INTRODUCTION/BACKGROUND

This guidance provides a tiered, staged approach for resuming human subjects research activities at the University of Maryland (UMD), 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. The overarching goal of these guidelines is to minimize the research risks while maximizing the research benefits for both the research investigators and the human research participants.

The UMD President, in consultation with the Vice President for Research (VPR), will determine UMD’s progression through the stages, based on the factors included herein and in consultation with the President’s Cabinet and other key stakeholders as determined by the VPR. In addition to the guidelines noted here, UMD’s President, and VPR/Institutional Official, with the Human Research Protections Program and Institutional Review Board, must make decisions based on current rules and regulations associated with human subjects research. Given the diversity and complexity of our research, it is understood that studies within schools/colleges may be operating at different stages until we have completely resumed face-to-face research.

These guidelines apply to all human subjects’ research at UMD or by UMD faculty, students, or staff, regardless of whether the research was approved by the UMD 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 federal directives regarding required safety measures during the COVID-19 pandemic, and institutional policies and guidelines.
2. Limit close physical interactions among all individuals involved in human subjects research to the minimum necessary for conducting research visits.
3. Anticipate and plan for unintended but possible events, given that human subject research is complex and diverse.
4. Recognize that some human subjects research has a potential direct benefit to participants that balances risk through promotion of safe practices.

5. Provide documented clear communication to all human subjects of the health and safety procedures taken by the research team and for themselves prior to, during and after their study encounters.

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 UMD operations stage and guidance as existing at that time.

8. UMD will need to be prepared for reverting to severe research restrictions if so directed by local, State, or federal agencies.

9. Support detailed mentoring for students on the research team.


FRAMEWORK FOR RESUMING HUMAN SUBJECTS RESEARCH ACTIVITIES

All resumption activities will be consistent with local, State, federal directives and UMD and University System of Maryland (USM) policies and procedures. Human subject research resumption activities will be conducted in two stages.

CATEGORIES OF HUMAN SUBJECTS RESEARCH

These are categories of research activity that vary in terms of potential exposure and risk related to COVID. Further, a designation of research into one of these categories will be evidence-based and consistent with UMD’s response to the current state of the pandemic. We recognize that some research may fit into more than one category depending on whether different types of data collection procedures are being implemented within one project.

Research has been classified according to the following:

Category A: New or restarted 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 intervention, endpoint measurement using mobile technology (currently allowable), and surveys) and is approved by the UMD IRB.

Additional Guidance: UMD 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 Institutional Review Board (IRB). Research activities that have no contact or remote contact only, including any contact required for the informed consent processes, can continue through the standard IRB approval protocols.
Researchers performing Category A research should continue to telework consistent with current UMD policy.

**Category B:** New or restarted human subjects research that requires in-person contact with research participants, where that research has the potential to directly benefit participants who would not receive such a benefit were they not enrolled in the research study, and is approved by the UMD IRB. The term “benefit” includes, but is not necessarily limited to, treatment for a disease or condition and/or the provision of social services that participants would not have access to if they were not enrolled in a related research study or service.

**Category C:** (1) New or restarted human subjects research in participants deemed low-risk for COVID-19, per CDC guidelines; or (2) new human subjects research with no intended therapeutic benefit to participants (e.g., includes interventional studies, projects with indirect or overall general benefits, screenings and/or diagnostics, and observational studies requiring in-person contact), which has been approved by the UMD IRB or an external IRB.

**Category D:** New or restarted human subjects studies in participants at high risk for COVID-19, per CDC guidelines.

**Category E:** New or restarted in-person, community- and school-based human subjects research studies and interventions at sites such as nursing homes, senior centers, schools, and community facilities.

Additional Guidance: Due to the vulnerability of the populations (including 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 CDC’s Preparing for COVID-19 in Nursing Homes at [https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html](https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html).

These entities will likely each have their own decision-making process regarding the allowance of in-person/contact-based human subject research activities. Context will be considered when reviewing plans that involve these entities and their populations.

**Category F:** Resumption of international human subjects research studies. Please see guidance posted on UMD IRB Website.

**PHASING IN HUMAN SUBJECTS RESEARCH ACTIVITIES: STAGES 1 & 2**

**Stage 1 Human Subjects Research**
Stage 1 will begin when the UMD President approves. Stage 1 will include the continuation of Category A studies, and the continuation of and initiation of approved Category B and Category C studies.
**Stage 2 Human Subjects Research**
Stage 2 will begin when the UMD President approves. Stage 2 will include the continuation of Category A studies, the continuation of and initiation of approved Category B and Category C studies, and the continuation of and initiation of approved Category D and E studies.

**Please Note:**
Category F studies will be considered separately keeping in mind local rules and regulations and the safety of all UMD employees and human subjects and following the guidance posted on UMD IRB Website.

**Plan Submission Guidance**
Principal Investigators should initiate the following preparatory action to allow for resumption of human subjects research operations. Currently permitted research protocols (i.e., current projects that have transitioned to non-contact, online, etc.) are also required to complete these preparatory actions prior to resuming or beginning any in-person contact with participants.

Principal Investigators are required to draft a plan for resuming Human Subjects Research Activity and submit the plan for institutional approval to restart or begin in-person research. These plans must be submitted by the Principal Investigator for individual studies. The Safety Assuredness & Guidance Plan for Resuming In-Person Human Subject Research will be submitted to the IRB by the PI after approval by the unit Chair and the Dean of the College. If a student is submitting a plan, it must also receive approval from the student’s advisor listed on the IRB Application. Once approved by the Chair and Dean (and advisor, if applicable), Principal Investigators will submit the Safety Assuredness & Guidance Plan for Resuming In-Person Human Subject Research through the Create New Package mechanism in IRBNet.

A special COVID19 Human Research Protections Review Team will review each plan and recommend for final approval by the IRB and Institutional Official.

The duty to draft and submit a plan for resuming human research activities is the Principal Investigator’s duty and cannot be delegated to other study team members.

The required elements of the Safety Assuredness & Guidance Plan for Resuming In-Person Human Subject Research, which are subject to change based on guidance from federal, State, local, USM, and/or UMD officials, are as follows:

1. Principal Investigators must recognize that screening and monitoring cannot eliminate the risk of COVID-19 infection. In order to reduce that risk, the research team must strictly adhere to the following safety guidelines.
   - All personnel must review the UMD Return to Campus Guidance and abide by the Community Responsibility Pledge found within that guidance.
   - In order to participate in research activities, all personnel must complete the Return to UMD Daily Self-Monitoring for COVID-19 questionnaire that is distributed each day by email.
If an employee provides any affirmative response to symptoms of COVID-19 (e.g., fever, difficulty breathing) via the Return to UMD Daily Self-Monitoring for COVID-19, the Principal Investigator or other supervisor must instruct the employee not to come to work and to contact the University Health Center.

2. 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 and instructions on what participants and required escorts should do if 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.

3. Principal Investigators will communicate with their appropriate school/college research boards or directors (those individuals in charge of approving research protocols at the schools/colleges) 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
   - 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. UMD Physical Distancing Guidelines

4. Researchers must identify essential personnel for conducting research activities, including any persons who may have contact with participants
   - Determine actions for responding to potential COVID-19 infection in research participants, and required escorts, including communication plan for providing notice to anyone in contact with potential or actual infected persons. Contact UMD Health Center.

5. In all Categories, if an employee is found to have COVID-19, or is exposed to an infected individual, the incident must be reported to the employee supervisor and the University Health Center.

6. Researchers must 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).
   - 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.

Provide training to all research personnel on the appropriate use of PPE and safety precautions;

Communicate with all members of the research team for reporting safety concerns or non-compliance with these guidelines. Compliance Reporting Line

Visitors/Escorts must follow the Campus Visitor Guidelines [Draft]

UMD Physical Distancing Guidelines

UMD COVID-19 Guidelines for Environmental Cleaning and Disinfection

7. Applications for resuming human subject research not consistent with the stage currently in effect will be denied and must be re-submitted for consideration in 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.

8. Please upload your completed and signed Safety Assuredness & Guidance Plan for Resuming In-Person Human Subject Research.

9. Submit these documents through IRBNet by Creating a New Package. Upload the documents, sign the package, and submit to the UMD IRB.

IMPORTANT NOTES:

**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 UMD. 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
Accountability is of paramount importance for all research personnel following these guidelines. This includes following all UMD, State, and County 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 reporting is encouraged through the Compliance Reporting Line. These compliance reports will focus on safety measures, social/population density, mask/PPE equipment use, and fidelity to approved Safety Assuredness & Guidance Plan for Resuming In-Person Human Subject Research. 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 UMD policies and procedures.

Please contact irb@umd.edu with any questions.