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From: IRB Key Personnel <IRBKEYPERSONNEL@list.uvm.edu> on behalf of Donna Silver <Donna.Silver@UVM.EDU>
Sent: Thursday, December 3, 2020 10:58 AM
To: IRBKEYPERSONNEL@LIST.UVM.EDU
Subject: Changes to Allowable Research Activities in the Clinical Setting UVM Medical Center/Health Network and the Clinical Research Center ~ Update Effective Monday, December 7th 5pm

Dear Clinical Trials Investigators:

Please find below some key updates regarding ongoing restrictions for clinical research **conducted at the UVM Medical Center/Health Network and the Clinical Research Center.**

1. As of Monday, December 7, 2020 at 5 pm, we are restricting **clinical research activities to interventions that offer potential for immediate benefit or contribute to COVID-19 research.** We are basing these restrictions on the current status of the COVID-19 pandemic. We will reevaluate this restriction frequently, but it is likely that we will remain at the current level of restriction for **at least two to three more weeks** while we monitor the anticipated post-Thanksgiving surge. Please appreciate that the level of restriction may change on short notice.

Clinical research activities include interventions that offer potential for benefit such as Drug/Device treatment trials and behavioral intervention trials, excluding phase I investigations. Whenever possible, participant research visits should be performed remotely (e.g., phone, Zoom, or other means).

If you are unsure if your research meets the definition of clinical research that offers potential for immediate benefit to the health and/or well-being of participants enrolled in a study, 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.

2. This clinical trials guidance for the UVM Medical Center/Health Network as well as the Clinical Research Center is distinct from the University of Vermont phased research guidance that was recently released on 11/23/2020. It is necessary to align research in these clinical settings with guidance from the UVM Health Network and the Department of Health. The recent UVM phase 4 guidance is intended to apply to human subjects research on the UVM Campus, in the community or other nonclinical settings.

Thank you,

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Director of Research, UVM Health Network

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