

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: December 7, 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, it is recommended that at this time, investigators not open new human subject research projects and not enroll any new participants in existing studies UNLESS: 1) the research involves only standard of care procedures, 2) the research study will not require additional visits to the study site, or 3) is considered essential therapy. Investigators should continue to carefully consider the risk-benefit ratio of conducting on-site visits for current participants 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, and new COVID-19 trials may be opened and enrolled. Appropriate measures should be followed to ensure safety of research personnel and participants.

At this time, only remote monitoring visits for clinical trials should be performed. Due to restrictions to vendors for the local hospital system, no on-site monitoring visits should occur until further notice.

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

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.

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