

**Clarion University  
Institutional Review Board  
COVID-19 Information**

**Tier 1 – High Direct Benefit to Research Participants or May Have a High Public Health Priority**

All protocols involving or about COVID-19 and protocols in which serious or immediate harm could be caused to the research participants if stopped. Tier 1 also includes the class of studies that may not have the prospect of high direct benefit but carry the risk of serious or immediate harm if study interactions were to cease.

**For example:**

- Research protocols involving treatments for acute, life threatening health conditions (e.g. some treatment trials for cancers)
- Protocols where stopping the intervention (e.g., some investigational drugs or vaccines or preventative drug regimens) could be harmful

**PIs may petition the IRB to continue or begin studies.**

**Tier 2 – Moderate Direct Benefit to Research Participants**

Protocols which, if stopped, may pose a risk to the research participant.

**For example:**

- Protocols in which research participants are receiving interventions or clinical care that is very interrelated to their research participation (e.g., test results coming back that might have clinical implications for their care)
- Some protocols evaluating treatments for chronic conditions (e.g., asthma, hypertension, depression, etc.).
- Protocols involving assessment of the safety or efficacy of an intervention in which, if stopped, the potential societal benefit of the science would be significantly and adversely impacted, for example where a research assessment (blood collection or imaging study) is only valuable if collected at a very specific time. **This must be measured against the risk to participants and staff, including the risk of exposure of COVID-19.**

**PIs may petition the IRB to continue or begin studies.**

### **Tier 3 – Low Direct Benefit to Research Participants and Other Impacts to Research**

- Cohort and natural history studies where delays in data collection have limited impact on scientific objectives
- Protocols in which delays to starting or pausing of research does not substantively impact on research objectives of the research protocol
- Protocols in which risks to research participants are higher (e.g., potentially exposing elderly vulnerable individuals to COVID) and benefits of the study to the participants remain minimal
- Research with healthy volunteers
- Any minimal risk studies that require research subjects to travel, that involve undergraduate students, or that are in a community setting and require direct interaction with researchers

**Research activities in Tier 3 must not enroll new participants in studies requiring face-to-face interaction nor continue to conduct face to face visits. PIs may petition the IRB to continue or begin studies.**

#### **Petition Guidelines**

If the PI feels there is a compelling justification to continue enrollment into a Tier 1 study or continuing in-person enrollment or in-person interaction in a Tier 2 or Tier 3 study, the study team should explain the justification. The IRB will review the submissions in order of priority.

The submission should contain the following information:

- What is the direct benefit to the subject that cannot be obtained outside the study? (Tier 1)
- Why can't the enrollment be postponed until restrictions are lifted?
- What is the harm to subject or value of data lost if in-person visits are to cease or be delayed until restrictions are lifted? (Tier 2 and 3)
- The reason the study must be completed face to face (in-person)
- Provide the reason that alternative methods are not appropriate.
- What measures are being taken to minimize in-person visits, e.g. visits may be done remotely or coincide with clinical visits?
- Any other pertinent information

The Petition will be reviewed by two IRB members.

Adapted from Johns Hopkins IRB protocol