

INSTITUTIONAL REVIEW BOARD TERMS OF REFERENCE STANDARD OPERATING PROCEDURE – COVID-19 PANDEMIC 2020

1. PREAMBLE

While the current COVID-19 pandemic crisis has generated enormous scientific interest and coordinated research efforts, it has also resulted in the disruption of many normal business activities and standard procedures related to research review and research conduct.

From an IRB perspective, the current crisis has led to a large number of Covid-19 study submissions requiring rapid turn-around time. The current social distancing guidelines have also impacted ongoing and planned research studies in new and unanticipated ways. The LAU Institutional Review Board (IRB) has adapted its conduct of business to meet these pressing challenges while continuing to offer uncompromising ethical review of submitted studies.

2. PURPOSE

The LAU IRB is closely coordinating with LAU researchers to accelerate study turn-around time in the current crisis. The purpose of this document is to highlight to the attention of researchers the Standard Operating Procedures followed during this pandemic by the LAU (LAU IRB) in its review of submitted studies.

3. PROCEDURE

3.1 Meeting schedule and timeline of review

- 3.1.1 Conduct pre-scheduled LAU IRB full board meetings via Webex to conform with the governmental restrictions of social distancing and the specific instructions and guidelines received from the university
- 3.1.2 Ensure an accelerated review of research for COVID studies and schedule urgent full board IRB meetings via Webex, as needed, to accommodate as rapid a review process as possible.
- 3.1.3 Ensure membership majority quorum during the LAU IRB full board meetings via Webex
- 3.1.4 Adopt a 24-hour initial review of COVID studies upon submission and assign reviewers as needed to ensure rapid review
- 3.1.5 Support from the IRB members to ensure an accelerated review turn-around time without compromising review thoroughness, expecting reviewers to complete their review within 3 days of receipt of the study files by email
- 3.1.6 Ensure sending of consolidated comments back to the researcher (PI) within a specified time-frame of 5 days at most from time of submission.

3.2 Review of Research and Prioritization

- 3.2.1 PI must submit IRB application and study documents by email with all relevant attachments. Signature pages can be circulated by email for e-signatures, as applicable.
- 3.2.2 COVID studies will be prioritized.
- 3.2.3 The review of student projects needed for fulfilment of graduation requirements will also be prioritized
- 3.2.4 Work closely with student and/or faculty researchers to ensure that appropriate measures and special restrictions are in place to honour social distancing recommendations. Encourage the use of Skype, Zoom, and alternative electronic platforms for data collection; maintain the same high standard of ethical conduct of research in these alternative formats, with a focus on ensuring online privacy and anonymity of participants.
- 3.2.5 Follow up on ongoing studies to ensure appropriate measures are in place to protect participants during the social distancing and current pandemic, especially where study visits are required.

- 3.2.6 As a gesture of support for the ongoing research efforts to tackle the epidemic, studies with funding limited to medical equipment and/or reagents may be eligible for waiver of LAU IRB fees.

3.3 Ethical and Scientific Consideration

- 3.3.1 In order to expedite study turn-around time, review of submitted studies can proceed even if not all documents have been submitted, while final IRB approval remains contingent on review of all study documents.
- 3.3.2 The LAU IRB will maintain close coordination with the Lebanese Ministry of Public Health (LMOPH) IRB accrediting committee for any guidelines, questions or concerns related to COVID-19 studies
- 3.3.3 The LAU IRB has relayed to the relevant LAU schools and medical center the LMOPH communication concerning required registration of all COVID studies on the Lebanese Clinical Trial Registry (LCTR)
- 3.3.4 The LAU IRB will ensure reviewed Covid-19 studies are in the spirit of the World Health Organization's [Coordinated Global Research Map 2019 Novel coronavirus statement](#): “research participants should be selected in such a way to minimize risk, protect vulnerable populations, maximize social value and collaborative partnerships and does not jeopardize the scientific validity of the research” .

References:

[WHO Ethical standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R&D](#)

World Health Organization, [The Coordinated Global Research Map 2019 Novel coronavirus](#)

[FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic](#) (for Industry, Investigators and IRBs)