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

Research in Tier 1 can continue if the PI agrees the research can be conducted in a safe manner that protects subjects, researchers, and the community. If not done already, self-assessed Tier 1 protocols must register with the IRB through the RNI process if the PI intends to continue in-person activities even if the study will not enroll new subjects at this time.

PIs must petition the IRB to continue enrollment. **Enrollment must be paused until the request is granted.**

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.**

Research in Tier 2 can continue but must cease in-person interactions. **PIs must pause on enrolling new research participants into Tier 2 stuides.** PIs may petition the IRB if they have a compelling reason to continue in-person interactions. Approved in-person contact will be limited to the minimum necessary.

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. On-line visits or data collection that does not require participant interaction may continue. PIs may petition the IRB if they have a compelling reason to continue in-person interactions (or conduct in-person enrolment).

Please contact askirb@pitt.edu with questions and concerns.

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(adapted from Johns Hopkins University)