

To: West Virginia University (WVU) Health Science Center Clinical Research Investigators and Coordinators

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

Date: February 3, 2021

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

The purpose of this memo is to update current recommendations related to clinical research. In response to the decreasing incidence of SARS CoV-2 across West Virginia, enrollment in all clinical trials or other research requiring in-person visits may resume on Monday February 8, 2021.

In December, accelerated spread of SARS CoV-2 infection in West Virginia necessitated pausing enrollment of most clinical study in-person visits unless the study was SARS CoV-2 related or involved essential therapy. As spread of SARS CoV-2 and number of COVID-positive patients in the local health system has recently decreased, the opening of new clinical trials and human research studies and enrollment of new study participants for research on the WVU Health Science Campus that did not meet the above criteria can be restarted from Monday February 8, 2021.

Noteworthy, however, is that in-person visits should take place only at the PI's discretion and only if measures are in place to ensure the safety of all involved. Where possible, continued remote visits should be considered unless in-person visits are required to enroll participants, monitor subject safety, or is part of a treatment plan. Noteworthy is that investigational product can continue to be shipped to participants using appropriate measures.

If onsite visits are conducted, the following procedures should be implemented, where applicable:

- 1) Participants should be pre-screened (prior to arrival in Morgantown) for symptoms consistent with COVID-19 and, if present, an in-person visit should not be conducted.
- 2) Masks must be worn by all participants, at all times when present anywhere on the WVU Medicine or WVU campuses, including any of the WVU Medicine buildings and the Health Sciences Center.
- 3) Adequate space to permit appropriate social distancing must be provided for all visits.
- 4) Areas and equipment used must be meticulously wiped before and after the visit with appropriate disinfectant.

In regard to study monitor or site assessment visits, we urge those visits to continue to be conducted remotely. However, if an in-person visit is absolutely necessary, all of the above procedures must be followed by visiting monitors. In addition, please ensure that any required tours avoid patient care areas with COVID-19 patients.

Federal, state/local public health and institutional policies (including mask-wearing and screening requirements) should continue to be followed to ensure safety of research personnel and participants. For further information, we refer you 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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