**Clarion University**

**Institutional Review Board COVID-19 Guidelines.**

Clarion University’s IRB will continue to process applications and conduct review processes. All investigators engaging in human subjects research should develop plans for continued data collection, communication, and data management to protect themselves and their participants from COVID-19.

**Undergraduate and Graduate Research**

Undergraduate and Graduate students should work with their faculty advisors on protocols for research. Additionally, the researchers must work with the research sites to ensure the health and safety of both the participants and the researchers.

**Interaction with Participants in Research**

Some clinical studies require in-person study visits in order to conduct safety monitoring

of the participants. For example, participants in a drug treatment study may need to

have regular examinations, interviews, or laboratory tests for specific possible side

effects.

Follow any guidelines or instructions from the specific facility where participant interaction would occur.

Consider the participant population (e.g., are they considered "high risk" for COVID-19?) and the setting in which the interaction would occur.

Develop possible alternatives to in-person study visits that are important for subject safety and monitoring.

Researchers should plan for alternatives to in-person. The Principal Investigator (PI) should consider contingency plans in the event that research participants are unable to attend scheduled study visits, especially those that impact participant safety.

**Modification to Research Protocol**

Many studies are modifying their procedures to replace in-person study visits with

“remote” options for questionnaires, surveys, check-ins, screening, and consenting.

*Remember that these changes must be approved in advance by the IRB as a*

*modification to the study, unless they are necessary to eliminate immediate apparent*

*hazards to participants*.

### ****Voluntary Suspension of Study Enrollment or Participation****

If the PI decides to voluntarily stop participant enrollment or participation in a research protocol, this action is reportable to via the IRB closure form. https://www.clarion.edu/faculty-staff/faculty-research-and-development/irb/irb-project-closure-form.pdf

It is important to describe how any actively enrolled participants will be managed, particularly with regards to any safety monitoring and follow-up.

### ****ClinicalTrials.gov Registration Updates****

Some studies registered at the federal site [ClinicalTrials.gov](https://clinicaltrials.gov/) are modifying their research procedures to include testing for SARS-CoV-2 and/or assessment of COVID-19 symptoms. The ClinicalTrials.gov information for the study should be updated to include these new procedures, if they are done for research purposes. If they are being added as public health surveillance activities in coordination with public health authorities, the registration information does not need to be modified. The federal requirement about modifications is that any research-related changes that are communicated to the subjects (past, ongoing, future) must be added to the study's ClinicalTrials.gov registration with 30 days after IRB approval of the modification.

For further information related to COVID-19: https://www.clarion.edu/student-life/health-fitness-and-wellness/health-care-services/trending-health-topics.html