

San Diego State University (SDSU)

Institutional Review Board (IRB)

Policy Title: Expedited Review of Retrospective Analysis of Identifiable Data

Policy Number: 26-001

Approved: 6/16/2026

Effective: 6/16/2026

1. Purpose

The purpose of this policy is to define the conditions under which the SDSU Institutional Review Board (IRB) reviews research involving retrospective analysis of identifiable data from prior research studies under expedited review procedures, consistent with 45 CFR 46.110.

2. Scope

This policy applies to all **non-federally funded human subjects research** submitted to the SDSU IRB that involves the retrospective review, analysis, or secondary use of identifiable private information or biospecimens originally collected for research purposes.

This policy does not apply to research that is federally funded or otherwise subject to federal agency requirements.

3. Regulatory Authority

- **45 CFR 46.110** – Expedited review procedures for certain categories of research

4. Definitions

- **Identifiable Data:** Information where the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

- **Retrospective Review:** Research involving analysis of data or biospecimens that were collected prior to the initiation of the proposed study.
 - **Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life.
 - **Expedited Review Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes.
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5. Policy

The SDSU IRB may review research involving the retrospective analysis of identifiable data collected during previous research studies under **Expedited Review Category 5** when all of the following criteria are met:

1. The research involves **no more than minimal risk** to participants.
2. The data or biospecimens were **collected prior** to the proposed research and no new data collection is planned.
3. The proposed activity is limited to **secondary analysis** of existing identifiable data.
4. Adequate provisions are in place to **protect confidentiality and data security**.

For the purposes of this policy, the IRB may extend the use of Category 5 to include identifiable data originally collected for research, provided the above conditions are satisfied.

The IRB retains discretion to require full board review if the study presents more than minimal risk or raises ethical concerns.

6. Limitation – Federally Funded Research

This policy **does not apply to federally funded research**.

Research that is funded, conducted, or otherwise subject to federal oversight must be reviewed in accordance with applicable federal regulations and interpretations of expedited review categories. The SDSU IRB will determine the appropriate level of review for such studies without applying this policy's interpretation of Category 5.

7. Determination

The IRB may:

- Approve the study under expedited procedures
- Require modifications prior to approval
- Refer the study to full board review

8. References

- 45 CFR 46 (Common Rule)
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