

Guidance for CofC Human Participant Research Investigators

Enacting CDC guidelines for Social Distancing

Enacted March 23, 2020

Revised: October 5, 2020, September 7, 2020, August 2021

Note: This guidance will be revisited during regularly [scheduled IRB meetings](#), or when major changes are announced to College-wide [Back on the Bricks](#) plan.

Purpose

Given the rapidly evolving circumstances regarding COVID-19 and the College of Charleston's continued commitment to the health and safety of faculty, staff, students, and the greater community, the Office of Research and Grants Administration, with authority from the Provost, have issued the following revised standards related to research involving human subjects. Please be aware that further restrictions may be implemented based on recommendations from State or Federal authorities.

All investigators are required to follow CDC Social Distancing Guidelines and College of Charleston policy during the conduct of human participant research. Failure by members of the research team to adhere to these guidelines and policies can lead to the suspension of research by the IRB.

In-person research is dependent upon the Back on the Bricks policy. In-person research is permissible as long as in-person classes are allowed. However, if classes are moved to virtual-only, in-person research will also be restricted at that time. Investigators submitting a new protocol for IRB review are encouraged to consider these potential changes during the academic year, and to include procedures for alternative data collection methods whenever possible. Inclusion of these considerations in the original protocol may reduce the number of modification submissions and other potential delays.

Permissible Human Participant Research

Ongoing research that does not require face-to-face interaction can proceed uninterrupted.

Ongoing research that does require face-to-face interaction may only continue if CDC Guidance for Social Distancing and College policy can be followed. **A protocol modification outlining how these guidelines will be followed for in-person research must be submitted to the IRB for review** (see "Submitting a Protocol Modification" section below). All interactions must follow the below guidance, based the recommendations of the South Carolina Department of Health and Environmental Control (DHEC) and the Centers for Disease Control, which emphasize the importance of practicing disease prevention measures and following recommendations for social distancing to protect the health and safety of all South Carolinians.

Examples of permissible remote human participant research

Research that does not involve in-person interaction, is allowed regardless of status of in-person classes.

- Online anonymous surveys
- Research involving pre-existing data
- Interview procedures performed remotely (e.g., via phone or Zoom)
- Some classroom research

Examples of permissible in-person human participant research

Research that is permissible, dependent upon the allowance of in-person classes being allowed by Back on the Bricks. Should in-person classes be moved to virtual, this research will need to be suspended or modified in order to continue.

- Classroom research, as permitted by the school
- Specimens collected by human participant. Participant must collect their own sample, leave it in a designated area for the research team, and proper PPE must be worn at all times. E.g., urine samples
- In-person interviews that can be conducted outdoors, in instances where alternate research collection strategies (e.g., virtual interviews) would jeopardize the integrity of the research. Research team members should wear a mask but can approach/interact with potential participants who are not wearing a mask. E.g., exit polling, man-on-the-street interviews.
- In-person interviews, interventions, and focus groups conducted indoors is allowed if proper spacing can be provided. PPE must be worn by all members of research team and human participants during the conduct of research.
- Specimens collected by research team (e.g., cheek swabs or blood draws) is permissible if research team members are wearing face masks at all times during the interaction. Specimen collection must occur in under 15 minutes.
- Exercise protocols that involve heavy breathing (e.g., VO2 max tests) is permissible if [COVID Check List](#) is submitted to and approved by IRB, which includes pre-screening requirements and [COVID Safety Information](#) that must be provided to participants.

IRB Operations

CofC's IRB is fully functional online and will continue accepting new applications and addendums through our [eForm system](#). IRB review and approval of new applications and addendums can continue remotely without interruption.

Approval of New Applications

New applications must be submitted through the eForm system for IRB review. The IRB will continue to assess the risk-benefit ratio of all proposed research.

Investigators are encouraged to include information in the application outlining how these guidelines will be followed. If a research study involves any interaction with human participants or their specimens, the following information to be included for IRB review:

- Physical location of the research study, and its occupancy limit (as assessed by Physical Plant)
- PPE to be worn by research team and human participants
- Sanitation procedures for shared equipment (pens, clipboards, iPads, chairs, desks, keyboards, etc.)
- For applications requiring full board review, completion of the [COVID Check List](#) is required.

Any deviation from the above requirements must also be stated and justified in the application. The IRB reserves the right to withhold approval if adequate protections for human participants are not provided.

Submitting a Modification

The type of modification required, if any, is dependent upon many factors. Please see the IRB COVID Requirements Matrix at the end of this document for more information.

Transitioning from in-person to remote data collection:

If your research can feasibly be transitioned from face-to-face interaction to remote interaction, an addendum to the IRB must be submitted prior to implementing any changes through the [eForm system](#).

The following information should be included in the protocol modification:

- New mode of contact: telephone, Zoom, Skype, etc.
- How contact information will be kept separate from research data
- If the audio/video will be recorded, and that it will be stored on OneDrive
- Recordings will be deleted after being transcribed
- All transcriptions and other research will be stored securely on OneDrive

Resuming In-Person Research:

For minimal risk research, investigators will be required to submit a protocol modification through the eForm Addendum system providing the following information:

- Physical location of the research study, and its occupancy limit (as assessed by Physical Plant)
- PPE to be worn by research team and provided to human participants
- Sanitation procedures for shared equipment (pens, clipboards, iPads, chairs, desks, keyboards, etc.)

For research involving more than minimal risk, a protocol modification must be submitted with the following information:

- Completed [COVID Check List](#), which includes certification of:
 - Pre-screening requirements
 - [COVID Safety Information](#) provided to participants

Continuations for Research that must be Postponed

Under the [College of Charleston's Flexibility Policy](#), only research that is federally-funded or deemed greater than minimal risk requires submission of a continuation request. Research that is minimal risk, but postponed due to COVID-19, may continue past the original protocol dates without submitting a continuation request through our addendum eForm system.

Research that required initial full board approval will be required to submit a continuation request.

Adverse Events and Suspension of Research

Investigators who fail to follow the above guidance will be required to submit an adverse event report. Based on the severity of the infraction, the IRB reserves the right to suspend the research study. Investigators must take great care ensuring that all members of the research team, including students, follow these guidelines during the conduct of research.

IRB COVID Requirements Matrix

IRB Review Level	Data Collection Type	PPE Required	Sanitation Requirements	Addendum Submission Required	Additional COVID Measures
Exempt	Remote data collection	None	None	No	No
Exempt	In-person classroom research	Yes, as required by school and CofC Policy	Disinfect any shared surfaces immediately before and after	Yes, protocol modification required if changing from in-person to remote data collection	May be additional requirements of school district
Exempt	In-person interview/focus group	Yes, as required by CofC Policy	Disinfect any shared surfaces immediately before and after	Yes, protocol modification required if changing from in-person to remote data collection	Focus groups may not be feasible, depending on space availability; consider transitioning to remote, if possible
Expedited	Remote data collection	None	None	No	No
Expedited	In-person interview/focus group	Yes, as required by CofC Policy	Disinfect any shared surfaces immediately before and after	Yes	Focus groups may not be feasible, depending on space availability; consider transitioning to remote, if possible
Expedited	In-person specimen collection	Yes, face masks and shields required to be worn by research participant and specimen collector	Biosafety standards for specimen handling, plus disinfect any shared surfaces in specimen collection site	Yes	Recommend providing COVID Safety Information to participants
Full Board	In-person	Yes, as required by CofC Policy	Biosafety standards for specimen handling, plus disinfect any shared surfaces in specimen collection site	Yes, must provide Check List as protocol modification	Prior to interaction: 1) Prescreening COVID Questions COVID and 2) Temperature checks; During interaction: Safety Information must be provided to participant along with consent form

College of Charleston Back on the Bricks Policy

Investigators are required to follow the guidelines of the Back on the Bricks policy during the conduct of research, regardless of the physical location of the research study. This includes any research that takes place off campus. For example, masks must be worn by all research and research participants even if the physical location of the study does not have a mask mandate. Select excerpts from the plan are available below, but see the website for full information: <https://cofc.edu/back-on-the-bricks/index.php>.

Face Covering Requirements

- “Face coverings are required at all times while on campus.” (Source: <https://cofc.edu/back-on-the-bricks/health-and-wellness/index.php>)

CofC Guest Limitations

- “All visitors to campus will be required to adhere to the City of Charleston's and the College's requirements for face coverings and social distancing as well as CDC and SCDHEC guidance. Visitors with COVID-19 symptoms or who are feeling ill should not come to the CofC campus. It is recommended that such individuals seek immediate testing and care by a licensed healthcare professional.” (Source: <https://cofc.edu/back-on-the-bricks/contacts-and-resources/index.php>)

CDC Social Distancing Guidelines:

- Maintain 6 feet of separation between yourself and others
- No more than 10 persons in a room
- Follow best practices for disease prevention

Disease Prevention includes:

- Washing your hands frequently, for at least 20 seconds using plenty of soap
- If soap and water are unavailable use hand sanitizers with a minimum of 60% alcohol, (the CDC recommends 70% alcohol minimum) and rub your hands for a minimum of 20 seconds
- Cover your cough, and avoid touching your eyes, nose, and mouth
- Stay home when you are sick and do not attend public gatherings, and
- Appropriately disposing tissues and other items that you have used when sneezed or coughed
- Wear a face mask if you are sick
- Clean and frequently disinfect all surfaces that have been contacted, which include tables, doorknobs, light switches, countertops, handles, phones, keyboards, toilets, faucets, sinks, etc.

More information on these topics are available at <https://www.cdc.gov/coronavirus/2019-ncov/prepare/prevention.html>.

Investigators should consider whether at any point their research procedures should be revised to limit personal contacts, for example by reducing the frequency of in-person visits or replacing in-person interviews with telephone or Internet contacts. Whether and when this may be advisable will vary depending on your protocol and the subjects with whom you are working.

If possible, we encourage the submission of protocol modifications to convert in-person data collection to remote procedures, outlined in the *Requesting a Modification to Perform Remote Data Collection* section below.

If you have any questions, please contact compliance@cofc.edu.