

TRIAGE FOR IRB REVIEWS DURING COVID-19 PANDEMIC

(4.17.2020)

This guidance and future updates will be posted on the RF Office of Administration website at: <https://research.downstate.edu/covid-19-updates.html>

Please direct any questions regarding this communication to the IRB Office at IRB@downstate.edu

BACKGROUND & KEY INFORMATION

As of April 16, the IRB has provided guidance to investigators on how to submit approximately 50 new COVID-19 studies to the IRB. As the pandemic continues, the number of submissions is expected to rise; therefore, the IRB must triage reviews of study at times when the daily workload is extremely high.

This guidance includes information on the following:

- New Studies
- Triage Priority
- Rapid Response (COVID-19) IRB Roster
- Review Process
- Table of Triage Priorities (Appendix)

NEW STUDIES:

For any new studies or projects submitted to the Downstate IRB during the COVID-19 pandemic, please provide the following with the submission in IRBNet:

1. Compelling reason to initiate new research/project.
2. Explanation on how the benefits of the research/project outweigh the risks of exposure of research participants and others (e.g., investigators, staff, family members of research participants) to COVID-19.
3. Procedures to mitigate the risk of COVID-19. See guidance on eliminating hazards for more details. This guidance and future updates are posted at: <https://research.downstate.edu/covid-19-updates.html>

TRIAGE PRIORITY:

Please refer to the triage priority in the attached appendix.

The IRB is reviewing the submission as they arrive; however, the IRB has established the scheme below to help prioritize the processing and review of these submissions in a way that is in the best interest of our community while advancing the scientific knowledge on COVID-19.

If the study includes extramural funding or collaborations with outside investigators or multiple departments or colleges within Downstate, these submissions will be moved up one level in terms of the priority rank listed below.

RAPID RESPONSE (COVID-19) IRB ROSTER:

Downstate has established a new IRB roster for the review of COVID-19 studies and other related submissions that must undergo full board review. These meetings will be called as needed; therefore, there are no submission deadlines for COVID-19 related submissions.

REVIEW PROCESS:

It is important to submit a complete and accurate submission since the review process is iterative. The IRB will review submissions based on the priority in the appendix and the time that the submission is received.

The IRB will assign reviews for COVID-19 to IRB members prior to Pre-Review by IRB Office to expedite the process; however, the submission must include at a minimum 1) IRB application, 2) Protocol 3) IRBNet registration form, and 4) Informed consent document or waiver request, as applicable to the submission.

As a result of this review process, the study team may receive comments from multiple reviewers at different times. The investigator can choose to revise a submission as they receive comments, or they can wait until all comments are finalized to avoid multiple revisions. The review priority is re-established each time a project is re-submitted to the IRB, so it is best to wait until all revisions are complete to reduce the number of re-iterative changes.

In any event, the submission must meet all requirements for approval before a final approval letter can be issued.

TABLE OF TRIAGE PRIORITY (APPENDIX)

Priority Rank	Description
1	Clinical trials and expanded access requests involving treatment for COVID-19
2	COVID-19 Research in the following topics: <ul style="list-style-type: none"> • Disease prevention • Diagnostic test development • Tracer methodologies • Specimen and data repositories • Plans to contain COVID-19, get people back to work, stimulate economy
3	Continuing review (progress report) applications of previously approved studies, so that lapse in approvals do not occur.
4	Check-In reports
5	Other full board studies related to COVID-19
6	Amendment request to mitigate the risk of COVID-19
7	Amendment request to lift a suspension of research activities related to COVID-19.
8	Acknowledgement of notices to eliminate hazards associated with COVID-19
9	Other COVID-19 studies which qualify for expedited reviews
10	COVID-19 studies which qualify for exempt reviews
11	Written Appeals related to COVID-19 studies
12	Acknowledgement request to lift suspensions that are approved via e-mail by both the IRB Chair and Chair of Downstate Coronavirus Task Force
13	New studies (not related to COVID-19) – Full Board
14	New studies (not related to COVID-19) – Expedited
15	New studies (not related to COVID-19) – Exempt
16	Appeals (not related to COVID-19)
17	Reportable Events
18	Amendments
19	Other Acknowledgements
20	Study closures