Office of Research & Development

Frequently Asked Questions (FAQs) Regarding COVID-19 Impacts on Research

Table of Contents

Changes in Current Version (3.2)

- New animal research question added related to resuming research (Question #38)
- New budget/finance question added related to PPE (Question #42)
- Renumbered questions as needed.

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.

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

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.

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

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

online, telehealth, or telephone recruitment, enrollment or follow-up visits) then you may proceed with your study after appropriate notifications (IRB/RD, ORD service). 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 in response to COVID-19 is a Project Modification Opportunity (PMO) required?

Diagram 1, ORD Guidance for Project Modifications (PMOs), at the end of this 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. (Please note that usual PMO requirements remain in place for all modifications to a study that are not related to the temporary 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.

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, all local facility policies must be followed.

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

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, including career development awardees who place their study on administrative hold must notify the ORD funding service by email (see #14 below). The investigator should document in a note to file in their study records and notification to the ORD service 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.

While the administrative hold is in effect as of March 17, 2020, the PI should notify the ORD service within 10 days.

14. How do I contact my ORD research service?

For Biomedical Laboratory (BLRD): VHABLRD-CSRD@va.gov
For Clinical Science (CSRD): VHABLRD-CSRD@va.gov
For Health Services (HSRD) and/or (QUERI):VHACO.HSRD.ProjectModifications@va.gov
For Rehabilitation (RRD): rrdreviews@va.gov
For Million Veteran Program (MVP): MVPComms@va.gov
For Cooperative Studies Program (CSP): CSP@VA.gov

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

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.

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 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.

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

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. 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 does not 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-19 response. (Note: this does not apply to future research directly aimed at studying the health system impacts of COVID-19).

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

23. Do I need to modify the enrollment status for studies registered in ClinicalTrials.gov that were placed on administrative hold because of COVID-19?

For trials that are in the recruitment phase and affected by the administrative hold, we are asking investigators to evaluate the definitions below and, in general, keep the recruitment status as "Recruiting" or update the status to "Active, not recruiting" depending on the specifics of the trial. We are not recommending the use of "Suspended" for trials on administrative hold.

- *Not yet recruiting*: Participants are not yet being recruited
- *Recruiting*: Participants are currently being recruited, whether or not any participants have yet been enrolled
- *Enrolling by invitation*: Participants are being, or will be selected from a predetermined population
- *Active, not recruiting*: Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled
- *Completed*: The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, the last participant's last visit has occurred)
- *Suspended*: Study halted prematurely but potentially will resume
- *Terminated*: Study halted prematurely and will not resume; participants are no longer being examined or receiving intervention
- *Withdrawn*: Study halted prematurely, prior to enrollment of first participant

To remain in compliance with the Final Rule for FDAAA, the recruitment status for a trial needs to be updated within 30 days of a change. Although we want to avoid unnecessary work for researchers, we also want to ensure that trial records remain in compliance. Also, protocol information available to the public should be kept up-to-date.

24. 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 ORD Service through which the project is funded (see Question #14 above for contact email addresses).

25. Can email messages be sent by VA Investigators and approved VA research staff to recruit and communicate with VA subjects?

For information on the use of electronic mail and text messaging for recruiting and communicating with VA subjects, please refer to the guidance from July 28, 2018 titled, Draft Guidance on the Use of Electronic Mail and Electronic Text Messaging for Recruiting and

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

Communicating with VA Subjects in VA Research. While that specific guidance is still posted as draft, it can be used as the privacy, information security, and human subject regulatory issues have not changed that are addressed in the draft guidance.

There are multiple other questions included in the draft guidance related to use of email and texting in research that may be of help. It is posted on the ORD Policies and Guidance website at https://www.research.va.gov/resources/policies/guidance/draft-electronic-mailtext.pdf.

Please also refer to the Frequently Asked Questions: Institutional Review Board (IRB) and VA Research and Development (R&D) Committee Considerations for Use of Azure Rights Management Services (RMS) in VA Research located at https://www.research.va.gov/resources/policies/guidance/FAQs-Azure-RMS.pdf. Azure RMS can be used by VA researchers to send a secure email to communicate personally identifiable information and protected health information (PII/PHI) to VA subjects.

26. Where can I find information that details the process to resume ORD-funded in-person research subject interactions?

This information was emailed out to ACOS/Rs and AOs on June 2, 2020 and is saved on SharePoint.

27. I would like to continue virtual research appointments for the foreseeable future despite the lift of the Administrative Hold. I am looking into the communication methods listed in the "VA Video Communication Technology Research Memorandum" dated April 7, 2020. Are the methods listed in this memo still applicable despite the hold being lifted?

If you added the video procedures into your research activities in an effort to decrease immediate apparent harms to study subjects and now want to incorporate these procedures as an approved research procedure, you will need to check with your IRB on next steps. In addition to working with the IRB, if permanent changes in methods are being proposed, a Project Modification (PMO) is required (refer to Diagram 1).

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

Award Application and Submission Questions:

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

ORD has a contingency 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.

29. 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 their 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 and must be received at least 2 weeks prior to the scheduled deadline).

30. 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. Requests for an extension must be received at least 2 weeks prior to the scheduled deadline.

Funding Questions:

31. 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.

32. Does ORD have plans to fund research on COVID-19?

Solicitations for rapid research projects funded by HSRD and CSRD have been released and is located on the ORD COVID-19 SharePoint. We are most interested in studies that can be

executed quickly and inform current practices. Proposed projects should be discussed with the local facilities, including the Associate Chief of Staff for Research (ACOS-R), to ensure that the project will not interfere with clinical activities or impose meaningful burdens on clinicians who are involved in specific aspects of the COVID-19 response. For questions, please email VHABLRD-CSRD@va.gov (CSRD) or vhacoordcoin@va.gov (HSRD).

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

The best way to contact your portfolio manager is via email. 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.

34. 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. The request should be submitted as a PMO, no later than 3 months before the end of the award period. In the meantime, all investigators are urged to use resources wisely especially as study activities are on hold.

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. 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.

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

Animal Research Programs:

37. Where can I find Frequently Asked Questions (FAQs) about how animal research is being impacted by COVID-19?

The FAQs for animal research may be found on the VA animal research website at https://www.research.va.gov/programs/animal_research/.

38. Do each of my protocols have to be reviewed and approved for restart by the Subcommittee on Research Safety (SRS) and Institutional Animal Care and Use Committee (IACUC)?

The Administrative Hold was NOT placed on Animal and Lab research. We recommend that each facility develop a plan that is vetted by the IACUC and SRS to ensure that there is continuity and consensus in the process of ramping research at your facility. However, if your institution formally placed a hold on IACUC and/or SRS protocols then each protocol that was placed on administrative hold should be reviewed by the committee for restart.

Budget/Finance:

39. Do I need to set up an ACC and/or FCP for COVID-19 Research expenses?

Not necessarily. Your local CFOs have been instructed to set up ACCs and FCPs on the health care side to track additional expenses associated with COVID-19. In Research, we do not anticipate that the mission will incur additional expenses at this time due to COVID-19. If you and/or your research staff are pressed into service to support the health care mission, then appropriate expense transfers should be executed between your research FCP and the health care FCPs for any incremental cost your research service might incur. The potential exists that ORD will fund specific protocols associated with COVID-19. If that occurs, project titles will contain "COVID-19" in the project number and remarks for tracking purposes at the national level. For additional questions please contact ORD Director of Finance, Allen Dunlow at Sherman.Dunlow@va.gov.

40. When research staff are called to support the Medical Care response to COVID-19, how should the incremental cost be captured?

Any incremental cost incurred by the research appropriation FCPs as a result of supporting the medical care response to COVID-19 should be expense transferred to the appropriate Medical

Care appropriation/ACC/FCP established to capture COVID-19 expenses. VATAS should be annotated with the "COVID-19" note in the comments when appropriate.

41. Should cost incurred by the Research Appropriation (0161A1) and the Research Office/staff in support of the medical care support to the COVID19 response be captured and expense transferred?

Yes, Facilities have been instructed on capturing cost associated with COVID-19. The medical care side has received or will be reimbursed for COVID-19 expenditures. The CFOs have been provided guidance on what COVID-19 cost to track. Part of that guidance states "Employees reassigned from one position to another position to support COVID-19 such as 1) Clinicians reassigned to other clinical positions due to the postponement of elective procedures, 2) Non-clinicians reassigned to non-clinical positions due to the postponement of elective procedures, and 5) Employees reassigned from normal duties to incident command center and/or labor pool." There is a 3 and 4 in the guidance to CFOs but is probably not applicable to research. The research appropriation did not receive any supplemental funds to support the COVID response. As such all cost in support of COVID19 need to be expensed transferred to the appropriate ACC/FCP on the medical care side that is capturing these expenses. CDA recipients who may be pulled to full time clinical duties should have their salary expensed transferred accordingly.

42. Should the facility purchase all Personal Protective Equipment (PPE) required to enhance safety and protection for staff and patients/research participants as a result of coronavirus with available COVID19 Supplemental funding?

Yes, to maintain the locally established standards of protection, the facility should procure and purchase all PPE for all staff and patients/research participants using the COVID Supplemental funding. To maintain continuity, it is important that the same guidelines applied to medical care regarding PPE needs are also applied to the research community. Should the nature of a particular research protocol require enhanced PPE above this standard level provided by the facility, the respective research protocol can bear the cost of the enhanced PPE after concurrence from the facility.

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

Communication:

The following questions concern the COVID-19 publication notification process that ORD disseminated to the field on May 1, 2020.

43. Does this process replace the use of PubTracker for COVID-19-related publications?
No. It is an additional requirement. PubTracker is for notifications about articles already accepted for publication. For COVID-19 publications, we ask that you notify us at ORDCOVID19@va.gov about articles when they are *submitted* to journals, even if they have not yet been accepted. We are also asking for notifications on articles being posted as preprints on the web. If an item was previously submitted via email [when it was submitted to a journal, or posted online as a preprint], it should still be submitted to PubTracker upon *acceptance* for publication in a journal.

44. If I notified ORD of a COVID-19-related article when it was posted online as a preprint, do I need to provide another email notification when it is submitted to a journal?
Yes, an additional email notifying us of the change in status would be helpful and appreciated.

45. Does this special COVID-19 publication notification process apply only if I am the lead, senior, or corresponding author on a study?
As with the standard PubTracker process, we ask that VA investigators notify us of *any* article on which they are a coauthor. That said, we need only one notification per article. If VA coauthors coordinate among themselves, it is necessary for only one author to notify us and to keep us abreast of changes in status for that article.

46. Does the COVID-19 notification process apply only to ORD-funded research?
As with the standard PubTracker process, it applies to any COVID-19-related article reporting on what is considered "VA research." This includes all research by VA investigators while on VA time or property. VA investigators are those who do research approved by a VA R&D Committee, whether they are FT, PT, WOC, or on detail via IPA. Research can be funded by ORD or other VA or non-VA entities, or unfunded.

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

Additional Information:

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

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

48. The protected research time for PIs (Merit awardees and CADEs) may be impacted during the pandemic (for example, clinician investigators may be required to engage in additional clinical activities and non-clinician investigators may be recruited to the general labor pool at the VAMC). How is ORD addressing this?

ORD understands that PIs must follow local VAMC policies/guidelines and that there may be significant impacts on PIs' ability to adhere to the documented time commitment to their research projects. As indicated in Diagram 1, a PMO for change in effort on the study is not required at this time. Each ORD Service is committed to successful completion of currently-funded projects and will be receptive to PMO requests based on the impact of interruptions due to the pandemic. The timing of such requests is detailed in Diagram 1.

All ORD Services are offering no cost extensions (NCEs) with a duration up to 6 months for studies with end dates between April 30, 2020 and September 30, 2020. A PMO is not required. On May 4, 2020, the field will receive a spreadsheet populated with the studies that qualify. The station will document the required duration of the NCE, if any, on the spreadsheet provided.

Please note: the station must confirm that the proposed research will be completed by the end of the NCE, as no additional extensions will be allowed.

For studies that do not meet the criteria above, we expect to receive PMOs during the last year of the project and no later than three months before the end date (Diagram 1).

49. Given the pandemic, has ORD changed the requirements/timeline for requesting extensions in JIT for studies that are approaching the 180-day deadline?

No. The process remains the same for all ORD Services.

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding COVID-19 Impacts on Research

Biorepository:

50. I have a locally approved project that includes collections of biospecimens from COVID-19 patients as part of a clinical interventional study; the biospecimens will only be used for the specific protocol. Do I need to report this study collection to ORD?

No. If the collection of biospecimens from COVID-19 patients will only be used for the specific protocol, the collection should not be reported to ORD.

51. I have a locally approved project that includes collections of biospecimens from COVID-19 patients as part of a clinical interventional study; the biospecimens will be used for future studies. Do I need to report this study collection to ORD?

Yes. The project should be submitted on the R&DC Approved COVID-19 Research submission form.   If you have already reported the project, please edit the information to address the biospecimen question.

52. I have a locally approved project that includes collections of biospecimens from COVID-19 for future studies. Do I need to report this study collection to ORD?

Yes. The project should be submitted on the R&DC Approved COVID-19 Research submission form.   If you have already reported the project, please edit the information to address the specimen question.

53. How do I report to ORD collections of COVID-19 specimens obtained for research purposes that will be used for future research?

Please complete the biorepository survey (https://dvagov.sharepoint.com/sites/vacovhacomm/ORD_Surveys/Lists/BioRep_survey/overview.aspx)

54. Will ORD provide funding to support the collection of specimens from COVID-19 patients for research purposes?

A number of funding opportunities are available through ORD (https://dvagov.sharepoint.com/sites/vacovhacomm/admin/projects/covid19/SitePages/Research-Opportunities.aspx). At this time, ORD is not reviewing applications that are solely for the collection and storage of biospecimens from COVID-19 patients for future research use.

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

55. Is ORD planning to issue guidance and coordinate nationally a collection of biospecimens from COVID-19 patients for research purposes?

ORD has organized a work group to provide recommendations to the Chief Research and Development Officer on how specimens from COVID-19 patients should be obtained and stored for research purposes at a national level ensuring that human subjects protections, privacy, and ethical considerations are addressed. Additional information will be provided in the upcoming weeks/months.

Mayo Clinic Convalescent Plasma Expanded Access Program:

56. Where can I find Frequently Asked Questions (FAQs) about the Mayo Clinic Convalescent Plasma Expanded Access Program (EAP)?

The FAQs for the convalescent plasma EAP may be found in the [Expanded Access – Convalescent Plasma for COVID-19 Treatment](#) folder on the [ORD Notices & Guidance](#) page of the [ORD COVID-19 SharePoint](#).

ORPP&E Guidance on Human Subjects Protections:

57. Where can I find Frequently Asked Questions (FAQs) about the 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?

The FAQs for the 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 may be found on the ORD Human Research website at https://www.research.va.gov/resources/policies/human_research.cfm#covid19.

Office of Research & Development

Frequently Asked Questions (FAQs) Regarding
COVID-19 Impacts on Research

Diagram 1:

ORD Guidance for Project Modifications (PMOs) COVID-19 Impact ONLY				
Change in Specific Aims	**Change in methods**	**Change in effort**	**Change in budget**	**Change in duration/ project extensions**
If the PI is making a change in the Aims that is anticipated to be temporary due to COVID-19 then a PMO is not required. If permanent changes in Aims are proposed, a PMO is required.	If the PI is making a change in methods that is anticipated to be temporary due to COVID-19 (example: change from in person to telephone visits), then a PMO is not required. (Please see Question # 1-3 in the FAQs.) If permanent changes in methods are being proposed, a PMO is required.	Changes in temporary effort by PI resulting from COVID-19 impacts are **not** required to be submitted on PMO	Currently, only submit budget changes related to COVID-19 that must be executed at this time. For budget changes (such as cost extensions) that will be executed later, please make the request during the last year of the award and no later than 3 months before the current end date.	If a project extension is needed, submit a PMO for review. Please make the request during the last year of the award and no later than 3 months before the current end date.

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