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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

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(GUIDANCE UPDATED ON MARCH 10, 2020 TO REVISE MAILBOX FOR QUERIES ON THIS QUIDANCE)

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 practicably 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 funding agency or sponsor as needed prior to initiating modifications to IRB approved protocols without IRB approval.

- 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 ORDCOVID19@VA.GOV.