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To: pharmacy.all@umich.edu
Subject: FW: COVID-19: New restrictions for human subjects research
Date: Friday, March 13, 2020 3:08:48 PM

Hello everyone. I realize that for some of you this may have huge implications. Please reach out to me if this is the case. We can brainstorm how to facilitate your path going forward!

Vicki

From: U-M Office of the Vice President for Research <targetemail@umich.edu>
Sent: Friday, March 13, 2020 2:51 PM
To: vellingr@umich.edu
Subject: COVID-19: New restrictions for human subjects research

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 is placing temporary restrictions on human subjects research effective Saturday, March 14, and continuing through Friday, 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 (e.g., electronic monitoring and/or data collection, as possible). 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 the teams.

Thank you again for your continued support of the U-M research enterprise. I encourage you to visit our [COVID-19: Research Operations at U-M page](#), 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

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