Research involving human subjects requires an understanding of the nature of the research procedures in relation to the available risk mitigation approaches. Indeed, a basic principle of the protection of human subjects is to compare risk to that encountered in the conduct of everyday life, which defines minimal risk. Thus, in the context of the community spread of COVID-19, there are important considerations to remember when conducting research with human subjects. First, all human subjects research must consider the balance of risks to benefits. Because many risk factors remain unknown, the preference for research with human subjects is for remote (virtual) interactions whenever possible, for safety. When research activities are in-person, additional precautions should be taken to protect both the research team members and the participating subjects. Separate guidance is available for science (wet) and engineering (dry) research laboratories, shared facilities for scientific equipment, computational facilities, and field-based research, on the Office of Research website: https://research.kennesaw.edu/coronavirus.

In-person human subjects research conducted on KSU campuses can begin only after the following requirements are met:

- If an in-person research protocol was approved by the IRB prior to the COVID-19 restrictions, an amendment to that protocol that documents changes you have made to maintain the health and safety of research personnel and participants must be submitted (including items below). IRB approval must be obtained before the restart of research.
- Research personnel must submit a Professional Ethics form to the Associate/Assistant Dean for Research (ADR) before in-person human subjects research on campus may resume.
- In-person research must be conducted in areas where efforts for disease mitigation can be maintained.
- When possible, social distancing must be in place during all in-person interactions. This will require a minimum of 6 feet distance between all individuals involved in in-person research.
- For those activities where social distancing is not possible (collection of specimens, for example), every effort should be made to limit the time required to be in close contact with participants, and to maximize the protections for the researcher and participant.
- Those allowed entry to the research area will be limited to only those directly involved with the research at that time.
- Shared labs will be allowed to conduct in-person research with human subjects if physical distancing requirements are in place and participants are staggered in their entry to the lab.
- Clean with soap and water (when possible; if not damaging to equipment) and then sanitize research area (this includes door handles, light switches, etc.) and equipment between participants. For more information on best practices for cleaning and disinfecting, please refer to: https://www.cdc.gov/coronavirus/2019-ncov/community/reopen-guidance.html.
- Frequently wash/sanitize hands during in-person activities.
- Plans for alternative staffing resources to replace high risk research staff and participants during the COVID-19 pandemic must be developed and implemented.
- Lists of human subjects and contact information should be retained for 30 days following the in-person activities, specifically related to possible COVID-19 exposure (see below).
- For faculty, staff or students conducting in-person research with human subjects:
  - Researchers must be screened for possible exposure to the virus (temperature, previous exposure, current perception of their health, etc.)
    - Temperature must be taken and found to be less than 100.4°F (38°C).
• Complete and submit **COVID-19 Health Screening for Research Personnel** - available as an [online form](#).
  o Researchers must wear gloves and a face mask (must be compliant with CDC guidelines). Gloves should be changed and hands washed between subjects.
  o 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.

• **For participants** engaged in in-person research on KSU campuses:
  o Participants must be pre-screened (via telephone, email, or virtual appointments) for possible exposure to the virus prior to coming to campus for in-person research. Ensure subject:
    ▪ Has not received a COVID-19 positive test result in the previous 14 days (or following current CDC recommendations)
    ▪ Does not self-report COVID-19 symptoms, as defined by current CDC guidelines.
    ▪ Has not had known contact with a person lab-confirmed to have COVID-19 in past 14 days (or following current CDC guidelines).
    ▪ Is not in a 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 the CDC Coronavirus Self-Checker ([https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html](https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html)) to determine whether the participant can come to campus for research or should stay home.
  o Participants must also be screened once arriving to the lab for the research project. Ensure subject:
    ▪ Temperature must be taken and found to be less than 100.4°F (38°C).
    ▪ Must be informed of the precautions being taken in that particular study to prevent spread of COVID-19 (this information should be part of the revised consent process approved by the IRB).
    ▪ Must sign an **acknowledgement of their COVID-19 risks** as an additional part of informed consent. It is the researcher's responsibility to ensure these forms are completed by each participant and properly stored as research materials.
    ▪ Must wear, at a minimum, a face mask provided by the researcher. Gloves should be made available to participants.
    ▪ Should be asked to self-monitor their temperature and symptoms for 14 days after in-person research activity, using the CDC Coronavirus Self-Checker, and to report to researcher if lab-tested positive for COVID-19.

• Explicitly state exceptions and motivations for mitigation to these requirements (e.g., close contact between researcher and participant, an individual participant’s degree of risk), in order to be approved by the appropriate Assistant or Associate Dean for Research.