To: Clinical Trial Principal Investigators

From: Sally L. Hodder MD, Associate Vice President for Clinical and Translational Research, West Virginia University Health Sciences Center

Re: Research Response to COVID-19

Date: March 12, 2020

Cc: Clay Marsh MD, Vice President and Executive Dean, West Virginia University HSC
Fred King PhD, Vice President for Research, West Virginia University
Clinical Trial Principal Investigators, West Virginia University
Shelley Welch RN, Co-Director, Clinical Trials Center of Excellence
Tanya Moran, Co-Director, Clinical Trials Center of Excellence

Changes to research procedures should be undertaken to maintain participant safety during the COVID-19 pandemic. Close and frequent communication with the sponsors is essential if changes to procedures are necessary. With regards to required changes to a protocol, FDA regulations state:

> "Each IRB shall … (a) Follow written procedures for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval **except where necessary to eliminate apparent immediate hazards to the human subjects.**" 21 CFR 56.108(a).

Eliminating immediate hazards may include actions to reduce potential exposure to COVID-19. 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 to the WVU IRB within 5 days**. Please check with central IRBs for their reporting policy. We recommend investigators discuss all proposed changes with study sponsors.

We encourage investigators to take such steps as necessary to eliminate apparent immediate additional risks to participants which may entail revising protocols to provide for remote visits.

It is also recommended that Principal Investigators (PIs) and their study personnel screen research participants prior to that participant coming to the study site for a research-related visit. The following questions are suggested:

- Have you traveled in the past 14 days to China, Iran, Italy, Japan, South Korea, or other area with identified COVID-19 cases?
- Have you had any of the following symptoms in the past 14 days without diagnostic confirmation of a disease other than COVID-19 (e.g., flu, other chronic medical condition):
  - Fever
  - Cough

    - Difficulty breathing
- In the last 14 days, have you lived with, visited, cared for, or otherwise had contact with someone who is under investigation or has been confirmed for COVID-19?

If a participant answers yes to any of the above questions, it is recommended that the PI be notified, consideration be given to instituting measures to prevent exposure to study staff and other patients (including postponing or canceling the study visit), and direct the participant to contact their healthcare provider.

If you have questions, please do not hesitate to contact Shelley Welch, Co-Director-Clinical Trials Center of Excellence, shelley.welch@hsc.wvu.edu or 304-293-7348