

From: LCOM Office of the Dean <COMOfficeOfTheDean@med.uvm.edu>

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To: McVeigh, Joann <Joann.McVeigh@med.uvm.edu>

Subject: Clarifications to the 2/3/21 Update to Allowable Research Activities in the Clinical Setting UVMMC/UVMHN & the CRC ~ on Behalf of Senior Associate Dean Jensen, CEO UVMHN Medical Group Claude Deschamps and Assistant Dean Kimberly Luebbers

Key updates regarding ongoing restrictions for clinical research conducted at the UVM Medical Center/Health Network, associated clinics, and the Clinical Research Center

As of Monday, February 1st the Office of the Vice-President for Research returned UVM campus research restrictions to level 3 (<https://www.uvm.edu/ovpr/covid-19-guidelines-research>). In view of recent downward trends in positive testing for COVID-19 in our state, we are further reopening clinical research activities at the University of Vermont Medical Center/Health Network (UVMMC/HN) with the below requirements.

Since December 7th, research at UVMMC/HN, associated clinics and the Clinical Research Center have been restricted to essential treatment trials with potential benefit to the participant. With this announcement, we are reopening clinical research activities to all clinical research at UVM Medical Center/Health Network provided the items noted below are fulfilled prior to resuming research activities.

- Researchers who oversee research activities on the UVM Campus, and will use these facilities in conjunction with research performed at UVMMC/HN, should review and update their area's approved return to campus plan to ensure any changes are made and all personnel are accounted for. These plans should be shared with the researcher's home department to ensure proper accountability. If you are unsure of your research program's status, please contact your department/center/program administrator.
- All UVM personnel (faculty, staff and students) are required to complete Training - [2021 UVM Coronavirus Refresher training](#).
- IRB approval of your research is required, including any protocol modifications necessary related to COVID-19, e.g. conducting remote activities, changes in testing/assessments to reduce exposure risks, etc..
- Access to/continued use of appropriate PPE as outlined by UVM and [UVM Health Network](#).
- Limit in-person activities to no more than one researcher and one participant per interaction per room.
- Continue the required COVID-19 screening of subjects 24-48 hours prior to their visit to campus if conducting in-person research activities. [Available screening tool](#).
- Whenever possible, participant research visits should be performed remotely (e.g., phone, Zoom, or other means).

- Undergraduate student engagement in the conduct of research can resume but must have prior approval and student must have completed UVM Researcher Credentialing to be able to conduct work at UVMHC/HN. Requests for review must be submitted by the mentor for each student via the UVM LCOM-based [online application](#). [UVM Researcher Credentialing](#) through the Office of Clinical Trials Research (OCTR) is required if the research utilizes UVMHC/HN resources/facilities, patients, or data. This applies to undergraduates engaged at research at both at UVM HN and in labs at UVM.
 - Undergraduates are still not allowed to support research in high-risk areas including ED, ICU, and COVID-19 wards at this time.

Please appreciate that the level of restriction may change on short notice depending upon the evolution of the pandemic and guidance from the State of Vermont.

This clinical trials guidance for the UVMHC/HN is distinct from the UVM phased research guidance that was recently released on February 1, 2021 (referenced above with URL). It is necessary to align research in the UVMHC/HN clinical settings with guidance from the UVM Health Network and the Department of Health. The recent UVM phase 3 guidance is intended to apply to human subjects research on the UVM Campus and in the community or other nonclinical settings.

Thank you,

Gordon L. Jensen, M.D., Ph.D.
Senior Associate Dean for Research
Director of Research, UVM Health Network

Kim Luebbbers, MSHS, RN, BSN, OCN
Assistant Dean for Clinical Research
Administrative Director, Clinical Research Center
Director, Office of Clinical Trials Research

Claude Deschamps, M.D.
President and CEO
UVM Health Network Medical Group