

**HRPP Study-Specific Plan for Reactivation Phase 2**

**COVID-19 Safety Plan**

Each principal and co-investigator (PI/co-PI) on a research project must establish specific COVID-19 health and safety procedures for in-person human subject research using this form, as part of a request to reactivate in-person research. The reactivation of in-person human subjects research will follow a phased approval plan based on project risks and community status of COVID-19.

Submit this form and other required documents as attachments to a Report of New Information (RNI) requesting reactivation in eCompliance. This form was created to acquire key information needed to evaluate each safety plan to help ensure the safety of the volunteer participants, study team members and community members. PIs have responsibility for ensuring adequate safety practices are in place for all constituents in the conduct of in-person research. Risks associated with the proposed human research activity, in light of COVID-19, must be eliminated or sufficiently mitigated. Procedures must be consistent with those described in the Environment, Health & Safety (EHS) “COVID-19 Return to Work Safety 101” training module and current Centers for Disease Control & Prevention (CDC), state and local guidelines and requirements.

**INSTRUCTIONS:** All fields are required. Upload your completed safety plan as an attachment to your Report of New Information (RNI) requesting reactivation in eCompliance.

|  |
| --- |
| **SAFETY PLAN for Reactivation of In-person Human Subjects Research** |
| PI/Faculty/Supervisor  |  |
| Department/Center |  |
| PI email |  |
| a) PI cell phone and b) PI KU Skype phone |  |
| HRPP Study number |  |
| Study title  |  |
| Status of study | [ ]  Currently approved (including pending modifications)[ ]  New submission pending approval[ ]  Relying on external Institutional Review Board (IRB)  |
| Sponsored project(s) (include agency and award number) or proposal submission deadlines (include sponsor) |  |

|  |
| --- |
| 1. **Location(s) of in-person research activity**
 |
| ***Location Description*** |
| ☐ KU campus (include buildings and room numbers)☐ Other (explain who is in control of the space and who is responsible for cleaning the space)  |  |
| For each research space, describe 1) what activity will occur in the space. 2) how many individuals may be in the space at one time, including an estimate of square footage per individual simultaneously in the space. 3) how many individuals will be in the space over the course of a day.4) whether other groups use the space.  |  |
| ***Location Safety Strategies*** |  |
| Describe your plan for maintaining social distancing among individuals in the space, including safe entrance, waiting and exit, safe exchange of items, and isolation areas for individuals at risk of disease. |  |
| Describe cleaning/disinfecting protocol (including EHS-approved cleaning solutions and materials), including frequency of disinfection for the research space, shared space, and any shared resources or equipment.  |  |
| **B. Participants** |
| ***Participant Description*** |
| To what degree is your population COVID-19 vulnerable? |  |
| How will you screen to reduce risk to COVID-vulnerable potential participants? When will screening occur? |  |
| ***Participant Safety Plan*** |
| Describe the protocol for preventive measures for participants (i.e. masks, hand sanitizer prior to entry and on departure, barriers or partitions, asynchronous transfer, cleaning floors) including who will provide items such as masks and who will track adherence to written safety protocol. |  |
| Describe your plan for safely dealing with a participant who reports or exhibits any symptoms of COVID-19. |  |
| 1. **Activities**
 |
| Briefly describe the activities that researchers and participants will perform. Note: 1) how long each activity will take per participant.2) whether proximity closer than 8 feet between individuals in the space is necessary, and if so, why and for how long.3) whether participants will interact with each other.4) whether any objects or equipment will be touched by the participant, and if so, how these objects will be disinfected between participants (or if disposable items will be used). |  |
| 1. **Study Team Safety Plan**
 |
| Describe health screening of study team, including documentation, plus face mask and other personal protective equipment (PPE) requirements for personnel while working in the research space. |  |
| Describe how you will disseminate, track and ensure compliance with this plan to your research team.  |  |
| In the event that your study team must quarantine due to COVID-19 exposure, what are your plans to ensure that participants are not adversely affected?  |  |
| Indicate a plan for covering research responsibilities for each study team member in the event they become ill or unable to move forward with project activities (e.g., Who will assume PI or project director roles?). |  |

|  |
| --- |
| **Study Team Members** who will engage in in-person research activities |
| Name  | Role (co-I,research staff, GRA) | Email and cell phone |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| **Daily Log:** Study team must maintain a daily log (see Procedural Integrity Checklist Template.xls) recording personnel arrival, departure and adherence to safety protocols described in this document. Describe where the log will be kept and who should be contacted if KU Public Safety officials need to access the log.) |  |

**CERTIFICATION AND SIGNATURES**

I agree to adhere to this safety plan and to keep and share (if requested) the Procedural Integrity Checklist documenting compliance with this safety plan.

PI Signature/ Date

Chair or Center Director Signature/ Date

HRPP Received/ Date