COVID-19: Application for Reactivation of In-Person Research

PURPOSE

The ambient risk of conducting in-person human subjects research has increased dramatically with the COVID-19 pandemic. KU recognizes that not all human subjects research can be conducted remotely and is taking a tiered approach to safely reactivating in-person research.

In Phase 1 of research reactivation, proposals will be reviewed on a case-by-case basis and approvals will be limited to:

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

PROCEDURE

- ☐ Read Requirements for Reactivation of In-Person Research Phase 1 and COVID-19 Safety Training and Information Resources.

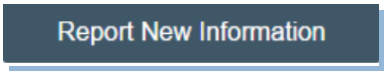
- ☐ Complete Environment, Health & Safety (EHS) "COVID-19 Return to Work Safety 101" training.
  - ➢ Refer to COVID-19 Safety Training and Information Resources for instructions to complete training.

- ☐ Complete HRPP Reactivation Safety Plan.

- ☐ Create Procedural Integrity Checklist to monitor implementation of safety plan.

- ☐ Revise HRPP Protocol with appropriate revisions as defined in HRPP Reactivation Safety Plan:
  - i. Procedures for promoting safety of physical environments (e.g., physical space, cleaning/decontamination between subjects etc.)
  - ii. Procedures for promoting safety of interactions between Individuals (e.g., limiting number of people, social distancing requirements)
  - iii. Procedures for promoting safety of activities (e.g., interacting with keyboards, manipulatives)
  - iv. Procedures for re-consenting participants
  - v. 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
  - vi. Procedural Integrity Checklist to monitor adherence to items above (e.g., progress monitoring logs)
- ☐ Update consent forms to include COVID-19-specific safety procedures. (Please see COVID-19 Consent Template for guidance.)

- [ ] Submit a Report of New Information (RNI) in *eCompliance* indicating REACTIVATION REQUEST in question 4.
    a) On the main study page, click the button titled “Report New Information.”



    b) Complete the questions on the RNI smart form. *Note: On question 4, indicate this is a reactivation request.
    c) Upload completed HRPP Reactivation Safety Plan.
    d) Upload Procedural Integrity Checklist.
    e) Upload verification of completed EHS training for all KU study team members and equivalent training for all external study team members.
    f) Upload revised protocol, revised consent form(s), and related study materials as appropriate per phase.
    g) Click “Submit” to send the completed RNI to the HRPP.

REVIEW TIMEFRAME

A panel comprised of IRB members will review requests for reactivation on a regular basis. Applications will be reviewed in the order in which they are received, as swiftly as possible. Depending on the risk-benefit analysis, the application may be referred to the full IRB for review. If full board is required, the application will be reviewed at the next scheduled monthly meeting.

Approved protocols will be reviewed regularly by the HRPP as part of a Post-Approval Monitoring (PAM) process. This may include the HRPP reviewing procedural integrity logs. A Procedural Integrity Checklist is required for PIs to track implementation of safety procedures as well as health screenings. The procedural integrity checklists may be reviewed by the HRPP to assure compliance.

**Please note: As we enter this phase of reactivation, we anticipate making adjustments to these documents and procedures based on the current guidance from the CDC and feedback from researchers.*