ROSEMAN UNIVERSITY
INSTITUTIONAL REVIEW BOARD

June 2021

WHAT'S NEW DOS AND DON'TS

WHAT'S NEW

STARTING JULY 1, 2021

- Students will now be able to collaborate on research as 'contacts' on research protocols. They will no longer be submitting protocols in IRBManager. See our Roseman IRB FAQ page (after July 1, 2021) for an outline that students may use to help the research team draft a protocol under the tutelage of faculty.

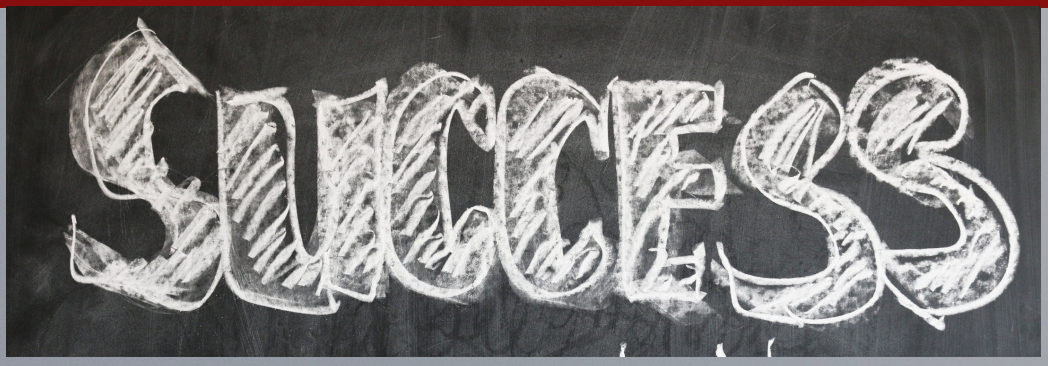
- For sponsored studies, Conflict of Interest (COI) questions will be added into IRBManager for all members of the research team. This will help the IRB in our review process.

- Faculty at Roseman who have an appointment containing 'Adjunct Faculty' will be asked to complete an 'Individual Investigator Agreement (IIA)' as part of the submission process.
  - Adjunct Faculty may continue to serve as mentors or submit their own protocol for review.
  - The IIA includes verbiage from the Faculty Handbook, which all Roseman faculty must abide by.

- For research involving surveys, if e-mail address will be collected (e.g. gift card distribution), the best practice is to collect the e-mail in a separate survey. IRB recommends to put a second survey link on the completion page of the research survey. See below for example.

  - "Below is a link to the survey which will collect your email address for distribution of the gift card. To better protect anonymity, we recommend saving this hyperlink and completing this second survey at a different time to avoid re-identification via timestamping mechanisms."

DOS AND DON'TS



PLEASE DO...

Based on successful submissions

- For clinical trials, IRB follows federal regulations for adverse event reporting. See below for a summary of the regulations.
  - Reporting to the sponsor:
    - Report promptly any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug.
    - If the adverse effect is alarming, the investigator shall report the adverse effect immediately.
  - Reporting to the IRB:
    - Serious and/or unanticipated adverse events (in IRBManager).
  - The PI is required to determine if the AE should be reported to the FDA.

PLEASE DON'T...

Based on submissions that were not successful the first time

- When making changes to any Word documents that are part of the protocol, please don't make the changes WITHOUT delineating what changes were made. The review process is more cumbersome. We recommend using 'track changes' and uploading a clean version and a track changes version to help make the review process more efficient.

CONTACT INFORMATION: IRB@ROSEMAN.EDU