# USM IRB Resumption Requirements

These materials are intended to help you design, conduct, and revise your face-to-face (FtF) human subjects research (HSR) in light of the ongoing pandemic. USM, along with virtually all other research institutions around the country and the world, is requiring additional scrutiny of proposed HSR projects and additional responsibilities of researchers. In most cases, these added responsibilities involve physical distancing, masking, cleaning precautions other measures as may be prudent on a case-by-case basis. Human subjects protocols involving only online modes of data gathering, such as Qualtrics surveys, are unaffected.

## Steps to Begin/Resume Face-to-Face Human Subjects Research

*Step #1*

1. Faculty submit *Request for Return to Research Form*(<https://forms.usm.edu/research/view.php?id=13688>)

This form, submitted to and reviewed by the Vice President for Research, must be reviewed and approved prior to IRB submission.

This step is required for resuming or initiating FtF HSR research, even if previously granted lab access through a similar process.

Additionally, members of the College of Education and Health Sciences must follow the *CoEHS Return to Research Guidelines*. Any must be approved by the Director. Graduate students and undergraduate students may access lab spaces but must follow safety protocols and adhere to capacity limitations. (Kimberly – are these guidelines posted in a website anywhere?)

Your contact person for queries involving the VPR Office part of the process is Kimberly.Wingo@usm.edu and see <https://www.usm.edu/vice-president-research/covid-19-research-guidelines.php>

*Step #2*

2. When the FtF HSR will be conducted off campus, an additional step is required: after review and approval of the Request for Return to Research, VPR Office sends COVID Authorization & Release Agreement to all identified individuals listed in request

Once all agreements have been signed and received and approved, VPR Office notifies IRB and the researcher(s), and the IRB approval process can begin.

*Step #3*

3. Researchers then have to submit in Cayuse a modification form to an existing active IRB protocols or submit a new proposal. In both cases, researchers need to explain in detail how COVID-related safety measures will be integrated into their FtF research procedures.

## Guiding Principles for Face-to-Face Human Subjects Research.

Access to on-campus buildings in conjunction with Face to Face (FtF) Human Subjects Research (HSR) must be consistent with the University COVID Response Status in effect at the time. Status information is always accessible at [USM COVID status](https://www.usm.edu/covid-19/index.php).

*Personal Protective Equipment (PPE)*

Compliance with standard laboratory safety protocols and PPE is expected when working within laboratory facilities. Do not share PPE with other research personnel. Non‐disposable PPE should be cleaned/disinfected on a daily basis.

Face masks or face coverings are to be worn at all times while inside the building, laboratory spaces, shared labs/facilities, and external sites.

*Consult and comply with CDC Prevention Guidelines*: [CDC Guidelines](https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html).

WASH HANDS frequently with soap and water.

AVOID touching your face or mask with unwashed hands.

AVOID close contact and practice social distancing.

## The Three “R’s” of FtF Resumption:

REDUCE: Regardless of University Response status, the number and duration of FtF personal interactions should be *reduced* to the minimum needed to conduct the HSR protocol in question.

Time and occupancy within the lab by research personnel should be limited; data workup, analysis, and writing activities should be completed remotely when practicable.

REPLACE: When practicable, interactions between researchers and interactions with human subjects should be *replaced* by online meetings using Microsoft Teams, Zoom, etc.

RESTRICT: Beyond researchers and human subjects, non-University personnel should not be brought to campus in conjunction with the research. Friends and loved ones should remain at home. Exceptions are permissible when necessary to the subject’s participation, e.g., a parent needed to drive a child subject to campus.

*Excluded Subjects:*

Individuals who have any of the symptoms of COVID-19 or who have tested positive are not permitted to be involved in FtF HSR.

Individuals who have previously tested positive for COVID-19 may participate in FtF HSR provided all three of the following conditions are met:

1) No fevers (temperature >100.4 F) for at least 72 hours (that is three full days of no fever without the use of medicine that reduces fevers such as Tylenol or Ibuprofen); and

2) Other symptoms (for example, cough or shortness of breath) have improved; and

3) At least 14 days have passed since symptoms first appeared.

*Asymptomatic persons exposed to a person with known or suspected COVID‐19 infection within 48 hours of symptom onset must follow these instructions as a condition of participation in FtF HSR:*

1) Self‐isolate and stay home until 14 days after last exposure to a close contact who is known or suspected to be positive for COVID‐19. (A close contact is defined as a household member, intimate partner, individual providing direct care or other individual -- including lab members on the same shift/rotation or prolonged overlap in the same lab space -- with whom the employee or student has had prolonged close exposure (<6 feet).

2) Self‐monitor for the development of COVID‐19 symptoms such as fever >100.4F, cough, or shortness of breath. If symptoms develop during the 14‐day isolation period, contact Student Health Services at Moffitt Health Center or your primary healthcare provider to discuss the symptoms and testing.

If symptoms are not developed after experiencing close contact exposure, the person may return to campus and research spaces after 14 days or upon testing negative for COVID‐19.

*PIs’ COVID Responsibilities*:

a) ensure compliance with additional COVID-related IRB protocol modifications.

b) ensure appropriate physical distancing measures are communicated and maintained by research personnel and ensure that when around others, research personnel and study subjects are wearing masks.

c) for individual contact tracing purposes, log interactions with all research subjects and who interacted with them.

d) when conducting FtF HSR at external sites, ensure that all USM personnel are adhering to USM and external site safety protocols. When conducting FtF HSR on campus, ensure all non-USM individuals have been properly prescreened using procedures below.

e) ensure the appropriate disinfection procedures below are implemented in shared spaces.

*In-Person Human Subjects Verbal Pre-Screens*

Has not received a diagnosis of COVID-19 in the past fourteen days

Does not exhibit any of the COVID-19 symptoms:

Cough

Shortness of breath or difficulty breathing

Chills

Repeated shaking with chills

Muscle pain

Headache

Sore throat

Loss of taste or smell

Diarrhea

Feeling feverish or a measured temperature greater than or equal to 100.0 degrees Fahrenheit

Has not had known close contact with a person who is confirmed to have COVID-19 for at least 14 days

Known high risk groups should not be invited to participate in face to face research at this time

People over 65 years old

Minors with known underlying health conditions that increase risk (e.g. asthma)

Adults under 65 with underlying health conditions (based on [CDC guidelines](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/groups-at-higher-risk.html))

Research personnel interacting with subjects must wear new gloves and remove them properly between subjects

*Research Conducted Externally (Schools, Community Settings)*

Both USM and external site safety regulations must be followed

*Cleaning and Disinfecting*

Faculty PIs are responsible for implementation of cleaning and disinfecting protocols for their individual lab spaces, including daily decontamination of all shared and high‐touch items/areas (lab benches, doorknobs, sink handles, freezer doors, fume hood sashes, keyboards, microscopes, etc.) according to CDC guidelines.

Use an [EPA‐approved disinfectant](https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19) that is effective against COVID‐19.

Use care when cleaning touch points on equipment to avoid damage.

References: Adapted from CoEHS Return to Research Guidelines