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| --- | --- | --- | --- |
| **Date:** | | | **IRB #:** |
| **Principal Investigator:** | | | **Title:** |
| **Department:** | | **E-mail:** | **Phone:** |
| Additional Contact Person: | | E-mail: | Phone: |
| **Project Title:** | | | |
| **Study Sponsor:** | | | **Funding #:** |
| **Study Location:**  *(check all that apply)* | SLU South Campus | SLU North Campus | SLU Madrid Campus |
| SLUCare Practice | SSM Health SLU Hospital | SSM Health St. Mary’s Hospital |
| SSM Health Cardinal Glennon Children’s Hospital | SSM Health Community Ministries (St. Clare – Fenton, DePaul, St. Joseph’s – St. Charles, St. Joseph’s – Lake St. Louis, St. Joseph’s – Wentzville) | |
| Other (please specify): | | |
| **Building Name:** | | | |

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| **NOTE:** To reduce the risk of COVID-19 transmission and implement appropriate social distancing practices, all research work that can be postponed or performed remotely, should continue to be conducted this way.  This includes the following (as long the value or integrity of the research study is not reduced): consenting, conducting interviews/questionnaires, data analysis, manuscript preparation, etc. |

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| **Does the human subjects research study fall into any of the categories listed below?**  \* Please select all that apply. | |
|  | Research that can be conducted without in-person intervention or interaction with research participant. |
|  | Research that explicitly improves or protects the lives of its participants by providing treatment or other medical care. |
|  | Research that is directly connected to addressing the COVID-19 crisis. |
|  | Research which is limited to procedures which are performed in conjunction with a regularly scheduled visit. |
|  | None of the above.[[1]](#footnote-1) |

Before approving a research transition and monitoring plan, the following criteria for approval will be considered:

* Risks to subjects have been minimized
* Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result
* The research plan includes adequate provisions for data safety monitoring
* The provisions to protect the privacy of subjects and to maintain the confidentiality of data are adequate
* Informed consent remains appropriate (e.g., the process, the elements, etc.)

If the above-noted criteria cannot be satisfied, then the research cannot be approved or allowed to re-commence until the criteria for IRB approval are satisfied.

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| **Research Transition and Monitoring Plan** | | | | | | | | |
| **NOTE:** This worksheet (or comparable planning) should be completed for all human subjects research studies. If the human subjects research study falls into one of the four categories listed above, this worksheet is not required to be submitted or approved by the IRB before resuming research activities. If the research study is “none of the above,” the completed worksheet must be submitted to the IRB Office via an amendment form (including the [PI Assurance](#PI_Assurance) and the [Department Chair Assurance](#Dept_Chair_Assurance)) and approved prior to resuming any research activities. | | | | | | | | |
| ***The SLU IRB approved protocol and/or sponsor COVID-19 risk mitigation plan may be submitted with this worksheet and referenced below, where applicable.*** | | | | | | | | |
| **Study Objective/Purpose:** |  | | | | | | | |
| **Study Summary:** |  | | | | | | | |
| **Number of participants:** | **Enrolled:** | | | **Currently active:**  (i.e. those who have not completed all study procedures) | | | | **Remaining to be enrolled:** |
|  | | |  | | | |  |
| **Indicate if the study includes participants who are at** [**increased risk for severe illness**](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html) **should they contract COVID-19, as determined by the CDC:**  \* Please select all that apply. | Adults 65 years of age and older | | | | Adults currently living in nursing homes or long-term care facilities | | | |
| Cancer | Chronic Kidney Disease | | | COPD | | Immunocompromised State | |
| Obesity (BMI of 30 or higher) | Serious heart conditions | | | Sickle Cell Disease | | Type 2 Diabetes | |
| ☐ Minors with medical complexities (i.e. neurological, genetic, metabolic), congenital heart disease, other underlying medical condition(s) which might increase the risk of severe illness | | | | Other conditions which might increase the risk of severe illness (i.e. asthma, cerebrovascular disease, cystic fibrosis, hypertension or high blood pressure, immunocompromised from blood or bone marrow transplant/immune deficiencies/HIV/use of corticosteroids, neurologic conditions, liver disease, pregnancy, pulmonary fibrosis, smoking, thalassemia, type 1 diabetes mellitus) | | | |
| **Describe the potential research-related risks, including the additional risks associated with COVID-19, and benefits:** |  | | | | | | | |
| **Describe any special considerations regarding the need to resume this research study:**  (i.e. funding requirements and/or dependencies, course/graduation requirement, time-critical accrual milestones, critical in-person visits for ensuring participant safety, etc.) |  | | | | | | | |
| **Describe the current standard of care/practice options without in-person research interventions:** |  | | | | | | | |
| **Describe any in-person research procedures required, including the number, frequency and estimated duration:** |  | | | | | | | |
| **Describe all modifications being made to minimize the risks of COVID-19 infection to participants and research personnel:**  (i.e. screening participants, use of facial coverings, reducing the time spent with participants by conducting some visits remotely and/or reducing the number of mandatory tests) |  | | | | | | | |
| **Provide an explanation for any research procedures that cannot be modified to reduce the risks of COVID-19 infection to participants and research personnel:**  (i.e. changes not supported by sponsor, etc.) |  | | | | | | | |
| **Describe any potential barriers for new recruitment or continued participation due to COVID-19:** |  | | | | | | | |
| **Indicate the departments from which support services are required for this research study (excluding standard of care services):**  \* Please select all that apply. | Clinical Research Unit (CRU) | | Radiology | | | Pathology | | |
| Anesthesiology | | Cardiology | | | Other (please specify): | | |
| **Describe the research-related services required from the departments indicated above:** |  | | | | | | | |
| **Describe any additional resources (i.e. PPE, lab equipment) needed to continue to conduct this research study and how these will be obtained:** |  | | | | | | | |
| **Does research involve clinical samples from patients that could contain SARS-CoV-2?** | Yes – continue to question 1  No | | | | | | | |
| **Institutional Biosafety Committee (IBC) Oversight** | 1. **Will manipulation of those samples involve anything other than routine diagnostic testing using Standard Precautions, appropriate PPE and engineering controls?**   (See CDC Guidance: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>) | | | | | Yes – continue to question 2  No | | |
| 1. **If manipulation of the clinical samples is likely to produce droplets or aerosols, or designed to purify viral proteins or genetic material, or virus will be cultured, you must submit an eIBC protocol to IBC.** | | | | | **Contact**: eIBC@slu.edu  **Website**: <https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-biosafety-committee-ibc.php> | | |

**Principal Investigator (PI) Assurance:**

**Before resuming any human subjects research activities, the following requirements will be met:**

* **University Community Policies and Practices**
  + **Symptom and exposure risk assessment:** Daily self-assessment will occur before research personnel or participants enter the workspace; research personnel will use the University’s daily symptom check system.
  + **Facemasks will be required in workspace, per University policy; surgical facemasks will be required when interacting with patients.**
* **Research Personnel Planning and Actions**
  + **Requesting Permission:** Permission has been granted from building manager to occupy the space for this study;
  + **Density (area per person):** There will be at least 85 square feet per person;
  + **Physical distancing:** Research personnel working in office and other environments will maintain social distancing practices of being 6 feet apart when possible and masking unless working alone in private offices with closed doors, and every attempt will be made to prevent queuing and congregating around shared spaces;
  + **Assigned workstations:** Work environments be assigned for individual use and will meet the regular cleaning standards
  + **Signage:** A reminder about the self-assessment for symptoms/exposure will be placed on the entry door, and wall signs or floor markings to promote physical distancing will be place inside the workspace;
  + **Personal Protective Equipment:** Adequate personal protective equipment will be provided to research personnel and participants, as needed;
  + **Handwashing:** Hand hygiene/hand-sanitizing will be maintained and stations will be available in workspace
  + **Cleaning and disinfecting:** All surfaces will be cleaned at least daily with Oxivir TB disinfectant (or equivalent)
  + **Training and Compliance:** Research personnel has completed training on the use of disinfectant for surface cleaning, and weekly safety and compliance reminders about facemasks, physical distancing, handwashing, etc. will be distributed;
  + **Entrance/exit procedures:** Congestion in doorways or hallways will be avoided
* **Research activities that can be postponed or performed remotely, will continue to be conducted this way.**
* **The risks associated with conducting this study will be continuously monitored and evaluated throughout the remainder of the COVID-19 pandemic, and the study resumption plan will be modified as needed to continue to minimize the risks to research personnel and participants.**
* **All research personnel will follow:**
  + **The** [SLU Guidelines and Safeguards](https://www.slu.edu/back-to-slu/fall-safeguards/) **for on-campus activities;**
  + **The** [OVPR Human Subjects Research Resumption Guidelines](https://www.slu.edu/research/faculty-resources/docs/human-subjects-research-reopening.pdf)**;**
  + **The** [SLUCare and/or SSM Health Guidelines for Clinical Care](https://login.ssmhealth.com/covid-19/), **if study procedures will occur at a SLUCare or SSM Health location;**
  + **The** [OHRP Research Guidance on Coronavirus](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html)**;**
  + **The** [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency)**, if the study is FDA-regulated.**

**I understand failure to follow this plan and University safeguards will result in restrictions up to and including immediate shutdown of this research study and any other research study for which I am responsible.**

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**Signature of Principal Investigator Date**

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**Print Name of Principal Investigator**

**Department Chair Assurance:**

**I have reviewed this research resumption plan and assure:**

* **The additional measures to minimize risks to participants are adequate and consistent with departmental and University policies and requirements.**
* **The PI has the requisite funding, credentials, training, and any necessary hospital privileges (if needed) to complete the research study as described above.**
* **There are sufficient resources (including but not limited to adequate study personnel, personal protective equipment, equipment, space) to complete the research study as described above, and proper oversights are in place to carry out the protocol.**
* **The resources required to ensure the safe resumption of this research study have been evaluated against the required resources already allocated for the other currently active human subjects research studies within the department, and the safe resumption of the research study is feasible.**
* **This research transition and monitoring plan is consistent with:**
  + **The** [SLU Guidelines and Safeguards](https://www.slu.edu/back-to-slu/fall-safeguards/) **for on-campus activities;**
  + **The** [OVPR Human Subjects Research Resumption Guidelines](https://www.slu.edu/research/faculty-resources/docs/human-subjects-research-reopening.pdf)**;**
  + **The** [SLUCare and/or SSM Health Guidelines for Clinical Care](https://login.ssmhealth.com/covid-19/), **if study procedures will occur at a SLUCare or SSM Health location;**
  + **The** [OHRP Research Guidance on Coronavirus](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html)**;**
  + **The** [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency)**, if the study is FDA-regulated.**

**I understand failure to follow this plan and University safeguards will result in restrictions up to and including immediate shutdown of this research study and any other research study for which the PI is responsible.**

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**Signature of Department Chair Date**

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**Print Name of Department Chair**

1. This worksheet must be submitted to the IRB Office via an amendment form and approved prior to resuming any research activities. [↑](#footnote-ref-1)