From:	LCOM Office of the Dean
To:	Vicki Gilwee
Subject:	Reopening of LCOM and UVM Health Network Clinical Research Activities - Phase II - On Behalf of Senior Associate Dean Gordon Jensen and Assistant Dean Kimberly Luebbers
Date:	Monday, July 6, 2020 12:58:02 PM
Attachments:	Research_Participant_COVID-19_Screening Tool.pdf Checklist for Clinical Trials to Resume 07-06-2020.pdf

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Dear Clinical Investigators and Staff:

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 guided plans for a cautious, phased reopening of clinical research activities for the LCOM and Medical Center/Health Network.

New updates

1. On **June 1, 2020**, we allowed resumption of IRB-approved **treatment trials** including those studies where research participants are traveling for the sole purpose of attending research visits.
2. Effective **July 6, 2020,** we will allow resumption of IRB-approved **non-treatment trials and community-based** human research. However, those clinical studies that are suitable for remote conduct, should continue to be done remotely.
3. **Clinical Research Center, Shepardson 2 and OCTR, Arnold 3 research** – The clinical research spaces are in the process of reopening with new guidance and requirements related to use of the space and resources, e.g. cleaning, PPE use, maximum room occupancies, etc.. To coordinate your research visits involving these facilities and resources please contact the Office of Clinical Trials Research, 656-8992 or Clinical Research Center, 847-2793 to discuss your needs.
4. At this time, **study monitors are not allowed** in UVM Medical Center/ Health Network facilities. Please continue to conduct monitoring visits remotely until such time this policy has been lifted.
5. 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**. You should implement your clinical research activities with that in mind and consider that it is possible that accrued research subjects may not be able to complete protocols.
6. 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 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. Modifications would include changes to the protocol to facilitate remote visits or changes in processes 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.
- 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.
- Completion of the UVM Health Network VOSHA Training Curriculum in Cornerstone is required for those clinical research personnel interacting with study participants in UVM Medical Center, Health Network or Clinical Research Center facilities. The curriculum in Cornerstone 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 and so it will not meet the above training requirement and cannot be substituted. To access this UVMHN training, log onto Cornerstone and type "VOSHA" in the search bar.
- Research participants/ potential participants will need to be screened for risk of COVID-19 infection per UVM Medical Center/Health Network protocols. 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. If the research is part of a clinical visit, then researchers should coordinate screening efforts with the clinical screening procedures associated with the clinical visit. Screening efforts should not be duplicated. For research only visits, the researcher or their designee is responsible for prescreening participants. This COVID-19 screening requirement applies to all types of research regardless of where the visits are conducted.
- Certain procedures warrant COVID-19 testing within 96 hours and quarantining of participants 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, protocol reopening checklists and institutional requirements related to screening and testing are available here.

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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