Guidelines for Resuming Human Subjects Research June 23, 2020

INTRODUCTION/BACKGROUND

The UMB COVID 19 Research Advisory Task Force was charged with developing guidance for restarting research considering the ongoing pandemic. The guidance is intended to be used to inform decision-making by the UMB President and the Institutional Official.

This guidance provides a tiered, staged approach for resuming human subjects research activities, responding to the varied need for personal contact, physical space, and the ability to maintain personal and environmental safety precautions. This guidance is informed by, and will be affected by, external factors as the COVID-19 pandemic continues to evolve and change.

UMB's President will determine UMB's progression through the stages, based on the factors included herein and in consultation with the Institutional Official, the Research Recovery Task Force and other key stakeholders. In addition to the guidelines noted here, UMB's President and Institutional Official must make decisions based on current rules and regulations associated with human subjects research.

These guidelines apply to all human subjects research at or by UMB, regardless of whether the research was approved by the UMB Institutional Review Board (IRB) or through an external IRB.

GUIDING PRINCIPLES

The following is a set of Guiding Principles for resuming human subjects research:

1. Follow the applicable Local, State, and National directives regarding required safety measures during the COVID-19 pandemic.
2. Limit close physical interactions among all individuals involved in human subjects research to the minimum necessary for conducting research visits.
3. Appreciation that human subject research is complex and diverse.
4. Recognize human subjects research with therapeutic intent has a potential direct benefit to patients that balances risk of infection through promotion of safe practices.
5. Conduct human subjects research with a focus on the need to minimize or eliminate the burden on clinical care personnel and medical health facilities.
6. Prioritize the physical and emotional health and safety of our campus community, our visitors, and our human research participants.
7. Encourage all research faculty and personnel to work from home whenever possible, in compliance with UMB operations stage and guidance as existing at that time.
8. UMB will need to be prepared for reverting to severe research restrictions if so directed by local, state, or federal agencies.

FRAMEWORK FOR RESUMING HUMAN SUBJECTS RESEARCH ACTIVITIES

All resumption activities will be consistent with local, state, national directives and institutional policies and procedures. Human subject research resumption activities will be conducted in stages with an initial Stage 0: Preliminary Planning stage. Progression through the stages will be evidence-based and consistent with UMB's response to the current state of the pandemic.

Category Definitions: Research has been classified according to the following:

Category A: Human subjects research that can be performed remotely

UMB currently permits, and encourages, human subject research with no or remote only contact to continue, based on the current requirements and guidelines provided by the Human Research Protections Office (HRPO). Research activities that have no or remote contact only, including informed consent processes, should continue throughout the stages.

Non-COVID-19 human subjects research that can be performed without human contact, e.g., research performed entirely using telehealth or other virtual methods including electronic consent, virtual study visits, mail delivery of study drug or intervention, endpoint measurement using mobile technology (currently allowable) and surveys. Researchers performing Category A research should continue to telework consistent with current UMB policy. All Category A research must comply with HIPAA when obtaining, accessing, or transmitting Personal Health Information (PHI) (See UMB's HIPAA and COVID-19 guidance at https://www.umaryland.edu/coronavirus/faq-content/-what-about-hipaa-compliance-and-covered-entities.php). Research protocols involving routine clinical appointments with no additional risk to the research, clinical personnel or participants are allowed under Category A.

Category B: Human subjects research with the potential for direct benefit to participants

Human subjects research with a potential for direct benefit to participants, which has been approved by the UMB IRB or an external IRB, and requires in-person visits at UMB related facilities. This includes therapeutic benefit for a disease or condition and social services that participants would not have access to if they were not enrolled in a related research study.

Category C: Research with no potential for direct benefit

Human subjects research with no therapeutic intent for participants, which has been approved by the UMB IRB or an external IRB. This includes interventional studies with no therapeutic intent, screening/diagnostic, and observational studies requiring in-person visits at UMB related facilities or in participants' residences.

Category D: Community based human subjects research

Research involving in-person, community-based interventions at sites such as nursing homes, senior centers, and community facilities. Due to the vulnerability of the populations (older adults) at these sites, in-person research increases the risk of COVID-19 infection to these participants, which requires additional planning for resuming this type of research. Researchers are encouraged to refer to the CDC's Preparing for COVID-19 in Nursing Homes at https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html.

Stages

Stage 0 – Preliminary Planning

This Stage is effective immediately. The following preparatory actions should be initiated to allow for resumption of human subjects research operations. Currently permitted research protocols are also required to complete these preparatory actions prior to any contact with participants. Principal Investigators will be required to complete a plan for resuming Human Research Activity (found on the UMB Human Research Protections Office website) as a submission through CICERO for institutional approval to resume research. These plans must be submitted by the Principal Investigator for individual studies. The duty to draft and submit a plan for resuming human research activities cannot be delegated to other study team members.

A plan to resume human subjects research may be developed by research units (Centers, Institutes, Departments) and referenced by all investigators within that unit when submitting their individual protocols as a Reportable New Information via CICERO.

Study personnel as outlined in these guidelines include any employee who has direct contact with participants and/or any employee who has delegated responsibilities under a human subject research protocol. Employees who do not meet this definition, but who are essential for functions that the study team may need (such as security guards, IT support, administrative support, etc.) should be monitored and screened for COVID-19 symptoms via protocols developed and approved by leadership (chairs, directors, deans, etc.) in the units they are employed. (Please see the Department of Environmental and Health Safety's (EHS) COVID-19 Clinical Research Safety guidance at https://www.umaryland.edu/ehs/)

The required elements of plans for resuming human subjects research are as follows:

- Recognizing screening and monitoring cannot eliminate the risk of COVID-19 infection, strict adherence to safety guidelines reduces that risk. All research personnel working in UMB facilities will be required to utilize the **SAFE** on Campus tool used by UMB, and modified for UMMC and more fully described in the UMB COVID-19 Research Advisory Task Force Research Guidelines. Research personnel working at partner institution worksites such as UMMC and FPI shall follow the screening procedures required to enter these worksites.
    - If an employee provides any affirmative response to symptoms of COVID-19 (fever, difficulty breathing, etc.), this tool will generate an email to the employee and the employee's immediate supervisor. The email will include instructions not to come to work (or to leave if already there) and to contact the Employee COVID-19 Hotline. This will also generate a flag email to Employee Health.
- For research personnel that are unable to access the **SAFE** on Campus tool, they will be required to provide the health monitoring information to their Principal Investigator prior to reporting to work each day.
    - Employees will be advised of the symptoms of COVID-19 and will be required to notify their immediate supervisor and the Principal Investigator of the relevant

research project. They are also required to report via the Employee COVID-19 hotline and Employee Health.

- ➢ Plan for screening and monitoring participants and required escorts for potential COVID-19 infection prior to any scheduled visits, interventions, or contact with research personnel.
    - o The Principal Investigator must outline how participants and required escorts will be screened and monitored for COVID-19. This should include providing participants and required escorts with the symptoms of COVID-19 to be aware of and instructions on what participants and required escorts should do should they exhibit any of these symptoms, have tested positive for the virus in the last 30 days or if they have been in contact with someone who has tested positive within the last 14 days. (Please see the Department of Environmental Health and Safety's (EHS) COVID-19 Clinical Research Safety guidance
    - o This requirement is subject to change based on modifications to guidance from federal, state, local, and institutional health officials.
- ➢ Principal Investigators must include patient care considerations that adhere to the Department of Environmental Health and Safety's (EHS) COVID-19 Clinical Research Safety guidance
- ➢ Principal Investigators will communicate with their Schools and adhere to any additional requirements for resuming research;
- ➢ Assess and describe the physical facilities and infrastructure necessary to resume human subjects research while maintaining physical distancing and other infection mitigation activities (include any special accommodations that will be needed) (Please see the Department of Environmental Health and Safety's (EHS) COVID-19 Clinical Research Safety guidance;
- ➢ Identify the social density of both research personnel, participants and required escorts that is anticipated upon resumption of research activities, plan for scheduling and staffing to minimize social density while maintaining adequate supervision and safe practices in the course of research;
- ➢ Identify essential personnel for conducting research activities, including any persons who may have contact with participants (Please see UMB's COVID-19 hotline information at https://www.umaryland.edu/coronavirus/hotline/);
    - o Determine actions for responding to potential COVID-19 infection in research personnel participants, and required escorts, including communication plan for providing notice to anyone in contact with potential or actual infected persons;
    - o ***At all Stages, if an employee is found to have COVID-19, or is exposed to an infected individual, the incident must be reported to the Employee COVID-19 Hotline***.

- ➢ Plan for appropriate and frequent disinfection and cleaning of spaces, including shared spaces, that are accessed by participants and research personnel (include additional disinfection and decontamination procedures for areas which were occupied by persons who test/tested positive for COVID-19). (Please see the Department of Environmental Health and Safety's (EHS) COVID-19 Clinical Research Safety guidance)
- ➢ Encourage all active members of the research team to receive a Flu vaccine upon availability prior to or during flu season;
- ➢ Identify and catalog Personal Protective Equipment (PPE) needs for research personnel participants, and required escorts for resuming and continuing research for the duration of the study. (Please see the Department of Environmental Health and Safety's (EHS) COVID-19 Clinical Research Safety guidance at https://www.umaryland.edu/ehs/)
- ➢ Provide training to all research personnel on the appropriate use of PPE and safety precautions;
- ➢ Communicate with all members of the research team on the use of the UMB Hotline for reporting safety concerns or non-compliance with these guidelines.
- ➢ Principal Investigators will prioritize their research protocols in the order that they wish them to be considered for resumption;
    - Institutional review and approval will be performed one study per investigator at a time. For each protocol, the Principal Investigator must submit a Plan for resuming human research activities. This plan must describe how the PI will implement Environmental Health and Safety's (EHS) COVID-19 Clinical Research Safety guidance at https://www.umaryland.edu/ehs/. The Principal Investigator may submit a unit specific plan that has been reviewed and approved by the appropriate decision-makers of that unit;
    - Applications for resuming human subject research not consistent with the stage currently in effect will be denied and must be re-submitted for consideration at the appropriate stage. The Institutional Official reserves the right to disallow resumption of a protocol if the number of protocols from a single PI seems excessive considering the safety steps required to resume research or if there is a concern related to the potential risk for resuming the research.

Stage 1: Minimal Risk Studies that are remote or no contact and research that has the potential for direct benefit to the research subject

This stage includes ongoing human subjects research that has been allowed during the severe restriction period as described in previous guidance documents (Category A) and the resumption of social, behavioral, and clinical human subjects research with a potential for direct benefit to participants requiring in-person visits, which has been approved by the UMB IRB or an external IRB (Category B).

Stage 2: Studies that do not have the potential for direct benefit to the research subject

Stage 2 includes research in Categories A and B. In addition, research may resume that involves human subjects with no potential direct benefit to participants, which has been approved by the UMB IRB or an external IRB (Category C). This includes interventional studies with no therapeutic intent, screening/diagnostic, and observational studies that require on-campus in-person visits.

Stage 3: Studies involving community-based interventions

Stage 3: Resume research involving in-person, community-based interventions at sites with populations (older adults) known to be more vulnerable to COVID-19 infection (e.g., nursing homes, senior centers).

Special Considerations

Research with Increased Risk of Aerosolization

Clinical research that includes or induces coughing, sneezing, or other aerosolization risks must include proper, and approved, infection control procedures. This includes testing all participants in such research for COVID-19 infection prior to any research visits. This includes, but is not limited to:

• Bronchoscopy	• Chest physiotherapy	• Sputum induction	• Manual ventilation
• Intubation	• Nebulized medication	• High-flow nasal cannula	• Exercise testing (CPET)
• Laryngoscopy	• Spirometry/Pulmonary function testing	• Non-invasive ventilation (BIPAP/CPAP)	• Selected oral and dental procedures
• Tracheostomy care	• Defibrillation	• Open suction	

Research Performed in Clinical Care Locations

Human subjects research performed in clinical care locations adds complexity and requires measures to protect the health and safety of health care workers while respecting and preserving the capacity of the facility to provide clinical care. Any research that requires access to clinical care locations may only resume with the approval of the leadership of the location and units (UMMC, UMMS, FPI, etc.) affected or included to ensure research activities do not interfere with essential clinical care or complicate social and population density management.

Research Performed at International Locations

For international research, the above guidance applies. Directives from local ethics committees or Ministries of Health may supersede this guidance. Follow local in-country directives and coordinate with UMB IRB.

Research Subject to VA Rules and Regulations

If the research is VA funded or is conducted using VA facilities, the Principal Investigator is responsible with complying with VAMHCS guidance on resuming human subjects research.

Research Including Increased Risk to Participants

Research that targets or includes participants with increased risk of contracting COVID-19 should include additional safety measures and protections when conducting in-person research activities.

Supply Management

The resumption of human subjects research may increase the amount of supplies necessary for operations to be received by UMB. Due to the general increased demand for specific supplies (e.g., PPE) and utilization of delivery, there are likely to be delays and shortages throughout existing and identified supply lines. The delivery and dissemination of supplies will also cause increased physical interactions. All human subjects research activities should be scheduled and conducted based on the available supplies and include plans for re-scheduling should supply deliveries be delayed.

Compliance Assurance

UMB's core value of accountability is of paramount importance for all research personnel following these guidelines. This includes following all UMB, UMMS, State, and City guidance for requiring masks when in public or shared spaces, ongoing good hygiene for infection prevention, and physical distancing.

To monitor the success of each stage, as well as identify any areas of concern in the implementation of these guidelines, compliance checks by safety and compliance specialists will occur. These compliance checks will focus on safety measures, social/population density, mask/PPE equipment use, and fidelity to approved Research Activities Resumption Plans. Any deviations or deficiencies will require corrective measures to minimize risk of infection and promote safety.

Principal Investigators are responsible for immediately addressing concerns regarding the conduct of research. The PI may seek the assistance of the appropriate department chair, dean, clinical unit leader, or research oversight committee for swift correction as needed. In addition to following these guidelines, PIs must continue to follow all UMB HRPP policies and procedures, including requirements for submitting RNIs.

The UMB Hotline allows for anonymous reports of concerns regarding safety and/or compliance with these guidelines during the staged resumption of human subjects research. Any such reports will result in a compliance check and potential corrective action plan.