COVID-19 and Human Subjects Research

(Updated December 30, 2021)

[*Note: Guidelines involving this pandemic are changing constantly. Investigators should check back often 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.]*

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

All federal, Nevada, Clark County, and Touro COVID guidelines on safety procedures must be followed for any study involving direct physical interaction with subjects; research with participants that takes place outside of Nevada or at an off-campus facility must take into account guidelines issued by that state and/or local jurisdiction and off-campus location. If an off-campus location has more stringent safety procedures in place, then those must be followed while conducting research at that location. Researchers should continue to carefully assess whether participation in their studies puts participants at undue risk of infection, particularly in areas with higher levels of transmission or lower vaccination rates. When feasible, we encourage the use of alternative research methods that reduce or eliminate the risk of COVID-19 transmission.

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

- Investigators who have had to temporarily suspend an approved study due to COVID may resume direct work with participants —consistent with guidance issued by the College and any COVID guidelines of off-campus facilities where research takes place.
- 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 guidelines for study participants are the same as for other visitors to the TUN campus.

Guidelines

No IRB protocol amendment submission is needed to implement these participant eligibility and screening requirements unless you are revising recruitment or informed consent materials.

Vaccination status

- The Touro Nevada Vaccination Policy must be followed for research activities.
    - Principal Investigators are responsible for enforcing this requirement if it applies to their participant population.
- Investigators, staff and students must follow the campus process for showing evidence of their vaccination status or obtaining an exemption.

Symptom screening & testing

- Symptom screening and testing should be congruent with current guidelines from the school, county, state, or CDC (links above).

Masks

- Any individual who chooses to do so, may continue to wear face coverings in any setting.

Distancing, Ventilation, & Sanitation

- Physical distancing should be followed as much as feasible. Maintain a distance of at least six feet from each other.
- Consider using supplemental HEPA filtration if working indoors with groups from different households or if a project requires individual participants to conduct research activities without a mask when community transmission is high.
- Avoid working in crowded spaces and minimize time spent with groups from different households, particularly if the space is poorly ventilated.
- Wash your hands often.

Contact Tracing

- To protect subject confidentiality, research subject information that is collected as part of the campus visitor log cannot be used as part of the research without IRB authorization.

Additional IRB Considerations

- **Decisions about bringing volunteers to campus for in-person study visits should be more conservative for people at higher risk for severe illness from COVID-19** per public health guidance. Researchers should take this into consideration as they develop plans for in-person human participant research protocols. For research involving participant populations at higher risk for severe illness, study consent forms may need to include information about this added risk.
- If your study procedures involve **use of any shared objects or devices** (e.g., pen, computer keyboard, blood pressure cuff), ensure that these items are cleaned and disinfected in between use.
- **If your study involves a significant risk of viral transmission**, (e.g., respiratory function testing, prolonged close contact between study participants and researchers, etc.), **then you must include details in your protocol application** about mitigation of risk of SARS-CoV-2 infection, and also include information in the study consent form about this risk and how it will be mitigated. One example of a mitigation strategy could be that participants are required to be vaccinated to take part in the study.
- Any **modifications to IRB protocols** (beyond simply adding COVID-19 screening procedures) will require an amendment request to be submitted to the IRB. If you previously amended your protocol to change all in-person activities to remote/virtual platforms and you would now like to shift back to in-person activities, an amendment request will be required.