

March 22, 2020

MEMORANDUM

To: Faculty, Students, and Staff

From: Thomas O. Obisesan, MD, MPH
Associate Vice President and Designated Institutional Official
Office of Regulatory Research Compliance

Reference: Human Subject Research Protection Program, Animal Care and Use Program, and The Institutional Biosafety (IBC) Research Program During COVID-19 Pandemic

As you are all aware, the highly infectious COVID-19 is now a pandemic and public health emergency. Given the absence of effective therapy, public health intervention is the only tool currently available to stem the increasing rates of infection in the United States and Worldwide. While the Office of Regulatory Research Compliance (ORRC) recognizes the challenge imposed on research by this pandemic, nonetheless, our most important priority is the protection of Human Subjects, Faculty, Staff, Students, and Animals used in research. Therefore, the ORRC recommends the following (Unless otherwise directed by the University):**

Human Subject Research Protection Program

Currently Enrolled Participants: Henceforth, the ORRC and the Institutional Review Board (IRB), direct that ALL presently ongoing research activities involving in-person (face-to-face) interaction/contact with currently enrolled research participants MUST CEASE until further notice. Therefore, study personnel should contact participants to cancel or postpone all study visits until further notice. However, you may consider “virtual study visits.” For multi-center clinical trials, “virtual study visits” must be approved by the sponsor/coordinating center.

Exemption to Visit Pause: However, to protect currently enrolled research participants, the ORRC will consider the following exceptions:

- Research protocols involving treatments for acute, life-threatening health conditions (e.g., some treatment trials for cancers) for which benefits are not available through standard care.
- Protocols, where stopping the intervention could be harmful (e.g., some investigational drugs or vaccines or preventative drug regimens).
- Protocols in which continued participation by enrolled participants is likely to result in the near term, direct benefit(s), and would, if stopped, pose some risk to the research participant.

- COVID-19 vaccine/clinical trial (in addition to IRB, approval of related protocol will require the ORRC and Institutional approval)

Research studies that qualify for one of the above exemptions may continue if the PI can conduct the study in a “safe manner” (i.e., protects participants, researchers, staff, and the community). For clarity, “Safe manner” **considerations must include alternatives to having the participant be on-site for all study visits, the safety of research staff, availability of required personal protective equipment to deliver research interventions safely and effectively monitor participants.**

For example:

- Utilizing remote assessment (i.e., by telephone, zoom, etc.) whenever possible
- Use of personal protective equipment (PPE) and extensive precautions that protect participants, researchers, and the community

Screening Visits/Diagnostic Tests: Until further notice, you should not recruit or schedule new volunteers/participants for diagnostic tests or procedures, strictly to determine eligibility for participation in a clinical trial, UNLESS the study offers the prospect of direct benefit(s) unavailable outside of the research protocol.

Prescreening: You MUST contact participants meeting above exemptions before any in-person visit and prescreen them (via phone) to determine the presence of symptoms. You can find the screening (Phone Screen/Checklist) resources on the ORRC website or use the hospital version.

Exposure/Symptom: Patients who have had exposure to coronavirus or showing fever or cold-like symptoms should be directed for COVID-19 testing and postpone their research visit.

Strategies for Protection: Always use of personal protective equipment when interacting with individuals who are showing symptoms, which include: eye goggles, gowns, gloves pulled over the wrist bands of the gowns, and masks, preferably N95.

International Studies: The ORRC directs that Investigators suspend all international studies until further notice.

Emergency Change to Protocols: If you need to make immediate and temporary changes to your procedures to protect the health of participants and or researchers, please make the changes using your best judgment. Then submit an amendment/modification form detailing such changes within three business days. You must also document the changes in your study records, and we will acknowledge the same in our records. Once normal operations resume, you must revert to the original procedures and communicate the same to the IRB/ORRC.

ALL investigators and staff must inform participants of any changes to their protocol/study and discuss monitoring plans.

IRB Meetings and Protocol Review: The ORRC will continue to manage Exclusion, Exempt, Expedited, and Full-Board application as planned. Consistent with University policy, the Full-Board review meetings will occur via Zoom conferencing. For studies that are approvable, but do not meet the referenced COVID-19 “Exceptions” (Not Exempt Application), the IRB will approve the research but explicitly note that enrollment cannot start until the “pause” in research activity is discontinued.

Timely Completion of Funded Studies:

<https://nexus.od.nih.gov/all/2020/03/13/covid-19-resources-for-applicants-and-recipients-of-nih-funding/>

Howard University Animal Care and Use Program

Program Continuity: During the COVID-19 Pandemic, Veterinary Services (VS) will continue to provide daily animal health assessment and animal care services 365 days a year per animal welfare and federal regulatory requirements.

The Director of VS: The Attending Veterinarian and Director of Veterinary Services will ensure adequate stock on animal feeds, bedding, and personal protective equipment. Further, she will ensure continuity of animal care and staff schedule, periodically assess the needs of the facility, and communicate updates, as necessary.

VS Staff: Each VS staff must document the COVID-19 symptom checklist and have their temperature recorded before entering the Vivarium. Regardless of symptom positivity, each person must wash their hands on entering the Vivarium, wear gloves, and mask.

Study Team: For the study team, we will restrict access to the Vivarium to one member/team/day. This person must provide the COVID-19 symptom checklist and have their temperature documented before entering the Vivarium. Regardless of symptom positivity, study staff entering the Vivarium must wash their hands, wear gloves, and mask.

IACUC Committee: The IACUC meetings will continue as planned, review, and approve animal protocols via Zoom conferencing. The Office of the Provost has issued a Zoom license to the ORRC. However, experiments on newly approved protocols may not begin until the COVID-19 national emergency is over.

Semi-annual Inspection: Fortunately, our last Semi-annual Inspection was concluded on March 11, 2020, meaning that another Inspection is not due for ~ six months. At that time, the ORRC will re-evaluate, and proceed per OLAW's guidance on COVID-19.

Funding and Delay in Completing Experiments: Contact your Program Officer and the Howard University Research Administrative Services.

<https://nexus.od.nih.gov/all/2020/03/13/covid-19-resources-for-applicants-and-recipients-of-nih-funding/>

Else, Veterinary Services and the Institutional Animal Care and Use Committee (IACUC) will continue their responsibilities in accordance to OLAW's COVID-19 guidance:

[**Flexibilities for Assured Institutions for Activities of Institutional Animal Care and Use Committees \(IACUCs\) Due to COVID-19**](#)

Institutional Biosafety Committee (IBC)

The IBC Program: The IBC Program will continue as presently constituted unless otherwise directed by the University. First, the safety of VS staff, investigators, study staff, and students remain our utmost priority.

COVID-19 and Animals: As previously noted by the HU Institutional Biosafety Chair, mouse does not have the hACE2 receptor for the COVID-19 virus, and therefore, cannot be infected. Further, because Howard University does not have a BSL-3 facility required for studies on SARS-CoV-2 (the formal name for COVID-19), research directly using an infectious SARS-CoV-2 or its infectious RNA is not allowed at the University.

Ongoing Review of IBC Protocols: The IBC will continue to review and approve submitted protocols. However, Investigators must comply with the Office of Research guideline on access to laboratories within the academic center.

COVID-19-Related Protocols: The IBC will not entertain the review of COVID-19 related protocol given the absence of a BSL-3 equipped laboratory/facility in the University.

You may also find the attached NIH guidance on grants and COVID-19 useful.

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html>.

<https://nexus.od.nih.gov/all/2020/03/13/covid-19-resources-for-applicants-and-recipients-of-nih-funding/>

<p>As previously noted by the Office of Research, “do all that is possible to temporarily cease engagement in research on the Howard campus. This is to reduce the human footprint on the Howard campus and prepare for the possibility of a shelter in place order by national and/or local authorities”.</p>

Communication with the ORRC

Please continue to use the relevant emails for your submissions:

Medical IRB - IRB-Medical.ORRC@howard.edu

Non-Medical IRB - IRB-NonMedical.ORRC@howard.edu

IACUC - Iacuc.orrc@howard.edu

IBC - IBC.ORRC@howard.edu

Excluded Research - Exclusions.ORRC@howard.edu

MTA - MTA.ORRC@howard.edu

****General Communication** - theorrc@howard.edu

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