ORD Guidance on Human Subjects Protections Issues Related to COVID-19
Concerns: Implementation of Clinical Screening Procedures for VA Research
Protocols and Modifying Study Procedures

Date: March 6, 2020

In response to VHA medical centers implementing clinical screening procedures for
COVID-19 infection and questions about modifying study procedures as a result of
concerns about COVID-19, ORD has been asked whether the addition of these clinical
screening procedures require amending VA research protocols. ORD is providing the
following clarifications to VA researchers:

- New mandatory VHA clinical screening procedures are not considered part of the
  “IRB approved procedures” for your protocol and therefore do not necessarily
  trigger the need for an amendment to the protocol. These screening procedures
do not constitute a change in IRB-approved research procedures unless you
choose to incorporate the data collected under the mandatory screening into your
study plan as part of the research, such as adding a research objective of
analyzing the results of the clinical screening procedures based on subject
demographics.

- Any changes in IRB-approved research procedures must be reported to the IRB
  and may not be implemented prior to review and approval by the IRB except
when necessary to eliminate apparent immediate hazards to the subject. This is
permitted by both the Common Rule (38 CFR §16.108(a)(3)(iii)) and FDA
regulations (21 CFR §56.108(a)(4)) in order to prevent investigators from
delaying the initiation of safety changes to eliminate apparent immediate hazards
to subjects. Beyond the regulation, VA also has a responsibility to ensure the
safety of its staff. As such, interim measures to eliminate immediate hazards to
staff, which may involve deviating from approved study procedures prior to
securing IRB approval, may be warranted.

- Examples of modifications or safety changes include, but are not limited to,
cancelling non-essential study visits, conducting phone visits in lieu of in-person
visits, conducting safety screening (initiated by the Principal Investigator) prior to
in-person visits occurring, or other changes as deemed appropriate to eliminate
immediate hazards to subjects because of the risk of exposure to this highly
communicable disease.

- If it is anticipated that immediate changes made to the study to eliminate
apparent immediate hazards will be sustained for a duration that would
practically allow for an amendment to cover such changes to be developed by
an investigator and reviewed and approved, as appropriate, by the IRB, then
approval of a protocol amendment must be sought.
In some cases, these protocol changes may involve the Principal Investigator temporarily stopping subject recruitment or placing a temporary hold on all study procedures. Principal Investigators are encouraged to communicate with the applicable ORD funding service, funding agency or sponsor as needed prior to initiating modifications to IRB approved protocols without IRB approval. For ORD funded projects, project modification opportunity (PMO) forms may be used to facilitate this communication.

For awareness, ORD is in the process of coordinating new research activities on COVID-19 as part of the larger national response being conducted by VA/VHA and other Federal agencies. Information will be provided separately on such activities. If an investigator is interested in initiating a new study protocol involving COVID-19 and/or who may have information that could be helpful for future research on this topic, please notify Dr. Vicky Davey (Victoria.davey@va.gov) and/or Dr. Jane Battles (jane.battles@va.gov) in ORD.

If you have questions about this guidance, please send inquiries to VHACOORDREGULATORY@VA.GOV.