Human Subject Restart Procedures

Gating Criterion (satisfy before proceeding to Restart Procedures)

1. Can the research be completed remotely?

☐ YES. End of request. Proceed with completing research remotely. If this is a deviation from the IRB-approved study submit an amendment to the IRB including this modification prior to enrolling study participants.

☐ NO. Proceed to restart procedures.
Human Subject Restart Procedures

The following information is provided to guide human subject researchers conducting in-person research (inclusive of clinical trials, clinical research, and field research involving data collection from human subjects) on steps required prior to restarting their in-person human subjects research activity. All ECU faculty, staff, and students are expected to follow applicable local, state, and federal guidelines as well as ECU recommendations.

1. All research personnel and volunteers (i.e., undergraduate students, graduate students, postdoctoral researchers, staff, and faculty) complete COVID-19 online training. Department chair and faculty/PI are responsible for maintaining documentation of training completion of study personnel and volunteers.

2. The COVID-19 Safety Plan for Human Subject Research needs to be completed. The faculty/PI is responsible for maintaining and updating the document.

3. The ECU COVID-19 Human Research Risk Assessment Form must be completed and approved by the department chair and associate dean for research. If the faculty is conducting in-person research affiliated with a Center/Institute, then the form must also be approved by the facility study site director.

4. Faculty/PI confirms adequate supplies of hand soap, hand sanitizer, and necessary PPE for research personnel and study participants.

5. Faculty/PI confirms adequate supplies of cleaning and disinfectant agents for common touch points and equipment that will not be cleaned by housekeeping per COVID-19 Safety Plan for Human Subject Research.

6. Faculty/PI emphasizes that research personnel who are sick should stay home.
   a. All personnel must complete COVID-19 screening checklist at the beginning of each day they are participating in research activities attesting that they do not have symptoms.
   b. If sick or experiencing symptoms, research personnel should follow CDC guidelines.

7. Faculty/PI emphasizes that research personnel who have been in “close contact” (defined as being within 6 feet) with someone with COVID-19 for a prolonged period of time follow CDC guidance.

8. Limit personal belongings in research spaces to those that are absolutely necessary. This includes food, drink, bags, and other personal items.

9. Department chair, faculty, and ADR/Facility clinical site director determine appropriate signage to be posted in areas that human research subjects will be. This includes building entries, hallways, lab spaces, etc…
10. Use PPE as appropriate for research activities.

11. Complete participant screening using the COVID-19 Screening checklist
   a. Pre-screen by phone prior to in-person human subject research activity.
      Recommend the day prior to study activity
   b. Screen upon arrival for in-person human subject research activity