SAINT LOUIS UNIVERSITY
EST. 1818

June 29, 2020

Dear SLU Faculty and Research Staff:

As the stay at home restrictions due to the COVID-19 pandemic are beginning to be lifted, we know many of you are eager to resume your human subjects research protocols. However, our primary concern remains the safety of our research participants, research team members and the St. Louis Community. We also want to make sure we preserve the scientific integrity of SLU's research protocols. We realize the research restrictions have been and continue to be challenging; however, it remains paramount to consider the additional risks now associated with conducting human subjects research.

At this time the following types of human subjects research is **PERMITTED**:

1. Research that can be conducted without in-person intervention or interaction with research subjects.
2. Research that explicitly improves or protects the lives of its participants by providing treatment or other medical care.
3. Research that is directly connected to addressing the COVID-19 crisis.
4. Research which is limited to procedures which are performed in conjunction with a regularly scheduled visit.

The University is carefully monitoring public health directives, including the St. Louis City Department of Health, the State of Missouri, the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration, and when it is deemed safe to open human subjects research more broadly it will do so at the direction of the SLU Office of the President.

NOTE: To reduce the risk of COVID-19 transmission, all research visits that can be postponed or performed remotely (e.g. by phone, Skype, Zoom, or other means) should continue to be conducted this way whenever possible.

All human subjects research must follow the **RESEARCH RESUMPTION GUIDELINES** detailed below. In addition, research occurring at a SLUCare or SSM site must follow the SLUCare and SSM guideline for clinical care detailed at its Centralized Website for COVID-19.

RESEARCH RESUMPTION GUIDELINES:

Before initiating or resuming a study, consider the latest FDA guidelines (https://www.fda.gov/media/136238/download):

- Whether COVID-19-related limitations on protocol implementation pose any new safety risks to participants, and whether those risks can be mitigated by amending study processes/procedures;
- The potential for alternative procedures for safety assessments such as using technologies to facilitate remote data collection and monitoring, e.g., video conferences, local laboratories;
- If any alternative delivery methods of investigational product (IP) and/or research materials can be implemented, e.g., IP that can be self-administered;
- The availability of investigators/sub-investigators to oversee trial and adequately monitor safety risks;
- The availability/ability of sufficient clinical trial staff, supplies (including sufficient PPE for staff and participants), and technological tools; and
- The feasibility of trial conduct given any COVID-19 public health measures required by the University and local, state and federal authorities.

- **Request to Initiate or Resume Human Subjects Research Protocol**
  To initiate or resume your human subjects research protocol, you must request permission from your Departmental Chair.

- Approval to begin research will depend on the researcher having a plan in place to meet the following requirements. Note these requirements pertain to on-campus research. Any human subjects research requiring in person contact with research participants may be subject to additional restrictions or requirements enacted by the sites of such research, e.g. schools, clinics, prisons, etc.

- **Meet Basic On-campus Research Requirements**
  - Conduct daily health screening via www.sludailycheck.com. Require people who feel sick or have COVID-19 symptoms to stay home. Employees with an illness other than COVID-19 must be symptom free for 72 hours to return to work on campus. Employees who have tested positive for COVID-19 must follow SLU Employee Health guidelines for returning to work.
  - Observe social distancing practices of maintaining 6ft of separation between researchers whenever possible. Rearrange distances between work spaces to better ensure compliance.
  - For any research taking place in a non-healthcare setting: Wear face masks as directed by the interim University policy on face masks effective May 18, 2020. Face masks are required, even when you are maintaining 6 feet of social distancing. Face shields are not replacements for face masks.
  - For research taking place in SSM healthcare or other healthcare settings: Follow the personal protective equipment requirements at that healthcare facility/agency.
  - Limited group interactions while wearing face masks.
  - Perform hand hygiene (wash hands or use hand sanitizer) frequently.
  - Maintain respiratory etiquette (i.e. cough/sneeze into disposable tissues or into your elbow when tissues are unavailable).

- Stagger start/end times or split staff to reduce the total number of staff in the research space at one time.
- Assign each individual a desk and work space to avoid sharing spaces.
- Regularly (e.g., 2x per day) disinfect shared spaces and surfaces in the research space with EPA-approved disinfecting solution.

Note: researchers working in one of the locations listed on the web site https://sites.google.com/slu.edu/resumeresearch/home must follow procedures outlined on that site.

- **Screen Research Participants for Potential Infectious Risk**
  - Research participants should be screened for potential infectious risk prior to any interaction. Per FDA, screening procedures mandated by a healthcare system or hospital do not need to be reported as protocol amendment, unless the sponsor will use this data as part of a new research objective.
  - Every participant must be symptom free for at least 72 hours before being allowed on campus.

- **Implement Required Safety Measures for Human Subjects Research Visit:**
  - All study team members and participants must wear face masks.
  - In the event specimens (i.e. blood, saliva, urine, etc.) are collected or the participant must be touched (i.e. placing electrodes, taking blood pressure, etc.) per the research protocol, gloves must be worn by the study team members and participants.
  - Participants should come to the research visit alone or be limited to one guest/caregiver per participant, who must also be masked.
  - Social distancing guidelines (specifically, staying 6 feet away from others when possible) must be observed. Accordingly,the study team must limit the number of participants allowed in waiting, examination, laboratory, research and study team spaces. To ensure compliance, mark floor locations with tape where people may or may not stand.
  - Study team members must frequently sanitize all high touch surfaces, such as doors, furniture, or any other surfaces or objects that may be frequently touched, and equipment used in a study visit.
  - Proper prevention hygiene practices must be followed.

- **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.

- **Contact the Appropriate Parties about Study Changes**

  Actions taken for public health or clinical purposes, and not for research purposes, are not considered research procedures and therefore do not require IRB approval before being implemented.

  The SLU IRB Office must be notified of any research procedure changes made in response to COVID-19 safety measures by filing a protocol amendment.

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).

In addition, depending on the study, other parties might also need to be notified of these changes.

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 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 research protocols to manage study conduct during any disruptions that result from COVID-19 safety measures. Investigators should develop a plan in the event there is a lack of personnel able to be present, there is a shortage or disruption in supplies, including PPE, or if operations must be suspended again. 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.

- **Conduct 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.