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1. Overview

Purpose

The purpose of these guidelines is to describe the process for approval of participants for study participation, regarding inclusion/exclusion criteria. Eligibility confirmation must be determined and documented before a participant can be enrolled into a study. To determine eligibility, always refer to the current, IRB approved version of the protocol, including any protocol clarification memos or letters of amendments. These guidelines apply to the Principal Investigator (PI) and designated research personnel conducting human subject research.

As a reminder, if there is significant new information pending IRB approval that could affect participants willingness to participate or mitigate risk of harm, the investigator is obligated to ensure appropriate selection and inclusion of participants.

2. Definitions

Source Documents: original documents, data, and records that document the existence of a research subject and the integrity of the research data collected.

3. Procedures

3.1 Prescreening Procedures

As part of determining a participant's eligibility there may or may not be prescreening procedures, depending upon the study and available information. Prescreening may include review of records, or intake forms obtained prior to consent, provided the process and data sources have been IRB-approved for the specific project and appropriate waivers obtained.

Prescreening activities are designed to determine whether potential participants meet the basic eligibility criteria for a study or project. There are certain activities that should **never** be included in prescreening to protect participants' privacy, rights, and well-being. These include:

1. Invasive Medical Procedures

- Prescreening should never involve invasive medical procedures such as blood draws, imaging, biopsies, or other intrusive tests for research purposes. These activities should only be performed after eligibility is confirmed and consent has been obtained.

2. Collection of Excessive, Irrelevant or Non-permitted Personal Information

- Collecting personal information that is not directly relevant to the study's eligibility criteria (e.g., unnecessary details about financial status, unrelated health information, or sensitive personal history) places potential participants at increased risk of harm. Data collection should be the minimum amount necessary to conduct the prescreening assessment.
- Collecting data must be conducted with the participant’s explicit consent or the appropriate IRB approval and relevant waivers (e.g., limited waiver of HIPAA for a chart review). Even in prescreening, whenever possible, potential participants must be informed about what data

is being collected and why, and they must consent to its collection (e.g., use of an information sheet prior to an interest survey).

3. Time-Consuming or Burdensome Activities

- Prescreening should not involve extensive or burdensome activities that require a significant amount of time or effort from potential participants without clear benefits or compensation.

4. Disclosure of Confidential or Sensitive Information to Unauthorized Parties

- Prescreening activities should never involve sharing a participant's personal or health information with third parties without consent or appropriate IRB waivers (e.g., partial waiver of HIPAA).

3.2 Review of Screening Documents

Ensuring participants are assessed for eligibility in a systematic, fair, and unbiased manner is crucial to participant safety and maintaining data integrity.

a) Ensure that the participant has signed the current IRB approved informed consent form and has been informed of any significant new study information that could affect participants willingness to participate in a trial and document the conversation accordingly (e.g., new risk information pending IRB approval of revised consent form).
b) Review screening documents to ensure that all screening procedures have been completed and that the participant meets all inclusion/exclusion criteria.
c) All laboratory reports, diagnostic reports, and original source records, as applicable, are available for documentation and review.
d) All screening documents are reviewed against the inclusion/exclusion criteria
    i) A copy of the inclusion/exclusion criteria or an eligibility checklist is used as a source document, labeled with the protocol number and participant identification number (see ORI-619 Supplement Eligibility Checklist Template).
    ii) The inclusion/exclusion checklist is completed by verifying each requirement against the data in the participant's medical record or source documentation.
    iii) The completed source document/eligibility checklist is kept with the participant's study record.
    iv) If external assessments (e.g., physician clearance forms, specialist clearance) are required for inclusion, ensure completion and review by individuals with appropriate expertise prior to enrollment or proceeding with study activities.
e) The participant's eligibility for enrollment is assessed and documented by the PI or qualified study personnel as delegated in the delegation of authority (DOA) log:
    i) If the participant meets the inclusion/exclusion criteria, their eligibility is documented in the checklist and supporting source documentation, and research activities can proceed.
    ii) If the participant does not appear to meet the criteria, enrollment does not continue.
    iii) If participant eligibility is unclear, clarification must be made with the study sponsor and PI in writing and documentation filed with the eligibility source in the participant's study records.
f) Any changes from the IRB-approved protocol for participant eligibility and enrollment must be approved by the IRB prior to participant enrollment.

3.3 Confirmation of Participant Eligibility for Study Participation

a) The PI or delegated personnel reviews the participant's screening data and compares them to the eligibility criteria, to determine if the participant qualifies for the study.
b) The PI or delegated personnel documents review of the participant's records eligibility of the participant for study participation, including physician clearance forms, specialist clearance, and other study documents as referenced in Section 3.2.
c) If a participant is eligible for study participation, they may be enrolled as per the study protocol.

3.4 Participant Notification

a) After the PI or delegated personnel determines eligibility of a participant, the study staff notifies the participant of their status.
b) If the participant is eligible, the study staff notifies the participant and reviews the study requirements with the participant, answering any questions.
c) If the participant is ineligible, the study staff notifies the participant that he/she is ineligible for participation in the study and may offer alternatives to participation as outlined in the informed consent form.

3.5 Screening & Enrollment Documentation

Ensure participant screening and enrollment is logged and appropriately documented (see ORI-619 Supplement Screening and Enrollment Log Template). Ensure this documentation and storage of information aligns with the study procedures and record storage/retention as approved by the IRB in the study protocol and consent form(s).

4. Responsibilities

4.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, and monitoring. For inquiries regarding these guidelines, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

4.2 Principal Investigator Responsibilities

The Principal Investigator retains overall responsibility for the study conduct, eligibility review, and delegating eligibility/screening procedures as appropriate to qualified personnel.

4.3 Study Personnel Responsibilities, as delegated by the PI

Study personnel, as delegated by the PI, are responsible for:

a) Completing screening procedures or ensuring that they are completed per protocol.
b) Reviewing eligibility criteria and maintaining original source documentation for inclusion/exclusion criteria.
c) Providing source documentation and eligibility documentation to the PI or delegated personnel for final review, confirmation, and enrollment.
d) Notifying participants if they were eligible for the enrollment in the study.

5. Resources

- ICH Guideline for Good Clinical Practice E6(R3)
- FDA Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects (October 2009)
- 21 CFR 50 – Protection of Human Research Subjects
- 45 CFR 46 – Protection of Human Subjects
- ORI-619 Supplement Screening and Enrollment Log Template
- ORI-619 Supplement Eligibility Checklist Template

6. Revision and Workgroup Members

6.1 Revision

Version 001/Effective Date 1/24/2025 – Original Document: Approval of Participants for Study Participation

6.2 Workgroup & Advisory Members

The Office for Research and Innovation appreciates the following individuals who served as Workgroup and Advisory Members:

Workgroup & Advisory Members	
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