March 13, 2020

Subject line: New restriction in human subject research due to COVID-19

Dear Colleagues,

The continued health and well-being of our entire University of Michigan community remains paramount. In an effort to minimize the risk of contracting or spreading COVID-19 in human participant research interactions, and to preserve personal protective equipment for clinical care, the university today is placing the following temporary restrictions on human subjects research effective Saturday, March 16 and continuing through May 1. We will continue to reevaluate this timeframe.

- 1. All research studies that currently require direct person-person interactions, but do not offer direct therapeutic (drug and device) benefit to subjects, must immediately pause new enrollment and discontinue in-person interactions unless study procedures can be modified to use alternative methods of gathering study data (e.g., telephone interviews, email, etc.). Studies involving no direct person-person interactions with participants may continue (e.g., secondary data analysis, remote or online contact, etc.).
- 2. Studies that involve the administration of drugs or monitoring of devices that provide therapeutic benefit to study participants may continue, but study teams should consider alternatives to having the participant be on-site for all study visits as possible (e.g., electronic monitoring and/or data collection). Study teams also should evaluate how illness and absences, drug shortages, facility closures, or lack of required personal protective equipment may impact treatment delivery or monitoring.
- 3. IRB review of new studies that are not essential for managing COVID-19 circumstances may be delayed.

Principal investigators, schools, colleges, and units will partner with their research staff, students, and graduate student research assistants who are impacted by this pause in work to identify an appropriate plan moving forward, including any financial ramifications this may pose. Faculty principal investigators should actively work to communicate this change to their teams.

Thank you again for your continued support of the U-M research enterprise. I encourage you to visit our <u>COVID-19</u>: <u>Research Operations at U-M</u>, which includes the latest information and resources so that our campus community can best manage their research and scholarship activities. This webpage will be updated regularly and will be the source of ongoing guidance in this evolving situation.

Sincerely,

Rebecca Cunningham, M.D.

Interim Vice President for Research

William G. Barsan Collegiate Professor of Emergency Medicine