Subject: FW: Human Subjects Research update and GUIDELINES

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Sent: Monday, July 6, 2020 4:48 PM
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Dear Deans/ADRs:

Updates related to human subjects research are provided below. These guidelines **do not** apply to faculty working in or with the Larner College of Medicine (who have been issued separate, in depth clinical guidelines that address work in UVMMC and LCOM clinical spaces). The guidelines below are intended for researchers resuming or beginning in-person human subjects research not already included in the LCOM clinical guidelines and who are not using LCOM clinical spaces to conduct their research.

New Updates

1. On **July 6, 2020,** IRB-approved **human subjects and community-based** research will be allowed to resume across UVM. However, those studies that are suitable for remote conduct should continue to be done remotely.
2. Research taking place in the **Clinical Research Center, Shepardson 2 and OCTR, Arnold 3 research** should follow guidelines provided by LCOM for use of these spaces. To coordinate your research visits

with these facilities and resources, please contact the Office of Clinical Trials Research, 656-8992 or Clinical Research Center, 847-2793 to discuss your needs.

3. Researchers resuming in-person human subjects research or planning new research should note that changing COVID-19 risk conditions **may require a suspension of in-person activities on short notice**. Multi-wave/multi-interview protocols and accrued research subjects may be particularly impacted by such a necessity. Information to this effect should be made available to participants.
4. We will continue to monitor the COVID-19 pandemic and the directives of the State of Vermont and guidance from VT Department of Health and the CDC in order to guide our plans for clinical research activities.

Requirements for Approved Trials to Resume

- As a reminder, all human subjects research requires IRB review and approval. If the COVID-19 pause in research has resulted in changes in your protocol or processes you must submit a modification (MOD) related to these changes for IRB review and approval. Modifications would include changes to the protocol that facilitate remote visits or changes in planned research processes made to ensure the safety of the participants and/or research staff.
- The protocol must not exceed Vermont Department of Health "Sectors with Exposure Risk – Medium" to research personnel for COVID-19.
- All UVM research staff must complete the VOSHA training through Blackboard at https://www.uvm.edu/it/kb/article/vosha-training/.
- The PI should develop an **interim research plan for resuming the in-person research activities** that describes how proper distancing will be accomplished, facial coverings requirement, etc. The plan should address the use of resources that may be limited due to the COVID-19 pandemic (PPE, lab space, disinfectant, etc.) and may require documentation of availability and approval of the appropriate department head, division leader or designee.
- There are many resources located on the UVM Risk Management and Safety Office page to assist you with safety plan development, including a plan template, checklist and FAQs. The site is https://www.uvm.edu/riskmanagement/covid-19-laboratory-information.
- If the completed plan deviates significantly from your IRB approved protocol, please submit the plan as an addendum (separate document) to the current protocol. We anticipate that most protocols will require this modification.
- If you use campus facilities for your research project, you **must obtain approval of your safety plan from the** appropriate department head, division leader or designee *prior to* submission of modifications to the IRB.
- Research participants/potential participants must be pre-screened for risk of COVID-19 infection per UVM Guidelines, including signs of fever, cough, flu-like symptoms, and recent travel history (per the CDC and State of Vermont guidelines) by research staff **prior to** the research visit. This COVID-19 screening requirement applies to all types of research regardless of whether the research is conducted on or off campus.
- While procedures for performing the COVID screening do not require an IRB modification, it is important that participants be informed of screening requirements prior to coming to campus. The IRB has developed an information sheet to be sent to potential new or ongoing participants whose research visits have been paused. The information sheet informs the individual as to how they will be treated during their research visits, as well as how study procedures may be postponed to further alleviate safety concerns to both the individual participant and others.

If you have questions regarding these requirements, please contact your department-assigned IRB Research Analyst or send an email inquiry to **irb@uvm.edu**.

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