Advanced Operational Guidelines to Improve In-Person Human Subjects Research

Fall 2020
All human subjects research must consider the balance of risks to benefits.

Remote (virtual) interactions preferred whenever possible.

With in-person activities, additional precautions should be taken to protect research team and participants.

Guidance on other aspects of research activities available:

https://research.kennesaw.edu/coronavirus.
Requirements to conduct in-person human subjects research on KSU campuses…

If an in-person research protocol was IRB-approved to the COVID-19 restrictions,

1. amendment to protocol, documenting changes made to maintain the health/safety of researchers/participants must be submitted (including items listed on the next slides).

2. Explicitly state exceptions/motivations for mitigation to these requirements (e.g., close contact between researcher and participant), in order to be approved by the appropriate Assistant/Associate Dean for Research.

3. IRB approval must be obtained before resumption.
Research must be conducted in areas where efforts for disease mitigation can be maintained.

- Entry limited to those directly involved with the research at that time.
- Min – 6 ft distance between all when possible & limit time required for close contact with participants (ex. specimen collection), maximizing protections.
- Shared labs allowed if observing physical distancing requirements & participants are staggered in their entry to the lab.
- **Clean with soap/water** (when possible; if not damaging to equipment) & sanitize research area (door handles, etc.) & equipment between participants.
- Frequently wash/sanitize hands during in-person activities.
- Plans for alternative staffing resources to replace high risk research staff & participants during COVID-19 pandemic must be developed and implemented.
- Lists of human subjects with contact info should be retained for 30 days following in-person activities, specifically related to possible COVID-19 exposure.
FOR RESEARCHERS (faculty, staff, students)

- Must be screened for possible COVID-19 exposure (temperature, previous exposure, current perception of health, etc.).
  - Temperature must be taken & be less than 100.4°F (38°C).

- Must must wear gloves and face mask (compliant with CDC guidelines).
  - Gloves changed and hands washed between subjects.

- Researchers should self-monitor their temperature and symptoms for 14 days after in-person research activity, and report to human participants if lab-tested positive for COVID-19.
Participants must be pre-screened (via phone, email or virtual appointment) prior to visit.

- Has not received COVID-19 positive test result in previous 14 days (or following current CDC recommendations).
- Does not self-report COVID-19 symptoms (defined by current CDC guidelines).
- Has not had known contact with person lab-confirmed to have COVID-19 in past 14 days (or following current CDC guidelines).
- Is not in high-risk category as defined by CDC (e.g., minors, > 65 years, underlying health conditions, travel restrictions), or included in State definitions for vulnerable populations that are required to Shelter in Place.
- Use [CDC Coronavirus Self-Checker](https://www.cdc.gov/coronavirus/2019-ncov/risk-factor-calculator.html) to determine whether participant can come to campus or should stay home.
Participants must also be screened once arriving at the lab.

- Temperature must be taken & be less than 100.4°F (38°C).
- Must use CDC Coronavirus Self-Checker to determine whether participant should continue.
- Participant must be informed of precautions taken in that particular study to prevent spread of COVID-19 (information should be part of revised consent process approved by the IRB).
Participants must follow additional precautions during visit.

- Participants must sign **acknowledgement of their COVID-19 risks** as additional part of informed consent.
  - *It is the researcher’s responsibility to ensure these forms are completed by each participant & properly stored as research materials.*
- Participant must wear, at a minimum, a face mask provided by researcher. Gloves should be available too.
- Participants should self-monitor temperature/symptoms for 14 days after in-person research activity, using CDC Coronavirus Self-Checker, & to report to researcher if lab-tested positive for COVID-19.
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