COVID-19 In-person Research Procedures
Southern Utah University
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1. Introduction

Southern Utah University (SUU) is permitting in-person research to resume (with IRB approval of researcher-submitted Research Safety Plan, see below) when classes start on Wednesday, 9 September 2020. This document details steps for how SUU faculty, staff, and students can begin some in-person research. The guidelines in this document will apply until SUU determines (a) they are no longer necessary because COVID-19 is not a sufficient danger, (b) COVID-19 spread is so high that in-person research is suspended again, or (c) the guidelines need to be adjusted.

Researchers should postpone in-person research, if possible. Collecting data online is encouraged, such as using online surveys or Zoom. If a procedure can be done remotely, it should be done remotely. If you need to update your procedures to collect data online, you should submit a Proposed Changes to a Previously Approved Protocol form to the SUU IRB. The only kinds of in-person research that the IRB will be consider are projects (a) that can only be completed in-person, or (b) where the researcher and participants are interacting regardless of the research itself.

The COVID-19 pandemic is unpredictable, and so researchers should realize that things can change anytime. This unpredictability is another reason researchers might benefit by focusing on research that can be conducted online. That is, a COVID-19 outbreak might result in in-person research begin suspended again.

The rest of this document describes the criteria that the IRB will use to evaluate the Research Safety Plans that researchers submit when they request to conduct in-person research. It then describes specific safety protocols that researchers should implement if possible, as relevant to their specific research scenario. Researchers should also take reasonable precautions and use common sense. It then provides a list of links to COVID-19 resources. Finally, the end of this document includes a template of a COVID-19 Infosheet for researchers to complete and provide to participants before they meet as part of their Research Safety Plan.

2. SUU IRB review of 8 factors in Research Safety Plans

Before any researchers can resume in-person research, the IRB needs to approve a Research Safety Plan for the research. Researchers with an already-approved IRB application should submit their Research Safety Plan using the regular form for Proposed Changes to a Previously Approved Protocol, but it should detail the safety protocols used, it should address the 8 factors detailed below, and it should include a completed COVID-19 Infosheet (see below). Researchers are encouraged to add an addendum in which each of the 8 factors are listed and briefly addressed. New IRB applications for in-person research does not need the Proposed Changes form, but it should address all of the same issues.

The SUU IRB will evaluate Research Safety Plans based on the following 8 factors. (This list of factors and the COVID-19 Infosheet are based on those from Utah State University.) No single category will remove a project from consideration. The IRB will examine all of these factors to generate a holistic risk profile for your project, and will make a resumption decision based on that risk profile.
<table>
<thead>
<tr>
<th>8 Factors for Research Safety Plans</th>
<th>Most desirable</th>
<th>Least desirable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Proximity</strong>: focuses on the amount of distance between people and exposure time</td>
<td>6+ feet always maintained</td>
<td>Closer than 6 feet for 10+ minutes or for multiple visits</td>
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<tr>
<td></td>
<td>One-time procedure</td>
<td></td>
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<tr>
<td></td>
<td>10 minutes or shorter</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>2 minutes closer than 6 feet</td>
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<tr>
<td></td>
<td></td>
<td>2+ interactions</td>
</tr>
<tr>
<td>2. <strong>Setting</strong>: focuses on the location where the research occurs, why participant is there, and how that setting increases or decreases chance of virus transfer.</td>
<td>Outdoors</td>
<td>Enclosed space</td>
</tr>
<tr>
<td></td>
<td>Participants already in that space</td>
<td>Participants not normally there</td>
</tr>
<tr>
<td>3. <strong>Enclosed Space Characteristics</strong> (does not apply to outdoors, un-enclosed spaces): focuses on factors that increase or decrease chance of virus transfer.</td>
<td>Controlled, separate rooms</td>
<td>Small, shared access space</td>
</tr>
<tr>
<td></td>
<td>Few people access rooms</td>
<td>Widely-shared ventilation system</td>
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<td></td>
<td>Independent ventilation</td>
<td></td>
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<tr>
<td>4. <strong>Number of People</strong>: focuses on how many people interact at one time, or between cleaning.</td>
<td>One researcher</td>
<td>Multiple researchers</td>
</tr>
<tr>
<td></td>
<td>One participant</td>
<td>Multiple participants</td>
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<tr>
<td></td>
<td>One or two researchers</td>
<td></td>
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<td></td>
<td>Five or fewer participants (some live together)</td>
<td></td>
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<tr>
<td>5. <strong>Participant Age</strong>: focuses on age of participants, due to elders’ greater COVID-19 health risk.</td>
<td></td>
<td>Aged 60+ years old</td>
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<tr>
<td>6. <strong>Participant Health Considerations</strong>: focuses on factors that increase risk for serious illness or death related to COVID-19. <a href="https://www.cdc.gov/coronavirus/2019-ncov/risk-factors/health-considerations.html">CDC’s current factors</a></td>
<td>No CDC risk criteria</td>
<td>1+ CDC risk criteria</td>
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<tr>
<td></td>
<td>Concerns about undiagnosed conditions for CDC risk factor</td>
<td></td>
</tr>
<tr>
<td>7. <strong>Participant Characteristics</strong>: focuses on considerations of what might put participants or others at greater risk, such as housing situation, home languages, and job categories.</td>
<td>Young, English-speaking adults</td>
<td>Older, close-proximity</td>
</tr>
<tr>
<td></td>
<td>Live in single family home</td>
<td>Limited English speakers</td>
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<tr>
<td></td>
<td>No at-risk residents</td>
<td>Multi-generation household</td>
</tr>
<tr>
<td></td>
<td>Adult.</td>
<td>Essential jobs</td>
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<tr>
<td></td>
<td>Household had COVID-19 diagnosis 2+ weeks prior</td>
<td></td>
</tr>
<tr>
<td>8. <strong>Research Risks and Benefits</strong>: focuses on standalone risks and benefits of the research.</td>
<td>Direct, therapeutic benefit</td>
<td>No benefit to participants</td>
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<tr>
<td></td>
<td>Therapy requires contact.</td>
<td>Greater than minimal risk</td>
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<tr>
<td></td>
<td>Direct benefit (not therapeutic)</td>
<td></td>
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<tr>
<td></td>
<td>Benefit requires contact</td>
<td></td>
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3. Safety Protocols

COVID-19 Infosheet. Before meeting with participants, if possible researchers should contact them and explain how the researcher is addressing the research-related risks associated with COVID-19. This should be done with a COVID-19 Infosheet. The COVID-19 Infosheet should include:

- details regarding COVID-19 itself
- precautions the researchers will take
- expectations for maintaining a safe environment for participants
- researcher name and contact information (for contact tracing)

The SUU IRB has prepared a template version of this sheet and included it at the bottom of this document. It is also on the SUU IRB webpage. Researchers should modify it to fit their own research scenario before submitting it for IRB consideration. If a research participant requests additional accommodations for their safety during participation, researchers should make reasonable efforts to accommodate those requests. If the researcher cannot accommodate the requests, the researcher should let the participant know so the participant can make an informed decision about whether or not they want to do the study.

Cleaning and hygiene regimen. Researchers should use hand sanitizer and/or regular handwashing routines. Hand cleaning options should also be available to participants. Researchers should regularly clean high-touch areas (handrails, doorknobs, computer labs/keyboards, elevator interiors, restroom surfaces and fixtures, and so on).

Health Screening. Researchers will conduct appropriate health screenings of themselves and participants for COVID-19-related symptoms or risk factors prior to starting in-person research procedures. Researchers and participants should be honest with themselves about their health.

Refer to CDC symptoms list for an updated list of symptoms. Some known symptoms of COVID-19 follow:

- fever or chills
- cough
- sore throat
- shortness of breath or difficulty breathing
- fatigue
- sudden loss in taste or smell
- muscle or body aches
- headache
- runny or stuffy nose
- nausea or vomiting (throwing up)
- diarrhea

All symptomatic researchers should stay off campus, or self-isolate or quarantine if residing on campus. If symptoms of COVID-19 are present, researchers must contact their doctor (or other local health professional) to see if they should be tested. If the medical professional recommends a test, proceed to a local testing facility, get tested, and then isolate yourself in your home/apartment until test results are received. Download Utah’s Healthy Together App for a 10-second health check. If results are positive, the researcher will isolate for 14 days, participate in
contact tracing led by the Southwest Utah Public Health Department, and report their positive test results to SUU. If the results are negative, stay home until you are symptom free. If the medical professional does not recommend a test, stay home until you are symptom free from whatever illness you have. Researchers should self-quarantine when returning from high-risk areas.

If participants have symptoms, researchers should encourage participants to contact their doctor immediately. Such participants should not do the study until symptom free for 14 days.

Unless there is a good reason, in-person research must be preceded by an active screening process to ensure that participants who are at the greatest risk for severe illness, serious long-term health outcomes, or death are excluded from participation. For this topics, see the next subsection.

**High-risk participants, researchers, and regions.** If you can, provide accommodations to higher-risk participants and/or researchers. Minimize face-to-face contact. Assign tasks that allow these individuals to maintain a 6-foot distance from others. Use flexible or staggered scheduling.

Researchers are responsible for monitoring the community where they are working to detect aggressive community spread, and should pause their own in-person research projects when necessary. The IRB advises using guidance from the Harvard Global Health Institute to help inform those decisions, and PIs should familiarize themselves with that resource.

**Personal protective equipment (PPE) and physical distancing.** Researchers and participants should be 6 feet apart from each other and other people where possible. Where not possible, researchers and participants should wear face coverings. Researchers should change or launder cloth face coverings after each day’s use.

All institutional, site-specific, and local policies and procedures regarding PPE, social distancing, sanitization, and other COVID-19 safety practices will be followed by all researchers at all times. This requires adherence to institutional, travel, events, and governmental (including state) guidance that may be relevant to any given research project as well as its programmatic (i.e. teaching, K-12, etc.) surroundings. Cloth face coverings should not be placed on young children under the age of 2, anyone who has trouble breathing, or is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.

**Contact tracing.** As possible, researchers should maintain records that allow for adequate contact tracing in the event of a positive COVID-19 case. Specifically, records should include the names and contact information of researchers and participants, and the meeting location, date, and time. The records will be shared with SUU, research participants, and public health authorities, as appropriate.

Researchers also must provide information to participants to enable participants to do contact tracing. The information should include the researcher name and contact information. If requested by participants, researchers should be able to also provide the meeting location, date, and time. Researchers can include the related information on the informed consent form (the copy kept by the participant) or the COVID-19 Infosheet.

If you will not come within six feet of a participant, you do not need to do contact tracing protocols.
4. Additional COVID-19 Resources

- SUU
  - SUU coronavirus webpage

- State of Utah
  - Utah Department of Health coronavirus webpage
  - Utah Leads Together
  - Reopening Utah's Colleges and Universities: Prepared by the USHE COVID-19 Higher Education Task Force
  - Southwest Utah Public Health Department

- US Federal Government
  - Centers for Disease Control and Prevention coronavirus page
  - CDC COVID-19 Guidance for Higher Ed
  - CDC COVID-19 Guidance for Increased Risk People

- World Health Organization
  - WHO COVID-19 page
COVID-19 Infosheet

Study Title: [Researcher put in the Title of Study here]

[Principal Investigator Name]
Principal Investigator
[Phone number; email@suu.edu]

[Other researcher name, if relevant]
[Other researcher title, such as Co-Investigator OR Faculty supervisor]
[Phone number; email@suu.edu]

Why this form? Due to COVID-19, you might not want to do this in-person study now. This form discusses how COVID-19 relates to this study. You are free not to do the study. Nothing bad will happen. No one will be upset with you. Please keep a copy of this form for later reference.

What is COVID-19? It is the illness caused by a novel, respiratory coronavirus called SARS-CoV-2. It spreads via droplets in the air from when people breathe, speak, cough, and so on. It spreads mainly between people within six feet of each other. It can also be spread by touching something that has the virus, and then touching your face.

What are symptoms of COVID-19? For most people, symptoms are mild to moderate, such as a fever and a cough. Some people have severe symptoms. It kills about 3% of people who get it in the USA. Danger is highest for people older than 65, or with existing health conditions. Currently, we have no proven treatment or effective vaccine for COVID-19.

How to avoid COVID-19. Socially distancing is the best way to avoid COVID-19. That includes staying home and staying a safe distance from others. Cleaning is also important.

COVID-19 and this study. This study cannot be done without interaction between people. [The researcher should use simple words to describe the in-person part of the study here, but not the precautions, which are described in the next section. In this study, …] Therefore, doing this study could increase your chance of getting COVID-19.

This study’s COVID-19 Precautions. We are taking the following precautions to reduce the chances that COVID-19 might be spread during this research study:

- [Researcher lists]
- [Precautions]
- [Here: (screenings, masks, time limits for direct interaction, social distancing, sanitization practices, etc.)]

Participant precaution requests. You can ask the researchers to make other precautions for your safety. Tell the researcher listed above. Researchers will make reasonable precautions, if they can. Please do the study only if you feel safe.

Screening participants. Even if you want to do the study, it might not be safe at this time. Researchers will screen participants for your safety and their safety. Example screening topics are your age, health conditions, and exposure to someone who tested positive for COVID-19.

[Additional information. Researchers should use this space if other topics need to be addressed. For example, if the reader has already completed an earlier part of the study. You might say]
something like, “If you want to stop doing the study, because of COVID-19 or any other reason, please” ... specify the procedure for withdrawal from the study. Delete this section if it is not used.]

**Questions?** Please ask the researchers questions, if you have any. You can also contact the SUU Institutional Review Board at 435-586-7864 or irb@suu.edu.