

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.

UVM Temporary Policy On Human Subjects Research Visits

Date: March 16, 2020

Effective: Immediately

In light of recent State of Vermont and University statements on COVID-19 and the rapidly evolving outbreak, UVM is issuing a temporary policy related to human subjects-related research visits. The focus of this policy is the safety of research participants. When applying this policy, the safety of staff and health care providers should also be considered when assessing whether a research visit should proceed.

Updates to this policy can be found on the [UVM COVID-19 webpage](#).

Applicability

This policy applies to all research studies conducted by faculty and staff of UVM/UVMMC (whether visits occur at a UVM/UVMMC site or not). This policy applies to visits in on-going studies and enrollment of new research participants. This policy does not apply to IRB-approved study activities that do not involve direct subject contact (e.g., chart review, Qualtrics/Redcap surveys, and remote interviews).

Participants

- Participant research visits, that are not part of a treatment trial, should be performed remotely (e.g., phone, Zoom, or other means) whenever possible. If that is not possible, the protocol dictated visit will need to be postponed until further notice.
- All human subjects research visits should be stopped unless otherwise determined to be of immediate benefit, as outlined below.
- The determination of whether or not research visits, as part of a treatment trial, provide an immediate benefit to the health and/or well-being of participants enrolled in a study must be made on a study-by-study basis. Investigators should consult with their department chair, clinic director, or division chief to make this determination. If you plan to use the Office of Clinical Trials Research resources, space and/or staff or the Clinical Research Center you

must obtain prior approval from the Senior Associate Dean for Research and Assistant Dean for Clinical Research Administration.

- Please contact the IRB if you are uncertain after consultation with your department/clinic leadership. Approval can be accomplished at the protocol level versus each individual visit. See guidance table below.
 - If visits are approved, research participants should be provided with information regarding the current COVID-19 epidemic and how best to reduce their risk of infection. This information may be provided in multiple forms suited to the type of contact, including a website link, a telephone script and an in-person handout. If possible, this information should be shared before the research visit.
 - Research staff must contact any participants enrolled in treatment trials prior to their scheduled visit to conduct screening. Participants should be screened for fever, cough, flu-like symptoms, and recent travel history per the CDC guidelines. If a participant self-reports fever or symptoms of respiratory illness, the research staff must discuss the participant's symptoms with the healthcare/study team prior to the visit to determine appropriate steps to ensure the continued safety of the participant.
- Enrollment of new patients on treatment trials should be allowed only if:
 - Participation in the trial is essential to a participant's health and/or well-being, as determined above; OR
 - The enrollment and longitudinal participant management can be conducted remotely for the duration of the COVID-19 outbreak; OR
 - All research visits occur in conjunction with standard of care ongoing medical treatment (i.e. inpatient studies where research participants are not traveling to attend research visits).

Research Personnel

- Research monitors must conduct their reviews remotely until further notice.

Institutional Review Board Requirements

Amendments

Changes to protocols to accommodate remote visits during the COVID-19 emergency have been determined by the IRB to meet the regulatory allowance that "change is necessary to eliminate an apparent immediate hazard" and therefore these changes do not require prior IRB approval. Please work with the IT department to assist with ensuring any technical means employed are secure.

Standard clinical screening for the COVID-19 virus does not require an amendment to the protocol.

IRB Reporting

Protocol deviations related to this policy do not require immediate reporting but must be reported at the time of the next continuing review, unless the deviation meets IRB reporting requirements as outlined in Section 18 of the IRB Policies and Procedures. This means you are expected to report any use of remote visits that are not currently part of your approved protocol at continuing review or by RNI.

All other reporting requirements remain in effect.