January 2025

# UPDATES AND REMINDERS

## Engaged in Research

- The IRB office has introduced a new form to determine whether Roseman University is engaged in research. This form applies to protocols where a Roseman Investigator is collaborating with external institutions. While the Roseman Investigator may be considered engaged in research, this does not automatically mean that the University is engaged as well. If an external IRB has reviewed the protocol and determined the level of risk, the Roseman Investigator may be able to bypass submitting a full IRB application or Initial submission and instead submit the 'Engaged in Research' form. This process aims to reduce unnecessary work for our Investigators and prevent duplication of efforts by multiple IRBs.

## When Investigators collect identifiable information to answer a research question:

- The collection of identifiable information affects which regulations must be followed by the IRB when reviewing the protocol.
  - The Investigator should expect to justify WHAT specific identifiable variables are being collected and justify WHY those identifiable variables will help answer the research question.

## Annual Review/Check-ins

- The Principal Investigator (PI) will receive a reminder email 30 days prior to an IRB protocol expiring.
  - The PI can also check their protocol approval/expiration dates on their dashboard in IRBManager.
  - Fill out the Annual Review/Check-in promptly to allow the IRB to complete their review without a lapse in approval.

## On the Initial Submission form, there is a question asking 'can the data being collected potentially re-identify a subject?':

- This question is not asking if an individual reading a publication of the protocol (poster, manuscript) could re-identify the data.
- This question is asking if anyone on the research team could re-identify the data.

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# WAIVER OF DOCUMENTATION OF CONSENT

- Are you stuck on the Initial Submission question asking about 'waiver of documentation of consent'? We hope one of the following responses may fit your protocol. If the response listed below applies to your protocol, feel free to use the verbiage!

- Does the research involve no more than minimal risk, and involve only procedures that do not require written consent outside of research?
  - Yes, this survey research is no more than minimal risk and would not require written consent outside of research.

- Is the consent document the only record linking the subject to the research?
  - Yes, the consent document would be the only record linking the subject to the research as we do not ask for demographic data or identifiers in the survey.

- Is the study's principal risk the potential harm resulting from breach of confidentiality?
  - Yes, breach of confidentiality and survey fatigue are the risks of this study. If required to obtain full informed consent, breach of confidentiality would be the principal risk.

- Explain how, in the absence of signed written consent forms, consent will be given.
  - Participants will be asked to read a Consent Cover letter. If the participant would like to participate they would “click-thru” to start the survey.

Visit our web page for more information at: https://www.roseman.edu/research/institutional-review-board/