ORD COVID-19 Frequently Asked Questions

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Administrative Hold Memo Questions

1. Does the ORD COVID-19 administrative hold apply to my study?

Yes, if your study is ORD funded (by BLRD, CSRD, HSRD, RRD, QUERI, CSP or MVP) and involves non-critical in-person interactions or interventions with human subjects as defined in the ORD Administrative Hold memorandum and below. If your ORD funded study involves non-critical in-person interactions and/or interventions with human subjects, an immediate administrative hold applies to the study. The Principal Investigator must review the study procedures of any ORD human subjects study he or she is conducting to determine if any of those interactions or interventions are non-critical.

2. Why is ORD placing an administrative hold on ORD funded human subjects studies involving non-critical in-person research interactions and interventions?

During this period of COVID-19 outbreak, any in-person human subjects research interaction or intervention may place research subjects, research study staff, or other VA patients/employees at risk, therefore, all non-critical, in-person interactions on all ORD-funded human subjects studies must be temporarily stopped in an attempt to decrease virus transmission. Furthermore, VA facilities are increasingly directing clinical resources to handling COVID-19 cases and their prevention. Therefore, an administrative hold will help with enabling these priorities to be met systematically.

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.

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4.   Does this administrative hold apply to both inpatient and outpatient in-person interactions with human research subjects?

Yes. All ORD-funded studies are impacted by this administrative hold if the study involves non-critical, in-person research interactions.

5.   Can I still hold group sessions for my research study?

ORD has placed an administrative hold on research activities involving non-critical, in-person contacts between study participants and VA research staff. If you can arrange to have your group meetings via a platform that is approved by the ISSO and you obtain IRB approval, you may continue. Please see the ORPP&E guidance on modifying study procedures: www.research.va.gov/resources/policies/guidance/ImplementingScreening-COVID19.pdf. Please note that if the change impacts the ability to maintain the integrity of the study, your sponsoring ORD service should be consulted before implementing the change.

6.   If my ORD funded 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, as well as the FAQs below. www.research.va.gov/resources/policies/guidance/ImplementingScreening-COVID19.pdf.

7.   If a PI needs to modify a research study (for example: temporarily suspend enrollment, cancel non-essential study visits, conduct questionnaires and follow ups by phone instead of in person), is a Project Modification Opportunity (PMO) required?

Diagram 1 (at the end of the document) is intended as guidance regarding when a PMO will be required for changes to studies impacted by COVID-19. If you are unclear as to whether a PMO is required, please contact your VA Portfolio Manager. The usual PMO requirements remain in place for all modifications to a study, independent of COVID-19 impact.

8.   If my ORD funded study involves only data analysis, does the administrative hold apply to data analysis activities?

No. Data analysis activities do not involve in-person research interactions or interventions with human subjects.

9.   Does ORD's administrative hold impact my ORD-funded study if it already only involves remote (online, telehealth, or telephone) recruitment, enrollment or follow-up visits?

No. There is no restriction on remote research study activities from ORD's administrative hold on non-critical in person interactions or interventions for human subjects studies.

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10.   Does the COVID-19 administrative hold apply to laboratory research, including any laboratory research involving biospecimens from human subjects?

This COVID-19 administrative hold is limited to non-critical, in-person research interactions with human subjects for ORD-funded studies. Analyzing biospecimens from human subjects is not an interaction or intervention with human subjects. However, facilities are encouraged to consider the criticality of the laboratory research and the risk to the employees to come to work if they travel on public transportation or must pass through populated patient areas.

11.   Are there other study activities I can do while my non-critical, in-person study interactions are placed on administrative hold?

All other approved study procedures may continue such as data analysis and other routine reporting that occurs by electronic transmissions.

12.   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.

13. If I place my study on administrative hold, what should I do?

All investigators who place their study on administrative hold must notify the research sponsor/ORD funding service, if applicable. If unfunded, notify the approving R&DC and/or overseeing subcommittee. The investigator should document in a note to file in their study records that they have:

> a. Implemented the administrative hold in response to the CRADOs message.
> b. Detail what study procedures are impacted by the administrative hold and what study activities may continue.

14. How do I contact my ORD research service?
For Biomedical Laboratory (BLR&D): VHABLRD-CSRD@va.gov
For Clinical Science (CSR&D): VHABLRD-CSRD@va.gov
For Health Services (HSR&D) or (QUERI):VHACO.HSR&D.ProjectModifications@va.gov
For Rehabilitation (RR&D): rrdreviews@va.gov
For Million Veteran Program (MVP): MVPComms@va.gov
For Cooperative Studies Program (CSP): CSP@VA.gov
For Career Development Awardees: vhacadereview@va.gov

15.   If my study is overseen by an IRB, do I have to report this administrative hold to the IRB?

Yes. The IRB must be notified in accordance with local policy or (CIRB policy) if certain study activities are being placed on administrative hold. This reporting must be done within 10 business days.

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16.   If my study is overseen by an IRB and I place certain activities on administrative hold, do I still need to continue other reporting activities to the IRB?

Yes. All other reportable actions in accordance with VHA Handbook 1058.01 must continue to be reported. If your continuing review is due, you must file your continuing review paperwork in accordance with your reviewing IRB's requirements. The VHA Central IRB has established a process for reporting changes to studies and reporting the administrative hold must follow that same process.

17. Should I screen my study participants for COVID-19?

If your VHA medical facility requires the screening of patients presenting for any type of clinical interaction, then you must follow your local guidance. If you are interested in adding the screening for the purpose of your research study, you must file an amendment with the IRB. www.research.va.gov/resources/policies/guidance/ImplementingScreening-COVID19.pdf

18.   What do I do if my medical facility director implements a more restrictive research policy?

The medical center director has final authority over actions occurring at his/her facilities. Please notify your ORD funding service or extramural research sponsor if additional restrictions are placed on your research project. If your facility has already notified ORD and provided a copy of the facility COVID-19 notification through the ORDCOVID19@va.gov email about your facility's policy(ies), no further action is required (please check with your Associate Chief of Staff for Research if they have taken this step).

19. If I have a good idea for a COVID-19 research, what should I do?

We are counting on the field to come up with good ideas. We would like you to submit your ideas to ORDCOVID19@va.gov.   We need to coordinate efforts that are alike in order to coordinate and maximize the VHA research response.

20. Can we collect patient generated data (surveys, questionnaires, etc.) via web-based forms?

VA has approval for two commercial systems outside the VA firewall for the express purpose of collecting patient generated data (surveys, questionnaires, etc.) via web-based forms. Both WESTAT and QUALTRICS can be contracted for using non-OIT funding (research funding). QUALTRICS is approved for FISMA moderate data and WESTAT is approved for FISMA HIGH data so you can select the services, price point and security level for your particular study. If this method of data collection is not part of your current IRB approved study procedures please see the instructions on modifying your study procedures. www.research.va.gov/resources/policies/guidance/ImplementingScreening-COVID19.pdf

21.   If I am a provider and I have an ongoing ORD-funded oncology interventional drug treatment trial involving Stage 3 cancer patients and a new patient comes to see me in clinic and meets my study enrollment criteria, may I enroll the patient in my study during this administrative hold?

Your study meets the criteria for a critical interaction because enrollment into the clinical trial may be potentially lifesaving. Screening and enrollment into your trial is not prohibited.

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However, you should evaluate your study procedures to see if any of the follow-up visits could be done remotely, additional risks are incurred by having participate during the COVID-19 pandemic and/or and if possible, modify the procedures as outlined in www.research.va.gov/resources/policies/guidance/ImplementingScreening-COVID19.pdf.

22.   My research doesn't involve interactions with patients but it does involve interviews or observations of clinicians. Does this need to be suspended?

Research that involves interactions with clinicians should consider the time demands on clinicians and possible exposures of research staff to infection risk. There may be some studies that can continue with telephone interviews as long as other concerns are managed. We advise you to consult local leaders who may already have issued guidance, but you should avoid research that imposes meaningful burdens on clinicians who are involved in specific aspects of the COVID response. (Note: this does not apply to future research directly aimed at studying the health system impacts of COVID).

23. Who should I contact if I have questions about an ORD funded project?
For most questions, your first point of contact should be your local research office. Ensure that you are following their prescribed protocol during work disruption. If additional guidance is needed the research office or the awardee may contact the Service through which the project is funded (see Question #13 above for contact email addresses), the Career Development mailbox, or the ORDCOVID19@va.gov mailbox.

Award Application and Submission Questions:

24. What will happen if ORD offices are closed at the time of research proposal submission?

ORD has a continency plan for review related staff to work remotely and continue the proposal review process. The field would be notified if any changes in the submission process were needed.

25. What If my facility's research programs are closed at the time of a deadline for research proposal submission?

Your local research office should notify you of its contingency plan. Some will be able to continue operations remotely (from home) while others will not. Those that are unable to continue to function remotely will notify ORD of that fact and will request an extension of deadlines (extensions will be considered on a case-by-case basis).

26. What if my research program is closed due to COVID-19 pandemic and I am unable to complete preliminary studies that are needed for my submission?

Facilities that are closed due to the pandemic should request a submission deadline extension and can be given a submission extension of up to 2 weeks.

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Funding Questions:

27. If research personnel paid on an IPA are unable to work during COVID-19 related laboratory closures will they continue to be paid?

Under the IPA agreement, payment is determined by the institution for whom the employee works, and continued salary payment would be based on local policies.

28. Does ORD have plans to fund research on COVID?

Solicitation for rapid research projects funded by HSR&D and CSR&D will be released this week with a two week turn-around. We are most interested in studies that can be executed quickly and inform current practices. You should get approval from your clinical COS for your project to ensure that it will not interfere with clinical activities.

29. Who should I contact if I have questions about an ORD funded project?

For most questions, your first point of contact should be your local research office. Ensure that you are following their prescribed protocol during work disruption. If additional guidance is needed the research office or the awardee may contact the Service through which the project is funded (see Question #13 above for contact email addresses), the Career Development mailbox, or the ORDCOVID19@va.gov mailbox.

30. Will I be able to contact my portfolio manager during a shut down?

The best way to contact your portfolio manager is via email. For the most part, portfolio managers will be working virtually. Please be patient and the portfolio manager will return your inquiry at their earliest convenience. If the matter is very urgent please make sure that it is clear in your message.

31. If a study is unable to continue operations due to COVID-19 facility closures, will ORD approve study budget extensions?

If a study is placed on hold for a period of time due to the COVID-19 pandemic, ORD will accept and review requests to provide additional funding at the end of the award period. At that time, the request should be submitted as a PMO. In the meantime, all investigators are urged to use resources wisely especially as study activities are on hold.

32. What happens if my research office is unable to complete and submit financial and Research Progress Performance Reports (RPPR) by the scheduled due date, due to the effects of COVID-19?

Please be sure to contact the assigned grants management and/or program official to let them know the reports will be late.

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Career Development Awards:

33. What do I do if my station is closed and I cannot conduct research for my Career Development Award?

Work with your supervisor to ensure you have telework capabilities to work from home. During this time, CDA awardees can engage in additional training activities such as, self-directed reading suggested by mentor(s) to acquire new knowledge; outline/draft manuscripts; develop/revise protocols; conduct analyses; plan and outline new experiments; participate in cyber seminars for additional training; draft Aims/research plan for Merit application for transition to independence (if applicable), etc.

34. If I have a Career Development Award, will I be paid while my research project is placed on hold?

Funding will continue during the disruption however, awardees are expected to be on telework during this time. Otherwise awardees would be on annual leave. Salary during a period of closure is a local HR/Fiscal decision.

35. Will my career development award be extended to make up for lost time?

Once operations return to normal, it is expected that awardees will work diligently to expedite activities on the project to help make up for lost productivity. Any request for extensions will be considered on an individual basis with appropriate justification. Consider asking for an extension just prior to the last 6 months of the award.

36. How do I deal with re-budgeting on my career development award, due to inactivity caused by COVID-19?

If the re-budgeting is an urgent matter, you may submit a PMO now. Otherwise please wait until later to submit a PMO.

37. May I charge non-refundable registration fees for conferences, symposia or seminars that have been cancelled due to COVID-19 to my career development award if they would have otherwise been allowable?

Yes.

Animal Research Programs

38. Does the COVID-19 administrative hold apply to animal research?

This COVID-19 administrative hold is limited to non-critical, in-person research interactions with human subjects. It is imperative that proper care continues to be administered to all VA research animals during the agency response to COVID-19 infections in people. Just as care of hospital and clinic patients must continue, care for the animals must continue. As containment procedures continue to evolve, all programs must remain in good communication with hospital response teams to ensure that any required employee PPE use or other practices are adopted as needed to ensure continued care for the animals.

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If your program is expecting an AAALAC site visit before May 8, 2020, contact AAALAC immediately to determine if AAALAC will postpone the visit. It is within the realm of possibilities that an agency decision to postpone all such visits could be forthcoming, but no such decision has been made at this time.

Please continue to read and monitor agency emails concerning ongoing containment practices. If there are concerns regarding the management of animals during this period, please do not hesitate to call 404-662-0200 (Mike Fallon) or email Michael Fallon (Michael.fallon@va.gov) and Alice Huang (alice.huang@va.gov).

39. Our program is experiencing challenges with maintaining our animal facility or supporting ongoing animal research activities due to COVID-19 restrictions. What should we do?
If the additional FAQ items on animal research do not resolve the problems, call Mike Fallon, CVMO, at 404-662-0200.

40. What is VA's position on maintaining operations in the animal facility?
The research animals in VA facilities must always be properly cared for, which includes provision of food, water, clean housing, and veterinary care as needed. The same mindset of fully protecting Veterans in the hospital should be in place for the research animals.

41. How do we deal with possible animal care staff shortages caused by COVID-19 infections, quarantine procedures, or other restrictive policies intended to prevent transmission between people?

Some ideas:
a. A very good approach is to immediately train some research technicians with animal research experience in the basic skills needed to care for the animals as backups, in case of disruptions in animal care staffing. The greatest threat to the animals is the loss of onsite personnel who know how to change cages, provide water and food, and provide treatments without compromising quarantine or special barrier procedures that could put many animals and studies at risk.   In addition to the animal care staff and veterinarian, research technicians have a great deal of knowledge about research animals, and in unusual circumstances, can be invaluable backups in maintaining animal care.
b. To reduce the opportunity for all caretaker staff to be exposed at the same time and to become ill at the same time, it is wise to consider varying the tours of duty so that all care staff are not present at the same time. Keep in mind that it is best to always have two animal care staff members present at all times, although this will not necessarily be possible in small facilities.

42. How can we mitigate the impact of COVID-19 containment procedures on VA funded animal studies?

a. Please reach out to groups conducting animal research and find out if there are any longitudinal studies underway with multiple time point interventions, or any studies that are heavily dependent on the current age or weight of animals. Find out what is needed and

coordinate with the Attending Veterinarian, VMU Supervisor, and animal care staff to make any needed arrangements so that those studies can continue to receive support.
b. For those studies that do not have time-sensitive studies, it would be wise to postpone them until the COVID-19 situation stabilizes, and the possibility of staffing disruptions decreases.
c. Likewise, it is best to postpone new animal research studies that are heavily resource dependent or would be compromised with the loss of just one or a few key staff members.

43. What if delays or unfortunate disruptions prevent an investigator from completing key animal studies, thus raising concerns about progress on a VA-funded project?

Please see the ORD plan for general research disruptions due to COVID-19, which will be considered on a case-by-case basis.

44. What about impacts on animal facility budgets?
Because the current VA cc105 subsidy is only about 30% of operating costs, any disruption in collection of per diems and other chargeable services could result in funding shortfalls. It is possible that a cc105 approach could be taken (across the board increase), but a major component of cc105 is the number of funded VA projects involving animals, so a case-by-case approach like that in item 5 might be better targeted to fairly address any problems. Some locales will certainly be impacted more severely than others. Please let Mike Fallon know of any problems you are experiencing as soon as possible (404-662-0200).

45. What about animal to human or human to animal transmission of COVID-19?
a. There were some initial reports that dogs might possibly carry the virus, but those reports appear to be false. The American Veterinary Medical Association has released the following guidance (https://www.avma.org/resources-tools/animal-health-and-welfare/covid-19):
"Out of an abundance of caution, it is recommended that those ill with COVID-19 limit contact with animals until more information is known about the virus. Have another member of your household take care of walking, feeding, and playing with your pet. If you have a service animal or you must care for your pet, then wear a facemask; don't share food, kiss, or hug them; and wash your hands before and after any contact with them."
b. Note: as is true of almost all pathogens, animals such as nude mice and SCID mice that have severely compromised immune systems could be at increased risk of becoming infected with COVID-19 (or any other virus). It is standard practice in the laboratory animal community to house these rodent strains under special conditions to carefully protect them from environmental infectious agents, which include the use of PPE such as masks and gloves for people who are handling them. Such practices should of course continue.

46. What about the use of Personal Protective Equipment in the animal facility?
Keep in mind that the very best safety practices are to wash hands frequently and to not touch the eyes, mouth, or face with unwashed hands. No changes in PPE practice in the animal facility are needed unless additional PPE is required per hospital policy or suggested by best practices to prevent the spread of COVID-19 between staff.

47. Where can I find more information about COVID-19 and research in VHA?

https://dvagov.sharepoint.com/sites/vacovhacomm/admin/projects/covid19

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ORD Request for Administrative Project Modification (PMO) Guidance (COVID-19 Impact ONLY)				
Change in Specific Aims	**Change in methods**	**Change in effort**	**Change in budget**	**Change in duration/ project extensions**
✔️ If the impact changes specific aim/s for study, please submit PMO to describe. Example: change intervention from in-person group to individual telehealth format	✔️ If method(s) change impacts specific aim(s), submit PMO for review. Example: change in-person assessment to mail-in questionnaire, or decreasing number or frequency of follow up assessments	❌ Changes in effort by PI resulting from COVID-19 impacts are **not** required at this time.	✔️ Only submit PMO for urgent budget changes directly related to COVID-19 that must be executed at this time.	❌ When it is known that a project extension and length of extension are needed, submit a PMO for review. Make the request no later than 3-months before current end date. Example: study holds on recruitment for 4 months, then restarts; request changes after study restarts

✔️	PMO required now			3/13/2020
❌	PMO not required at this time			

CONTINUE TO USE ORD Form (https://www.research.va.gov/resources/policies/guidance/ORD-ProjectModification.pdf) SEND to appropriate Service mailbox

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