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Guidelines for Conducting Human Subject Research during the COVID-19 Pandemic

OSF Research Administration offers the following information for study personnel to consider as they plan for and respond to operational and administrative challenges to ongoing human subject research during the COVID-19 pandemic:

1. Risks to Consider
 - a. Study Population
 - i. Does the study involve person-to-person contact?
 - ii. Does the study population have a high risk profile (e.g., age, co-morbidities, etc.)?
 - iii. Do interruptions/suspensions/alterations of study activities, including standard of care, expose participants to risks?
 - b. Study location risks:
 - i. Do research activities occur in locations where the virus is or may be more prevalent (e.g., hospitals, clinics, etc.)?
 - ii. Do travel/social gathering restrictions interfere with safe conduct of study activities (e.g., delivery of study related products/materials, travel of participants/research personnel, etc.)?
 - c. Study personnel risks:
 - i. Do study personnel have high risk profiles (e.g., pre-existing conditions, multiple exposures, etc.)?
 - ii. Do priorities in response to pandemic detract from/compromise availability/capacity to conduct ongoing study activities?
 - iii. Do changes to study activities have implications for other stakeholders, such as, but not limited to coordinating centers for multi-center trials, sponsors, funding agencies, and academic institutions (e.g., student research in partial fulfillment of graduate requirements)?
2. Options to Mitigate Risks
 - a. SAFE suspension of some or ALL research activities
 - b. Relocate studies activities to alternative locations where COVID-19 exposure maybe less prevalent
 - c. Use remote modes of communication/interaction (e.g., telephone, online, telemedicine, etc.)
 - d. Replacing/suspending research personnel who may be of higher risk
 - e. Home delivery of investigational product or study-related materials
 - f. Early, proactive communication with stakeholders (e.g., sponsors, IRB of record, etc.)

BEFORE research personnel make or implement ANY changes, they MUST:

1. Contact specific study sponsor (when applicable) to ensure alignment with sponsor plans and/or recommendations
2. Submit change(s) for review/approval by the IRB of record UNLESS the change(s) is/are necessary to eliminate immediate threat(s)/hazards(s) to participants. You should contact the IRB of record with questions or concerns about IRB operations **(Over for Page 2)**



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3. Assess whether and how pandemic conditions and/or study modifications alter criteria for ongoing IRB approval of the study, namely:
 - a. Conditions/changes minimize risks by using procedures that are consistent with sound research design, and when appropriate use procedures already implemented for diagnostic and/or treatment purposes;
 - b. Risks to participants remain reasonable relative to:
 - i. any anticipated benefits to participants and
 - ii. the importance of knowledge one may reasonably expect to result from the study;
 - c. Applicable data monitoring continues adequately to ensure safety of participants; and
 - d. Adequate provisions to protect privacy of participants and confidentiality of data
4. Inform current and prospective participants of information that may influence willingness to participate, such as, but not limited to changes to risk exposure, study activities, etc.
5. Have plans for prompt reporting and management of COVID-19-related unanticipated problems that involve risk to subjects or others.

We encourage you to contact OSF Research Administration with any questions or concerns.

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