PARTICIPANT REQUESTS FOR ACCESS TO RESEARCH DATA	SOP 11.1.06

1. PURPOSE & POLICY

The purpose of this SOP is to establish procedures for handling study participant requests to access their individual research data.

2. GENERAL INFORMATION

As a general policy, research study participants are not granted access to their individual research data. This is communicated to participants during the informed consent process and documented in the IRB-approved informed consent form.

Exceptions to this policy are rare and require prior IRB review and approval. Release of research data may only be considered under special circumstances, specifically when:

- There is a medically justified request for the data;
- The request is supported by a qualified healthcare professional; and
- The IRB determines that release of the data is appropriate and does not compromise the study, participant safety, or confidentiality protections.

Research data are collected for investigational purposes and may be incomplete, unvalidated, or not clinically actionable. Such data may require specialized interpretation and may pose risks of misunderstanding or harm if misused.

An incidental finding is a finding concerning a study participant that has potential importance to the health of the individual and is discovered while conducting research but is beyond the aims of the study. Incidental findings differ from participant requests for research data because they are investigator identified findings that may warrant consideration for disclosure, rather than participant-initiated requests for access to data.

The identification, evaluation, and potential disclosure of incidental findings involve distinct considerations and are not governed by this SOP. All incidental findings must be managed in accordance with the IRB's separate Incidental Findings SOP, which outlines criteria for assessment, communication, and documentation of such findings.

3. TRAINING

Other than the normally required and study specific training for all human subjects research, there are no additional specific training requirements associated with participant requests for access to research data; however, investigators should carefully read and follow this guidance.

4. PROCEDURES

A. Participant Requests

1. All participant requests for access to their research data must be directed to the Principal Investigator (PI) or study investigators.

2. Participants should be informed that access to research data is generally not permitted and this was described in the informed consent document. Investigators should provide a clear, respectful explanation of the rationale.

B. Escalation for Exceptional Requests

If the participant indicates a medical justification:

1. The participant must provide written documentation from a licensed healthcare provider explaining the justification for receipt of research data.

2. The PI/investigator will forward the request and supporting documentation to the IRB Administrator for review.

C. IRB Review Process

The IRB Chair, Institutional Official (IO), and Office of General Counsel (OGC) will review:

1. The medical justification of the request

2. Risks and benefits of releasing the data

3. Potential impact on study integrity and participant confidentiality

The entire IRB may be consulted for a final decision on providing participants with research data.

The IRB Chair, IO, and OGC may:

1. Approve the request with conditions

   If IRB approval is granted, only the minimum necessary data should be released. The data must include appropriate disclaimers regarding the research nature of the data and any releases recommended by counsel. The data should be provided to the participant's healthcare provider (preferred) rather than directly to the participant, unless otherwise approved. The release must be documented in the IRB study records.

2. Deny the request

3. Request additional information