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.

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PROCESS FOR RESUMPTION OF HUMAN RESEARCH

FOLLOW THESE STEPS:

1. Principal Investigators will have prioritized their research protocols (in Phase 0) in the order that they wish them to be considered for resumption.
2. Complete this UMB Environmental Health and Safety Checklist (below) for Resuming Clinical Research **FOR EACH** currently approved (UMB or external IRB) human research protocol the Principal Investigator want to resume. This tool can be found at https://www.hrpo.umaryland.edu and the UMB COVID-19 website https://www.umaryland.edu/coronavirus/
3. Principal Investigators should ensure that their individual plans are consistent with their School's and Department's Operations Assessment Tool. This tool can be found at https://www.hrpo.umaryland.edu and the UMB COVID-19 website https://www.umaryland.edu/coronavirus/
4. All requests for resumption of research must be submitted under the appropriate Stage. Any requests that are submitted during an incorrect Stage will be denied and must be re-submitted during the appropriate Stage for consideration.
5. Submit BOTH this Checklist and the Operations Assessment Tool through the Reportable New Information (RNI) pathway in CICERO.
6. It is mandatory for ONLY the Principal Investigator to submit the RNI in CICERO for each study. RNIs from team members will not be accepted.
7. The Checklist and the Operations Assessment Tool will be reviewed by institutional representatives for appropriateness.
8. Acknowledgement of your submission through CICERO RNI pathway will be the documentation to proceed with resumption of research.
9. Do not proceed with research resumption until such time as you receive the acknowledgment in CICERO.

For questions regarding completion of these forms please contact Dr. Julie Doherty at jdoherty@umaryland.edu

Checklist for Resuming Clinical Research

The following checklist outlines actions to consider for resuming clinical research. This checklist is meant as guidance for assessing safety for clinical studies and sites. When working at non-UMB clinical sites, safety procedures for the host site should be followed. Concerns that the host site does not have adequate safety procedures in place should be reported to the clinical site leader. Some items may not apply to every clinical site. Check N/A, or customize this form, as needed.

CLINICAL OPERATIONS

ITEM	COMPLETE	N/A	NOTES
Develop a work schedule to minimize onsite personnel.			
Enroll approved personnel in SAFE on Campus screening tool or create alternate screening plan for any personnel unable to access SAFE on Campus.			
Plan to maintain physical distancing (6 feet of separation) whenever possible and promote use of face coverings when physical distancing cannot be maintained.			
Ensure you have sufficient Personal Protective Equipment (PPE) supplies to conduct research safely. Take inventory and order well in advance.			
Cross-train research staff to fill in for others who may be sick or unable to come to work.			
Train all research personnel on appropriate use of PPE and safety precautions.			
Develop a plan for cleaning and disinfection of high-touch surfaces within the clinic and ensure supplies are available.			
Routinely back up critical research data.			
Make a plan for the sudden cessation of operations, such as in the event of COVID-19 infections of clinical staff or participants.			

CLINICAL FACILTIES

ITEM	COMPLETE	N/A	NOTES
Secure approval from EACH clinical site(s) for resumption of research activities (e.g., UMB, UMMS, FPI).			
Waiting and clinical areas have been reconfigured to promote physical distancing (see EHS Guidelines).			
Physical distancing signage in place.			
Adequate alcohol-based (60% or more) hand sanitizers are available.			
Plexiglass or clear barriers are installed between reception and waiting areas.			
Protocols are in place for custodial service cleaning.			
Adequate IT is available for telemedicine visits.			

PARTICIPANT MANAGEMENT

ITEM	COMPLETE	N/A	NOTES
Participants advised to make appointments online or call before arrival.			
Measures are in place to limit participant contact with computers, keyboards, or other equipment.			
Measures are in place to promote continued use of telemedicine.			
Protocols are in place to promote online or telephone participant check-in.			

Updated screening protocols are in place for COVID-19 symptoms.			
Communication plan for informing participants of any potential contact with suspected COVID-19 infected person(s).			
Protocols are in place for managing participants with acute respiratory symptoms.			
Protocols in place to limit the use of nebulizers.			
Requirements for the use of facemasks and other PPE are in place.			
Procedures are in place to prohibit visitors, children, or guests			
Protocols are in place for transporting participants with respiratory symptoms to home or to the local hospital.			
Communication messages have been developed and implemented to inform participants on scheduling appointments and which visits should be in person or virtual.			

COMMUNICATIONS

ITEM	COMPLETE	N/A	NOTES
Personnel are subscribed to receive UMB alerts.			
Communication plan for informing research personnel or other exposed persons of any potential contact with suspected COVID-19-infected person(s).			
Communicate with all involved persons the availability of the UMB Hotline for reporting safety or other non-compliance concerns.			
COVID-19 procedures applicable to the clinical site have been reviewed with all members of the team.			

List of critical contacts has been complied and provided to all team members.			
Expectations and roles have been communicated to all personnel to avoid potential confusion and conflicts.			
Personnel have access to materials and resources that may be needed to work from home.			
Meetings have been transitioned to remote formats, such as Zoom, Webex, or Microsoft Teams whenever possible.			

CLINICAL SUPPLIES

ITEM	COMPLETE	N/A	NOTES
Ongoing inventory plan for clinical materials, particularly those that are controlled, high value, and/or high risk is in place.			
As possible, a plan to maintain backup stocks of materials (e.g., cell lines) to ensure any disruption to operations does not result in their loss is in place.			

SECURITY

ITEM	COMPLETE	N/A	NOTES
Personnel have been provided the following contact information: • Emergency – 911 • UMB Police Non-Emergency and Safe Walk/Safe Ride – 410-706-6882 • EHS – 410-706-7055 • UMB Hotline – 866-594-5220 • COVID-19 hotline - 866-594-5220			

System for monitoring for life-threatening emergencies is in place (due to fewer people in the workplace, life-threatening emergencies may go undetected, consider implementing a "text-in/text-out" or similar system).			
Guidance to all personnel to properly store valuables (e.g., laptops are out of sight and in locked drawers) has been provided.			
Clinical doors will be locked at the end of each day.			
Ensure windows are closed, if applicable.			
Guidance to all personnel to take needed personal belongings home at the end of each day has been provided.			

ENERGY REDUCTION

ITEM	COMPLETE	N/A	NOTES
Any non-essential equipment will be unplugged when not in use, even if it is turned off.			
Fume hoods will be closed when not in use and at the end of each day.			
Lights will be turned off when personnel leave.			
In UMB facilities, plans to avoid working 7 p.m.-7 a.m. are in place (most UMB buildings are on energy setbacks during this time and non-research buildings are also on energy setbacks on weekends and holidays).			

Campus Operations
Proposal Assessment Questions for
COVID-19 Recovery Task Force Teams

Current State w/Operational Questions	Need Being Requested
Location – Please provide building and floor, PI name if applicable (address).	
Hours and days of operations requested; please be detailed, including needs for weekend support.	
Purpose – What will you be doing in the space requested (laboratory research, experiential teaching/learning, etc.).	
Parking/Transportation needs? (24-hour access available in Pratt, Grand, Plaza, and Lexington garages). Consider who may need access to garages and which garages you would like to access (e.g., re-assignment may be required). Consider whether existing parking access to requested garages is already in place.	
Utility Needs – Detailed list of HVAC, water, electricity needs by location (floor, room, etc.). Please consider laboratory equipment, lunch room use, etc. Goes toward energy reduction plans currently in place and which may need to be altered.	
Custodial Services – What custodial needs are you requesting – e.g., trash bag disposal, cleaning common rooms (bathroom, lunch rooms). Current hours of operation are Monday-Friday, 7 a.m.-3:30 p.m. (EVS cleans requests by Work Order, only after EHS decontaminates lab and clears it for EVS cleaning.) Please identify if the needs apply to laboratory, office, or common spaces. Two-week lead time for deep cleaning of space is required.	
Public Safety – Security Officers need to be present for building during open hours; current operations support 8 a.m.-4:30 p.m. Please outline additional weekly and/or weekend needs.	

Campus Access – Procedure requires advance approval via temporary campus access form on UMB's COVID-19 site. Will those requesting access be staff/faculty, students, or contractors?	
Other Comments:	