June 8, 2021

Re: Human Subject Research and COVID-19 Concerns

Dear Colleagues:

The health and safety of our University of Toledo and regional communities continues to be top priority during the COVID-19 pandemic. This is an update on my prior letters regarding temporary restrictions on human subject research.

All fully vaccinated people entering campus facilities (meaning they have received the final dose of the COVID-19 vaccine at least two weeks prior) are no longer required to wear a face covering unless in a healthcare setting. Therefore, as of June 8, 2021, I am further easing the restrictions on face-to-face interactions with human subjects for non-essential studies taking place in non-medical settings. Research activities with human subjects that take place in healthcare settings must follow the protocols established by the healthcare establishment.

Face-to-face research with human subjects taking place at UToledo locations must continue to use the COVID pre-screening questionnaire or researchers must have similar communication with participants before they arrive on campus. If someone voluntarily discloses that they are not fully vaccinated, masks and distancing requirements are required for participants and researchers. Since researchers cannot guarantee that participants do not have COVID-19, a statement to this effect is required in the risk section of the informed consent form when more than one participant is present in-person (e.g., focus groups).

Please see the COVID-19 Research Guidance website (https://www.utoledo.edu/research/rs/ rsp/coronavirus/#human) webpage for more detailed information. This decision will be periodically reevaluated.

Sincerely,

Frank J. Calzonetti
Vice President for Research