COVID-19 Guidance and Opportunities from Office of Clinical Research:

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Research Guidance and Plans

Coronavirus (COVID-19) – Research Guidance and Plans

The coronavirus (COVID-19) outbreak infection has reached Ohio with confirmed reports as of March 9, 2020. Study teams and personnel should develop appropriate ways to protect the safety of their study participants and study personnel.

In general, study participants who are taking study product that is treating a health condition should continue on their assigned study product and undergo study visits per their individual protocol. Study medications should be refilled and safety labs obtained per protocol. Some study visits that can be delayed or postponed safely should be done where there is concern about the transmission of COVID-19. This should be decided on a case-by-case basis by the local study lead investigator in consultation with study teams/protocol teams and local institutional officials. For studies that do not involve a study product/medication or device, visits should be postponed and/or conducted by telephone where feasible. Investigators should reach out to protocol/study teams for guidance on how best to proceed when in-person visits are not feasible.

In addition, each investigator should limit study staff to be utilized to conduct visits to limit contact for study personnel, study participants and other individuals. Supervisory research personnel should discuss upcoming schedules in the next 6-8 weeks and how to limit the number of study personnel required to conduct visits that must be completed. All study participants should be contacted by telephone and asked about any respiratory symptoms or fever prior to their visits on the day prior to the scheduled visit. If study participants have any respiratory symptoms or fever they should be referred for appropriate testing before coming to a study visit. Upon arrival to UC Health or UC Medical Center, study participants should be asked again about respiratory symptoms or fever, and, if they report any, should be immediately moved to an isolated room and asked to put on a mask. Study personnel should wear appropriate personal protective equipment when conducting a study visit with a participant who is having respiratory symptoms or fever and refer the study participant for appropriate testing for infectious diseases.
Study investigators should use their best judgment to limit contact that is not absolutely necessary to ensure the safety of the study participant and ensure the integrity of the research.

UC IRB Guidance

Updated 3/23/2022

As we make decisions on how to respond to the COVID-19 outbreak we want to begin by stating that our primary concern is the safety of our research participants and the research team members who work for the University and UC Health. Our secondary goal is to preserve the scientific integrity of the research protocols.

As the need for social distancing increases, the number of UC faculty and staff on site is decreasing even in the clinical areas. Research participants may be less willing and facing even greater risks to come to our facilities. Demands for remaining clinical care resources continue to increase, making it more difficult to safely complete research. We must prioritize safe clinical care and practices that minimize spread of COVID-19. Informed advice about how long clinical research activities will be reduced is difficult to give, as the situation is changing rapidly. As you plan for what to do with your own research protocols, our current advice is to assume there will be no decrease in restrictions for at least two months. We will continue to reevaluate this timeframe.

COVID-19 research is a priority because of societal need for information.
All COVID-19 protocols must still have IRB review and approval before starting enrollment. Please contact Dr. Linke before submitting a study involving COVID-19 linkemj@uc.edu

The latest guidance and information will always be available at the UC Coronavirus website and the Office of Research site.

Per the memo *Research Priorities during a Civil Emergency or Regional Crisis* from the Vice President for Research, the following criteria describe which UC research projects will be given priority for ongoing access to facilities during a university-wide emergency. For purposes of this determination, UC research projects are divided into three categories:

- Level I Research: **Critical Research** efforts that are directed at responding to or mitigating the crisis that has caused the University closure, and which holds the potential for significant contribution in resolving the crisis;
- Level II Research: **Essential Research** efforts that involve a significant investment of University resources, agency sponsorship, or contractual obligation, or effort on the part of researchers and staff that cannot be interrupted without jeopardizing those investments or the research results and overall project outcomes;
- Level III Research: **Routine Research** that is in the initial stages, does not require completion of imminent, critical milestones, or may be continued at an alternate site by reprioritizing or resequencing the research structure. Though there may be a loss of data, efficiency or early investment, current efforts can be recreated or resumed after minimal disruption, with little loss of investment.

These criteria are incorporated into the below guidance.

What should I do about human-subject research?

The Human Research Protection Program (HRPP) staff are working remotely but are operating on our normal schedule. The UC IRB will continue to hold weekly meetings using remote access technology. Please contact the HRPP office at irb@uc.edu or 513-558-5259 with any questions.

Some Human Participant Research Studies or Activities Must Be Paused.

1. **Why must some human participant research studies or specific activities be paused?**

The real or perceived risk of viral transmission, the risk/benefit ratio for in-person contact associated with research activities must be assessed for each protocol. Ethical principles of research and federal regulations for the protection of human research participants require an acceptable risk/benefit ratio.

2. **Which studies or study procedures must be paused? (updated 3/23/2020)**

- All Level III human subjects research activities must be paused.
- All studies for which there is little to no prospect of direct benefit to participants that involve in-person contact or participant travel for research purposes must be paused, effective immediately or as soon as can be implemented. This includes social-behavioral and biomedical studies. Please contact Dr. Linke linkemj@uc.edu or Dr. Holden holdenjn@ucmail.uc.edu with any questions on whether your studies offer direct benefit to participants.

- All studies involving blood draws or other collection of biological samples with no direct benefit to the research participant.
- If part of the protocol, procedures such as telephone contact or monitoring or remote data collection may continue. If these procedures are not part of the protocol, the study may be modified to use remote data collection procedures per the IRB determination described below when appropriate.
- For studies at the College of Medicine that do not involve a study product/medication or device, visits should be postponed and/or conducted by telephone where feasible. Investigators should reach out to protocol/study teams for guidance on how best to proceed when in-person visits are not feasible. If these procedures are not part of the protocol, the study may be modified to use remote data collection procedures when appropriate per the IRB determination described below.

3. May new enrollment into existing studies continue? (New Information 03/23/2020)

- All Level III human subjects research must cease enrollment until further notice.
- Studies with no in-person participant interaction may continue to enroll participants.
- Level I IRB approved studies on COVID 19 may enroll participants.
- Level II studies with in-person interactions must cease enrollment until further notice. Limited exceptions for life-saving clinical interventions must be approved beforehand:
    - Clinical trials approved by the UC Cancer Center Protocol Review and Monitoring Committee (PRMC) may continue to enroll.
    - For all other clinical studies, Principal Investigators should contact Dr. Linke linkemj@uc.edu

4. Which studies may continue? (updated 3/23/2020)

- Level II studies for which there is direct benefit to participants may continue.

Please contact Dr. Linke linkemj@uc.edu or Dr. Holden holdenjn@ucmail.uc.edu with any questions on whether your studies offer direct benefit to participants.

- To the extent possible, study activities that can be done remotely by telephone or electronically should be done in this way. If these procedures are not part of the protocol, the study may be modified to use remote data collection procedures when appropriate per the IRB determination described below when appropriate.
- Studies that do not involve face-to-face interactions with participants may continue.
- Studies conducted electronically or via telephone or involving secondary data analysis may continue.
- UC IRB approved studies on COVID 19
- Additional information for studies conducted at the College of Medicine
    - It is assumed that trials with investigational treatments, including drugs and devices, provide the potential for benefit and should continue.
    - In general, study participants who are taking study product that is treating a health condition should continue on their assigned study product and undergo study visits per their individual protocol. Study medications should be refilled and safety labs obtained per protocol.
    - Clinical trials approved by the UC Cancer Center PRMC may continue.

- Some study visits that can be delayed or postponed safely should be done where there is concern about the transmission of COVID-19. This should be decided on a case-by-case basis by the local study lead investigator in consultation with study teams/protocol teams and local institutional officials. If these procedures are not part of the protocol, the study may be modified to use remote data collection procedures when appropriate per the IRB determination described below.

5. How should research interactions go forward? (New Information 03/23/2020)

- For research interactions that cannot be done remotely, opportunities for exposure should be reduced as much as possible without reducing the efficacy of the treatment or increasing risk to the participant. Examples of exposure reduction may include: reducing non-essential visits, reducing the number of blood draws, eliminating non-essential visit time, or maximizing the use of remote technologies in lieu of "face-to-face" interactions.
- For cancer-related studies, interim guidance from the National Cancer Institute for clinical trials supported by the NCI, such as delegation of visits or procedures to local providers or mailing of oral study drugs, see https://ncicirb.org/announcements/memorandum-interim-guidance-patients-clinical-trials-supported-nci-cancer-therapy .
- For FDA-regulated clinical trials, refer to FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic
- Limit study staff to be utilized to conduct visits to limit contact for study personnel, study participants and other individuals. Supervisory research personnel should discuss upcoming schedules in the next 6-8 weeks and how to limit the number of study personnel required to conduct visits that must be completed.
- Limit the possibility that research staff will be too close to each other and unable to meet the social distancing needed to halt the spread of the COVID-19 virus.
- Essential research visits that cannot be performed remotely may be performed in person, with the following additional guidance:
    - All study participants should be contacted by telephone and asked about any respiratory symptoms or fever prior to their visits on the day prior to the scheduled visit. If study participants have any respiratory symptoms or fever they should be referred for appropriate testing before coming to a study visit. Upon arrival to UC Health or UC Medical Center, study participants should be asked again about respiratory symptoms or fever, and, if they report any, should be immediately moved to an isolated room and asked to put on a mask. Study personnel should wear appropriate personal protective equipment when conducting a study visit with a participant who is having respiratory symptoms or fever and refer the study participant for appropriate testing for infectious diseases.
    - Study investigators should use their best judgment to limit contact that is not absolutely necessary to ensure the safety of the study participant and ensure the integrity of the research.
    - Participants should be provided with information regarding the current COVID-19 pandemic and how best to reduce their risk of infection. This information may be provided in multiple forms suited to the type of contact, including a website link, a

telephone script and an in-person handout. If possible, this information should be shared before the research visit.

6. **What if my study is reviewed by an external IRB? (New Information 03/23/2020)**

This COVID-19 guidance is effective immediately for all human subjects research conducted at UC, regardless of reviewing IRB. If you need to make changes to your research, follow the reviewing IRB's procedures for submitting amendments or deviations.

7. **What if a human research study needs to be modified in response to COVID-19? (updated 3/23/20)**

Per UC SOP HRP-029 Review of Study Modifications "Modifications in approved research may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards". If protocols must be modified to address immediate safety concerns to participants or study staff related to the COVID-19 epidemic, the UC IRB has determined that these modifications meet this exception. Any modifications made per this exception should be subsequently submitted for IRB notification using the Reportable New Information (RNI) function in RAP as an Unreviewed change: *Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject*.

Protocol modifications to eliminate immediate hazards may include;

- Actions taken to reduce potential exposure to COVID-19
- Suspension of all or some research activities
- Decreasing the number of in-person study visits
- Replacing protocol-mandated visits to healthcare facilities with home visits or telemedicine
- Allowing blood draws at remote or commercial laboratories
- Shipping investigational products directly to research participants

Protocol modifications that are not made to eliminate immediate hazards must continue to be approved by the IRB prior to implementation.

Please contact the HRPP office at irb@uc.edu or 513-558-5259 with any questions.

8. **Can I submit new studies for IRB review during the COVID-19 outbreak? (New Information – 03/23/2020)**

- Yes, you may submit new studies in RAP. New studies will be screened and forwarded for expedited or convened IRB review in accordance with standard UC HRPP procedures and timelines; however, enrollment of new participants must adhere to the following:
- Any research studies involving COVID-19 should include COVID-19 in both the Title and Short Title of the protocol submission. Please contact Dr. Linke before submitting a study involving COVID-19 linkemj@uc.edu
- Level I COVID-19 studies may commence after receiving appropriate approvals.
- Clinical trials approved the UC Cancer Center PRMC may initiate enrollment.
- Other studies with in-person interactions may not commence enrollment until further notice.

- Studies with no in-person participant interaction may commence after receiving IRB approval.

Guidance for Research Study Visits

Guidance for Research Study Visits and Conduct-COVID-19

PURPOSE

Provide guidelines to the UC/UCHealth research community for COVID-19 screening of research study participants scheduled for campus/hospital research study visits.

Prior to study visit

1. Call study participant 24 hours prior to visit.
2. Review following symptoms with study participant in the last 7 days:

    a. Coughing or Sneezing
    b. Runny nose or congestion
    c. Cold symptoms
    d. Shortness of breath
    e. Fever or chills
    f. Nausea, vomiting or diarrhea
    g. Contact with anyone with the above symptoms in their home, work or school in the last 14 days

3. If the study participant answers yes to any of the above, reschedule the study visit.

On the day of study visit

1. Review following symptoms with study participant in the last 7 days:

    a. Coughing or Sneezing
    b. Runny nose or congestion
    c. Cold symptoms
    d. Shortness of breath
    e. Fever or chills
    f. Nausea, vomiting or diarrhea
    g. Contact with anyone with the above symptoms in their home, work or school in the last 14 days

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Study participants with respiratory symptoms

1. Evaluate clinically and determine need for further medical evaluation.

2. If further evaluation is needed:

    a. Immediately move study participant to a room
    b. Provide study participant a mask
    c. Contact study physician to evaluate

3. If no further medical evaluation is needed:

    a. Tell participants to contact their primary care physicians to ask about arranging for testing for respiratory viral panel and COVID-19
    b. Conduct study visit quickly
    c. Remove from research area
    d. Limit contact with study participant
        i. Wear Personal Protective Equipment to conduct visit (gown, gloves, N-95 mask, face shield)
    e. Perform a clinical assessment for further medical evaluation
    f. Disinfect all surfaces of research area

Also note:

1. When in doubt, contact study physician to evaluate the study participant.
2. Notify appropriate study investigator and study protocol team for guidance on delayed visits, out of window visits or missed visits.

Study product may be shipped to the study participant after consultation with the local PI of record and the study team to avoid interruption.

Policy on Remote Monitoring UPDATED

COVID-19/Coronavirus Clinical Research Auditor/Monitor Guidelines
Click here to review this policy in Compliance 360.
As of March 24, 2020, UC Health is no longer allowing on-site auditing and monitoring visits until further notice.
This is in order to remain compliant with state law, which mandates a stay at home order as of 3/24/2020, with travel permitted for essential purposes only.

For required study auditing and/or monitoring during this time, UC Health offers remote options and will work with external entities to conduct these visits remotely:

1. Most study sponsors offer a platform where information for auditing and monitoring can be uploaded and shared for remote auditing and monitoring purposes.

    a. Be sure to speak with your external auditing and monitoring entity regarding their remote options.

2. Individual departments may have remote auditing and monitoring options in place that can be utilized during this time.

3. For use of Epic Care Link for remote monitoring options, please use this link/form:

    a. https://survey.uchealth.com/redcap/surveys/?s=WW3F9KTN3A

4. For assistance with any questions or concerns regarding remote auditing and monitoring, please contact The Office of Clinical Research at research-admin@uchealth.com.

For auditing and monitoring visits scheduled prior to this official 3/24/2019 update to this policy, auditors and monitors must be sent an email canceling or rescheduling the visit until further notice.

Remote Monitor Screening Form (Epic Care Link)

For use of Epic Care Link for remote monitoring options, please use this link/form:
https://survey.uchealth.com/redcap/surveys/?s=WW3F9KTN3A

IDS Update

Effective Monday, March 23, 2020, IDS will begin reduced staffing on campus consistent with guidance from UC Health to work where able to decrease unnecessary exposure.
There will be one or two individuals each day in the office while the others practice remotely from home accessing all current resources. The hours of IDS will be 0700 to 1530 Monday through Friday. All usual contact numbers and emails can continue to be used. If a staff member does not answer the phone, please leave a message and IDS will return the phone call as soon as they are able to do so.

Currently, IDS will continue to accept patient returns. THE RETURNS MUST BE DELIVERED TO IDS COUNTED AND IN A SEALED BAG. A bag label will contain the IDS #, patient's name and number of pills returned.

IDS is beginning to see an increase in the volume of Investigational Product (IP) shipped. At this time, IDS is able to store the IP; however, one should not assume that IDS has this long-term capability. Any increase in the number of vials IDS can accommodate should be discussed with IDS.

UC Health Hospital Updates

March 23, 2020 COVID-19 Updates

- The rate of COVID-19 positive test results continues to increase across our community and Ohio. As one of Greater Cincinnati's largest employers and largest healthcare systems, we have been prepared for the reality that some portion of our team would likely eventually test positive for COVID-19.

- Today, we can now confirm that two UC Health employees have received positive test results for COVID-19. These individuals are in self-isolation at home. We have taken the appropriate steps to notify those who may have been in close contact with these individuals.

- The health and safety of our patients, visitors and our people is our top priority. We continue to encourage you to take the appropriate steps to protect yourselves and others.

- If you are having any of the following symptoms: fever, cough or shortness of breath, you should call the Employee Health Injury Hotline at 513-585-8000; UCP clinicians should email uhstravel@ucmail.uc.edu. Employee Health will respond with appropriate health guidance based on your individual situation.

Personal Protective Equipment (PPE)
Your wellbeing is our utmost priority – all decisions regarding PPE are made with your safety in mind. We are regularly monitoring our supply, stock and use of PPE while evaluating best practices and new innovations through designated multidisciplinary task forces. All possible options, including UV irradiation, limited reuse and alternative protective equipment are being considered. Before implementing any new plan, employee and clinician safety is thoroughly evaluated using accepted science. In the coming days, we will collect unsoiled, used N95 masks for possible personal reuse after decontamination. Despite these plans, it is important to conserve and use PPE appropriately.

Visitor Restrictions – Updated
The safety of our patients, visitors, staff and clinicians is of utmost important to UC Health. Our visitor restrictions are set in compliance with public health agency guidelines and best practices as well as those of the Ohio Hospital Association and with consideration of the Ohio Governor's "stay at home" guidelines.

Effective March 24, at 9:00 a.m., UC Medical Center and West Chester Hospital will no longer allow visitors on their campuses. More details can be found here. There are two exceptions:
- In cases where visitor restriction will produce an undue hardship for the patient or family.
- In cases where the restriction is detrimental to the care of the patient.

COVID-19 General Update
Infectious Disease specialist Carl J. Fichtenbaum, MD recently presented on COVID-19 at Grand Rounds. His presentation is now on The Link. Click here and then look under "videos" to view the presentation.

Donations – Process & Guidelines
Members of the community continue to approach people in our organization regarding donating supplies, food and other items. We have published a number of ways for people to get involved; these are listed on our external website at https://www.uchealth.com/en/covid-19/three-ways-to-help. While we appreciate the public's desire to donate items, we must first prioritize the health and safety of our employees, clinicians and patients. We have seen in other crisis situations that sometimes a generous donation can unintentionally cause harm. Beginning today, please direct anyone looking to donate items to: donations@uchealth.com. Please note that food and non-perishable items should not be accepted in clinical care settings. Due to federal and state laws, we cannot accept cash or gift cards.

Pharmacy Changes
As of Monday, March 23, Holmes Pharmacy is temporarily closed. Prescribers can continue to send electronic prescriptions to Holmes Pharmacy; these will be filled at Hoxworth Pharmacy. A pharmacist will contact the patient for delivery or pick-up unless the prescription is needed immediately. For urgent prescriptions, providers and offices should call Hoxworth Pharmacy at (513) 584-8828. Prescription pick-up is located at the back entrance (Goodman Ave) of the Hoxworth Blood Center Building on Level 1. The Specialty Pharmacy process remains the same. Additional information about pharmacy changes, including employee prescriptions, can be found here.

Employee Health & Wellness
UC Health's Employee Assistance Program is available for employees and their adult household members at no cost. If you are experiencing panic, anxiety or fear; noticing increased emotional stress surrounding the coronavirus outbreak, or having difficulty concentrating or sleeping, it may help to speak to a professional clinician. Please feel free to contact EAP at (513) 585-6100 Monday-Friday between 8:00 a.m. – 4:30 p.m. to schedule an appointment or for more information.

New on the Link
Resources continue to be added to The Link on a regular basis. Some new additions include:

- Employee Exposure Algorithm
- PPE instructional videos
- Respiratory Therapy SOP
- What Mask Do We Use?
- Visitor restrictions
- PPE Guidelines

Questions/Contacts
For employees and physicians:
UC Health Clinical Guidance Questions: 513-584-WASH or covid19@uchealth.com
UC Health Employee Health Injury Line: 513-585-8000
Screening appointments for healthcare workers/first responders: 513-41VIRUS (513-418-4787)

For Patients and the Community:
Ohio Department of Health COVID-19 Line: 1-833-4-ASK-ODH (1-833-427-5634)
Centers for Disease Control and Prevention: https://www.cdc.gov/coronavirus/2019-ncov/index.html

FDA Guidance

(NEW) Food and Drug Administration (FDA)

- The FDA released guidance for industry, investigators, and institutional review boards on the conduct of clinical trials of medical products during the COVID-19 pandemic: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic

NIH Guidance

National Institutes of Health (NIH)

- **(NEW)** The National Heart, Lung, and Blood Institute (NHLBI) issued a Notice of Special Interest (NOSI) "to highlight the urgent need for research on Coronavirus Disease 2019 (COVID-19) and on biological effects of its causative agent, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Topics of specific interest to NHLBI include host response, associations with heart, lung, and blood (HLB) diseases, potential impacts on transfusion safety, and clinical outcomes of infected individuals." Investigators can apply for both Administrative Supplements and Urgent Competitive Revisions through this NOSI. https://grants.nih.gov/grants/guide/notice-files/NOT-HL-20-757.html

CDC Guidance

(NEW) CDC will award approximately $560 million to states, localities, territories, and tribes using "existing networks to reach out to state and local jurisdictions to access this initial funding." A breakdown of funds funneled to states and jurisdictions can be viewed here: https://www.hhs.gov/about/news/2020/03/11/cdc-funding-information.html.

HHS/BARDA Opportunities

Department of Health and Human Services (HHS)/Biomedical Advanced Research and Development Authority (BARDA)

(NEW) Federal agency partners in the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) are leveraging the existing Biomedical Advanced Research and Development Authority (BARDA) TechWatch program to engage with industry, academia, and other stakeholders to accelerate technologies related to the novel coronavirus. Traditionally, TechWatch is a virtual meeting with BARDA scientific, technical, and contracting staff, as well as representatives from other interested federal agencies. For CoronaWatch, representatives from the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health, the Department of Defense, Department of Veterans Affairs, and the Department of Agriculture, among others, will be contacted to participate as relevant and needed. There are specific submission options for therapeutics, vaccines, diagnostics, and other products through CoronaWatch. Additional information on CoronaWatch, as well as submission instructions, are available at: https://www.medicalcountermeasures.gov/Request-BARDA-TechWatch-Meeting/

DOD Opportunities

Department of Defense (DOD)

- **(NEW)** The U.S. Army's Medical Technology Enterprise Consortium (MTEC) released a pre-announcement for a potential Request for Project Proposals (RPP) focused on the "development of prototypes aimed to combat the coronavirus (COVID-19)." MTEC seeks technologies that are deployable as soon as possible and no later than December 31, 2020. MTEC's potential areas of interests for the upcoming RPPs include:
    - "**Point-of-care diagnostic** that provides rapid and accurate determination on exposure to COVID-19.
    - **Prophylactic(s)/Therapeutic(s) that can prevent and/or treat in a rapid manner (few hours to 2 days) potentially in a non-hospital environment**. Repurposing FDA-approved drugs/biologics for prevention/treatment of COVID-19 or testing of drugs/biologics that

have already demonstrated safety in humans for the prevention/treatment of COVID-19 are preferred.

- **Disease predictive modeling** that provides early warning through data capture from several different streams of data to include **social media and artificial intelligence (AI)** parameter decision tools that would provide actionable information to medical service providers and command structures.
- **Patient monitoring, tracking, and management system** for in-home or non-hospital environment patient tele-health services to include interface into the Cerner electronic health record."

There is currently no funding commitment at this time, but "MTEC believes that there may be tens of millions of dollars available for combating COVID-19 programs with a likelihood of follow-on funding." Responses are required no later than **15 days after the official RPP release date**. MTEC's preannouncement can be found here, and Lewis-Burke will continue to monitor for the formal RPP release.
Note: MTEC membership is not required for the submission, but membership will be required for applicants recommended for awards. More information on joining MTEC can be found at http://mtec-sc.org/how-to-join/.

WCG guidance

Changes to Research Made in Response to COVID-19

WIRB-Copernicus IRB has received questions from several research sponsors about the appropriate process for making changes to clinical studies in response to the current COVID-19 epidemic. These changes may include things like:
Decreasing the number of protocol-mandated in-person study visits to healthcare facilities
Replacing protocol-mandated visits to healthcare facilities with home visits or telemedicine, allowing blood draws at remote or commercial laboratories
Shipping investigational products directly to research participants

We want to provide information on the requirement for IRB review of changes in research made in response to this situation.

The FDA regulations require that:

Each IRB shall … (a) Follow written procedures for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects. 21 CFR 56.108(a)(4).

If a sponsor or investigator needs to make a change to research plans in order to eliminate apparent immediate hazards to research participants, these changes can be made and then reported to the WIRB-Copernicus IRB within 5 days, as per WCG policy. Eliminating immediate hazards may include actions to reduce potential exposure to COVID-19, or to continue to provide medically necessary study care (including study drug) to participants who have been placed in isolation or quarantine because of

suspected or known exposures. WCG encourages sponsors and investigators to take such steps as necessary to eliminate apparent immediate additional risks to participants.

The notification to the IRB may be a full protocol amendment, but it does not have to be. The notification of the change in research (CIR) plans may also be a memo, letter, or other document that explains the changes being made, and provides enough information for the IRB to assess the relative risks resulting from the changes. The amendment or CIR document will proceed through IRB review as per the usual process.

If you have questions, please contact your WIRB-Copernicus IRB representative, or Client Services, and they will be able to connect you with a member of our regulatory, medical or compliance teams as needed.

Advarra Guidance

Advarra COVID-19 Update Links

Subscribe to receive regularly updated content on new COVID-19 guidance

COVID-19 FAQ reference page

Impact of Coronavirus Outbreak on Protocols Under Advarra IRB Review

MARCH 11, 2020

Advarra has policies and processes in place to keep IRB operations functioning as normal during the current coronavirus outbreak.

The coronavirus outbreak has raised concerns among sponsors and study teams about how the outbreak may impact Advarra's operations as well as protocols overseen by Advarra's IRB that are currently enrolling. Advarra continues to have 15 IRB meetings a week, and the IRB has been prioritizing the review of the numerous coronavirus protocols received as well as amendments relating to changes in research conduct because of unforeseen circumstances.

IRB meetings and processes are not impacted by any restrictions on travel. As a standard practice, the IRB meets remotely via video conference technology, and Advarra staff have the resources and flexibility to work remotely.

For sponsors and study teams navigating the outbreak situation, Advarra recommends the following:

1. Submit all changes to research protocols for IRB review and approval prior to implementation, with the exception of incorporating screening questions as described below as well as any measures needed to avoid an immediate apparent hazard to a patient/participant. These exceptions must be promptly reported to the IRB.
    - Screening of research participants: Research participants may be asked to complete a short screening for exposure to coronavirus infection/COVID-19 before in-person interactions. The incorporation of this screening procedure does NOT require IRB approval. The wording below may be changed to accommodate changes in the current public health outbreak landscape but should be comparable to the following:

        - Have you traveled to China, Iran, Italy, Japan, or South Korea in the past 14 days?
        - Have you had any of the following symptoms in the past 14 days without confirmation as something other than COVID-19 (such as a positive flu test, chronic medical condition, etc.)?
            - Fever greater than 100.4 degrees Fahrenheit
            - Cough
            - Difficulty breathing
            - Sore throat
        - In the last 14 days, have you lived with, visited, cared for, or been in a room for a prolonged period of time with someone who is under investigation or has been confirmed for COVID-19?
    - If a participant says yes to any of the above questions, it is recommended that study staff identify a resource to direct the participant to.

2. Report to the IRB only protocol deviations and violations that result in an increased harm to participants or others or adversely impact data integrity.
    - This is Advarra's standard reporting requirement; other IRBs' policies may vary.
    - For more information, see section 18.3 of the Advarra IRB Handbook for Investigators, Institutions, Sponsors, and Sponsors' Representatives (available in the Reference Materials section of the Advarra CIRBI Platform [login required]).
3. Review the study to determine if any study procedures that require participants to come to a hospital or a clinic can be eliminated or managed remotely through telemedicine or home visits.
    - This would require an IRB determination stating that changes in these procedures to either eliminate them or manage them remotely would not impact the integrity of the research.
4. If, at the time of continuing review, some studies appear to not be meeting enrollment goals due to coronavirus outbreak-related issues, describe the impact of this outbreak on the study in the continuing review report.
    - The IRB will be mindful of the current situation in its continuing review assessment.
5. If research participants are not able to come to hospitals or clinics because of infection, self-quarantines, or travel restrictions, submit an amendment identifying alternative processes such as:
    - Digital technology to record symptoms.
    - Telemedicine options to provide virtual visits.
    - Visits from visiting nurses or home health aides to conduct study related procedures.

- Please note that shipping study agents to participants is subject to state and federal laws.

6. Consider remote work options if there may be shortages of study team staff.
    - Also consider establishing back-up coverage plans even when fully staffed.
7. Conduct monitoring activities remotely if appropriate.
    - During this time when travel is discouraged, remote monitoring is a viable alternative to sending monitors to a site. Email, video conferencing and secure file transfer can facilitate this process.

As always, all changes to research should have prior review by the IRB. Investigators are permitted to implement study changes to eliminate immediate hazards to participant safety. Amendments should be submitted to Advarra promptly, describing any changes that have already been implemented and, as appropriate, justification for why changes were put into place prior to IRB review.