

Guidelines for Resuming Human Subjects Research at Merrimack College Under COVID-19

August 21, 2020

Overview

Institutional Review Boards (IRBs) in Massachusetts and across the country are working diligently to find pathways and provide guidelines for their faculty and students to safely resume human subjects research. The IRB's work is complicated by changing State and federal guidelines, and by the reality that any resumption of research in the new COVID-19 reality needs to consider protecting the health of human subjects, their social contacts, principal investigators and researchers, and the health of the broader Merrimack College community given our residential nature. These guidelines have been developed to prevent possible harm to human subjects while enabling research to continue.

On Friday, March 20, 2020, the Office of the Provost at Merrimack College sent an email to the community, calling for the immediate suspension of all personal contact human subjects research. It was determined that most research activities involving in-person interactions with subjects must stop until further notice. It was noted that the failure to comply would result in the research being considered as non-compliant by the institution.

This suspension, however, did not include two key types of research: (1) research using virtual surveys (e.g., SONOS, MTurk) or analysis of data that includes no person-to-person contact with study participants; and/or (2) research where the person-to-person contact was completed and the researchers are now in the analysis phase remotely. Effective August 24, some additional human subject research suspended during the COVID-19 emergency may resume or begin. These guidelines are meant to provide researchers with information critical to the resumption of their research. To address the great variety of research projects involving human subjects being conducted at Merrimack College, the IRB has adopted a plan based on tiering research into various categories of risk.

All researchers should be aware that human subjects research can be suspended again, or that the categories described in this document may be changed (requiring the researcher to resubmit) as more information on COVID-19 becomes available or as the pandemic changes in the region, in the Commonwealth, and in the country.

Guidelines for Resuming Human Subjects Research

These new guidelines for resuming suspended human subject research at Merrimack College are in line with with current federal and state laws and regulations, guidance from the [Office of Human Research Protections](#) (OHRP), the [Centers for Disease Control](#), and the [Reopening](#)

[Massachusetts and Safer-At-Home advisory](#), as well as the Commonwealth's [Reopening: Higher Education](#) plan.

The guidelines are also linked with [Merrimack's reopening plan](#) that includes a phased approach in order to give the College time to safely implement and modify reopening processes as needed. Merrimack's [Fall 2020 Return to Campus Handbook](#) contains processes, protocols, and guidelines for all employees and students and any and all members of our community, including research Principal Investigators (PIs), research staff, and undergraduate and graduate researchers are expected to follow them.

IMPORTANT: Please note that in the ongoing COVID-19 crisis, research involving human subjects should be performed remotely **whenever possible**. That said, if research involving human subjects is approved by the IRB and will be conducted on any campus location and/or in campus facilities or laboratories, specific safety measures must be taken as outlined in the College's [Fall 2020 Return to Campus Handbook](#). Off-campus studies will be reviewed on a case by case basis.

Human Subjects Research Categories

To address the great variety of research projects involving human subjects, the IRB has adopted a plan based on tiering research into various categories of risk. The four categories (A-D) are summarized below. Please know that it is the principal investigator (or his/her faculty adviser if applicable) that is responsible for determining which category their research project fits into. If there are any doubts, then this individual should contact the IRB chair to discuss. Also know that you as an investigator are free to modify your research if possible such that it fits into a different category. In this case, a protocol modification form must be submitted that includes a rationale for why this updated protocol qualifies as, for example, a "Type A Project." Please note that any research involving any type of pulmonary function and breathing, if permissible, will require highly specific protocols and human subjects protection.

Type A Projects/Research.

These come in two forms: **(1)** research where all interactions with subjects, research personnel, etc. are done remotely. Examples include using virtual surveys (e.g., SONOS, MTurk), interviews or focus groups using a virtual platform like Zoom, or analysis of data that includes no person-to-person contact with study participants; and/or **(2)** research where the person-to-person contact was previously completed and the researchers are now in the analysis phase (which can be done remotely).

Type A projects approved by the IRB can resume immediately and new projects, or those suspended previously due to the pandemic, may be initiated or re-initiated without any modification of IRB protocols. *No modification of the existing approved protocols or informed consent forms is needed.*

Type B Projects/Research.

These are Merrimack College campus-based projects involving Merrimack faculty, students, and staff that include person-to-person contact but pose minimal risk so long as proper safety procedures and protocols are followed. Type B projects include: classroom work, interviews, or small focus groups, with mandatory adherence to social distancing, face covering, and hygiene practices in each instance as outlined by the College. It is important to note that based on the fall 2020 campus guidelines, generally, visitors and guests will be prohibited from campus, with exceptions including visiting parents and family, admissions visitors, essential vendors and contractors, and Islander hockey participants. Researchers considering human subjects visits to campus will be required to request and gain approval through the [Task Force](#) prior to any visit. All visitors must review the COVID-19 Return to Campus Policies and Procedures, the COVID-19 Return to Campus Checklist, and sign a waiver each time they arrive on the campus. Visitor experiences on campus will be limited depending on the visit. There will be no exceptions, unless approved by the Office of the Executive Vice President. Any visitor to Merrimack's campus for these purposes is responsible to submit to those actions required of all other vendors/visitors - self-assessment of symptoms and execute a waiver. This will also need to be coordinated with the Merrimack College Police Department.

Thus, human subjects research involving bringing a single person or groups of non-Merrimack students/staff/faculty to campus, will need to adhere to these guidelines and will be rigorously evaluated. At this time, you should not include in-person research subjects who are at higher risk for severe COVID-19 illness according to the Centers for Disease Control ([CDC](#)).

For details on indoor gatherings, please refer to the [Massachusetts guidelines](#). It is strongly encouraged that **whenever possible**, interviews/interactions should be conducted remotely. If groups are part of the research, the groups should be kept as small as possible, adhering to the limit on the number of people permitted in a space as dictated by the above Massachusetts guidelines, and be held in rooms and/or facilities that allow for adequate social distancing.

Each session or experiment should be scheduled such that it minimizes overlap between subjects in the facility/room/laboratory and any adjacent spaces, in order to reduce the density of people in the area and to allow time for cleaning the equipment and surfaces. Any persons taking part in research who self-identify as being vulnerable to severe illness from COVID-19 should not be brought to campus. As noted above, and in the [Fall 2020 Return to Campus Handbook](#), all visitors must review the COVID-19 Return to Campus Policies and Procedures, the COVID-19 Return to Campus Checklist and sign a waiver each time they arrive on the campus. Visitor experiences on campus will be limited depending on the visit. There will be no exceptions, unless approved by the Office of the Executive Vice President.

If using campus offices and/or facilities, researchers are responsible for the cleaning of the research areas following procedures outlined in the College's [Fall 2020 Return to Campus Handbook](#). As specified in the Handbook, cleaning should take place before use, in between each encounter, and at the end of the day. All researchers and subjects should also practice

hand hygiene before and after each encounter and all persons must wear a personal mask/face covering at all times during any person-to-person interaction.

All Type B projects will require a modification of protocols in the Cayuse IRB system. The modification will need to explain how COVID-19 transmission risk will be reduced. All modifications of person-to-person human subjects research will be assessed by the IRB to ensure that it meets state guidelines and College guidelines for safety. It will also require updating the informed consent form with COVID-19-related risk language (see below).

Type C Projects/Research.

These are research projects that involve person-to-person contact regardless of location, including international sites, and pose greater than minimal infection risk. Type C research and/or interventions include on-campus direct physical contact with a human subject, long periods of continuous contact in close proximity, procedures which are strenuous on the subject (such as exercise-testing), and/or any human subjects research conducted off campus that involves person-to-person interactions/interventions. This includes all research conducted at any and all partner sites (e.g., schools, businesses, private residences, etc.) including Hands to Help.

You will need to obtain a new approval letter from the partnering institution indicating that they approve the research and the safety steps taken by the investigator(s). At this time, you should not include in-person research subjects who are at higher risk for severe COVID-19 illness according to the [CDC](#).

There are also some additional procedures Type C projects should follow, aligning with what is mentioned in the [Fall 2020 Return to Campus Handbook](#). For physical contact interventions, only one researcher should interact with the participant, with both individuals wearing proper PPE, including face coverings and gloves, and if possible, a protective shield should be placed between the two. All laboratory equipment, sensors, surfaces, and supplies (e.g., pens, keyboards, etc.) should be wiped down with a disinfectant before and after each test/experiment.

Each session or experiment should be scheduled such that it minimizes overlap between subjects in the facility/room/laboratory and any adjacent spaces, in order to reduce the density of people in the area and to allow time for cleaning the equipment and surfaces. Any persons taking part in research who self-identify as being vulnerable to severe illness from COVID-19 should not be brought to campus.

All Type C projects will require a modification of protocols in the Cayuse IRB system. The modification will need to explain how COVID transmission risk will be reduced. All modifications of person-to-person human subjects research will be assessed by the IRB to ensure that it meets state guidelines and College guidelines for safety. It will also require updating the informed consent form with COVID-19-related risk language (see below).

Type D Projects/Research.

These are projects that involve research with any participants that are categorized as being vulnerable to severe illness from COVID-19 according to the [CDC](#). **These projects are still under suspension.** Please know this applies to any in person work with these individuals. Remote-only work with high risk individuals is acceptable and would qualify as a Type A project.

COVID-19 Risk Adjustments to the Informed Consent Form

For all research (non-Type A) projects requiring a modification by the IRB, the informed consent form **must be modified in two key ways**: (1) information on hygiene and health safety procedures must be included; and (2) under the 'Risk' section of the form two items should be added: first, a link to general information about the virus (<https://www.cdc.gov/coronavirus/2019-nCoV/index.html>); and second, additional language regarding risk as provided below:

I also understand that the novel coronavirus, COVID-19, has been declared a worldwide pandemic by the World Health Organization and that a national emergency was declared in the United States concerning the COVID-19 Outbreak. I further understand that COVID-19 is contagious and is believed to spread by person-to-person contact; and, as a result, federal and state health agencies recommend social distancing. While the researchers have put in place preventative measures aimed to reduce the spread of COVID-19, given the nature of the virus, I understand there is an inherent risk of becoming infected with COVID-19 by proceeding with this research project. I understand that I should not participate in this study if I am experiencing any signs or symptoms of the virus, even those that are mild. I also understand that I should not participate in this study if I, or anyone I regularly interact with in person, has tested positive for the virus within the last two weeks. Lastly, I understand that I should not participate if I recently traveled outside of the region within the past two weeks. If I have any questions on whether my risk of infection is higher than normal (due to interactions in my life within two weeks prior to the study or through my participation in this study), I should discuss with [name and contact info of PI], whether it's safe for me and others around me, to participate.

Project Modification Form in Cayuse

All researchers required to submit a COVID-19 related modification to their IRB project, must do so through the Cayuse IRB software portal. The process will be the same as any modification, except that for COVID-19 related modifications, researchers will need to review CDC website information on [underlying medical conditions](#) and [older adults](#) before proceeding with their modifications as needed.

Researchers will be required to address the following:

- Acknowledgement that the researcher has read the new guidelines
- Does your research involve COVID-19 vulnerable subjects?
- In what category is your project/research (B, C, or D)?
- Describe new health and safety protocols
- Attach an updated informed consent form

Once submitted, the modification will be reviewed by the IRB following the same process as other protocol modifications.