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.
3. 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
	* This is a multi-site study where Emory is not the lead site for the research

**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 |  |

**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* |  |
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***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 4](#_Toc2012663113)

[2. Objectives 5](#_Toc1799176046)

[3. Background 5](#_Toc899839832)

[4. External Collaborators 6](#_Toc1638357944)

[5. Study Endpoints 7](#_Toc1843482182)

[6. Procedures Involved 7](#_Toc292067745)

[7. Study Timeline 9](#_Toc2097680838)

[8. Analysis Plan 11](#_Toc578214099)

[9. Population 12](#_Toc1021970200)

[10. Inclusion and Exclusion Criteria 13](#_Toc1665270663)

[11. Projected Enrollment 13](#_Toc388528941)

[12. Advertising, Recruitment, and Screening 14](#_Toc1259315841)

[13. Informed Consent 17](#_Toc10468541)

[14. Reporting Results and Incidental Findings 19](#_Toc2124665058)

[15. Withdrawal of Participants 20](#_Toc1013014554)

[16. Risks and Burdens 21](#_Toc754696546)

[17. Potential Benefits to Participants 22](#_Toc1744652433)

[18. Data and Safety Monitoring 22](#_Toc696308913)

[19. References 26](#_Toc1765059119)

# 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)(only list protocol driven procedures) |  |
| [**Length of involvement for individual participants**](#_Study_Timeline) |  |
| [**Research design**](#_Analysis_Plan) |  |
| **Key abbreviations and definitions**  |  |

# 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.

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| **Objective Narrative** |
|  |

# 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.

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| **Background Narrative** |
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# 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](https://irb.emory.edu/_includes/documents/sections/policiesandprocedures.pdf), 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.

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| **External Collaborators and Sites**  |
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# 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.

|  |
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| **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.

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| **Endpoint Narrative** |
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# Procedures Involved

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| **Clinical Impact**  |
| **Does enrollment in this study potentially 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:** clarify 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.
	* **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.
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)

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| **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

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

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| **Schedule of Assessments** |

See above for instructions on completing the Schedule of Assessments.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **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 |

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| --- |
| **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

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| **Analysis Plan Narrative** |
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# Population

**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.)
* **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
* **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**

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| **Population Narrative** |
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# 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.)

|  |
| --- |
| **Inclusion/Exclusion Criteria Narrative** |
| 1. General Eligibility Criteria |
| Inclusion Criteria:Exclusion Criteria:Describe how will eligibility be determined: |

# Projected Enrollment

 **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; if any groups are specifically excluded provide justification.**

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| **Enrollment Summary Narrative** |
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# Advertising, Recruitment, and Screening

**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:*** In this summary, include the following:
	* **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 attachments section of the submission.
	* **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 attachments section of the Insight submission.
2. ***Specialized Recruitment:***
	* **If recruiting using social media platforms or advertisements:** Review [this guidance](https://emory.sharepoint.com/sites/InformationSecurityArchitecture/SitePages/List-of-OIT-Reviewed-Apps-and-Software-for-Research-using-Identifiable-Information.aspx?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:** Please refer to the instructions for using Research Match on our [website](https://irb.emory.edu/guidance/getting-started/study-submission.html)
	* **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 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:* 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)*.*

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

**Provide a detailed description of 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.)
	* **Clarify 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:* If screening consents are required then the following apply.** When applicable, a screening consent form must be submitted to the attachments section in the Insight sumission.
		+ **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)

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| --- |
| **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

**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 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 participants will 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://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html).
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 |
|  |

# 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 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.*

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| **Participant Results Reporting Narrative** |
| 1. Routine Results |
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| 2. Incidental Results |
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 **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.

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| **Study-Wide Result Reporting Narrative** |
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# 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).

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

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

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| **Benefits Narrative** |
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# 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.

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| **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 *à This is a complexity cat. A study, insert table 1*[ ]  No *à 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*à This is a complexity cat. B study, insert table 1*[ ]  No*à 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.**  |

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| **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.
5. ***Frequency of DSMB Meetings:*** *If there is a DSMB Charter, upload a copy to the attachments section in the Insight submission. Indicate frequency (e.g. annually, every 6 months, other: after XX number enrolled)*

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| **Data Safety Monitoring Parameters** |
| 1. Data Safety Monitors  |
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| 2. Subject Safety Monitoring |
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| 3. Subject Stopping Rules |
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| 4. Study Stopping Rules |
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| 5. Frequency of DSMB meetings |
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**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.
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.).

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| **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.
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| 2. External Reporting Plans |
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# References

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

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| **References** |
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