The University of Vermont

THE University of Vermont HEALTH NETWORK

COMMITTEES ON HUMAN RESEARCH
NEWSLETTER – MAY 29, 2020
SPECIAL ISSUE – RESUMPTION OF HUMAN SUBJECT RESEARCH

The following communication regarding resumption of research **applies to all departments** across the University and **replaces** the *UVM Temporary Policy on Human Subjects Research Visits (March 31, 2020)*. Questions regarding resumption of research for LCOM departments can be addressed as noted within the email. Questions from other UVM departments may be addressed to RPO@uvm.edu.

May 29, 2020

Update on current status of clinical research activities

Dear Clinical Investigators and Staff:

The UVM Medical Center and Health Network have begun gradual reopening steps related to clinical services. The COVID-19 pandemic has presented many challenges for the clinical research community. Our approach to reopening of clinical research activities must be guided by the directives of the State of Vermont and guidance from VT Department of Health and the CDC. We must also be in close alignment with the reopening plans for the Medical Center/Health Network. A working group comprised of clinical research leadership and investigators that was charged by Claude Deschamps, President and Chief Executive Officer, Executive Vice President, The University of Vermont Health Network Medical Group and chaired by Gordon Jensen, Director of Research for the UVM Health Network, has begun to develop plans for a cautious, phased reopening of clinical research activities for the Medical Center/Health Network. We will keep you apprised as things progress.

1. **Update on hospital and clinic-based human subjects research treatment trials**

Effective June 1, 2020, we will allow resumption of IRB-approved treatment trials including those studies where research participants are traveling for the sole purpose of attending research visits. IRB-approved COVID-19 related research activities may continue. However, those clinical studies that are suitable for remote conduct, should continue to be done remotely.

Requirements for approved treatment trials to proceed

- 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.
- The protocol must not exceed Vermont Department of Health "Sectors with Exposure Risk – Medium" to research personnel for COVID-19.
- Use of clinical resources (space and PPE) that may be limited due to the COVID-19 pandemic requires documentation of availability of PPE and approval of the clinic director as well as the appropriate department head, division leader or designee.
    - Please appreciate that as clinical patient care activities begin to ramp back up, resources may not be available to support some clinical research activities in these settings. PPE use for research activities must be carefully considered and availability of adequate supplies must be confirmed prior to study initiation. In some cases, the conduct of aerosolizing procedures (e.g. Pulmonary Function Testing) will require specific PPE and at this time the use of negative pressure rooms. Research protocols engaging in these types of procedures may need to be reviewed by the PPE Committee at UVMMC or at a minimum a discussion with the lead contact of the PPE Committee is required. Researchers should contact Travis Beebe-Woodard to discuss specific protocol procedure requirements.

- All clinical research personnel must complete the UVM Heath Network VOSHA Training Curriculum in Cornerstone. This training includes VOSHA requirements as well as current information from the CDC, Vermont Department of Health and UVM Health Network policies and procedures. Unfortunately, the additional information on UVM Health Network clinical policies and procedures is not available in the University of Vermont version (in Blackboard) of the VOSHA training. Therefore, completion of UVM VOSHA training will not, in this case, substitute for the UVM Health Network VOSHA Training Curriculum in Cornerstone. To access this UVMHN training, log onto Cornerstone and type "VOSHA" in the search bar.
- Treatment trial participants will need to be screened for risk of COVID-19 infection per UVM Medical Center/Health Network protocols. Research participants must be screened for fever, cough, flu-like symptoms, and recent travel history per the CDC guidelines by either clinic or research staff prior to the research visit. Researchers should coordinate screening efforts with the clinical screening procedures associated with a clinical visit. Screening efforts should not be duplicated. For research only visits, the researcher or their designee is responsible for prescreening participants. Certain procedures warrant COVID-19 testing and quarantining of participants 72 hours prior to the procedure or visit. Any participant who tests positive for COVID-19 should not be brought into the hospital or clinic for research related activities until resolution of their infection. Information regarding participant screening, screening resources and institutional requirements related to screening and testing are available here.

2. **Non-Treatment Trials and Community-based human research** – Non-treatment trials and Community-based human research activities must continue to be done remotely at this time.

3. **Clinical Research Center, Shepardson 2 and OCTR, Arnold 3 research** – Research involving these facilities and resources are not yet fully open or available. Please contact the Clinical Research Center, 847-2793 to discuss any plans that you may have that may require use of these facilities and resources.

Currently, we are able to resume specific, approved research activities; however, depending upon the evolution of the COVID-19 pandemic and associated resource needs, it is possible that we may need to ratchet down activities on short notice. 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.

We are still unable to allow *guests* on campus, e.g. vendors or monitors, please continue to conduct monitoring visits remotely until such time this policy has been lifted.

Depending on how things progress, we will consider further expansion of allowable clinical research activities on June 30, 2020 and again at 4-week intervals thereafter.

If you have questions regarding these requirements please email or call either the Office of Clinical Trials Research, 656-8990 or the Clinical Research Center, 847-2793.

Thank you,

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