

ROSEMAN UNIVERSITY

INSTITUTIONAL REVIEW BOARD

April 25, 2020

Dear Colleagues:

Roseman's IRB office hopes you are all in good health. During this time of social isolation, we are still busy reviewing protocols and engaging our investigators... albeit in a virtual format. We are anticipating that you may have questions about how COVID-19 recommendations impact research here at Roseman. While most of the protocols that Roseman IRB reviews currently do not involve face-to-face interactions with human subjects, below are some highlights from the research community to consider during this time of recommended isolation.

- Pending IRB Applications for Human Subjects Research - The IRB will continue to review and approve submissions.
 - For studies that are approvable, but include face-to-face interactions with participants, the IRB will approve the study but explicitly note that enrollment cannot start until the pause in clinical research activities is lifted.
 - For research studies that involve no face-to-face interactions with subjects, the IRB will continue to work towards approval and these protocols may continue.
- New Enrollment into Existing Studies – We advise against new enrollment into existing studies in which participating includes face-to-face interaction.
 - The exception is studies with the potential for direct benefit, that is, benefits that are not available through standard of care.
- Follow-Up Visits for Existing Studies – We advise against any follow-up visits that require face-to-face interaction.
 - The exceptions are:
 - 1) The research holds the potential for direct benefit to the subject (e.g., investigational drug, devices or surgical procedure) and the interaction is required to deliver that potential direct benefit
 - 2) Collection of safety data (based on clinical judgment of the importance of the visit to detect potential adverse events)

We are learning right along with you on how the Coronavirus impacts our workflow so if you have any questions, please contact irb@roseman.edu



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Chair, Institutional Review Board