

Rowan IRB Guidance for Gift Card SSN Collection Exceptions

Purpose

This guidance outlines the requirements for Principal Investigators (PIs) and research teams seeking an exception to collect identifying information (including SSNs) for participant compensation via gift cards. To qualify for an exception, all three of the following criteria must be met:

1. The study data remain anonymous;
2. The IRB has determined that the participants constitute a vulnerable population, based on regulatory criteria or other criteria deemed appropriate by the IRB; and
3. Each subject receives no more than a total of \$50 for participation in the protocol.

Core Requirements

Protocols must clearly demonstrate that:

- Identifying information is collected only for eligibility and payment purposes
- Research data are anonymous
- There is no persistent link between identifying information and research data after payment is completed

Protocol Requirements for Exception Requests

The following elements must be explicitly addressed in the IRB protocol when requesting an exception.

1. Separation of Identifiable and Research Data

Protocols must describe how identifiable information will be:

- Collected and stored separately from research data
- Maintained in a different system from study responses
- Not retained within research datasets

Example:

- Screening/enrollment data in one system (e.g., Form A)
- Research data in a separate system (e.g., Form B or Rowan secure server)

2. Elimination of Persistent Linkages

Protocols must explain how the connection between identity and responses is prevented and removed:

- Assign a random participant code at screening
- Use a temporary linking document for payment purposes
- Delete the linking document after:
 - Participation is confirmed, and
 - Payment is issued

No identifiers may remain linked to research data after payment is completed.

3. Payment Tracking Requirements

Protocols must include a clear payment tracking process:

- Maintain a separate payment log
- Ensure payment records are:
 - Not stored with research data
 - Not linked to study responses

Payment logs must not include research data or survey responses.

4. Role-Based Access Controls

Protocols must describe how access to identifiable data is limited:

- Separate personnel responsibilities for:
 - Screening/enrollment/payment activities
 - Data analysis activities

Example:

- Researcher A's or Group A's work/tasks are only in screening/enrollment and not analysis
- Researcher B's or Group B's work/tasks are only in analysis not screening/enrollment

OR

- Define conditions under which data may be accessed only after:
 - De-identification
 - Aggregation
 - Removal of linking variables (e.g., IP addresses, timestamps)

Example:

Researcher A or Group A will have access to screening file/conduct enrollment and payment log, BUT can only participate in analysis when any of the following criteria is met:

- Dataset does not include any linking ID, time stamps, IP address, rare variables, or other data and variables that may lead to re-identification
- Aggregated data
- All screening data and information is deleted or permanently de-identified

5. Data Retention and Destruction

Protocols must specify:

- Identifiable data will be retained only as long as necessary
- Identifiers will be deleted or permanently de-identified after payment

Retention of identifiable information beyond payment must be justified and minimized.

6. Data Collection and Management Plan (Required Language)

Protocols must include language consistent with the following:

Identifiable information collected during screening and enrollment will be stored separately from research data and used only for eligibility determination and participant compensation. No identifiers will be included in the research dataset. Any temporary linkage between identity and participation will be destroyed after compensation is issued. Following this process, no information will remain that allows responses to be linked to individual participants.

7. Systems and Data Security

Protocols must identify:

- The systems used to store:
 - Screening/enrollment data
 - Payment information
 - Research data
- Confirmation that secure and approved systems are used

Consent Form Requirements

Consent forms must clearly state that:

- Identifying information (if collected) is used only for eligibility and payment
- Research data are collected without identifiers
- Identifying information is stored separately from research responses
- The link between identity and participation is temporary and removed after payment
- Participants may decline compensation if they prefer not to provide identifying information

Additional Considerations

Protocols requesting SSN-related exceptions must also:

- Justify the need to collect identifying information
- Address risks associated with handling sensitive data (e.g., SSNs)
- Describe safeguards to prevent unauthorized access and ensure data security