

To: WVU Health Science Center Clinical Research Investigators and Coordinators

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

Date: November 16, 2020

Re: **Additional Recommendations for Health Sciences Center Clinical Research**

The purpose of this memo is to update current recommendations related to clinical research for purposes of ensuring continued safety of research participants and study personnel. This memo is in response to accelerated spread of SARS CoV-2 across West Virginia, including Monongalia County, and increases of COVID-positive patients in the local health system.

Relevant to non-COVID clinical research, investigators should carefully consider the risk-benefit ratio of conducting on-site participant visits unless required for ongoing standard of care or to ensure participant safety or essential therapy in relation to the study. COVID-related clinical research should proceed as planned. Appropriate measures should be followed to ensure safety of research personnel and participants.

Further guidance will be provided if there are continued increases in SARS CoV-2 spread that warrant halting certain research activities.

As a reminder, remote monitoring visits for clinical trials should be performed, unless there is a critical need for an on-site visit. For on-site visits:

- 1) Monitors should be pre-screened (prior to arrival in Morgantown) for symptoms consistent with COVID-19 and, if present, the external monitor is not permitted to conduct the monitoring visit on-site.
- 2) Masks must be worn by all visiting monitors at all times when present in any of the WVU Medicine buildings, the Health Sciences Center, and on the campus.
- 3) Adequate space to permit appropriate social distancing must be provided for all monitoring visits.
- 4) Areas and equipment used by the external monitors must be meticulously wiped before and after the visit with appropriate disinfectant.
- 5) Monitors are prohibited from any areas where there are known COVID-19 patients. Please ensure that any required tours avoid patient care areas with COVID-19 patients.

Federal, state/local public health and institutional policies, including PPE/mask-wearing and screening requirements, should continue to be followed. Refer to the following websites:

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>

WVU Coronavirus website: <https://coronavirus.wvu.edu/>

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](mailto:shelley.welch@hsc.wvu.edu) (304-293-7348)

[tanya.moran@hsc.wvu.edu](mailto:tanya.moran@hsc.wvu.edu) (304-293-0216)