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Institutional Review Board
Assurance No. FWA00005304

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Dear SLU Faculty and Research Staff:

As the ongoing COVID-19 outbreak continues to change rapidly and we continue to make decisions on how to respond, we want to begin by stating our primary concern is the safety of our research participants, research team members and St. Louis Community. We also want to make sure we preserve the scientific integrity of SLU's research protocols. We realize the COVID-19 outbreak may cause hardship to SLU's research infrastructure; however, it is paramount to consider the additional risks now associated with continuing to conduct human subjects research protocols.

In line with public health directives, including the Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19 and the FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic, the following actions should be taken immediately:

- Eliminate Non-Essential Research Visits
  To reduce the risk of COVID-19 transmission and implement appropriate social distancing practices, all clinical research visits that can be postponed or performed remotely (e.g. by phone, Skype, Zoom, or other means) should be conducted this way whenever possible. Research that does not explicitly improve or protect the lives of its participants, by providing treatment or other medical care, should be regarded as non-essential.

- Screen Research Participants for Potential Infectious Risk
  For essential research visits that cannot be performed remotely, all study teams should immediately implement procedures to screen research participants for potential infectious risk prior to any interaction and incorporate a plan for mandatory screening prior to the research visit. Exposure to the novel coronavirus, symptoms of illness before they arrive, and international and domestic travel history should all be included in the screening. Research participants with possible exposure or symptoms of illness or high-risk travel history should be scheduled (or re-scheduled) for a future appointment and monitored for illness progression.

- Notify Research Participants
  Research teams should consider developing a script for research participants with information regarding the COVID-19 outbreak, how best to reduce their risk of infection, and what Saint Louis University and associated hospitals are doing to make the environment as safe as possible.

  As COVID-19 is spreading easily and sustainably through person-to-person interaction, it is imperative to limit the interaction with an infected individual as much as possible. Even if an existing study was previously approved with a full written consent form, the notification of the changes in response to the COVID-19 outbreak are eligible for an alteration of the approved consent procedure. This alteration allows the researchers to leave out or alter some of the elements of informed consent otherwise required under 45 CFR 46.116(a) and (b). The IRB Office has procedures in place to allow

for various alterations, including the use of a phone consent or e-consent, depending on the study. Please contact the IRB Office at irb@slu.edu for help with your participant notification.

- **Contact the Appropriate Parties about Study Changes**
  In addition to notifying the SLU IRB Office of any changes in response to COVID-19, other parties might also need to be notified of changes in IRB-approved study procedures.

  This could include, but is not limited to:
  - the study sponsor, pursuant to the terms of the clinical trial agreement or other contract governing the study;
  - ClinicalTrials.gov, for studies registered there for which the institution is the "responsible party" under 42 CFR Part 11 if required by 42 CFR § 11.64, or for other studies that the institution has registered on ClinicalTrials.gov because of the funding source, Medicare reimbursement requirements, or journal publication policies;
  - the FDA, for studies where the PI or institution holds the investigational new drug application (IND) or the investigational device exemption (IDE), pursuant to 21 CFR § 312.30 (for drugs) or 21 CFR § 812.35 (for devices);
  - the NIH (if the study is NIH-funded), depending on the change in procedures, after consulting with the SLU's grant management office and the Grants Management Officer and Program Official at the NIH awarding Institute/Center;
  - the reviewing IRB, if an external or central IRB (e.g., WIRB, Advarra) is providing IRB review and oversight for the study.

- **Develop Contingency Plans**
  Study teams should proactively prepare contingency plans for their active research protocols to manage study conduct during disruption as a result of the COVID-19 safety measures. Please reference HRP Consulting Group's Management of Ongoing Human Research Studies during the COVID-19 Pandemic for additional considerations while developing your contingency plans.

- **Remote External Research Monitoring**
  Monitoring activity may be affected during this period, and should be converted to remote monitoring whenever possible. If a study requires in-person monitoring, monitors should comply with the SOM Travel Policy by contacting Employee Health at 314-268-5499. Please also reference ACRO's Considerations to Support Clinical Trial Monitoring Oversight During COVID-19 for additional considerations.

IRB Review of Changes in Response to the COVID-19 Outbreak

The regulations allow for any protocol change made to eliminate apparent immediate hazards to research participants to be initiated without prior IRB approval.

In urgent situations, please immediately begin the revised plan to help protect both the participant and the study team. In this case, the study team will need to submit a Protocol Violation (Report Form in eIRB) to the IRB Office within 5 business days to describe the change.

In less-urgent situations, before the change is implemented, the study team can either submit a Protocol Deviation (Report Form in eIRB) or an Amendment (eIRB) to the IRB Office. The Protocol Deviation would have a quicker review time (1-2 days), but the revisions would only be allowed during this outbreak. Once the threat is over, the study team would be expected to resume the protocol as previously approved. The Amendment would have a slightly longer review time (5 business days) and would permanently change the research procedures (at least until another Amendment is submitted to request a separate revision).

IRB Operations

The SLU IRB Office is fully operational. Staff are currently working remotely, and all IRB Meetings will continue as scheduled, but will be held remotely via Zoom. Please don't hesitate to reach out to our office at irb@slu.edu for additional help. Please note, while e-mails are being monitored with the same or greater frequency as before, responses to inquiries and applications that are not related to COVID-19 or its impact on research may be delayed.

The IRB is actively working to develop additional guidance and resource materials to assist study teams navigate this trying time. These should be made available soon. If there is anything else we can do to help, please let us know.

Thank you,

The SLU IRB Office
irb@slu.edu