Division of RESEARCH Research Compliance

Check List for Preparing to Resume In-Person Human Subjects Research

INTRODUCTION

The purpose of this document is to provide guidance for your assessment and planning to resume in-person research with the approval of the Institutional Review Board (IRB). The items in this check list incorporate the Healthy Clemson guidelines, best practices from other research institutions, CDC guidelines, and scenarios considered by a Clemson University task force consisting of faculty, Occupational and Environmental Safety (OES) staff and IRB staff.

You do not have to send the checklist to the IRB office. Please use the checklist to develop your safety protocol and describe your procedures on the IRB form. Also, follow the additional protections sections for the vulnerable populations identified by the CDC.

REQUIRED STEPS

Regardless of the level of IRB review of your research, follow these steps to develop your safety protocol before resuming in-person data collection:

1. Whenever possible, continue remote data collection until we return to Normal Operations on campus; incorporate a plan to return to remote data collection should the University status change.
2. Follow University status:
    - **Work From Home Order** = remote data collection (e.g., online surveys, telephone interviews, Zoom focus groups). Interactions with research participants that cannot be conducted remotely must stop until University status changes. Any exceptions must be approved by the Vice President for Research (VPR), your Associate Dean of Research (ADR) and IRB office.
    - Any T**ransition Phase** between full Work From Home Order and Normal Operations = in-person collection must adhere to University guidance and elements in the check list. Requests to resume on- campus interactions must be approved by the VPR and IRB office;
    - **Normal Operations** without COVID protocols required = restrictions lifted.
3. Assess space, population, PPE and other factors to prepare for resuming in-person data collection.
4. Notify the IRB with an Amendment request if you:
    - Have any changes to your research methods (i.e., recruitment process, instruments/measures) that were not previously approved.

ASSESSMENT

This check list is for guidance purposes only, to help you plan for a safe return to in-person data collection. You must address the applicable items in your IRB form. For items not applicable, mark "N/A" beside the box. *You do not need to provide this check list to the IRB office.*

RESEARCH SPACE

- ☐ How many people (i.e., team members and study participants) will be present during the data collection?

  _____ team members _____ study participants

- ☐ How large is the research space where the data collection will occur? _____ square feet
- ☐ For research areas, Clemson recommends allowing 150 sq feet per person in an enclosed space. An estimate of the number of people permitted can be determined by dividing the usable (net) square footage by 150. For example, a 600 square foot area can have 4 people present. (Calculation: 600 ÷ 150 = 4) What is your maximum number of people for the research area? _____
- ☐ How long will the interaction take? How long will data collection take place? _____ minutes/hours (Note: mark N/A if this is an observation study.)

- ☐ Can you conduct data collection outside? ____ Yes or ____ No
- ☐ Can seating for data collection be arranged for to achieve social distancing of 6 feet? ____ Yes or ____ No
  - If no, can study participants be separated in different rooms/spaces?

    ____ Yes or ____ No

- ☐ Will you schedule so that participants will be waiting in a separate area prior to the procedures? If so, how many will wait together? Will any team members, family members, etc. be present?

  _____ Study participants _____ Non study participants

- ☐ How large is the space where people will wait? _____ square feet
- ☐ For waiting areas, Clemson recommends allowing 133 sq feet per person in an enclosed space. An estimate of the number of people permitted can be determined by dividing the usable (net) square footage by 113. For example, a 600 square foot area can have 5 people present. (Calculation: 600 ÷ 113 = 5.3) What is your maximum number of people for the waiting area? _____

Additional Protections

- ☐ How is ventilation/air circulation in both spaces?
  - Is there a window that could be opened? ____ Yes or ____ No
  - Can you leave the door open and maintain privacy? ____ Yes or ____ No
  - If needed, contact Clemson facilities or Environmental Safety to assess airflow, especially if data collection requires a group of people in an enclosed space not already modified by Facilities.

Consider steps to reduce or limit the amount of time two or more people are in the space to minimize aerosol transmission.

PERSONAL PROTECTIVE EQUIPMENT

- ☐ All team members are required to wear appropriate face coverings, in concurrence with Clemson's requirement: https://www.clemson.edu/coronavirus/index.html
- ☐ Encourage face coverings for study participants
  - Can you provide masks for participants? ____ Yes or ____ No
- ☐ Single-use gloves required for all team members who make physical contact with participants. How will you provide? _____
- ☐ Will additional PPE (e.g. face shields) be warranted if population is high risk and procedures increase likelihood of prolonged close contact? (describe)_____
- ☐ Is there a location to wash hands? Location: _____
- ☐ Will hand sanitizer be provided to:
  - Team members? ____ Yes or ____ No
  - Participants? ____ Yes or ____ No
  - Those in waiting area? ____ Yes or ____ No

ENVIRONMENTAL CLEANING MEASURES

- ☐ Disinfect surfaces where interactions will occur, after each data collection interaction—e.g., door handles, desk or table surfaces, etc. List surfaces _____
- ☐ Disinfect surfaces that made contact with participant—e.g., blood pressure cuffs, VR headsets, touch screens, keyboards,[1] etc. List potential surfaces _____
- ☐ Disinfect waiting area surfaces
- ☐ How will you provide cleaning and disinfecting supplies for team members? _____

[1] If possible, use keyboard covers.

SCREENING

- ☐ Team members should complete same Screening Questions as participants before beginning in-person contact with research participants
    - The Screening Questions tool is available on the IRB website.
    - Consider how this will be communicated and verified
- ☐ Observation studies where no consent or in-person interactions is required do not require screening of participants
- ☐ Studies involving interactions or interventions with participants require participant screening prior to <u>each</u> study interaction by that participant
    - Keep completed screenings with participant study documents
- ☐ When possible and appropriate, screening should be conducted over the phone or virtually
- ☐ Participants who identify as members of a high-risk population group that is <u>not</u> the intended population should be encouraged not to participate at this time.

PARTICIPANT NOTIFICATION

Note: You do NOT need to revise your informed consent form to accommodate the changes you are making specific to COVID-19. You should revise your consent form if you are making changes in your procedures or other changes that normally require a revised consent. The COVID-19 Safety Procedures Notification is a means for you to communicate to current and future participants the steps you are taking to reduce potential exposure to COVID-19. It can be used as a handout or script.

- ☐ The COVID-19 Safety Procedures Notification DOES NOT REPLACE your Informed Consent document.
- ☐ The COVID-19 Safety Procedures Notification should NOT be embedded in the study's Informed Consent document. Provide the COVID-19 Safety Procedures Notification as a handout (or read as a script) to returning participants and as an addendum to Consent Form for new participants.
    - The COVID-19 Safety Procedures Notification is available on the IRB website.
    - You may add a supplement to the Safety Notification to add specifics or additional protections but do not modify the basic information.
- ☐ Consider whether the COVID-19 Safety Procedures Notification could be included in recruitment materials for new participants.

Additional Protections

If your participants are members of a high risk group which <u>is</u> the intended population, consider whether to provide additional protections based on your assessment of the space, PPE, etc. These protections should be added to the Safety Notification.

IF SOMEONE SHOULD TEST POSITIVE

Participants

In the event of a participant notifying you they tested positive for COVID-19 after your interaction, you should

- Please follow CU guidelines regarding testing and reporting for team members who may have been exposed.

Team members

If a team member tests positive, please follow CU guidelines for reporting. Determination for notifying research participants will be made by Clemson University.

NOTIFYING THE IRB (AMENDMENT PROCEDURES)

Unfortunately, the risk for contracting COVID has become a part of our everyday life for the time being. Therefore, resuming in-person data collection does not change the risk level of your IRB. However, if you will be making adjustments to your data collection procedures to accommodate COVID, then an amendment request form is required.

Exempt Review Protocols

If your research was previously determined Exempt by the IRB and in-person research activities will occur on-campus, keep this completed check list and any training records from your team members on file.

You do not need to submit an amendment to the IRB unless you are changing the research methods from what was determined exempt. Moving research activities remotely does not require an amendment request. An update site letter/notification is required for all off-campus locations. Send the documentation to IRB@clemson.edu.

Expedited Review Protocols

If your research was previously approved under Expedited review by the IRB, then you do not need an IRB amendment to resume in-person research activities that were previously approved. Until the University returns to normal operations, the VPR's approval is required to access on-campus research labs and facilities. Use the check list to develop your safety protocol and submit an amendment to the IRB office if you make any changes to your research methods (i.e., recruiting process, instruments/measures).

Full Board Review Protocols

If your research was previously approved under Full Board review by the IRB, please complete an amendment request to resume in-person research activities. Using the completed fields in your check list as a guide, you must provide the following information in your amendment request:

- A plan for ensuring social distancing between team members and participants (a minimum of 6 feet) and minimizing time in an enclosed space whenever possible.
- A plan for minimizing close contact in procedures as it is possible.
- A plan for PPE of team members (and participants if applicable), including masks, hand washing, hand sanitizing, other PPE.
- A plan for screening participants including rescheduling high risk participants as appropriate.
- A plan for providing the Safety Notification.
- Include site permissions and safety protocols from off-campus sites and any revised documents with your amendment request.
- You do not need to include this check list.

The IRB office will notify you when your amendment is approved. Failure to resume data collection without the approved amendment will be addressed as noncompliance.