

HAPPY NEW YEAR TO ALL OUR INVESTIGATORS! ON BEHALF OF THE IRB! WE HOPE YOU HAD A RESTFUL AND JOYOUS BREAK.

UPDATES & REMINDERS

Initial Submission form

- The Initial Submission form will look a little different this year.
- The IRB has added a few questions at the beginning of the form that will help the Investigator determine if their research project meets the definition of 'Human Subjects Research'.
- If your project does NOT meet the definition of 'Human Subjects Research' then you will no longer have to answer questions that don't apply to your project!
 - For those Investigators who have had to type 'N/A' multiple times before... you will be able to skip this cumbersome step.
- As a reminder, IF the IRB determines that your project is 'non-HSR' (non-Human Subjects Research) or 'not-HSR', the project does not fall under IRB purview. This means the research team should NOT use any IRB documents when carrying out their project.
- A reminder on when to select "Secondary research" in your application:
 - Most common type of HSR at Roseman University of Health Sciences
 - Can include data that will exist as part of routine educational practice and medical/dental care.
 - IRB is tasked to review fewer items with this type of research
 - If you aren't sure if your study qualifies as secondary research, please reach out to us (irb@roseman.edu)

ANNOUNCEMENT

- The IRB Office will be working with an Interim IRB Director from February to May 2023 so please plan accordingly for submissions.
- We appreciate our Investigator's patience during this time.

IRB MANAGER TIPS

- Sometimes, the research team is asked to clarify an answer to a question in the 'Initial submission' form.
 - When the question has been appropriately addressed, you will notice that the comment will be marked 'resolved'.
 - That is how the research team will know they have addressed the issue and the IRB Office has resolved the issue.
- If you are using our recruitment template, it is recommended to use the term 'may' instead of 'will' when describing to the recruitment pool the benefits of the study or the risk of the study.

DEFINITION REVIEW

- Think of inclusion criteria as a 'net' if you were trying to catch fish
- Think of exclusion criteria as the fish you have caught in your net that you will then 'toss out' from the study

- All studies that are determined to be HSR have an inherent risk to the human subject. It is not appropriate to answer 'no risk to human subject' in the application. If the research team need help identifying the risk, please contact IRB at irb@roseman.edu and we can help guide the investigators to identify the risk.