As we make decisions on how to respond to the COVID-19 infections we want to begin by stating that our primary concern is the safety of our research participants and the research team members. Our secondary goal is to preserve the scientific integrity of the research protocols. We are providing this guidance to all Upstate researchers. Please contact the IRB office for specific questions about how this may impact your protocols.

All changes to the research protocol still need to be reviewed and approved by the IRB except for the incorporation of the mandatory screening and except for changes necessary to eliminate immediate apparent hazards including those based on the risk of exposure to COVID-19. Changes implemented to eliminate immediate apparent hazards should be promptly reported to the appropriate IRB.

The IRB staff are working remotely as of 03/18/2020 and are available during regular business hours. If you have questions about your research, and you know the staff member you wish to speak with please contact them directly. There is a list of contacts on the IRB website at: https://www.upstateresearch.org/compliance/committees/institutional-review-board-irb/contact-us/

You may also leave a message at (315) 464-4317. While working remotely, we will make every effort to respond as quickly as possible.

Monitoring Visits:

All external monitor onsite visits for clinical research protocols must be postponed.

All site initiation visits must take place remotely effective immediately. Onsite SIVs for COVID 19 trials and other life-saving trials may be allowed in exceptional circumstances where these may not be performed remotely.

GUIDANCE ON THE CONTINUATION OF RESEARCH WITH HUMAN SUBJECTS

Tier 1 – High Direct Benefit to Research Participants

All protocols involving COVID 19 and protocols in which serious or immediate harm could be caused to the research participants if stopped.

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, research, and the community**. PIs must pause on enrolling new research participants unless there is a compelling reason.** PIs should document in study and subject records the compelling reason for not following this new policy. For studies approved by an external IRB, follow all change in research and reporting requirements.*

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, including the risk of exposure of COVID-19.

*Research in Tier 2 can continue if the PI agrees the research can be conducted in a safe manner that protects subjects, researchers and the community**. PIs must pause on enrolling new research participants.***

Tier 3 – Low Direct Benefit to Research Participants

- 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.*