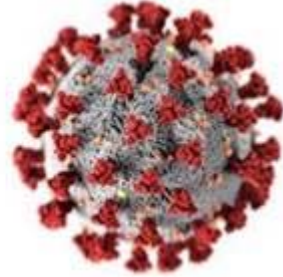


Subject: FW: ORD COVID-19 update

ORD COVID-19 UPDATE



April 13, 2020

In This Issue

[Message from the CRADO](#)

[Regulatory Updates](#)

[Research Activities](#)

[FAQs](#)

[Animal Research](#)

[Opportunities](#)

[Upcoming Events](#)

[Field Operations](#)

[Open and Active Studies](#)

[Useful Links](#)

Message from the CRADO

Dear ACOS-R&Ds, AOs, investigators and research staff:

As of Saturday, VA was [tracking](#) 3,754 Veterans with a COVID-19 diagnosis, and ORD has continued to step up research efforts focused on the pandemic. The past week has been an eventful one, and this newsletter will highlight a number of new developments. Please share this update with research personnel at your site who may not be receiving it.

I'd like to draw your attention to the following points in particular:

- **The COVID-19 pandemic is a unique opportunity to leverage VA research to address many critical questions.** To enable that, all ORD-funded studies are expected to include language in the consent process and HIPAA Authorization making clear that collected biospecimens and data may be used for future research studies. See below, under [Regulatory Updates](#), for further guidance.
- **ORD is working to coordinate the efforts of local VAMCs that are establishing COVID-19 biobanks and registries.** Dr. Holly Krull, deputy director of BL&RD, is leading a work group focused on this issue, and we expect to issue guidance in the near future.

- **ORD is supporting a new clinical trial looking at the impact of hydroxychloroquine and azithromycin on COVID-19 patient outcomes.** The project is being led by teams at the Cleveland and Durham VA medical centers, in collaboration with Duke University, and some 35 VA sites have already expressed interest in participating. More details can be found [below](#).
- **The VA COVID-19 Cohort Master File has been distributed to the VA Informatics and Computing Infrastructure (VINCI) environment and is available for use by VA researchers.** The same file has also been shared with DOE's Oak Ridge National Laboratory to support collaborative VA-DOE research. The dataset will be updated regularly by VA to reflect current COVID-19 caseloads. We believe these data will enable important studies that shed light on the progression of COVID-19 and point to the best preventive and treatment strategies.
- **Each week, I ask that you use the [form](#) on our SharePoint site to report any new R&D Committee-approved COVID-19 research at your site that may have come about through individual facility or investigator contacts.** Please enter any relevant information by noon on Thursday, April 16. This will help give us a complete picture of what COVID-19-related research has been approved by R&D Committees across the enterprise and improve our planning and coordination.

This week, I'd like to give a shout-out to the Evidence Synthesis Program (ESP), part of HSR&D. As noted further down in this newsletter, they are doing great work in producing high-quality evidence reviews on COVID-19 in a very tight timeframe. Also, the Portland ESP group that serves as the Coordinating Center for the nationwide network of four ESP centers has done a wonderful job of setting up a new website to provide easy access to systematic reviews and syntheses of available evidence on COVID-19 to address specific questions. Some of the information they are compiling is not yet published in the medical literature, and cannot easily be found on other sites, such as those of the WHO or NIH. As such, it promises to be a valuable resource for researchers in VA and beyond. See [below](#) for more details.

Thanks for your continued support and cooperation, and for the important work you are accomplishing on behalf of Veterans and the nation.

With gratitude,
Rachel

Rachel Ramoni, DMD, ScD
Chief Research and Development Officer (10X2)
Department of Veterans Affairs



- The COVID-19 pandemic is a unique opportunity to leverage the VA research system to answer many questions. To enable that, all ORD-funded studies are expected to include language in the consent process and HIPAA Authorization making clear that collected

biospecimens and data may be used for future research studies. All interventional and observational studies involving human subjects should include language on the need for researchers to check the electronic health record for subject health updates related to the study. All observational and interventional studies should also request contact with study participants for future studies, as an optional part of the studies. In cases when another federal agency or an industry partner is funding the study, we encourage you to negotiate these options if possible. Of course, research participants may decline any of these requests.

- The Mayo Clinic IRB has worked with ORD and the VA Office of Research Oversight (ORO) on establishing a mechanism for VHA facilities to rely on the Mayo Clinic IRB to participate in the FDA expanded access (compassionate use) program. Instructions are on the Single IRB Implementation webpage of the Office of Research Protections, Policy and Education (ORPP&E) at www.research.va.gov/programs/orppe/single_irb.cfm, and on [SharePoint](#). Look for the document titled “VA Facility Participation in the Expanded Access Program: Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19.”
- ORD has placed instructions on the application process for use of a commercial IRB approved by ORD at www.research.va.gov/programs/orppe/single_irb.cfm. As of today, Advarra and Western Institutional Review Board (WIRB)-Copernicus Group (WCG) are approved by ORD for cooperative research studies.
- A memorandum on the use of video communication technology for VA research activities under COVID-19 can be found on [SharePoint](#). The memo is signed by Dr. Carolyn Clancy, Deputy Under Secretary for Health for Discovery, Education and Affiliate Networks.
- Additional announcements concerning COVID-19 from ORPP&E can be found on the [SharePoint site](#). This page also houses other important administrative and regulatory memos and guidance. See also the [guidance](#) posted on ORPP&E’s web page concerning any human subjects research (i.e., irrespective of disease focus) within VA.
- ORO issued a memo with important COVID-19 guidance for research compliance officers at VAMCs. ORO is exercising discretion and flexibility with regard to portions of audits that cannot be completed given the restrictions on in-person contact. This memo, too, [can be found](#) on SharePoint.

Animal Research

An FAQ document titled, “COVID-19 and VA Animal Care and Use Programs”, is available on [SharePoint](#) and the [VA Research website](#). It currently includes 19 FAQs.

If these FAQ items on animal research do not resolve problems, or you have an emergency issue, call Mike Fallon, CVMO, at 404-732-5471. If there are less pressing concerns regarding the management of animals during this period, email Michael Fallon (michael.fallon@va.gov), Alice Huang (alice.huang@va.gov), and Joan Richerson (joan.richerson@va.gov).

The first priority is to ensure the continuity of proper care for 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. Please continue to read and monitor agency emails concerning ongoing containment practices.



Field Operations

An updated version of the FAQs related to the ORD services has been uploaded to the ORD COVID-19 SharePoint found [here](#). The question below, relating to field budget operations, is this week's selected FAQ to be highlighted.

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.



Research Activities

The section below summarizes activities being undertaken and coordinated by ORD, in collaboration with VA and external partners, aimed at: (1) facilitating and expediting the clinical trial process, (2) maximizing opportunities for VA investigators to lead or participate in trials, and (3) leveraging other VA research capabilities—including in areas such as biomedical research, rapid evidence reviews, and informatics—to add value to the national and international effort.

We expect this list to expand as a result of ongoing conversations between ORD and federal partners, such as HHS' Biomedical Advanced Research and Development Authority (BARDA), as well as with industry. We are working toward a comprehensive list of our activities to post on SharePoint.

Opportunities

With regard to the following opportunities related to COVID-19, please note that all ORD funding decisions will be highly coordinated with existing research efforts. As a result of the announcements to date, a number of proposals are under review. We plan to post on SharePoint a comprehensive overview of what is being supported to help ORD and the field identify possible collaborations and reduce overlap and redundancy. (Note: Any study that is a multisite study and gets funded by ORD in response to the COVID-19 RFAs will be supported by the Central IRB.)

- The VA COVID-19 Cohort Master File has been distributed to the VA Informatics and Computing Infrastructure (VINCI) environment and is now available for use by VA researchers. The same file has also been distributed to Oak Ridge National Laboratory, part of the Department of Energy, to support collaborative VA-DOE research.
- Rehabilitation R&D has announced a Special Emphasis Area in its Summer Merit Review RFA/FOA. The emphasis is on physical, cognitive, and psychosocial disability and rehabilitation approaches following COVID-19 infection or social distancing. Check the [RR&D intranet site](#) for further information.
- Biomedical Laboratory R&D has issued a funding opportunity for pilot awards to support studies using cell culture and animal models that will lead to improvements in the prevention and treatment of COVID-19. Submissions are due April 28, 2020. The earliest funding start date will be Oct. 1, 2020. The announcement is posted on [SharePoint](#) and on the [BLR&D section](#) of the VA Research website.
- A request for Health Services and Clinical Science R&D proposals is focusing on planning projects, short-term pilots, and data-analysis projects. Applicants are counted on to ensure that their projects *not interfere* with critical clinical and operations work. First submissions were due April 6, and more than 200 applications were received and are under review, but the solicitation will remain open and subsequent submissions will be reviewed on a rolling basis. This RFP features a very short application process and rapid turnaround. The announcement can be found on [SharePoint](#) and the [VA Research website](#).
- All standing funding mechanisms in ORD, as appropriate, may also be used to propose research relevant to COVID-19.

For the following three opportunities, please contact ORDCOVID19@va.gov to let us know of your interest:

- Sites are being sought to collect and send two- to eight-week post-infection (convalescent) serum to the National Institute of Allergy and Infectious Diseases (NIAID), which will distribute the samples to vaccine and therapeutics researchers.
- A collaboration with NIAID/NIH on development and testing of COVID-19 intravenous immune globulin is being discussed and will require VA investigators and sites.
- VA will participate in serology and seroepidemiology studies with other federal agencies to help determine when it is immunologically safe to return to work. VA investigators may be needed for this effort.

Note: To help support the use of convalescent plasma as an investigational treatment for patients with COVID-19, please encourage Veterans, friends, and family members who have a lab diagnosis of COVID-19 and have been symptom-free for 28 days to identify themselves as a “friend of VA” when donating blood or plasma at an AABB-certified lab. VA will then get credit toward receiving plasma to give to Veterans who are ill with COVID-19. See <https://covidplasma.org/> for more information.

Open and Active Studies

Some of the following studies may present opportunities for additional VA sites and investigators to become involved, either in the near or longer term. Unless otherwise directed for a specific item, please email your interest to ORDCOVID19@va.gov.

- VA is organizing a clinical trial addressing the impact of hydroxychloroquine and azithromycin on COVID-19 patient outcomes. The project is being shepherded by the Cleveland and Durham VA medical centers, in collaboration with Duke University and with support from ORD. The study aims to enroll 500 VA patients. The title of the trial is, “A Pragmatic Factorial Trial to Assess the Efficacy and Safety of Hydroxychloroquine, Azithromycin, or Both for Treatment COVID-19 in Hospitalized Veterans.” As of now, in response to email communications from study lead Dr. Robert Bonomo in Cleveland, about 35 VA sites have already expressed interest in taking part, and additional sites are not being sought.
- The VA Cooperative Studies Program is planning a trial on hydroxychloroquine to prevent transmission of COVID-19. The VA will be looking for sites soon.
- VA is funding a phase 2 clinical trial exploring whether degarelix, a treatment used in prostate cancer, may be effective reducing time to improved clinical outcomes.
- VA is collaborating with the Department of Defense on an observational, natural history study of COVID-19 illness titled “Epidemiology, Immunology and Clinical Characteristics of Emerging Infectious Diseases with Pandemic Potential” (EPICC-EID). The study will contribute to a better understanding of the COVID-19. This study will be looking for sites soon.
- VA sites are included in two Gilead-sponsored clinical trials (one for moderate disease and another for severe disease) of remdesivir, one of the more promising medications for COVID-19. To date, the Bronx VA has launched the studies. Currently, Gilead is not looking for any additional VA sites.
- VA sites are taking part in an NIAID-sponsored randomized, placebo-controlled study of remdesivir for hospitalized patients with COVID-19. VA sites currently include Palo Alto, Denver, and New Orleans. (As noted previously, this trial has marked the first time in VA history that VA clinical trial sites have relied on a commercial IRB.)
- An industry-sponsored clinical trial on sarilumab (sold as Kevzara), an IL-6 inhibitor, is being conducted at the Atlanta VA. ORD is working with the sponsor to have other VA sites considered.

Other Research Activities

Below are other activities ORD has been initiating and overseeing to support researchers and clinicians in the field:

- **Synthesizing evidence from publications:** Researchers from our [Evidence Synthesis Program](#) are working with the World Health Organization and the VA RAPID/biosurveillance group to help synthesize publications about the novel coronavirus and COVID-19, and to translate that information into usable guidance for clinicians. To date, the ESP group has completed three reports: “Risk of Transmitting COVID-19 During Nebulizer Treatment”; “Intensive Care Unit Length of Stay and Ventilation Days”; and “Corticosteroid Therapy & ARDS for COVID-19 Infection.” More are in the works.
- Those three reports can be found on a new website that ESP has just stood up to catalog evidence reviews and make them widely available: www.covid19reviews.org. The goal is to capture the work of evidence-synthesis groups, like VA’s, around the U.S. and the globe and thereby avoid duplication of effort and maximize the contribution of these researchers. The catalog will be maintained by the VA ESP Coordinating Center in Portland, Oregon. New reviews are identified by ESP librarians searching LitCovid, MedRxiv, the WHO COVID-19 database, and other sources. The team has also set up a list-serve to facilitate collaboration among systematic review researchers.
- **Facilitating access to investigational drugs under compassionate use:** This allows access, through a research pathway, to drugs that are not yet available on the market, such as remdesivir. The team has streamlined and organized a central assistance process for VA medical centers seeking expanded access (a.k.a. compassionate use) under FDA rules to investigational drugs for COVID-19 treatments. As part of this process, as noted above in *Regulatory Updates*, ORD has worked out an arrangement whereby VAMCs can use the Mayo Clinic IRB to participate in this program.
- **Examining off-label use of existing approved drugs:** Drugs that are already FDA-approved for other health conditions are being used to treat COVID-19. These include chloroquine and hydroxychloroquine, sarilumab (Kevzara from Regeneron), and tocilizumab (Actemra from Roche). ORD can contribute to the understanding of whether these drugs are safe and useful by helping to track data on prescriptions, side effects, and outcomes; and working with VHA Public Health Surveillance and Research in Palo Alto and Pharmacy Benefits Management on longitudinal tracking of data on COVID-19 patients, including those prescribed off-label drugs.



FAQs

ORD continues to frequently update its “[FAQs Regarding COVID-19 Impacts on Research](#)” based on questions from the field. Below are two examples. Please check the full document for guidance before emailing your question to ORDCOVID19@va.gov.

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. 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.

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 (IRB/RD, ORD service). See [ORD guidance](#) on modifying study procedures, as well as the [FAQs below](#).



Upcoming Events

- **Webinar:** “Expanded Access to Convalescent Plasma: The Mayo Clinic Protocol,” **Wednesday, April 15, 2020, 2 – 3 pm EST**. Registration details will be sent out via email. A recording of the webinar will be available on the [ORPP&E website](#) for those unable to attend.



Useful Links

- [Office of Research Protections, Policy and Education](#)
- [VA Animal Research Program](#)
- [Office of Research Oversight COVID-19 SharePoint site](#)
- [COVID-19 Reviews \[maintained by VA ESP\]](#)
- [Department of Veterans Affairs Public Health](#)
- [Department of Homeland Security Science & Technology Directorate Master Question List for COVID-19](#)
- [Centers for Disease Control and Prevention](#)
- [National Institutes of Health](#)
- [NIH National Library of Medicine - LitCovid](#)
- [World Health Organization - Global Research on COVID-19](#)
- [Department of Defense](#)
- [Johns Hopkins University Coronavirus Map](#)
- [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19](#)

Internal VA resources

- [VA Posters and Fact Sheets](#)
- [Guidance for HR flexibilities for employees impacted by COVID-19](#)

To communicate with ORD about COVID-19: ORDCOVID19@va.gov

To access ORD resources on COVID-19:

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

If you would prefer to not receive these messages in the future please email ORDCOVID19@va.gov.

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