

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: January 5, 2022

Re: Additional Recommendations for Health Sciences Center Clinical Research

The purpose of this memo is to update current recommendations related to clinical research.

While the time course of the current Omicron variant surge is unclear, the following recommendations are in effect for the following month (until at least February 4, 2022), with follow-up recommendations to follow.

Where possible, we recommend investigators conduct remote/telehealth visits or delay study visits unless timely in-person visits are required to enroll participants, monitor subject safety, or are part of a treatment plan. In-person visits should take place only at the PI's discretion. Noteworthy is that investigational product can continue to be shipped to participants using appropriate measures. Study monitor or site assessment visits should be conducted remotely.

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

- 1) Participants should be pre-screened (prior to arrival in Morgantown) for symptoms consistent with COVID-19, any recent COVID exposure, or a recent positive COVID test. If any of these are present, an in-person visit should not be conducted.
- 2) N95 or KN95 masks must be worn by all participants and research personnel, 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. N-95 or KN-95 masks should be available to give to participants if needed.
- 3) Adequate well-ventilated space that permits 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.

Federal, state/local public health and institutional policies (including mask-wearing, screening and quarantine/isolation requirements) should continue to be followed to ensure safety of research personnel and participants. Refer to the following websites:

CDC: <https://www.cdc.gov/coronavirus/2019-nCoV/index.html>

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

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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