To: WVU Health Science Center Clinical Research Investigators and Coordinators

From: Sally L. Hodder MD, Assoc. Vice President, Clinical and Translational Research, WVU HSC

Re: Additional Recommendations for Health Sciences Center Clinical Research

Date: May 8, 2020

In March, the SARS CoV-2 pandemic necessitated recommendations for WVU Health Sciences Center clinical research investigators to ensure research personnel and participant safety by minimizing on-site visits. The March recommendations included pausing enrollment of open clinical studies as well as not opening new studies to enrollment unless related to COVID-19 or with a waiver granted by the COE.

In order to continue protection of research participants and research staff during the COVID-19 pandemic, the following tiers and timelines for reinstating enrollment of study participants on the WVU Health Science Campus are recommended. Noteworthy, however, is that in-person visits should take place only at the PI's discretion. Where possible, continued remote visits should be considered unless in-person visits are necessary to monitor subject safety, is part of a treatment plan, or coincides with a patient care visit. When needed, investigational product can continue to be shipped to participants using appropriate measures.

Currently Operational

- Human subject research for which a waiver has already been obtained or that is COVID-19 related research.
- Clinical studies considered to provide direct benefit to participants (ie. therapeutic intervention that is life-saving or disease-altering) and for which there are no appropriate alternative clinical treatments.
- Expanded access (compassionate use) drug or humanitarian-use device clinical studies.

Tier 1: May 11, 2020

- Registry studies for which onsite visits are not required beyond what is needed for standard of care.

Tier 2: May 17, 2020

- Reopen enrollment in studies that had been previously open to enrollment prior to implementation of COVID-19-related research restrictions.
- Conduct any necessary on-site visits for previously enrolled participants.

Tier 3: June 1, 2020

- Open enrollment in "new studies," i.e., those that had not yet opened to enrollment prior to implementation of measures restricting research due to the pandemic.

Principal Investigators (PIs) and their study personnel should continue to screen participants for COVID-19 symptoms prior to the participant coming to the study site for a visit. Study participants with symptoms should be referred to their healthcare provider. Measures to prevent exposures to study staff and other subjects must be instituted. Subjects should be instructed to wear a mask to the visit and must be provided with a mask if they come to the visit without a mask. COVID-19

testing of participants and research personnel must be performed prior to any study procedures involving increased risk of aerosol production or increased risk of transmission by prolonged close contact where use of personal protective equipment (PPE) is not possible or in cases where the participant has symptoms.

Human subject research studies should not be restarted if there is a lack of resources to safely conduct all activities. It is expected adequate PPE, supplies and staffing will be available to ensure safety of research personnel or participants, continuity of therapeutic intervention, and monitoring of participants. The PI must be available to provide appropriate oversight for all active studies. If an investigator needs to make a change to research plans in order to eliminate apparent immediate hazards to research participants, these changes can be made and then reported promptly to the IRB and to the sponsor if applicable.

Federal, State and local public health and hospital policies must be followed for all interactions with human subjects. Training should be performed to ensure research personnel understand personal PPE requirements and procedures for effective use. Any PPE used by research personnel or participants must be provided by WVU or affiliated hospital system.

For instructions on how to properly use PPE visit https://www.cdc.gov/hai/pdfs/ppe/PPE-Sequence.pdf

For additional resources for healthcare providers, researchers, faculty and staff of WVU visit WVU Coronavirus website at https://coronavirus.wvu.edu/ .

Other useful websites include:

CDC: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html

WV Department of Health and Human Resources: https://dhhr.wv.gov/COVID-19/pages/Provider-Resources.aspx

For clinical trials, external monitors from Sponsors or Clinical Research Organizations (CRO) can return to performing on-site visits only when restrictions to hospital visitors and telework requirements for the University personnel are lifted. Monitors must be presented with and follow precautionary measures in place to prevent the spread of COVID-19. Remote monitoring visits, with the exception of site initiation visits, are recommended to continue where possible.

The very real possibility remains that a new phase of the pandemic may create a renewed need for more restrictive clinical research procedures that will be disseminated.

If you have questions, please do not hesitate to contact Shelley Welch or Tanya Moran, Co-Directors, Clinical Trials Center of Excellence.
shelley.welch@hsc.wvu.edu (304-293-7348)
tanya.moran@hsc.wvu.edu (304-293-0216)