THE UNIVERSITY OF TOLEDO | Office of Research and Sponsored Programs

March 17, 2020

Dear Colleagues,

The continued health and safety of our University of Toledo and regional communities remains a top priority. In an effort to minimize the risk of contracting or spreading COVID-19 due to human participant research interactions and to preserve personal protective equipment for clinical care, the University is placing temporary restrictions on human subjects research effective Tuesday, March 17, 2020 and continuing through Friday, May 1. We will continue to reevaluate this timeframe.

1. **Applicability:** All human subject studies that involve face-to-face interactions with participants must pause new enrollment and discontinue face-to-face interactions unless these interactions are ***essential*** to the immediate health and well-being of the participant (meaning that the interactions provide immediate and necessary therapeutic benefit for a participant's medical condition, or the interactions cannot be safely discontinued). All face-to-face interactions with participants for ***non-essential*** studies are temporarily halted unless procedures can be modified to use alternative methods of gathering study data (e.g., on-line technologies, telephone interviews, email, etc.). Studies involving no face-to-face interactions with participants may continue (e.g., tissue collection for subjects undergoing standard care, secondary data analysis, remote or online contact, etc.). These statements also apply to "Not Human Subject Research" studies such as program evaluations, quality improvement/quality assessment studies, and class projects.

   Investigators who believe that their study meets the definition of ***essential*** must notify the HRPP of their plans to continue face-to-face interactions by March 20, 2020. If you are unsure how these measures apply to your study, please review the companion FAQ document, and contact the Human Research Protection Program (HRPP) for guidance.

2. **Amending Research Procedures:** If you currently have face-to-face interactions scheduled with human participants through Friday, May I and can feasibly continue research through alternative means (video conference, online technology. etc.), you must submit a request for a modification to the Institutional Review Board (IRB) prior to implementing changes in the protocol. Please include revised informed consent documents and describe the modifications in the consent process, data collection

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procedure, and revised data management plans in your request. All requests to modify a study should be done via the regular amendment process in IRB Manager.

3. **Conduct of Essential Studies:** Studies that meet the above definition of ***essential*** may continue face-to-face interactions, but study teams should consider alternatives to having the participant 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 study treatment delivery or monitoring and consider whether amendments to procedures may be necessary to protect participants or study staff. If a change must be made immediately to eliminate apparent immediate hazards to participants, notify the IRB by following the procedures in the Deviation Procedure.

4. **IRB Review Time:** IRB review of new studies that are not essential for managing COVID-19 related issues may be delayed.

5. **Study Funding Issues:** Please contact the Office of Research and Sponsored Programs if you require a no-cost extension for your funded project.

Thank you again for your continued support of The University of Toledo research enterprise. I encourage you to visit the COVID-19 website (Research Guidance). This webpage will be updated regularly and will be the source of ongoing guidance in this evolving situation.

Sincerely,

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