UVM Temporary Policy On Human Subjects Research Visits

UPDATE March 31, 2020

To facilitate UVM’s COVID-19 related research, effective immediately, UVM will allow enrollment and data collection in studies related to COVID-19 that do not hold the prospect of direct benefit. These studies need IRB approval before they can begin. These submissions must address why research activity will

1) not increase risk to participants;
2) not increase risk to non-clinical research staff; and
3) not require additional use of PPE resources necessary for clinical purposes.


PLEASE NOTE: TO ENSURE TIMELY REVIEW OF YOUR COVID-19 RELATED PROTOCOLS, PLEASE INCLUDE “COVID-19” IN THE TITLE OF YOUR PROTOCOL.

IRB Submission Expectations During the Temporary Policy

The recent announcement to the research community, UVM Temporary Policy on Human Subjects Research Visits, Effective March 16, 2020, updated March 31, 2020 above, represents a change in institution-wide procedures to address the current public health situation. Changes to research protocols as a result of the institution-wide procedure, that would normally require prior IRB review and approval are not necessary. This is LIMITED to the activities identified in the Temporary Policy, and ONLY applies to UVM IRB-reviewed studies.

The UVM IRB has determined that any changes necessary to avoid risk of COVID-19 spread are being done to eliminate an “apparent immediate hazard,” therefore, these types of temporary changes can be made using investigator discretion prior to IRB approval. If protocol changes were made to avoid hazard, those changes must be reported to the IRB either at time of next continuing review or by RNI.

While UVM IRB review is not necessary, any external IRB, regulatory agency or funder may require that the change be submitted for assessment.

NIH or other sponsors (government, industry, or non-profit) may require notification that select protocol activities or in-person visits of a funded research study will be paused.

If a continuing review progress report is due to the UVM IRB and the research study is impacted by the policy, information relating to the impact should be included in the progress report.

IRB approval of communications to study subjects explaining the impact to activities due to COVID-19 is not necessary. Examples of various tools and letters can be found on the Larner College of Medicine Commons Site.

New studies and follow-on submissions will continue to be processed and approved during this time, with a caveat that the current institution-wide Temporary Policy override IRB approvals to begin or continue work.