

## Notice to UMB Research Community Regarding Current COVID Pandemic Surge

Dear UMB Investigators,

We wanted to follow up on our previous correspondence and the subsequent meetings regarding Human Subjects Research during the current COVID-19 surge.

Representatives of Occupational and Environmental Medicine, Emergency Services, the IRB, HRPO, Infectious Disease, Medicine, and IHV met to discuss the current surge conditions.

As you may know, there are ongoing discussions regarding the re-deployment of UMB personnel to assist the medical system during this surge. It is important that all research be considered for its potential impact on clinical care personnel.

The discussion centered on the following considerations related to Human Subjects Research:

- Safety to participants
- Safety to research personnel
- Impact on research locations
- Impact on clinical care staff
- Potential capacity to effectively conduct research activities

At this time, we are not recommending a return to the previous Phases regarding cessation and resumption of human subjects research. Based on this, and previous discussion(s), the consensus is to recommend a deceleration in new projects and a deceleration in aggressive enrollment in current research projects. Any new projects should include consideration for pandemic responses, as needed.

At this time, we are also strongly recommending moving to remote research activities, whenever possible.

Faculty researchers should assess their current individual projects to determine the ongoing safety of and the feasibility to perform research activities.

Our recommendation is the Principal Investigator's assessment should include review for:

- Adequate staff with appropriate expertise, as required by the research
- Availability of PPE, consistent with the needs of the research activities
- Availability of COVID-19 testing for research personnel
- Conditions under which the research may need to be paused

Your School and department may require additional considerations.

This review is internal to the Principal Investigator's department/division. Submission of reportable new information to the IRB regarding deceleration decisions is not required by UMB. Please consult sponsors and follow any requirements they set forth.

Suggested questions Principal Investigators should consider when assessing their research for potential deceleration include:

- Is continuation of my protocol (s) essential during this period?
- Have I discussed plans for continuing research with my supervisor and sponsors?
- Do I have a contingency plan for adequate, qualified staffing to support ongoing research activities?
- Can my research continue without reliance on clinical staff?
- Would interruption of enrollment/research activities negatively affect the rights or welfare of potential or established research subjects?
- Can any of the research procedures be continued virtually?
- If direct contact with research subjects is required, does my team have adequate PPE to allow safe interactions?
- Do I have a plan for verifying vaccination of research subjects/staff?
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As discussed herein, human subjects research activities must not create an additional burden on clinical care personnel at our partner institutions.

We will continue to monitor the ongoing COVID-19 conditions and will provide updates, as necessary.

For questions, please contact Dr. Julie Doherty, Assistant Vice President, Research Compliance at [jdoherty@umaryland.edu](mailto:jdoherty@umaryland.edu) or Robert Rosenthal, MD, UMB IRB Chair at [rrosenthal@som.umaryland.edu](mailto:rrosenthal@som.umaryland.edu)

Thank you.

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