Frequently Asked Questions related to the Administrative Hold

1. Do I have to notify the study sponsor about this Administrative Hold?
Yes. Study sponsors should always be notified when an Administrative Hold is placed on your study. Additionally, you should place a note to file in the study regulatory binder.

2. Do I have to notify the VANEOHS IRB or the VA Central IRB about this Administrative Hold?
No. You do not need to notify the VANEOHS IRB or the VA Central IRB. We will notify them of this Administrative Hold. However, if the study sponsor initiates an Administrivia Hold, that must be reported to the IRB.

3. What is meant by critical interactions?
Critical interactions are defined for the purpose of this memorandum as interactions that involve a potentially lifesaving intervention (e.g., IV oncology drug delivery) or an intervention that is required to maintain essential activities of daily living or subject well-being, including mental health and suicide prevention research that cannot occur remotely.

4. Does this administrative hold apply to both inpatient and outpatient in-person interactions with human research subjects?
Yes. All studies are impacted by this administrative hold if the study involves non-critical, in-person research interactions.

5. If my study involves non-critical, in-person interactions but I would still like to continue other parts of the study, is there anything I can do?
Yes. If it is possible to modify your study procedures to eliminate apparent immediate harm to subjects to eliminate the in-person requirement (e.g., modify current procedures to include online, telehealth, or telephone recruitment, enrollment or follow-up visits) then you may proceed with your study after appropriate notifications. See ORD guidance on modifying study procedures, www.research.va.gov/resources/policies/guidance/ImplementingScreening-COVID19.pdf.

To report an exception to an approved research project due to taking COVID-19 safety precautions to protect the health and welfare of participants and study members, submit the COVID-19 Exceptions form to the VANEOHS IRB (attached). Submission of a protocol amendment will not be required unless these changes will be made permanent. If a study team does not need to take any precautions, no report needs to be submitted.

6. May I use my personal cell phone to contact my study subjects in order to reschedule visits or conduct follow up visits?
Yes. While it is preferred for you use your government phone for government business, if you do not have access to a government phone, there is no prohibition to use your personal phone for telephone calls. Do not use your personal phone to send text messages or emails regarding study visits. Use of *67 will block your number from caller ID.

7. Are there opportunities to initiate and or participate in studies related to COVID-19?
Yes. ORD has assembled a COVID-19 Steering Committee to help with coordinating and prioritizing new research that ORD will support on COVID-19 within VA and in collaboration with other federal agencies. Below are highlights of these efforts. The ORD COVID-19 Steering Committee has been identifying research activities to study, diagnose, treat, and manage COVID-19 infections. In addition to national studies done by NIH, DOD, or industry, the

committee will help coordinate VA-supported studies. This approach allows us to deploy resources quickly to most efficiently support the national research response to COVID-19. We ask that if you have started or intend to start a new study directly on COVID-19, or that is related to understanding this disease, please notify ORDCOVID19@va.gov . We ask for this information so we can ensure full awareness of VA's research activities, optimize communication within the VA research community, and match interests and research opportunities with investigators within and outside of VA.

Among the targets for VA research activities are multisite studies (e.g., clinical trials, specimen collections, etc.). We need to be prepared to have investigators and sites who are willing to support the nation in this way. If you or any VA colleague you know are interested, please email ORDCOVID19@va.gov with the subject heading "COVID-19 Research Site Interest." In that email, please provide information about the potential site Principal Investigator(s), site/facility name, and any other relevant details.

If you are interested in conducting COVID-19 research, you are asked to notify neal.peachey@va.gov and holly.henry@va.gov prior to contacting ORD.