Framework for the Resumption of In-Person Human Subjects Research at Utah State University
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Adopted by the Institutional Review Board August 2020. IRB rosters are available [here](#).
Introduction

The Human Subjects Research Resumption Working Group was formed in June 2020 to provide guidance to the Institutional Review Board and to Utah State University’s research leadership about the safest way to resume in-person research activities with living people. Members were selected for their expertise in the four areas identified by the CDC as important considerations for mitigation strategies (epidemiology, community characteristics, health care capacity, and public health capacity) during the spread of SARS-CoV-2, which causes the disease COVID-19.

This document represents guidance that has been developed with considerations of public health and participant well-being at the forefront. Originally, the Working Group had a focus of determining what community-based parameters would indicate the safe resumption of in-person human subjects research. However, the more the group discussed the data that was available and its serious limitations (at the local, state, and national level), it quickly became apparent that relying exclusively on testing and hospitalization data would not be useful for the IRB’s principal goal of protecting human participants in research. With a necessarily shifted perspective, this framework is now geared specifically at identifying the parameters for the safe resumption of in-person research within the confines of the proposed project as they relate to the CDC criteria for mitigation strategies within communities. It has been designed to assist both the IRB and researchers in identifying low to high risk factors that already exist within proposed research projects.

This Framework does not discuss the requirements that should be in place to affirmatively keep participants and researchers safe while that project is carried out (e.g. masking, social distancing, sanitizing practices), since institutional, site-specific, and other local policies and procedures will dictate different requirements. These types of factors, which necessarily live “outside” of the existing protocol, should be managed as appropriate by the research staff, the Institutional Review Board, departmental or institutional leadership, and public health entities. With that said, the following assumptions are being made by the Working Group, and should precede the implementation of any resumption activities:

- All institutional, site-specific, and local policies and procedures regarding PPE, social distancing, sanitation, and other COVID-19 safety practices will be followed by all researchers at all times
  - Specifically, this requires adherence to institutional, departmental (which your department head or director would have on file for your review), research-specific, 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.
- Researchers and participants will undergo appropriate health screenings for COVID-19-related symptoms or risk factors prior to engaging in-person research procedures
- Records that allow for adequate contact tracing in the event of a positive COVID-19 case will be maintained. Those records will be shared with research participants or public health authorities as appropriate
- Details regarding COVID-19 itself, precautions the researchers have taken, and expectations for maintaining a safe environment for participants, will be shared with participants
- If a research participant requests additional accommodations for their safety during participation, researchers should make reasonable efforts to accommodate those requests
- This framework and other decisions made by the IRB and USU institutional leadership may be adapted as objective public health evidence suggests appropriateness of loosening or tightening restrictions on in-person research
Primary Considerations

The Working Group identified nine primary areas that the Institutional Review Board should consider when taking up the resumption of in-person human subjects research. They are:

1. Potential for New Exposure
2. Proximity
3. Setting
4. Space & Procedural Characteristics
5. Number of People
6. Participant Age
7. Participant Health Considerations
8. Participant Characteristics
9. Benefits and Risks of the Research

The consideration of these factors will assist both the IRB and researchers themselves in the generation of a holistic risk profile that will guide resumption decisions. Each factor is examined in more depth below, and provides examples of low risk (represented in green, or the leftmost, squares) and high risk (represented in red, or the rightmost squares) characteristics within each factor. The presence of red or green areas in any given project does not make or break a researcher’s resumption request. They are simply data points that the IRB will utilize in generating a risk profile, and making a decision regarding resumption.

Researchers can best utilize the framework in two ways:
1. This framework provides an opportunity to assess current projects, and determine whether opportunities exist to lower its overall risk profile. In many cases, amendments would be appropriate for the lowering of risk (e.g. moving previously in-person survey data collection to Qualtrics to limit in-person interactions to only physical procedures). In some cases, a new protocol would be required (e.g. moving to a child population from a previously-approved adult population). Any change in the risks or benefits of a protocol must receive a new review.
2. This framework permits researchers to plan for their upcoming year, by gaining a better understanding of which procedures or projects might be able to resume sooner, and which may need to be delayed. The Working Group suggests, for example, that research with populations over the age of 60 be limited to remote procedures until a highly effective vaccine is widely available.

The Institutional Review Board can best utilize the framework in the following ways:
1. Work in tiers for resumption requests, in order to ensure careful consideration of risk factors. Establish a number of factors that could move outside of the “green” for the first round of resumption requests. The Working Group recommends beginning with no more than two.
2. Utilize the yellow (second from the left) and orange (second from the right) spaces to appropriately fit the factors present in each individual protocol. No framework would adequately capture the complex and intricate nature of all of the research occurring on USU’s campus, but this guide and its intentional spaces should assist in gauging the risk of the projects under consideration.
3. As the IRB considers resumption requests, the IRB might add more information to the existing spaces on the framework, so that researchers obtain additional and better information about the risks of their individual projects.
4. If needed, establish areas of priority for resumption (e.g. funded projects, potential for catastrophic data loss, pending return of federal funds absent resumption) to permit the focus to remain on participant safety.
5. Allow researchers to self-identify their projects as falling within certain areas of the framework; just as the IRB examines a researcher’s asserted level of risk to ensure appropriate categorization during the review process, the IRB should examine the researchers’ assessment of the risk of resumption of in-person activities without affirmatively making assignments to projects for which it may not hold all relevant information.
Process for Resumption

At its August 11, 2020 meeting, the IRB formally adopted this framework as the structure it will utilize to make decisions regarding resumption. The Framework was adapted in Fall 2020 meeting to include a new core tenet and primary area of consideration. The IRB has determined to consider resumption requests at its bi-monthly meetings. Requests for resumption will be made using Kuali Protocols, where instructions for requesting resumption are available throughout the application.

The IRB has adopted three core tenets guiding resumption activities (underlines are new for the Spring 2020 semester):

- In-person research will not physically resume until there is a fourteen-day downward trend in new COVID-19 cases in Utah. However, requests for resumption may be filed and acted upon as of the release of this document. The IRB will notify researchers when the benchmark for actually resuming those procedures has arrived.
  - An exception to the fourteen-day downward trend is permissible where the research staff and the targeted participants are already interfacing, and the activities in the research do not inherently increase transmission risk relative to the underlying non-research interactions. To qualify for this exception, the following elements must be true:
    - The existing interactions are for a purpose unrelated to the approved research protocol;
    - The interaction is in a location where the participants would be anyway;
    - Only research staff that the participants would have interacted with anyway will carry out the in-person research procedures;
    - The duration of time for the research does not present additional risk of infection;
    - The other participants or bystanders exposed to the research would have been exposed to each other anyway for at least the duration of the expected research interactions; and
    - The research procedures comply with all of the underlying requirements of the jurisdiction and specific location where the research interaction will take place.

- If a procedure can be done remotely, it should be done remotely. Reviewers will work with the PI to determine when procedures cannot be completed remotely during the review of specific resumption requests.

- PIs 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 will be utilizing guidance from the Harvard Global Health Institute to drive those decisions, and PIs should familiarize themselves with that resource.

Local COVID-19 positivity rate increases that sustain a fourteen-day period, utilizing a seven-day rolling average, should warrant re-assessment by the IRB and institutional leadership of continued in-person research procedures.

The Framework

The framework is a visual guide to assist in the assessment of projects that request resumption of in-person human subjects research activities.
**Proximity**
The amount of distance between individuals and amount of time appropriate distance can be maintained is a primary consideration for this factor.

- Greater than six feet distances can be maintained at all times for one time procedures totaling ten or fewer minutes
- A few minutes of interaction six feet or closer is required, or more than one interaction is needed
- Procedures require participants and researchers/other participants to be closer than 6 feet apart for more than 10 minutes or spanning several visits

**Setting**
The location where the research occurs, and the reason for participants being there, is the primary consideration for this factor.

- Outdoors, or participants are receiving services in that space already
- A mix of procedures; some in un-enclosed spaces, and some in enclosed spaces
- An enclosed space, or participants would not otherwise be in that space

**Space & Procedural Characteristics**
Factors that make the space or research procedures more or less conducive to spreading a highly contagious virus are the primary consideration for this factor. If research takes place in outdoor, un-enclosed settings, this consideration would not apply to a resumption.

- Separate rooms accessed by a controlled, small number of masked people with independent ventilation systems. Procedures allow for great distance between individuals and no heavy breathing
- Masked individuals will be 6 feet from each other with limited opportunities for aerosol/droplet spread. The facility is reserved for research procedures with controlled but shared access
- Unmasked interactions or high potential for aerosolized/droplet spread take place in a small or shared access space or a widely shared ventilation system

**Number of People**
The total number of people interacting at one time or between sanitization procedures can occur is the primary consideration for this factor.

- One researcher and one participant interact at a time
- One or two researchers interact with five or fewer participants, some of whom share households
- Multiple researchers and multiple participants interact at one time
Participant Age
COVID-19 has more dangerous risk profiles for serious illness or death as age increases. While younger populations may be less severely affected, they also may not have the capacity to understand all of the relevant circumstances. The age of the participants is the primary consideration for this factor.

Participant Health Considerations
The CDC has outlined many factors that increase the risk for serious illness or death as a result of contracting COVID-19; the presence of those conditions is the primary consideration for this factor.

Participant Characteristics
This includes the consideration of participants’ housing situations, home languages, job categories, and other special considerations that may put participants and others at greater risk of contracting or developing complications from COVID-19.

Benefits and Risks of the Research
The standalone risks and benefits profile of the research is the primary consideration for this factor.
Future Directions

The IRB revisits the guidance contained in this framework from time to time and as appropriate for emerging data and new trends. This includes, but is not limited to:

- whether re-infection is resulting in more severe health outcomes, as indicated by some early case studies published on this matter. If that is the case, actively screening for past infection may become required in the future.
- severe but uncommon impacts on children, who are being tested less frequently due to fewer symptomatic cases.
- Increased access to important data points, such as testing positivity rates, vaccination availability, and vaccination adoption.

Questions regarding resumption of in-person research should be emailed to irb@usu.edu. Sending questions there ensures a) that they gain the fastest possible response time, as all members of the office monitor that inbox; and b) will allow the IRB to develop new guidance and resources, by ensuring questions go to a centralized location where they can be reviewed and acted upon by several members of the IRB.