Memorandum

To: Researchers conducting Human Subjects Research
From: Chris Winders, Director, UMKC Research Compliance Office
Date: March 17, 2020
RE: COVID-19 FAQs Relating to Human Subjects Research

As we continue to grapple with the consequences associated with the COVID-19 coronavirus outbreak, the risk/benefit ratio for biomedical and social behavioral research participation must be carefully assessed. Both the ethical principles of research delineated in the Belmont Report and Federal Research Regulations (OHRP and FDA) for the protection of research participants dictate that we ensure the risk/benefit ratio be acceptable at all times.

There are several Universities across the country that have already paused research presenting little to no direct benefit to participants. While we do not believe that research at UMKC should be brought to a halt at this time, we do require that investigators evaluate their need to take steps to decrease the likelihood they put themselves, members of their study teams, or their study participants at risk of becoming infected with or spreading COVID-19. Below are guidelines to follow with respect to overall planning and data collection activities for research.

Establish Formal Plans
All investigators engaging in human subjects research should develop concrete and actionable plans for:

- Continuing or halting data collection in accordance with study sponsors’ requirements and federal regulations.
- Regularly communicating with the following to ensure everyone is operating under the procedures recommended by the University:
  - The study team
  - All study sites
  - Participants and their caregivers.
- Managing data in the event the University campuses are closed.

Investigators and study teams conducting research activities that involve medications and/or devices should create plans for participants who have had new devices or recent procedures and/or who require close monitoring because of the nature of the medications or investigational products. These plans should include contingency plans for providing medications, cross training of staff, and ensuring access to required care.
Review Data Collection Procedures

As part of planning, investigators and study teams must revisit data collection procedures as well as the extent to which, or circumstances under which, data collection should be brought to a halt, either temporarily or permanently. Suggestions for biomedical and social behavioral research are provided here:

**Ongoing Studies with the Potential for Direct Benefit to Research Participants**

On-going trials with direct potential benefit to participants may continue for enrolled subjects. Consider the impact to participant safety to enrolling new participants.

From an IRB perspective, participant safety is paramount, so any changes to an existing protocol must first be in the best interest of the participant.

- Consideration must be given to reducing the number of in-person contacts with research participants. If study visits, data collection efforts, etc., can be moved to a remote visit, taking into consideration the overall safety of the research participant, the research team should pursue those options.

- Consider:
  - Decreasing the number of protocol-mandated in-person study visits to healthcare facilities.
  - Replacing protocol-mandated visits to healthcare facilities with telemedicine, allowing blood draws at offsite or commercial laboratories.
  - If allowable, shipping investigational products directly to research participants.

**Ongoing Studies without Direct Benefit to Research Participants**

Researchers must initiate modifications to their procedures, to replace in-person study visits with “remote” options for questionnaires, surveys, check-ins, screening, and consenting. If this makes the conduct of the research an impossibility you will need to temporarily halt research activities until such time that they can resume without risk to participants.

- Consenting procedures may be modified to exclude obtaining participant signatures through a waiver of documentation. This is an action that requires IRB review and approval.
  - An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:
    - That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Applicable to All Currently Approved Human Subjects Research

- Temporary halt to study enrollment

Some studies may voluntarily halt, stop, or delay research participant enrollment due to COVID-19 related public health recommendations, facility requirements, study team availability, and/or risks to participants susceptible to contracting COVID-19. This does not need to be reported to the UMKC IRB unless the study hold is initiated at the request of an external funding agency, Data Safety Monitoring group, or federal agency. Changes in IRB-approved research must be submitted to the IRB.

- An exception is when changes are necessary to eliminate immediate hazards to the subject (permitted in both OHRP and FDA regulations)
  - If this happens, the changes must be reported to the IRB (in eCompliance via an “Emergency Use of a Test Article” submission) within 5 days
  - If the changes need to be sustained for multiple visits/subjects, then an amendment to the protocol must be submitted.

- Eliminate bringing groups of people together for data collection activities (e.g., focus groups, whole group interventions).
- Move face-to-face data collections (e.g., interviews, surveys administered in person, forms of observation) to telephone or online (e.g., Zoom) formats.
  - Follow recommended guidelines for reducing exposure and, if prudent, pause study activities.
  - Determine whether it is necessary to completely suspend research activities and if so, pause recruitment until the situation changes.

Proposing Studies with the Potential for Direct Benefit to Research Participants

Research directly related to COVID-19 will be prioritized for review.

All other research that provides the potential for direct benefit to research participants must follow the guidelines established above in the section for “Ongoing Studies with the Potential for Direct Benefit to Research Participants” as it relates to the collection of data and interaction with research participants. Unless all research activities can be conducted remotely, consideration should be given to determining if now is the best
time, for potential participants and the research, to initiate such a study. If the answer is no, then it is suggested that you not initiate an IRB application at this time.

**Proposing Studies without Direct Benefit to Research Participants**

You should not submit an application at this time that includes any type of person-to-person interactions. All submitted applications must address consenting, data collection etc., from a position of remote access only. Tools such as Qualtrics and REDCap can be used for data collection and Zoom for research participant interactions.

**Amendments to Existing IRB Approved Protocols**

For IRB full board and expedited reviewed studies, if an investigator or study team needs to alter data collection activities by shifting to phone or online, or another change needs to be made to a study protocol in order to protect participants or study personnel, an amendment should be submitted with the language “COVID” in the title. This will allow the IRB to flag the amendment and review and if appropriate approve the amendment quickly. If a sponsor or investigator needs to make a change to research plans and is unable to submit an amendment (e.g., immediate hazard or risk to research participants exists), these changes can be made and then reported to the IRB within 5 days, as a reportable event. Eliminating immediate hazards may include actions that reduce potential exposure to COVID-19, or to continue to provide medically necessary care (including investigational products) to participants who have been placed in isolation or quarantine because of suspected or known exposure. The UMKC IRB encourages sponsors and investigators to take such steps as necessary to eliminate apparent additional risks to participants.

At the current time, the UMKC IRB will continue to review and approve research protocols that have been or will be submitted, including those submissions that require full board review. However, any research team that has not yet begun research activities should ensure that doing so will not jeopardize members of the research team or research participants. In addition, should the COVID-19 landscape change significantly, there may come a point when human subjects research will be restricted and application reviews might be paused in the interest of individual and public health.

We have developed a resource page that includes additional FAQs for researchers conducting Human Subjects Research that may be helpful as we navigate through this challenging time.
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