of local enrollment**](#_Projected_Enrollment)**s** |  | **Maximum number of study-wide enrollments** |  |
| **Key abbreviations and definitions**  |  |

|  |
| --- |
| **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
* Adaptive 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 |

# Objectives

**In the Objective Narrative box, describe the purpose, specific aims, and objectives of the research**. State the hypotheses to be tested as part of the research.

|  |
| --- |
| **Objective Narrative** |
|  |

|  |
| --- |
| **FDA Reporting**  |
| **Is there any intent to submit the data from this protocol to the FDA?** *Select one* | [ ]  **Yes:** Data or findings from this protocol will/may be submitted to the FDA[ ]  **No:** Data or findings from this protocol will not be submitted to the FDA[ ]  **Maybe:** Data or findings may be submitted to the FDA in the future, but will be done so as part of a future IRB submission |

# Background

**In the Background Narrative box, describe the following:**

* **Provide an overview** of any relevant scholarly literature/scientific background
* **The rationale for the proposed research**, including how it will contribute to existing knowledge
* **Relevant prior experience** and research conducted by the study team
* **Any preliminary data and findings** **that are relevant**, such as that from prior research studies pilot projects.

|  |
| --- |
| **Background Narrative** |
|  |

# External Collaborators

**In the External Sites and Collaborators table below, list the external collaborators who will conduct research activities under this protocol**, keeping in mind the following:

* **Confirm each collaborator is engaged in the research** [**by reviewing this guidance**](https://www.irb.emory.edu/_includes/documents/sections/guidance-engagement-determination-checklist.docx)**.**
* **Do not include any international collaborators:** Emory does not provide IRB review for collaborators outside the U.S.; these collaborators must obtain their own local IRB/ethics committee approval.

To avoid unnecessary delays, review the Collaborative Research wepage and send any questions to irb.reliance@emory.edu, before submitting your protocol to the IRB.

|  |
| --- |
| External Sites and Collaborators |
| List all external sites and independent, non-Emory investigators that are [engaged in the research](https://www.irb.emory.edu/_includes/documents/sections/guidance-engagement-determination-checklist.docx) |
| Name of External Site/ Organization | Site’s Principal Investigator (PI) | Site PI’s Email  | Reviewing IRB |
|  |  |  | [ ]  Emory[ ]  Local IRB |
|  |  |  | [ ]  Emory[ ]  Local IRB |
|  |  |  | [ ]  Emory [ ]  Local IRB |
|  |  |  | [ ]  Emory[ ]  Local IRB |
|  |  |  | [ ]  Emory[ ]  Local IRB |

*(Add rows as needed)*

**In the External Collaborators and Sites Narrative box, describe how each site/collaborator listed above is involved in the research.** For each site, provide the following details:

* **Indicate the procedures conducted at the site/by the collaborator.** Indicate the locations where the procedures will take place.
	+ *Note*: If a site will conduct all protocol procedures (including enrollment), list the site and indicate “ALL” next to the site’s name.
* **Describe the data/specimen collection, access, and sharing plans** **for each site/collaborator.** Throughout, indicate if any of the [18 identifiers](https://irb.emory.edu/_includes/documents/sections/phi_identifiers.pdf) will be included and address all of the following:
	+ **Data/specimen collection and access:** Indicate the data to be *accessed or* *collected by the collaborating site.*
	+ **Data/specimen sharing scope:** Describe what will be shared between Emory and the collaborating site (e.g., aggregate data, individual-level data, specimens, etc.).
	+ **Data/specimen sharing methods:** Indicate how data will be shared between Emory and the collaborating site.

|  |
| --- |
| **External Collaborators and Sites**  |
|  |

# Study Endpoints

**In the Endpoints Summary box, describe the study and safety endpoints for the study, as applicable.**

* An example of how to determine study endpoints [can be found here](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6881606/).
* *Reminder:* Study endpoints should not be based on timing/termination of research funding.

|  |
| --- |
| **Endpoint Summary** |
| **Study Endpoints** |
| **Primary** |  |
| **Secondary** |  |
| **Safety Endpoints** |
|  |

**In the Endpoint Narrative box, provide additional details on the primary, secondary and safety endpoints.** Include any other endpoints relevant to the research, such as surrogate endpoints or non-clinical and participant-specific endpoints.

|  |
| --- |
| **Endpoint Narrative** |
|  |

# Study Drugs, Devices, and Interventional Agent Details

|  |
| --- |
| **Drugs, Devices, and Interventional Agent Questionnaire** |
| **Question/Description** | **Response** |
| **1. Does this study *direct* the use of drugs, biologics, or** [**dietary supplements**](https://www.irb.emory.edu/_includes/documents/sections/dietary_supplement_faq.docx)(even if use is a standard of care)? | [ ]  Yes*🡪**Complete #1a-1d*[ ]  No *🡪**Go to #2* |
|  | a. Are any study drugs investigational? | [ ]  Yes [ ]  No  |
|  | b. Will the Emory Investigational Drug Service (IDS) be used for the study (**please note:** radiopharmaceuticals are not subject to IDS management)? | [ ]  Yes[ ]  No *🡪* [*Complete Exemption Form*](https://www.cores.emory.edu/ids/resources/resource_study_teams.html) |
|  | c. Are any drugs under an [FDA Risk Evaluation and Mitigation Strategy (REMS)](https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems) | [ ]  Yes*🡪 Complete* [*REMS Checklist*](https://rcra.emory.edu/oric/fda/forms.html)[ ]  No  |
|  | d. Are any drugs listed as Schedule I Controlled Substances? | [ ]  Yes *🡪 Complete* [*ORIC Checklist*](https://rcra.emory.edu/oric/controlled-substances/forms.html)[ ]  No  |
| **2. Does this study involve the use of any devices?** *(Including mobile medical applications/software, etc.)* | [ ]  Yes*🡪**Complete #2a-2c*[ ]  No *🡪* *Go to #3* |
|  | a. Are any study devices investigational? | [ ]  Yes[ ]  No |
|  | b. Does this study evaluate the safety or effectiveness of any device (including software as a medical device)? | [ ]  Yes *🡪* *Complete* [*Device Checklist*](https://www.google.com/url?sa=t&source=web&rct=j&opi=89978449&url=https://irb.emory.edu/documents/Emory_IRB_Checklist-IDE_Exempt-NSRD-SRD.docx&ved=2ahUKEwj51d7678KGAxVZbzABHecUGy8QFnoECCAQAQ&usg=AOvVaw1HCg5_8aR-7k9Il_KUtFiO)[ ]  No |
| **3. Select all of the following which apply to the study submission.** | [ ]  IND or [IND Exempt](https://irb.emory.edu/_includes/documents/sections/investigator-justification-ind-exemption.docx)[ ]  IDE or [IDE Exempt](https://irb.emory.edu/_includes/documents/sections/emory_irb_checklist-ide_exempt-nsrd-srd.docx)[ ]  None of the above apply |

**In the Study Intervention Narrative box, describe the study investigational agents being evaluated** (e.g., drugs or devices). This narrative should include the following:

1. **Identify and briefly describe the study drugs and devices that are investigational or being evaluated.**
	* ***Reminder: Dietary supplements*** *intended to evaluate the dietary supplement’s ability to diagnose, cure, mitigate, treat, or prevent a disease,an IND is required.* [*This form*](https://irb.emory.edu/_includes/documents/sections/dietarysupplements-medicalfoods-research.docx) *must be completed if dietary supplements are included in the research.*
2. **Describe the plans to store, handle, and administer any drugs or devices** to ensurethat they will be used only by the authorized investigators, with the appropriate research subjects.
	* **Cite any established and approved organizational Standard Operating Procedures** that will be used (e.g., IDS SOPs) or describe the alternative approaches that will be used.
3. **For any investigational drugs or devices**, identify the holder of the IND, IDE, and/or Abbreviated IDEs/Non-significant risk device.
	* **Clearly state if an Emory Investigator holds any IND/IDEs.** If so, they are considered to be a **Sponsor-Investigator (S-I)** and [all S-I requirements](https://irb.emory.edu/guidance/research-types/sponsor-studies.html) should be addressed.
	* Explain the procedures that will be followed to comply with the sponsor requirements for FDA-regulated research (i.e., 21 CFR 11, 21 CFR 812, 21 CFR 820, etc.).

|  |
| --- |
| **Study Intervention Narrative** |
|  |

# Procedures Involved

|  |
| --- |
| **Clinical Impact**  |
| **Does enrollment in this study inform, modify, or change a patient’s care?***Examples: length of a clinical intervention is extended, additional imaging is completed, a new clinical workflow is applied, a specific clinical standard is chosen/used with the patient*  | [ ]  Yes[ ]  No |

**In the Procedures Narrative box, address the following** in the designated narrative sub-section**:**

1. ***Study Design and Interventions*:**
	* **Describe the study design and include a study schema**, if available.
	* **Describe all interventions/activities that will occur, including use of drugs and devices,** even if not investigational. For each, address the following:
		+ **For each activity:** clarify whether the intervention is established as a standard of care or deviates from typical clinical practice.
		+ **For drugs and devices:** thepurpose of use, regulatory approval status, if they are used solely within their approved indications/labeling
	* **Briefly describe the timing and frequency procedures,** including procedures to monitor participants for safety and minimize the magnitude or probability of risks.
	* Any expected overlap with standard of care clinical appointments or procedures.
	* Identify the physical locations in which research activities will take place.
	* **If the study includes deception or incomplete disclosure** (other than drug placebos), describe why the deception is necessary and outline how participants will be deceived.
2. ***Data and Specimens Collected:* Describe all data and specimens to be collected** about/from participants, including:
	* **Methods of data collection** (e.g., surveys, recordings, laboratory tests), including any procedures used to mitigate and [minimize the receipt of ‘bot’ or erroneous data](https://rcra.emory.edu/_includes/documents/ask-rcra_presentations/05.15.2024.catfishing-irb.pdf)
	* **Descriptions of any secondary data/record sources** (e.g., medical records, data from prior research studies, etc.)
		+ Note: If data will be obtained from the medical record, then *HIPAA Authorization* or a *waiver of HIPAA Authorization* will be required for the research.
	* **Details on any specimens to be collected**. For each specimen, describe the timing, frequency, quantity, and method of collection, as well as all associated testing to be completed with the specimens.
	* **Additionally, indicate if any data about minors will be collected**, regardless of the enrollment of minors in the research. If not enrolling minors, will there be any indirect data collection about children, such as details about a participant’s non-adult child?
	* *Note: Any tools, questionnaires, or scripts used with participants to collect study data should be included in the eIRB submission under Local Site Documents #3.*
3. ***Long-Term Follow-up Plans*: Describe the plans for long-term follow-up of participants,** including:
	* Data collection to occur after all research-related procedures are completed
	* The expected frequency of interactions with participants or follow-up visits
	* Plans to track participant outcomes/survival using publicly available data (e.g., vital statistics records)

|  |
| --- |
| **Procedures Narrative** |
| 1. Study Design and Interventions |
|  |
| 2. Data and Specimens Collected |
|  |
| 3. Long-Term Follow-Up Plans |
|  |

# Study Timeline

**In the Study Timeline Narrative box, describe the following** in the designated narrative sub-section**:**

1. ***Study-wide timeline*: Describe the expected timelines in which key study milestones or steps will be completed**, including:
	* **The anticipated timeline to complete enrollment of study participants** (i.e., the length of time until the study is “closed to enrollment”)
	* **The anticipated time needed to complete all distinct sub-studies or consecutive research activities**. For example: if sub-study/activity 2 cannot begin until findings from sub-study/activity 1 are complete, describe the expected duration for the completion of each sub-study/activity separately.
	* **Estimated date in which primary analyses are expected to be completed**.
2. ***Participant-Specific Time Commitment*: The duration and scope of involvement for *individual study participants***, including:
	* **The total number of research-related interactions or study visits** (i.e., the estimated total number of days in which participants will complete study activities/visits/etc.)
	* **The total time commitment expected from individual participants** (i.e., the sum of hours in which participants will engage in study activities/visits/etc.)
	* **The length of time individual participants will be enrolled** (i.e., the total number of days between enrollment and completion of interactions with the study team)
	* *Note*: Additional details may be included in the “Schedule of Assessments” section, below

|  |
| --- |
| **Study Timeline Narrative** |
| 1. Study-Wide Timeline |
|  |
| 2. Participant-Specific Time Commitment |
|  |

**In the Schedule of Assessment section (next page), provide a tabular summary of all study activities and scheduled participant interactions.** You may use the schedule template adapted from Winship, below; insert the original schedule from the [Winship template](https://www.irb.emory.edu/_includes/documents/winship_clinical_protocol_template1.docx); or insert your own version below.

Note: If the study is limited to a single participant interaction, then you may replace the template table with a brief description of the interaction with participants.

|  |
| --- |
| **Schedule of Assessments** |

See above for instructions on completing the Schedule of Assessments.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Screening (phone)**Day -7 to -1 | **Enrollment Visit 1**Day 0 | **Visit 2**Day 14 + 5 days | **Visit 3**Day 21 + 5 days | **Visit 4**Day 28 + 5 days | **Visit 5**Day 35 + 5 days | **Visit 6**Day 42 + 5 days | **Visit 7**Day 49 + 5 days | **Visit 8**Day 56 + 5 days | **Visit 9**Day 63 + 5 days | **Final Visit 10**Day 70 + 5 days | **Follow-up 1**Day 180 + 30 days |  | **Follow-up 2**Day 365+ 30 days |
| **Participant Activities** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Screening consent and eligibility questions | X |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Demographics, medical hx | X |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Medication review |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Informed Consent |  | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Randomization |  | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Physical exam |  | X | X |  | X |  | X |  | X |  |  |  |  |  |
| Pregnancy testing |  | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Intervention administered |  |  | X |  | X |  | X |  | X |  |  |  |  |  |
| Vitals |  | X | X |  | X |  | X |  | X | X | X |  |  |  |
| Height | X | X | X |  | X |  |  |  |  |  |  | Ph |  | Ph |
| Weight | X | X | X | X | X | X | X | X | X | x | X | Ph |  | Ph |
| Lab type 1 |  | X |  | X |  | X |  | X |  | X | X |  |  |  |
| Lab type 2 |  | (I) |  | (I) |  | (I) |  | (I) |  | (I) | (I) |  |  |  |
| Procedure/assessment 1 |  |  | X |  | X |  | X |  | X |  | X |  |  |  |
| Procedure/assessment 2 |  |  | X |  | X |  |  | X |  |  | X |  |  |  |
| Questionnaire 1 | X | X |  | X |  | X |  | X |  | X | X | Ph |  | Ph |
| Questionnaire 2 | X | X |  | X |  | X |  | X |  | X | X | Ph |  | Ph |

|  |
| --- |
| **Footnotes/Key** |
| X | To be completed |
| (I) | Completed only if clinically indicated |
| Ph | May be completed over the phone |
| --XXX-- | Continuous activity continuing between visit |

#

# Analysis Plan

**In the Analysis Plan Narrative box, describe all analytical plans for the study, including:**

* **Statistical analyses or procedures** to be completed
* **Qualitative methods and analyses**, including:
	+ Plans for transcription and/or coding of qualitative data (e.g., manual data entry, fee-for-service vendors, etc.)
	+ Plans to extract exact quotes, images, or other details from individuals for publication
	+ *Note: Use of AI/ML transcription or coding tools may require additional OIT review.*
* **Laboratory analyses** to be conducted, including any genetic sequencing
* **Any analytical software or online platforms** that will be utilized

|  |
| --- |
| **Analysis Plan Narrative** |
|  |

**Complete the Laboratory and Biosafety Questionnaire to determine if an** [**EHSO Biosafety submission**](https://www.ehso.emory.edu/) **is required.** If any of the items listed under #1 are answered as *Yes*, a Biosafety review and approval is required before the IRB can issue approval for the study.

|  |
| --- |
| **Laboratory and Biosafety Questionnaire** |
| **1. Will any of these be brought to an Emory research laboratory for manipulation/experimentation?** |
|  | a. Microorganisms or infectious materials | [ ]  Yes [ ]  No |
|  | b. Genetically modified live or live-attenuated microbes (bacteria, fungi, viruses) | [ ]  Yes [ ]  No |
|  | c. Nanomaterials, including genetically modified primary cells or cell lines | [ ]  Yes [ ]  No |
|  | d. Human blood, blood products, or tissue | [ ]  Yes [ ]  No |
|  | e. Human cells, cell lines, stool samples, or other human source materials  | [ ]  Yes [ ]  No |
|  | f. Arthropods or plant products, toxins, environmental samples, or other items  | [ ]  Yes [ ]  No |

# Data and Specimen Identifiability, Storage, and Sharing

**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://emory.sharepoint.com/sites/InformationSecurityArchitecture). 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://emory.sharepoint.com/sites/InformationSecurityArchitecture/SitePages/List-of-OIT-Reviewed-Apps-and-Software-for-Research-using-Identifiable-Information.aspx) 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://emory.sharepoint.com/sites/InformationSecurityArchitecture/SitePages/List-of-OIT-Reviewed-Apps-and-Software-for-Research-using-Identifiable-Information.aspx)? | [ ]  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://emory.sharepoint.com/sites/InformationSecurityArchitecture/SitePages/List-of-OIT-Reviewed-Apps-and-Software-for-Research-using-Identifiable-Information.aspx)? | [ ]  Yes *🡪 Review not required*[ ]  No *🡪* [*Request an OIT Security Review*](https://emory.sharepoint.com/sites/InformationSecurityArchitecture/SitePages/Security-Reviews.aspx) |

**In the Data and Specimen Storage and Sharing Narrative box, describe 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.)
	* **For biospecimens: whether you want the possibility of Whole Genome Sequencing to be done in future studies** – if so, this **must** be included in the consent form (if not, future WGS will not be approvable)
* Reminder: Ensure that future potential uses of data/specimens are also included in the informed consent of the study (e.g., genetic testing or WGS may be completed in the future). If applicable, include language similar to that in the [Modular Language for Informed Consent Forms](http://irb.emory.edu/documents/modular-consent-language.docx)

|  |
| --- |
| **Data and Specimen Storage and Sharing Narrative** |
| 1. Storage and Access |
|  |
| 2. Sharing |
|  |

# Population

**Complete the Special Population Inventory.** Indicate when you will interact withany of the listed populations or collect data about individuals in these groups. Note that if you respond *Yes* to any option listed below, additional details on the special populations may be needed in the Population Narrative, below.

|  |
| --- |
| **Special Populations Inventory** |
| **For each, indicate if the listed populations *will or may* *be* included in the study** | **Included?** |
| 1. [**Children or minors**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html)(i.e., persons under age 18 or the age of majority) | [ ]  Yes [ ]  No |
| 2. **Pregnant persons**, human fetuses, or neonates | [ ]  Yes [ ]  No |
| 3. [**Prisoners**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html)(i.e., persons involuntarily confined/detained in a penal institution) | [ ]  Yes [ ]  No |
| 4. **Cognitively impaired adults** (i.e., persons unable to provide consent) | [ ]  Yes [ ]  No |
| 5. **Employees or students** at Emory, CHOA, Grady, or a related research site | [ ]  Yes [ ]  No |
| 6. **Persons who are not able to clearly understand English** | [ ]  Yes [ ]  No |
| 7. **International populations** (specify below) |
|  | a. **Citizens or residents of the** **EU or UK**, in a [country with GDPR protections](https://www.gdpradvisor.co.uk/gdpr-countries) | [ ]  Yes [ ]  No |
|  | b. **Citizens or residents of Mainland China** (i.e., persons [protected under PIPL](https://www.vpaa.uillinois.edu/resources/policies/u_of_i_system_and_international_privacy_laws/china_s_personal_information_protection_law)) | [ ]  Yes [ ]  No |
|  | c. **Citizens or residents of** **other countries**: *(list here)* | [ ]  Yes [ ]  No |
| 8. **Persons otherwise vulnerable to coercion or undue influence**: *(list here)* | [ ]  Yes [ ]  No |

**In the Population Narrative box, describe any relevant populations and communities**. Include the following:

* **Identify the populations to be studied or populations relevant to the phenomena being researched.** Include the following, as relevant:
	+ **Clearly define** thepopulations and phenomena being studied. As applicable, identify important diagnostic criteria or defining features of the populations studied
	+ **Size of the populations or prevalence of the phenomenon** being studied (e.g., provide a basic quantitative or Epidemiologic overview)
	+ **Local or regional details about the population/phenomenon,** as relevant to the research (e.g., size of prevalence in Metro Atlanta, Emory patient populations, etc.)
	+ **Address if race and/or ethnicity will be incorporated in the research.** If including race/ethnicity, describe:
		- How race/ethnicity categories will be defined (e.g., as defined by JAMA, JHM, AHA)
		- The source of race/ethnicity information (e.g., self-report, medical record fields)
		- How race/ethnicity will be incorporated into analyses (descriptive only, model covariates)
		- Any uses of race/ethnicity as a proxy measure and proposed mechanisms of action
* **Identify communities relevant to the research and address involvement**, including:
	+ **Groups uniquely affected by the research aims or outcomes**
	+ **Groups specifically targeted for enrollment**
	+ **Relevant cultural groups** whose involvement may require special considerations (e.g., cultural sensitivities), compared to the larger affected population
	+ **Special populations listed above**, including why involvement of these populations is necessary
* **Describe how you will engage with relevant populations and local communities**, including:
	+ **Plans to involve** the affected communities/groups in the research study design
	+ **Plans to communicate** general findings and outcomes with the involved communities/groups
	+ **Culturally or socially relevant elements** **of the research plan**

|  |
| --- |
| **Population Narrative** |
|  |

# Inclusion and Exclusion Criteria

**In the Inclusion/Exclusion Narrative, list the inclusion/exclusion criteria and then detail how participant eligibility will be determined and assessed.** This narrative should address the eligibility criteria relevant to the study scope as well as eligibility criteria related to the involvement of special and protected populations. Make sure to address all relevant details in the appropriate narrative sub-section.

1. ***General Eligibility Criteria*: Outline the specific criteria used to determine eligibility for the study,** such as: diagnostic criteria, membership in a specific group (e.g., self-identification, employment, patient status), etc.
	* **Identify any differences in eligibility for study sub-groups** (e.g., experimental vs control groups, sub-study eligibility, etc.)
2. ***Eligibility of Special Populations*:** In the relevant section, describe plans to identify, handle, and include/exclude each of the following:
	* **Minors:** Address the following:
		+ **Methods for screening** to identify minors or persons not old enough to provide consent
		+ **Age-based inclusion or exclusion criteria** that will be used
	* **Pregnancy:** Address if pregnancy is relevant to the research.If relevant, include the following:
		+ **Methods for screening** for pregnancy, including who will be screened
		+ **Plans for inclusion or exclusion** or pregnant persons
			- **If excluding**: Provide a clear justification for why pregnant persons are excluded.
		+ **For longitudinal research:** Address how changes in pregnancy status will be assessed and handled (e.g., routine screening, withdrawal from the research)
	* **Prisoners:** Clarify if prisoner status is relevant to the research and, if relevant, how prisoners will be identified
	* **Cognitive impairment or impaired decision-making capacity (i.e., those requiring a Legally Authorized Representative):** Address if cognitively impaired populations or persons with impaired decision-making capacity may potentially be involved or included in the recruitment pool. As relevant, address the following:
		+ **Methods for screening** for cognitive impairment and/or impaired decision-making capacity
		+ **Plans for inclusion or exclusion** for cognitively impaired persons
		+ **For longitudinal research:** Address how changes in cognitive impairment/decision-making capacity will be assessed and handled (e.g., routine screening, withdrawal from the research, pre-involvement of future legally authorized representatives)
		+ *Note*: Studies focusing on brain injuries or cognitive decline, or research involving populations likely to experience these phenomena must address cognitive impairment in their protocol.
	* **Ability to communicate in English:** Address the following:
		+ **Clarify: is it *necessary* for participants to be able to communicate in English** in order to conduct the research?
		+ **Plans for inclusion or exclusion** of persons based on limited English proficiency.
			- **If excluding:** Provide a clear justification for why persons unable to communicate in English will not be included in the research

|  |
| --- |
| **Inclusion/Exclusion Criteria Narrative** |
| 1. General Eligibility Criteria |
| Inclusion Criteria:Exclusion Criteria:Describe how will eligibility be determined: |
| 2. Eligibility of Special Populations |
| Minors |  |
| Pregnancy |  |
| Prisoners |  |
| Cognitive impairment or impaired decision-making capacity |  |
| Ability to communicate in English |  |

# Projected Enrollment

**Complete the Projected Enrollment Table**, keeping in mind that **enrollment is defined as the completion of the informed consent process or the waiving of consent.** Persons who are consented (or whose consent is waived) should still be considered enrolled, even if they never complete study activities or their study data is not utilized for analysis.

* *Note:* Enrollment totals must be tracked and reported at the time of Continuing Review (if required) and study Close-Out. Over-enrollment may be reportable to the IRB.

|  |
| --- |
| **Projected Enrollment Table** |
| **1. Describe the enrollment projected at the local study site** (i.e., Emory, CHOA, and Grady) |
|  | **a. Enrollment**: *Maximum* count of persons to be consented for the research |  |
|  | **b. Number of evaluable subjects:***Minimum*count of participants needed to complete the research activities in order to achieve the research aims/goals |  |
| **2. Indicate the total enrollment goal across *all study sites*** (if a multi-site study)  |  |

 **In the Enrollment Summary Narrative**, provide the following:

* Expected rates and reasons for screening failures (if applicable) and withdrawals.
* **Describe and break-down enrollment counts** based on the following categories:
	+ **Distinctions between study sub-groups** (e.g., experimental vs control groups or variation in enrollment between different interventions/sub-activity)
	+ **Demographic breakdown of participant enrollment** (e.g., percentages by race, sex, gender, etc.)
	+ **Any other key characteristics for which enrollment rates should differ**

|  |
| --- |
| **Enrollment Summary Narrative** |
|  |

# Advertising, Recruitment, and Screening

|  |
| --- |
| **Advertising and Recruitment Inventory** |
| **1. Indicate which *advertising/recruitment materials* may be used** | **Included?** |
|  | a. **Physical advertisements** (posting flyers, print advertisements, mailers) | [ ]  Yes [ ]  No |
|  | b. **Digital advertisements** (e.g., online posts or advertisements) | [ ]  Yes [ ]  No |
|  | c. **Audio, video, or other multimedia advertisements** (e.g., radio or television) | [ ]  Yes [ ]  No |
|  | d. **Outreach messages or canned statements** (e.g., listserv messages) | [ ]  Yes [ ]  No |
|  | e. **Community presentations or engagements** (tabling or speaking at events) | [ ]  Yes [ ]  No |
| **2. Indicate what *general outreach methods* may be used** | **Included?** |
|  | a. **Use of Emory student research pools/programs** (e.g., SONA) | [ ]  Yes [ ]  No |
|  | b. **Non-Emory research recruitment platforms** (e.g., Research Match, Prolific) | [ ]  Yes [ ]  No |
|  | c. **Website or social media posts** (e.g., paid web advertising, online groups)  | [ ]  Yes [ ]  No |
|  | d. **Referral-based recruitment** (partners, external organizations, or providers identify and/or refer participants)  | [ ]  Yes [ ]  No |
|  | e. **Snowball-sampling** (research participants provide referrals) | [ ]  Yes [ ]  No |
| **3. Indicate what *targeted recruitment methods* will be used** to contact participants | **Included?** |
|  | a. Contacting possible participants based on their employment, enrollment in a course, or other employment/educational membership | [ ]  Yes [ ]  No |
|  | b. Contacting possible participants based on their involvement in a prior research or recruitment protocol: *(list IRB submission IDs here)* | [ ]  Yes [ ]  No |
|  | c. Contacting possible participants who were treated or seen by the study team | [ ]  Yes [ ]  No |
|  | d. Contacting possible participants based on searchers of medical records, clinic schedules, or other administrative records | [ ]  Yes [ ]  No |

**Complete the Recruitment Methods Narrative box, below, to provide all necessary details about the recruitment strategies for your study.** Make sure to organize recruitment details into the appropriate sub-section and, if a method or sub-section of the narrative does not apply, confirm its inapplicability to the current protocol.

1. ***General Recruitment Overview:*** Expand upon the methods indicated under questions 1 and 2 the Advertising and Recruitment Inventory. In this summary, include the following:
	* **Indicate all** **locations where recruitment materials will be shared or posted**
	* **Indicate the next steps to be taken by potential participants**. For example: Will they need to open a link/QR code to access a study website, complete a sign-up survey, send an email to the study team, make a phone call, etc.?
		+ If there is an interest form/sign-up survey is included, upload a copy of this form to the submission under “Local Site Documents” #2.
	* **Identify any partner groups or organizations** that will assist with recruitment and describe the scope of their involvement.
	* **Distinguish any differences in how study sub-groups are recruited.** For example: will the intervention and control groups be targeted with through different platforms or methods?
	* *Note*: All recruitment materials must meet the IRB’s guidelines for advertising and recruitment. All materials should be uploaded to the eIRB submission under “Local Site Documents” #2.
2. ***Specialized Recruitment:***
	* **If recruiting using social media platforms or advertisements:** Review [this guidance](https://www.google.com/url?client=internal-element-cse&cx=045d620e1a428f218&q=https://irb.emory.edu/_includes/documents/sections/guidance-using_social_media_recruit_participants.pdf&sa=U&ved=2ahUKEwj6k9yWi8OHAxUfSTABHcwcDI8QFnoECAMQAg&usg=AOvVaw02vUzeiT_4hJzFp3uF-sWq&arm=e) and insert all of the required elements of the Social Media Management Plan in this section.
	* **If recruiting using existing research platforms:** Describe how these platforms will be used and any parameters used to identify or connect-with eligible participants.
		+ **If using Research Match:** Insert the required Research Match template language into this section
	* **If relying on referrals (e.g., provider referrals, snowball-sampling, etc.):** Identify what who will be asked to refer participants. Describe how referred participants and the research team will be connected.
3. ***Targeted Recruitment:*** In this sub-section, provide details on any methods in which potential participants will be directly contacted by the study team.
	* **If using classroom enrollments, rosters, declared majors or other administrative academic data** to identify or contact potential participants:
		+ **Describe what records will be used** or obtained to contact potential participants.
		+ **Describe the process for outreach** to potential participants, including who is responsible for contact, the method of contact, etc.
		+ *Note:* [*FERPA*](https://www.google.com/url?client=internal-element-cse&cx=045d620e1a428f218&q=https://irb.emory.edu/_includes/documents/sections/ferpa_guidance_and_worksheet.docx&sa=U&ved=2ahUKEwiv88zZi8OHAxVmM1kFHbzuCbUQFnoECAAQAQ&usg=AOvVaw174DmUH26W9GR71iUK7Sz-&arm=e) *most-likely applies to studies using these recruitment methods.*
	* **If utilizing existing recruitment protocols, sign-up lists, or contacting participants of another study** to recruit potential participants**:**
		+ **List the relevant protocols/studies** to be used along with the organization overseeing the protocol and IRB study IDs (if local to Emory)
		+ **Describe the existing participant details** to be used or obtained in order to contact potential participants
		+ **Describe the process for outreach** to potential participants, including who is responsible for contact, the method of contact, etc.
	* **If using medical records, clinic schedules, or other HIPAA-protected information** to identify and contact potential participants:
		+ **Describe what records will be used** or obtained to contact potential participants
		+ **Describe the process for outreach** to potential participants, including who is responsible for contact, the method of contact, etc.
			- *Note*: “cold calling” patients is not permitted, per IRB guidance
		+ *Note:* Use of HIPAA-protected information for to identify or recruit potential participants prior to their consent requires a [Partial Waiver of HIPAA Authorization](https://irb.emory.edu/forms/waivers/index.html)*.* Ensure that your responses in the “HIPAA Applicability and Waivers Requested” section of eIRB reflect the need for this waiver.

|  |
| --- |
| **Recruitment Methods Narrative** |
| 1. General Recruitment Overview |
|  |
| 2. Specialized Recruitment Requirements |
|  |
| 3. Targeted Recruitment Details  |
|  |

**Provide a detailed description the eligibility screening process that is completed before subjects are enrolled.** This summary should address the following, in the designated sub-section:

1. ***Screening Methods Overview:*** Outline the process in which you will determine that interested participants are eligible to participate in the research, including the following:
	* **Describe all methods in which eligibility of potential participants will be determined.** For example:
		+ A single self-attestation to meeting the eligibility criteria
		+ Surveys or questionnaires (e.g., demographic questionnaire, depression scale)
		+ Confirmation or review of medical history data (e.g., study team reviews medical records for a documented diagnosis)
		+ Physical assessments or laboratory tests (e.g., fitness testing, pregnancy tests, laboratory testing, etc.)
	* **Clarity where screening activities will take place** (e.g., asynchronously through an online survey/form, over a phone or video call, in-person visit, etc.)
		+ **If the screening process includes multiple steps/interactions:** Describe each of the screening activities separately and the purpose of each screening activity.
	* **State the estimated time to complete screening** for potential participants
	* **Describe what information will be collected from potential participants,** including:
		+ What identifiers and question responses, if any, will be stored
		+ Will data from ineligible persons be saved or stored?
	* Describe any precautions taken to identify inauthentic screening information and prevent enrollment of participants who may provide fraudulent responses
	* **If using a third-party to recruit/screen participants (e.g., Prolific):** describe the parameters that will be implemented by the third-party to determine participant eligibility prior to enrollment.
2. ***Screening Consent Requirements:* Clarify if a screening consent will be completed as part of the screening process,** by answering questions 2a-2d, as instructed.
	* ***Note:* Screening consents are required then the following apply.** When applicable, a screening consent form must be submitted to the IRB under “Local Site Documents” #1.
		+ **Authorization to access a person’s medical records is requested** (i.e., HIPAA authorization is requested)
		+ **Screening interventions are completed** (e.g.,blood draws, pregnancy testing)
		+ **Identifiers and sensitive or health information are saved** (e.g., the responses to the screener questionnaires are stored with contact information)

|  |
| --- |
| **Participant Screening Narrative** |
| 1. Screening Methods Overview |
|  |
| 2. Screening Consent Requirements |
|  | a. Is a screening consent used or required for this study? | [ ]  Yes *🡪*  *Complete the rest of the section*[ ]  No *🡪*  *Move to next section* |
|  | b. Will HIPAA Authorization be added to the screening consent? | [ ]  Yes[ ]  No  |
|  | c. Indicate how consent for screening will be obtained (Select all that apply) | [ ]  Signed, in-person/physical signature[ ]  Signed, electronically (i.e., e-signature)[ ]  Verbal (waiver requested)[ ]  Online, without signature (waiver requested) |
|  | d. Briefly describe the screening consent process |  |

# Informed Consent

**Complete the Consenting and Assenting Parties Inventory to determine which groups should be addressed in the Informed Consent Narrative.**

|  |
| --- |
| **Consenting and Assenting Parties Inventory** |
| **1. Indicate which consenting groups are included in the research** (even if waived) | **Included?** |
|  | a. **Adults able to consent for themselves**  | [ ]  Yes [ ]  No |
|  | b. **Persons with limited English proficiency** (e.g., requiring an interpreter) | [ ]  Yes [ ]  No |
|  | c. **Legally Authorized Representatives (LARs), including parents of minors** | [ ]  Yes [ ]  No |
|  | d. **Other groups**: *(Describe here)* | [ ]  Yes [ ]  No |
| **2. Indicate which assenting groups are included in the research** (even if waived) | **Included?** |
| \* | a. **Children/Minors** (e.g., persons under age 18 in Georgia) | [ ]  Yes [ ]  No |
|  | b. **Cognitively impaired adults** | [ ]  Yes [ ]  No |
|  | c. **Persons otherwise unable to provide consent** (e.g.,incapacitated adults) | [ ]  Yes [ ]  No |
|  | d. **Other groups**: *(Describe here)* | [ ]  Yes [ ]  No |
| **3. For each method of consent or assent, indicate if/when the method will apply to the study.** |
|  | a. C**onsent will be signed, in person/physically** | [ ]  Always [ ]  Sometimes [ ]  Never  |
|  | b. C**onsent will be signed, with a valid eSignature** | [ ]  Always [ ]  Sometimes [ ]  Never  |
|  | c. **Consent will be provided verbally** (waiver of documentation) | [ ]  Always [ ]  Sometimes [ ]  Never  |
|  | d. **Consent will be provided online, without signature** (waiver of documentation) | [ ]  Always [ ]  Sometimes [ ]  Never  |
|  | e. **Consent will NOT be obtained** (complete waiver) | [ ]  Always [ ]  Sometimes [ ]  Never  |
|  | f. ***Assent* will be signed/completed** per Emory’s age-based guidance | [ ]  Always [ ]  Sometimes [ ]  Never [ ]  N/A |
|  | g. ***Assent* will be verbal or online for all ages** (waiver of documentation) | [ ]  Always [ ]  Sometimes [ ]  Never [ ]  N/A |
|  | h. ***Assent* will NOT be obtained** (complete waiver) | [ ]  Always [ ]  Sometimes [ ]  Never [ ]  N/A |
|  | i. Describe any other methods of consent or assent to be used *(describe)* |  |
| \*Indicates that a separate consent/assent form is needed if the requirement is not waived |

**In the General Informed Consent Narrative, detail the consent process to occur**. Ensure that the appropriate details are outlined in each sub-section of the narrative box.

1. ***Informed Consent Overview:*** Outline the general process for obtaining informed consent:
	* **Responsible parties:** Who, if anyone, will complete the consent process with participants? Identify the personnel roles involved in consent (e.g., PI, coordinator, etc.), but do not name specific study team members in the protocol
	* **Timing**: **Describe when the consent process will occur,** including:
		+ **Waiting period**: Will there be any waiting period between informing the prospective participant of the study and obtaining the consent?
		+ **Review/preparation time**: Will participants have access to consent documents prior to the consent discussion?
		+ **Length of time** devoted to the consent process, or the expected amount of time participants will need to appropriately complete the consent
	* **Location**: **Describe where the consent process will take place** and how will participants receive the information needed to consent to the study.
		+ **Is the process synchronous or asynchronous**? In other words, will a study team member be present and guide the review and completion of the consent?
		+ **Access to the consent documents**: Will participants receive a physical or digital copy of the consent for their records? How will copies be provided?
	* **If electronic consent (“eConsent”) will be collected**: Describe the eConsent method you will use, based on the IRB’s [eConsent guidance](https://irb.emory.edu/_includes/documents/sections/guidance-eicf_use.pdf).
	* **If complete waivers of consent are requested:** Use this space to indicate why it is impracticable to obtain informed consent.
2. ***Intentional Consent Practices:*** Describe all of the following, as they apply to the study
	* **Steps taken to assess and ensure understanding** of participants (e.g., participants restate the key points until and review the consent until complete understanding is demonstrated)
	* **Steps to minimize the possibility of coercion or undue influence**.
		+ *Note*: studies likely to enroll employees, students, or other persons where there may be a power differential with the PI must address these efforts. For example, someone without the potential power differential would obtain consent.
	* **Processes taken to ensure consent is ongoing** (e.g., checking-in with participants after each intervention; reviewing the consent at the start of each visit or call, etc.)
	* **If the study includes deception or incomplete disclosure to participants:**
		+ Indicate how participants will understand that deception or incomplete disclosure is a part of the research.
		+ Describe how participants will be debriefed regarding the elements of the deception, and given an opportunity to ask questions

|  |
| --- |
| **General Informed Consent Narrative** |
| 1. Informed Consent Overview |
|  |
| 2. Intentional Consent Practices |
|  |

**In the Special Consent and Assent Narrative, complete each of the listed following sub-sections, as they apply to your study.** These groups align with the groups indicated in #1b-#1f and #2 of the Consenting and Assenting Parties Inventory. Prior to completing these sections, review the following [IRB Policies and Procedures](https://irb.emory.edu/_includes/documents/sections/policiesandprocedures.pdf):

* + [44](https://irb.emory.edu/_includes/documents/sections/policiesandprocedures.pdf#%5B%7B%22num%22%3A513%2C%22gen%22%3A0%7D%2C%7B%22name%22%3A%22XYZ%22%7D%2C88%2C720%2C0%5D): Informed Consent of Non-English-Speaking Subjects
	+ [45](https://irb.emory.edu/_includes/documents/sections/policiesandprocedures.pdf#%5B%7B%22num%22%3A525%2C%22gen%22%3A0%7D%2C%7B%22name%22%3A%22XYZ%22%7D%2C88%2C720%2C0%5D): Legally Authorized Representatives and Surrogate Consent
	+ [52](https://irb.emory.edu/_includes/documents/sections/policiesandprocedures.pdf#%5B%7B%22num%22%3A600%2C%22gen%22%3A0%7D%2C%7B%22name%22%3A%22XYZ%22%7D%2C144%2C720%2C0%5D): Research Involving Children – Additional Protections
1. ***Consent of Participants with Limited English Proficiency*:** Complete this section if you will enroll persons with limited English proficiency and include the following:
	* Indicate which languages you expect prospective participants to understand
	* Describe how you will provide oral and written information to participants in a language they understand, including plans for:
		+ Using interpreters
		+ Using ShortForms for consent ([see here for additional information](https://www.irb.emory.edu/forms/consent/shortforms.html))
		+ Translating consent and other study documents ([see here for guidance on approved translation methods](https://irb.emory.edu/guidance/getting-started/participant-materials.html))
2. ***Parental Consent for Minor Participants****:* Complete this section if you will enroll minors and obtain consent/permission from parents/guardians. Include the following:
	* **Indicate when parent/guardian consent will be required** prior to enrollment of minors in the research.
		+ Note: Parental consent is usually required when children are under the legal age of 18; however, some variations and jurisdictional differences in the legal age exist.
		+ Address any jurisdictional differences or deviations from the standard practice that will be applied the study and provide references/justification for such differences.
	* **Indicate the number of available parents who must consent** to the research when the minor has multiple parents who are alive, known, competent, reasonably available, and hold legal responsibility for child’s care and custody.
	* **Indicate if persons other than parents can consent** to the involvement of minors in the research and, if so, describe how these individuals’ authority to consent to the child’s medical care will be confirmed.
3. ***Other Legally Authorized Representatives*:** Complete this section if you will enroll persons with cognitive impairment or impaired decision-making capacity to address the requirements for legally authorized representatives (LARs). Include the following:
	* **Indicate who can provide consent** and indicate the order of priority for obtaining permission from those who may consent (e.g., durable power of attorney for health care, a court-appointed guardian for health care decisions, spouse, adult children, etc.)
	* **Address any jurisdictional differences** in who may serve as a LAR, if research is conducted outside of Georgia.
4. ***Assent Plans:*** Use this section to describe the assent methods for groups listed in #2 of the Consenting and Assenting Parties Inventory, if included in the research. **Address each of the following elements separately for the enrollment of minors, cognitively impaired persons, and persons with impaired decision-making capacity.**
	* **Indicate which groups will provide assent for the research:**
		+ **If enrolling minors:** indicate if assent be obtained according toEmory’s age-based guidance or will deviate from the age-based approach
		+ **If only a subset of participants will provide assent**, indicate how the requirement for assent will be determined.
		+ **If seeking to waive the requirement for assent,** briefly justify why assent cannot be, or is impractical to be obtained from some or all participants.
	* **Describe the assent process, including if/how assent will be obtained and documented**, including:
		+ **Who will discuss the study with the assenting groups**, prior to obtaining and documenting assent
		+ **Describe how assent will be documented:**
			- **If obtaining assent from minors:** Briefly describe plans for the use of the child assent script/document and, if used, ensure a copy of the child assent form is uploaded in the IRB submission under “Local Site Documents” #1.
			- **If obtaining assent from adults:** Briefly describe any plans for an assent process with adults who may have some capacity to understand the study, including documentation.
	* **In studies where participants may become eligible to consent for themselves in the future (e.g., aging into adulthood or capacity is regained):** Describe when and how consent will be obtained from these participants.

|  |
| --- |
| **Special Consent and Assent Narrative** |
| 1. Consent of Participants with Limited English Proficiency |
|  |
| 2. Parental Consent for Minor Participants |
|  |
| 3. Other Legally Authorized Representatives |
|  |
| 4. Assent Plans |
|  |

# Reporting Results and Incidental Findings

**In the Participant Results Narrative box, describe the plans for managing routine and incidental results that may arise from the research.**

*Note:*[Incidental findings](https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf) are results that may arise but are outside the original purpose for which a test or procedure was conducted.Some tests/procedures that may produce incidental findings include imaging procedures, such a CAT scans and fMRIs, and genetic testing, such as paternity/donor match tests or genetic sequencing.

**For both the *Routine or Expected Results* and *Incidental Results* sub-sections, address the following:**

* **The participant-specific findings or results that may be generated**, such as those generated from certified laboratory tests, genetic testing, investigational/exploratory diagnostic results, or clinical imaging.
	+ **In the incidental findings section, identify which activities may produce incidental findings** and how these findings will be recognized, analyzed, and handled. Identify any secondary findings that are being sought actively, findings that may be anticipatable, and findings that might be un-anticipatable.
* **Plans for reporting our or sharing participant-specific findings *or* a clear rationale for why results will not be reported.** If reporting findings, this plan should include:
	+ Effort to validate or confirm findings prior to reporting out (e.g., validation with an alternate test, completion of a secondary a etc.)
	+ **How and to whom findings will be reported** (e.g., direct to participants, reported to a care provider, etc.).
	+ **What information the research team will provide when disclosing findings**, including additional educational information; referrals or guidance to seek care from a clinician or specialist; guidance on obtaining health insurance coverage, as appropriate; etc.
* **How participants will be made aware of the study’s result reporting process during the Informed Consent discussion**
	+ **Describe if/how participants can opt-in or opt-out** **of receiving results**, if applicable.
	+ *Note: Result reporting plans should also be described in the informed consent document.
	If research imaging or genetic sequencing is included in the research, include language similar to that in the* [*Modular Language for Informed Consent Forms*](http://irb.emory.edu/documents/modular-consent-language.docx)*.*

|  |
| --- |
| **Participant Results Reporting Narrative** |
| 1. Routine or Expedited Results |
|  |
| 2. Incidental Results |
|  |

 **In the Study-Wide Result Reporting Narrative, describe any plans to report aggregate findings from the research.** This should address the following:

* **Plans to share results with research participants** (i.e., general findings and outcomes)
* **Plans to share results with the research community**, including plans or goals to publish the study results or report results more widely
* **Plans to share the study results with relevant communities/groups** affected by, or engaged in, the research.

|  |
| --- |
| **Study-Wide Result Reporting Narrative** |
|  |

# Withdrawal of Participants

**In the Withdrawal Narrative,** describe the following in the specified sub-section:

1. ***Researcher-Initiated Withdrawals*:**
* **Identify any anticipated circumstances for which participants will be withdrawn** from the research without their consent.
	+ Example: If pregnancy or cognitive impairment is identified
* **Describe the withdrawal procedures.** This may include:
	+ If and how participants will be notified that they have been withdrawn
	+ Personnel responsible for notifying participants of their withdrawal
	+ Follow-up activities or additional plans (e.g., medication tapering, follow-up data collection, etc.)
1. ***Participant-Initiated Withdrawals:***
* **Describe procedures that will be followed** when participants withdraw from the research
* **Describe plans for managing partial withdrawals** (i.e., study interventions are concluded with the participant, but they remain available for continued data collection or follow-up).

|  |
| --- |
| **Withdrawal Narrative** |
| 1. Researcher-Initiated Withdrawals |
|  |
| 2. Participant-Initiated Withdrawals |
|  |

# Risks and Burdens

**In the Risks Narrative, provide a comprehensive summary of the study’s risks,** discomforts, hazards, and inconveniences (including side-effects associated with study drugs), **and the efforts taken to minimize these risks**. Organize this narrative as follows:

1. ***Risks, Discomforts, and Burdens*:**
* **Describe *all* physical, psychological, social, legal, or economic risks and burdens**, including**:**
	+ **Risks to others who are not participants** (e.g., children, family members, etc.)
	+ **Risks to an embryo or fetus**, should a participant be or become pregnant
	+ **Economic burdens to participants** (i.e., costs that participants may be responsible for in order to participate)
* **For each risk/discomfort identified:** describe the likelihood of the risk, its magnitude, duration, and reversibility (if known).
	+ **When describing the likelihood of each risk**, either provide the known numeric probability (with a citation) or a qualitative summary of its expected frequency (e.g., common, uncommon, rare).
* **If multiple, distinct procedures/interventions will occur**, organize the risks/discomforts/etc. by the specific procedure/intervention.
	+ *Note:*If the same risk is present for multiple interventions/activities, the risk should be identified under each section.
	+ For each procedure/intervention: indicate when there may be **unforeseeable risks that are not currently known**
1. ***Steps to Minimize Risks:***
* **Describe efforts to minimize the risks, discomforts, hazards, and inconveniences** to participants. Efforts should include the following, as applicable:
	+ **Medical or psychological resources** for participants, including the availability and length of access to these resources.
	+ **Efforts taken to prepare participants for possible burdens or discomforts** prior to their occurrence (e.g., introduction to a simulation of the intervention or practice-run for interventions, such as a mock MRI-scanner).

|  |
| --- |
| **Risks to Participants Narrative** |
| 1. Risks, Discomforts, and Burdens |
|  |
| 2. Steps to Minimize Risks |
|  |

# Privacy Interests of Participants

**In the Participant Privacy Interest box, describe the steps to ensure the privacy interests of participants are met.** This narrative should address the following, by section. If a section is not applicable, provide rationale for why the section does not apply to your study.

1. ***Participant privacy interests:*** Describe the steps you will take 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.**
2. ***Access to participant information:*** Indicate how the research team is permitted to access any sources of information about the participants.

|  |
| --- |
| **Provisions to Protect Participant Privacy** |
| 1. Participant Privacy Interest |
|  |
| 2. Access to Participant’s Information |
|  |

# Potential Benefits to Participants

**In the Benefits to Participants Narrative, describe the benefits that *individual participants* may experience** as part of their involvement in the research.

* **If no benefits are identified:** clearly state that there are no direct benefits for participation.
* *Note*: Do not describe benefits to broader society or non-participants or include compensation as a benefit.

|  |
| --- |
| **Benefits Narrative** |
|  |

# Compensation to Participants

**In the Compensation Narrative, provide an overview of the compensation schema for the study**. Compensation is not limited to financial payments and may include distribution of other incentives such as course credit, discounts, food, merchandise, reimbursements/stipends, services, etc. The narrative should address the following:

* **Describe the methods and amount of compensation for individual participants**, if any, including:
	+ **Disbursements provided (e.g., cash, debit or store gift cards, school credits)**
	+ **Timing and frequency of compensation** disbursements (e.g., compensated at study visit, at the completion of the study, etc.)
	+ **Schemas for determining compensation**, such as:
		- Compensation amounts tied to specific study activities or based on sub-group enrollments
		- Rates or defined compensation amounts (e.g., hourly, pro-rated rates)
		- Upper limits to compensation amounts
		- Compensation bonuses provided, such as increases based on participant’s performance
* **Describe how compensation will be provided**, such as: disbursed during specified participant interactions, sent via email or mail, dispersed through a third-party agency
* **Identify any possible scenarios in which respondents may not be compensated** (e.g., clarify if/how certain suspicious or improbable responses will be identified and may disqualify participants from compensation)
* **Clarify if raffles or drawings for compensation/prizes will be used to incentivize participation.** If included address all of the following:
	+ Describe how the raffle/drawing will align with [state and Emory requirements](https://www.ogc.emory.edu/downloads/advisories/RafflesAndOtherContestGiveaways.pdf)
	+ Outline how individuals will be able to register for the raffle/drawing *without requiring participation in the* *research*.

|  |
| --- |
| **Compensation Narrative** |
|  |

# Data and Safety Monitoring

**Complete the Data Monitoring Requirements Assessment below to determine which Data and Safety Monitoring Table should be used in this investigator-initiated protocol.** 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. Do any of the below, highest-complexity categories apply to the research?** *(i.e., did you answer “yes” to 1a or 1b?)* | [ ]  Yes *🡪 This is a complexity cat. A study, insert table 1*[ ]  No *🡪 Go to #2* |
|  | 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 |
| **2. Do any of the below, high-complexity categories apply to the research?** *(i.e., did you answer “yes” to one of items listed in 2a-2d?)* | [ ]  Yes*🡪 This is a complexity cat. B study, insert table 1*[ ]  No*🡪 Go to #3* |
|  | 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 |
| **3. If none of the above categories apply, insert the medium-complexity table 2.**  |

|  |
| --- |
| **Data and Safety Monitoring Table** |
| **1. What Data and Safety Monitoring type and table is required,** based on theData Monitoring Requirement Assessment, above? | [ ]  Complexity Category A, table 1[ ]  Complexity Category B, table 1[ ]  Medium Complexity, table 2 |
| **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]***

**In the Data Safety Monitoring Parameters Narrative box, describe the data safety monitors, subject safety monitoring, subject stopping rules, and study stopping rules:**

This narrative should include the following, by section. If not applicable to your study, use the narrative box to provide rationale for why the section is not applicable.

1. ***Data Safety Monitors:*** Review [this guidance](https://irb.emory.edu/_includes/documents/sections/dsmb-guidance.pdf) to determine if a Data Safety Monitoring Board (DSMB)/Safety Committee is required. Include the following details:
	* **Indicate what monitoring is required:** DSMB, Committee, Self-monitoring
	* **Composition:** If required, indicate the composition of the DSMB or Committee
	* **Frequency:** If DSMB or Committee or Self-monitoring, indicate frequency of meeting or review
2. ***Subject Safety Monitoring:***
	* **Describe** **specific subject safety parameters**
	* **Include frequency of subject safety observations**
	* **Specify Individual responsible for safety monitoring**
3. ***Subject Stopping Rules:*** Describe under what conditions the study intervention will be stopped, who will make the decision, and any procedures needed for safe withdrawal.
4. ***Study Stopping Rules:*** Describe under what conditions the study will be modified or stopped and who will make the decision.

|  |
| --- |
| **Data Safety Monitoring Parameters** |
| 1. Data Safety Monitors  |
|  |
| 2. Subject Safety Monitoring |
|  |
| 3. Subject Stopping  |
|  |
| 4. Study Stopping |
|  |

**In the Events Reporting box, describe adverse events and external reporting plans**, in the appropriate sub-section. If a section is not applicable to the study, provide a clear rationale as to why.

1. ***Adverse Events:*** As applicable, define Adverse Events and event classifications, as appropriate for the present study.
	* *Note:* The definitions provided in the template are adapted from the [Winship protocol template](https://www.irb.emory.edu/_includes/documents/winship_clinical_protocol_template1.docx). Teams should delete, edit, or adapt, as appropriate.
2. ***External Reporting Plan:***
	* **Describe** **the plan for reporting events and key information to groups other than the IRB** (e.g., study supporter/funder, FDA reporting for S-I studies, etc.).

|  |
| --- |
| **Events and Reporting** |
| 1. Adverse Events |
| ***The following definitions and classifications have been adopted from the Winship Protocol Template:*****Definition of Adverse Events (AE):** Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).**Definition of Serious Adverse Events (SAE):** An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes:* Death
* Life-threatening adverse event
* Inpatient hospitalization or prolongation of existing hospitalization
* A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.
* Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. (Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

**Classification of an Adverse Event:**Severity of Event: For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity. * **Mild** – Events require minimal or no treatment and do not interfere with the participant’s daily activities.
* **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
* **Severe** – Events interrupt a participant’s usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term “severe” does not necessarily equate to “serious.”

Relationship to Study Intervention: All adverse events (AEs) must have their relationship to study intervention assessed by the clinician who examines and evaluates the participant based on temporal relationship and their clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect. * **Definitely Related** – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study intervention administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study intervention (dechallenge) should be clinically plausible. The event must be pharmacologically or phenomenologically definitive, with use of a satisfactory rechallenge procedure if necessary.
* **Probably Related** – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the study intervention, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal (dechallenge). Rechallenge information is not required to fulfill this definition.
* **Potentially Related** – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of the trial medication). However, other factors may have contributed to the event (e.g., the participant’s clinical condition, other concomitant events). Although an AE may rate only as “possibly related” soon after discovery, it can be flagged as requiring more information and later be upgraded to “probably related” or “definitely related,” as appropriate.
* **Unlikely to be related** – A clinical event, including an abnormal laboratory test result, whose temporal relationship to study intervention administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study intervention) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant’s clinical condition, other concomitant treatments).
* **Not Related** – The AE is completely independent of study intervention administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.
 |
| 2. External Reporting Plans |
|  |

# References

**List all references in the box, below.**

|  |
| --- |
| **References** |
|  |