DATE: May 27, 2021  
TO: MTU Researchers  
FROM: Kathleen Halvorsen, Associate Vice President for Research Development  
       Christina Lehmann, Director Human Research Protection Program  
RE: Discontinued: Human Subject Research Ramp Up Guidance

On March 24, 2020, all studies and procedures involving person-to-person interaction were suspended by the MTU Administration due to the onset of COVID-19 prevalence within the State of Michigan and the restrictions enacted at both the State and Michigan Tech levels. In July 2020, guided by the MTU Flex Task Force, the implementation of safety protocols available at each MTU Health and Safety Level, and specific human subject research (HSR) COVID-19 guidance and requirements, some person-to-person research activities began to safely resume.

Under the continued guidance of the Centers for Disease Control and Prevention (CDC) and Michigan Occupational Safety and Health Administration (MIOSHA), the MTU Flex Task Force moved the Institution to Health and Safety Level Two on May 25th, 2021. In addition to this move to Level Two, COVID-19 vaccinations are readily available. For these reasons, the HSR-specific guidance and additional requirements found in the “Human Subject Research Ramp Up Guidance” are discontinued effective June 1, 2021.

Moving forward, researchers are responsible for the following when conducting research that includes person-to-person interaction:

1. Remaining vigilant in knowing the current MTU Health and Safety Level and adhering to the protocols at each level;
2. Providing all potential human subject research volunteers with the most current version of the “Participating in Research During COVID-19” information sheet; and
3. Maintaining contingency plans in the event of a shift into any of MTU Health and Safety levels three, four, or five.

It is important to note that while the vaccine data shows reduced risk and severity of infection, the vaccine is not proven to completely prevent infection. Therefore, research teams must continue to prioritize the health and safety of human subject volunteers and their research teams as they conduct their research projects. Researchers may NOT restrict recruitment and participation based on vaccination status of potential participants. Additionally, in order to adhere to the MTU Flex Task Force guidance and to prevent unnecessary collection of private health information, researchers may not directly ask participants about their vaccination status. If the information is voluntarily provided by participants, the information may not be officially documented by the research team. Due to this, in addition to the minimal requirements found in the MTU Flex protocols, each research team may elect to require additional protections. For instance, additional protections might include asking all participants and research team members to remain masked throughout the research activities and symptom monitoring at all levels.

It is the primary researcher’s responsibility to ensure that only person-to-person activities that can be done safely and in accordance with the current MTU Health and Safety Level protocols are conducted.

Any questions regarding allowability or for special considerations, please contact irb@mtu.edu.