

Requirements for Reactivation of In-Person Research - Phase 1

Principle of Remote Procedures: Regarding risk of contracting or spreading COVID-19, the safest interpersonal interaction today is via remote means. If it is possible to meet research objectives without in-person interactions and activities can be conducted using remote procedures, plan to use remote techniques. Researchers should continue to submit modifications through eCompliance for any changes from in-person to remote procedures, to be reviewed by the Human Research Protection Program (HRPP). You are encouraged to explore resources to facilitate remote procedures (e.g., Zoom pro, telehealth licenses, and other platforms supported by the University of Kansas), with attention to maximizing security and minimizing risk.

Reactivation Plan for In-Person Research: The ambient risk of conducting in-person human subjects research has increased dramatically with the COVID-19 pandemic. Nevertheless, KU recognizes that not all human subjects research can be conducted remotely and is taking a tiered approach to safely reactivating in-person research. Requests to re-engage with or begin projects requiring in-person interaction will be evaluated using a KU-developed risk assessment rubric, the **Risk Matrix for Assessing In-Person Human Subjects Research**. The risk matrix assessment considers: (1) the nature of the activity, (2) attributes of the participant population and (3) characteristics of the location, with careful consideration of project-related risks relative to direct benefits to participants and potential advancements to knowledge.

Phase 1 proposals will be reviewed on a case-by-case basis and approvals will be limited to:

1. Projects studying COVID-19, with the goal of addressing public health issues where risks can be managed.
2. Certain longitudinal studies, where risks can be managed.
3. Certain studies that have direct benefit to participants, where risks are low and can be managed.

In general, studies associated with moderate-high or higher risks and/or those that have limited or no benefits to participants will not be approved during Phase 1. See information below regarding risk characteristics and mitigation strategies.

Note: Shifts between phases of reactivation are safety-bound rather than time-bound. Safety precautions may increase or decrease based on Centers for Disease Control & Prevention (CDC), institutional, state and local guidelines and policy.

Request for Reactivation, Phase 1: If you are unable to conduct activities remotely AND you believe your study may meet Phase 1 dimensions, you may submit a request to HRPP to have your project assessed for possible reactivation.

To submit a reactivation request to HRPP, you must do the following:

- Submit a Report of New Information (RNI) in eCompliance indicating REACTIVATION REQUEST in question 4. This will identify your submission as a request to resume in-person human subjects research.
- Attach the **HRPP Reactivation Safety Plan** form, which must be completed in full.
- Attach a **Procedural Integrity Checklist** for your safety plan.

- Previously enrolled subjects must be re-consented for COVID-19 risks. Use the **COVID-19 Consent Template** to update your consent form(s).
- Revise HRPP protocol with appropriate revisions as defined in **HRPP Reactivation Safety Plan**.
 - Procedures for promoting safety of physical environments (e.g., physical space, cleaning/decontamination between subjects etc.)
 - Procedures for promoting safety of interactions between individuals (e.g., limiting number of people, social distancing requirements)
 - Procedures for promoting safety of activities (e.g., interacting with keyboards, manipulatives)
 - Procedures for re-consenting participants
 - Requirements for collaborations (e.g., IAA, IIA, district partners, agencies letter: “I have read and approved the full set of procedures, taking into account potential risks related to COVID-19) **dependent upon reactivation phase*
 - Procedural Integrity Checklist to monitor adherence to items above (e.g., progress monitoring logs)
 - Attach your revised protocol, revised consent form(s), and any other materials if you need to make changes to reflect COVID-19 procedures.

Note: The COVID-19 Safety Review Panel may request additional information and will provide specific instructions for review requirements.

Review of Reactivation Request: A COVID-19 Safety Review Panel comprised of IRB Members will review requests for reactivation regularly, in the order received and as swiftly as possible. Depending on the risk-benefit analysis, the proposed reactivation may be referred to the full IRB for review. If full board approval is required, your request will be reviewed at the next scheduled IRB meeting.

If approval is granted, the HRPP will conduct Post-Approval Monitoring (PAM) to ensure safety plans are in place. This process may include a semi-structured interview with the principal investigator (PI) or other study team members, review of procedural integrity logs, and tour (virtual/in-person) of research facility as deemed necessary to ensure the full set of safety procedures are being implemented as planned.

Training: Prior to initiating in-person human subjects research, all research study team members must complete the KU Environment, Health & Safety training course, [COVID-19 Return to Work Safety 101](#) available on [MyTalent](#) (log in and enter “COVID-19” in the “Find Learning” dialog box) and Blackboard. Verification of training completion for all study team members to be engaged in in-person procedures must be provided to the IRB with the reactivation request. Please see **COVID-19 Safety Training and Information Resources** for considerations.

In addition, all study team members involved in in-person human subjects research must be trained on the specific safety procedures for the approved in-person procedures. The PI is responsible for ensuring documentation of training is kept and a **Procedural Integrity Checklist** is completed at every in-person session.

Creating Your Safety Plan: PIs must provide explicit, detailed information to participants regarding the general risks created by the COVID-19 pandemic and the strategies the study team will take to eliminate or mitigate those risks.

When creating safety procedures, please abide by all up-to-date recommendations from the CDC, World Health Organization (WHO) and local authorities regarding acceptable practices and any restrictions imposed to prevent transmission of COVID-19. These requirements and recommendations should be your primary source of guidance outside of KU requirements for limiting virus transmission.

When creating your safety plan, please consider:

- characteristics of your situation.
- potential mitigating strategies to reduce risk to participants.
- study team and community.
- resources available to help meet safety objectives.

Charts below provide examples of types of risks and possible mitigation strategies that may be applicable to your project.

Resources

Center for Disease Control and Prevention (CDC)

- [Guidelines](#)
- [Factsheet](#)
- [People at higher risk](#)

Kansas Department of Health & Environment (KDHE)

- [Guidelines](#)

World Health Organization (WHO)

- [Advice for public](#)

Occupational Safety & Health Administration (OSHA)

- [Preparing workplaces](#)

CONSIDERATIONS: PROJECT RISK CHARACTERISTICS

COMMUNITY	PARTICIPANT
<ul style="list-style-type: none"> • Size of community and population density • Level of community engagement/support • Size and characteristics of vulnerable populations • Access to healthcare • Transportation (e.g., public, walking) • Relationship of community to other communities (e.g., transportation hub, tourist destination, etc.) • Level of community transmission • Potential impact on community of virus spread due to research activities 	<ul style="list-style-type: none"> • Personal Protective Equipment (PPE) • Visitor permission (campus/provost/study site approval) • Vulnerable populations • COVID-19 symptom screening and monitoring • Ability of participants to comply with precautionary requirements (children, cognitively impaired) • Number of participants and key study personnel at a site at any time, social distancing
LOCATION	RESEARCH ACTIVITY
<ul style="list-style-type: none"> • Requirements of physical space (who is in control of the space?) • Safety of entry/exit • Safety of waiting room • Need for protective barriers, markers or cues required for social distancing • Size of space adequate for maintaining social distancing • Frequency of cleaning of surfaces • Removal of items that can't be disinfected between participants, such as magazines, toys, carpets, soft surfaces 	<ul style="list-style-type: none"> • Duration of activity • Reduction of direct contact (asynchronous transfer of items, ability to maintain social distance) • Protocol for preventing or mitigating contamination of equipment (keyboards, exercise equipment, manipulatives) • Proper disposal of items used to prevent contamination (masks, gloves, pens given to participants)

continued

CONSIDERTIONS: STRATEGIES AND PROCEDURES FOR PREVENTING OR MITIGATING SPREAD OF COVID-19

PROJECTS	STUDY TEAM PREPARATION
<ul style="list-style-type: none"> • Written protocols for hygiene, precautions, social distancing • Logs to document adherence to written protocols • CDC guidelines met • Participants and study team screened daily or by session for COVID-19 symptoms • All parties must wear cloth masks at all times • All parties must wear gloves if touching objects; hand washing and/or sanitizing materials are available • Frequent disinfection of high-touch surfaces and objects or equipment used • Groups of 5 or fewer total researchers and participants, with appropriate Personal Protective Equipment (PPE) and social distancing (SD), at any time 	<ul style="list-style-type: none"> • Know where to find and refer to on a regular basis, CDC, state and local information on COVID-19 and local trends of COVID-19 cases. • All study team members are expected to have taken the KU EHS training module, “COVID-19 Return to Work Safety 101” and have been trained on study-specific written protocols for hygiene and behavioral protocols, including documentation, to mitigate virus spread. • All study team members should know the signs and symptoms of COVID-19 and what to do if a participant or study team member becomes symptomatic at the research space. Study team members should self-screen for illness symptoms daily or prior to each research session and should not report to the research session if symptomatic; participants who arrive or become ill at the research space must be asked to leave. • Train and monitor research team members regarding protocols for escorting participants to and from the research space (if applicable), screening participants for symptoms of illness and exposure to COVID-19, using personal protective measures (e.g., stay home when sick, handwashing, respiratory etiquette). • Train and monitor research team members regarding protocols for cleaning and disinfecting frequently touched surfaces, objects or equipment to prevent virus spread among participants and study team members. • Ensure sufficient supplies, including masks for study team members and participants, hand hygiene supplies and cleaning/disinfectant supplies are readily available in the research space. • It is recommended that the study team have a practice session in the research space to demonstrate proper setup and take down and rehearse protocols for managing participants and activities.
LOCATION PREPARATION	
<ul style="list-style-type: none"> • Ensure there is adequate space to maintain SD given number of individuals in the space – allow ~50 square feet per individual. Conversations should be at a distance of 8 feet in diameter (taking into account 2 feet for the body). • Use signage and markers such as tape to cue social distancing. • Barriers such as Plexiglas can prevent spread for transactions closer than recommended 8 feet between individuals. • Ensure there is an adequate supply of masks, gloves, other PPE as required. • Ensure there is an adequate supply of cleaning and disinfecting agents and supplies, including soap/sanitizer. • Have available in the research space written protocols for activities such as: <ul style="list-style-type: none"> ○ safe arrival and departure ○ controlling flow and SD of participants/bystanders through research space ○ cleaning and disinfecting objects and surfaces • Consider rearranging or removing furniture to better control flow, maintain social distance. • Consider removing difficult-to-clean objects and small objects (e.g., magazines) that individuals could handle while waiting. 	