March 17, 2020

TO: Researchers currently conducting work using human subjects

FROM: Joseph R. Haywood
Assistant Vice President, Regulatory Affairs
Professor, Pharmacology and Toxicology

Dear Colleagues,

As the situation with the novel coronavirus continues to rapidly evolve, ensuring continued public health and safety is of greatest importance. To reduce the risk that the coronavirus poses to the health and safety of our research community and after considerable discussion and consultation, the university is placing temporary restrictions on human subject research effective immediately. These restrictions will last until Monday, May 4, and we will reevaluate this decision on an ongoing basis, sharing additional updates or modifications as more information becomes available.

1. Unless there is the potential for direct therapeutic benefit to the participant (drug or device), any in-person participant interaction must immediately pause. Research procedures involving no direct in-person interactions with participants may continue (e.g. data analysis, online surveys, telephone interviews). This applies to both exempt and non-exempt research studies.

2. During this pause, researchers should consider whether it is feasible to modify their in-person participant research procedures to use alternative methods to gather study data (e.g. telephone, online). For non-therapeutic studies, if the study cannot be conducted without the in-person participant interaction, new participant enrollment and any ongoing in-person participant interactions must pause.

3. For studies that have the potential for direct therapeutic benefit to participants, any in-person participant interactions must be minimized and alternatives for in-person data collection should be considered as feasible. Before new participant enrollment, researchers should consider their ability to enroll new subjects based on current and future staffing resources, facility restrictions, and any other factors specific to the study. Researchers should also consider the rapidly evolving environment and plan for research continuity, such as planning for facility restrictions or closures, illness or absence of research team, drug or device shortage, or lack of required personal protective equipment.

This pause will require coordination and communication with many individuals in the research community. We ask that Principal Investigators and their college and units work with their research team, study sponsors, and others to evaluate impacted studies and develop a plan appropriate to their research procedures, including financial considerations. For more information about considerations related to sponsored projects, please visit the MSU Office of Sponsored Programs Administration webpage related to the coronavirus (COVID-19).

We recognize the significant impact to ongoing research that these restrictions will have, and the difficulty that this poses to research teams and others. Our office and teams are here to help researchers navigate these requirements. Please note that COVID-19 related submissions will be
prioritized by the MSU Human Research Protection Program (HRPP) office, and this may delay the review of new submissions and modifications that are not related to COVID-19.

Resources will also be available through the SVPRI COVID-19 webpage which provides information as it relates to the conduct of research. This webpage will be updated to address changes in this rapidly evolving environment. The SVPRI webpage also links to the HRPP webpage which includes information about the impact of COVID-19 on the HRPP and addresses questions from researchers, including Institutional Review Board requirements for modifications.

Thank you for your continued support of MSU research and for your help in protecting our research participants and research teams.