Participant Withdrawal Policy

Purpose

This policy document is intended for San Diego State University (SDSU) investigators and research staff conducting human subjects research. It outlines investigator responsibilities and regulatory requirements when a participant withdraws from a research study, including how participant data must be handled and additional considerations for federally funded and FDA-regulated clinical trials.

This document synthesizes federal regulations and guidance, institutional standard operating procedures, and best practices reflected in peer institution policies.

Best Practices for SDSU Researchers

- Address withdrawal procedures clearly in the consent form
- Discuss data retention during the consent process
- Avoid making assurances about data destruction that cannot legally be honored
- Consult the IRB when withdrawals raise unexpected ethical or scientific concerns

Fundamental Principle: The Right to Withdraw

All human participants have the right to voluntarily withdraw from research at any time, without penalty or loss of benefits to which they are otherwise entitled. Investigators also may withdraw a participant for safety, non-compliance, or other protocol-specified reasons.

Withdrawal may involve:

- Complete withdrawal from *all* study activities, or
- Withdrawal from the *interventional component* only, while permitting limited follow-up or data use

Investigators must clarify the scope of withdrawal with the participant whenever feasible.

What Activities Must Stop at Withdrawal

When a participant withdraws from some or all components of a study, investigators must immediately stop:

- Study-related interventions or interactions to collect new data
- Collection of additional identifiable private information
- Observation or recording of private behaviors for research purposes

These activities must end unless the participant explicitly agrees (with appropriate consent) to continued non-interventional participation.

What Happens to Data Collected Before Withdrawal

General Rule (All Studies)

Data collected up to the point of withdrawal:

- **Must remain part of the study record** unless specifically stated in the consent
- **May continue to be analyzed** if analysis is within the scope of the IRB-approved protocol
- For unfunded research, an investigator may honor a participant's request to destroy or exclude data, unless an alternative is specifically stated in the consent.

Continued Follow-Up After Withdrawal

A participant who withdraws from the primary intervention **may agree** to:

- Safety follow-up
- Outcome assessments
- Medical record or chart review

To continue these activities:

- The participant's consent must be clear and documented
- The distinction between interventions and follow-up must be explained
- IRB approval of consent language is required if not already addressed in the original consent.

If the participant does **not** agree to any continued follow-up, investigators may not collect additional identifiable information.

HIPAA Considerations

For studies involving Protected Health Information (PHI):

- Participants who withdraw may revoke HIPAA authorization in writing only
- Data obtained before revocation may continue to be used and analyzed **only to the extent necessary to protect the integrity of the research**

(Note: FDA-regulated research always meets this standard of necessity.)

Federally Funded and FDA-Regulated Clinical Trials

FDA-Regulated Clinical Trials

For FDA-regulated research (including many federally funded clinical trials):

- Data may not be destroyed or excluded at participant request
- All data collected before withdrawal **must remain in the study database**
- This requirement exists to ensure scientific validity and participant safety

Investigators may ask withdrawing participants if they are willing to continue safety follow-up, but may not require it.

Non-FDA-Regulated Federally Funded Research

For federally funded studies not subject to FDA regulation:

- Retention and analysis of previously collected data is generally recommended
- For funded research an investigator **only with agreement from the funding agency may** honor a participant's request to destroy or exclude data

Biological Specimens

If a participant fully withdraws:

- Specimens already analyzed may remain in the dataset
- Specimens collected but **not yet analyzed** may generally not be analyzed after full withdrawal, unless the participant consents to continued use.

Investigator-Initiated Withdrawal

When an investigator withdraws a participant:

- The participant must be informed of the reason for withdrawal
- The investigator should explain available alternatives or follow-up options
- Continued safety follow-up should be requested when appropriate

Documentation and IRB Reporting

At a minimum, investigators must document:

- Date of withdrawal
- Whether withdrawal was participant-initiated or investigator-initiated
- Reason for withdrawal (if known)
- Whether withdrawal applies to all study components or only interventions

Withdrawals must be reported to the SDSU IRB at the next continuing review or study follow-up, or sooner if required as a reportable event.

Questions and Support

Investigators with questions about participant withdrawal or data retention should contact IRB@sdsu.edu before taking action that may affect participant rights or regulatory compliance.