COVID-19 and TUN HUMAN SUBJECTS RESEARCH (*updated September 23, 2020)*

[*Note: Guidelines involving this pandemic are changing constantly. Investigators should often check back for updates to this policy, paying close attention to the date of the posting to ensure that the most recent directive is the one being worked with. Also, current CDC and other government guidance on safe practices must be reviewed and followed.*]

Foremost in the conduct of human subjects research at Touro University Nevada (TUN) is the protection of our subjects. With the advent of the COVID-19 pandemic, and consistent with "to prioritize public health and safety," the ethical focus of the TUN IRB takes on particular resonance—***not only for our study participants, but also for our faculty, students and staff involved in human subjects research*.**

Additionally, all federal and Nevada government guidelines on social distancing and other safety procedures must be followed for any study involving direct physical interaction with subjects. The dashboard for Nevada COVID-19 is here.

Touro University Nevada's IRB issues the following guidance to all investigators conducting research with human subjects:

- Most ongoing research involving direct physical interaction with human subjects should have ceased with the stay at home order that began in March 2020. The following guidance pertains to those on-going projects:

    - An exception to the directive to cease projects involving direct physical interaction are studies involving COVID-19 where such in-person interactions are necessary to conduct the study. The COVID research-related proposal filed with the appropriate Touro IRB for approval must describe the need to conduct the study in an in-person manner and the precautions being used by the investigator must be fully delineated.

    - Investigators who believe they can continue an approved study by switching to a virtual mode for interaction with subjects should explore that option, *but must take into account software and security issues*. Investigators are advised to file an appropriate amendment form with the TUN IRB and be approved prior to implementation of the study changes. As appropriate, such an amendment must include revised solicitation and consent forms, and must address issues of confidentiality (including with respect to HIPAA or FERPA where appropriate), and record retention (including with respect to any recordings proposed to be made).

    - Investigators who have had to temporarily suspend an approved study due to COVID may plan to resume direct work with participants at a later date—consistent with phased reopening guidance issued by the College and the State of Nevada. Prior to recommencing the study, an amendment for the already approved protocol must be filed with and approved by the IRB prior to restarting the study. That amendment must describe: (1) the site-specific status of the pandemic; (2) the possible COVID-related vulnerabilities of the study population; (3) how the study will be conducted in a manner consistent with government directives and approvals in place at the time of application, as well as College and school/departmental requirements that have been implemented to reduce the risk of exposure to the SARS-CoV-2 (COVID) virus; and, (4) any other proposed changes to the originally approved protocol, including changes to the period of performance.

    - Investigators who have a continuing review while their project is temporarily suspended should note on the continuing review form what conditions would trigger the re-start of their study.

    - It is also possible that the current COVID circumstances may preclude continuation of an approved study and, thus, necessitate its termination. If that situation should occur, notice of early termination and the reason for it should be filed with the TUN IRB.

- If the TUN IRB is not the reviewing IRB for a study, compliance with any more stringent restrictions or requirements established by the reviewing IRB is required.

- New studies will be evaluated in the context of evolving government directives and permissions as gradual re-opening phases are implemented and as the College establishes appropriate guidance and policy. All efforts should still be made to limit in-person procedures and interactions as much as possible. If study goals can be met by using study procedures without in-person contact with participants, such procedures should be used. It is the responsibility of investigators to comply with all government directives and approvals in place at the time of application, as well as TUN requirements that have been implemented to reduce the risk of exposure to the SARS-CoV-2 (COVID) virus. If the TUN IRB is not the reviewing IRB for a study, compliance with any more stringent restrictions or requirements established by the reviewing IRB is required.

The TUN IRB recognizes that the pandemic and its impact on human subjects research involves significant unknowns and unpredictable components. Investigators should not hesitate to reach out to the IRB Chair (Cheryl Vanier: cheryl.vanier@tun.touro.edu) with any questions they may have. Early communication with the IRB may help in addressing some of the project-related challenges associated with these unprecedented times. The TUN IRB is fully committed to assisting investigators as they seek resolution to complications in their research plans caused by the pandemic.