Alma College Institutional Review Board response to COVID-19

Introduction

Due to the COVID-19 pandemic and the high risk of person-to-person spread of disease, there are necessary modifications that must be made in order to safely conduct human subjects research (HSR) sanctioned by Alma College. At this time, **data collection for institutional review board (IRB) approved studies involving in-person interaction must be paused** (see below on steps to be able to resume a paused study). IRB-approved HSR which does not involve in-person interaction (e.g., online surveys) and studies which are no longer collecting data (e.g., data analysis being conducted) may continue as normal.

Restrictions on human subjects research

The following restrictions have been placed on HSR approved by the Alma College IRB which involves in-person interaction:

- Investigators must exclude from HSR any person at high risk for complications of COVID-19, including all persons ≥60 years of age, and people of any age (including children) who have serious underlying medical conditions. This includes all HSR conducted at hospital, nursing home, and extended care facilities (e.g., Masonic Pathways).
    - Investigators may request approval of protocols that include persons at higher risk only if the protocol is justified by clear, measurable, and direct therapeutic benefits to subjects.
- Studies that require close contact (i.e., <6 feet) between investigators and subjects, or with subjects to each other, cannot yet be resumed or started.
- For HSR which involves in-person interaction, all investigators and subjects must wear facemasks or other facial coverings which cover the nose and mouth at all times.
    - Exceptions:
        - Children under 5 years of age are not required to wear facial coverings.
        - Facial coverings can be removed for eating/drinking if necessary as part of the study.
        - Facial coverings are not required if the study is performed outside and subjects are not within 6 feet of individuals who are not family members.
- HSR studies using equipment which does not allow for facemask or facial covering use (e.g., pulmonary function testing, metabolic analyzer) cannot yet be resumed or started.
- All surveys, interviews, focus groups, etc. should be conducted remotely, unless the investigator can justify to the IRB why in-person interaction is needed. Such investigators should include this rationale in their IRB application (for new protocols), or in a study modification request (for studies already approved by the IRB).
- For research conducted in an off-campus location (e.g., hospital), approval for the research must be granted (or re-granted, if previously approved) by the facility or owner of the premises at which the research is to be conducted and for any facility/premises employees involved with the research process.
- If personal protective equipment (PPE) or items for proper disinfection of research spaces become unavailable during the data collection process, studies must be paused until such PPT/disinfecting items are available again.

For investigators who paused their IRB-approved research

Before resuming in-person research activities for IRB-approved research, investigators must submit and receive approval of a study modification which includes a COVID-19 plan. Changes include the following:

- Addition of a statement in the Informed Consent document describing the risks of COVID-19 exposure and how such risks will be minimized by the study investigators.
- Explicit exclusion from participation individuals who are aged 60+ or who have serious underlying medical conditions.
- Stated safety precautions which adhere to social distancing guidelines. The recommended guidelines can be found later in this document.
- Submission of a COVID-19 plan (found later in this document).

For investigators who intend to initiate new research

Investigators planning a new study should submit an application and supporting materials to the IRB as normal. In the "Risks" section of the application and informed consent, include a brief discussion of the plan for minimization of risks associated with COVID-19. Also, investigators must submit a COVID-19 plan (found later in this document) to accompany the normal submission materials.

Changes to IRB policies regarding COVID-19

Knowledge about COVID-19 is rapidly expanding. The IRB reserves the right to change the COVID-19 checklist and HSR procedures in the event that new information comes out regarding disease transmission, at-risk populations, etc. or in the event of an outbreak in the local area. In the event of changes, the IRB will notify all principal investigators for active protocols of changes as quickly as possible.

Cleaning, disinfecting, and minimizing risk in research spaces

Research staff should clean and disinfect the research space and high-touch locations with high frequency. At minimum, spaces should be disinfected at the beginning of the day, before/after each subject's research participation, and the end of the day. The following are common examples of high-touch surfaces. Research staff should identify specific high-touch areas in their research spaces and prioritize these for frequent disinfection.

- Benchtops and counters
- Equipment handles and latches
- Equipment controls and touchpads, on/off switches
- Drawer and cabinet handles
- Door knobs and light switches
- Hand tools, micro-pipettors, power tools (drills, skill saws, reciprocating saws)
- Faucet handles and sprayer grips
- Chemical bottles and lids, glaze and paint containers
- Chair backs and arm rests
- Pens, whiteboard markers, paint brushes

When possible, it is recommended that surfaces be washed with soap and water prior to use of disinfectants. Then, research staff should use an EPA-approved COVID-19 disinfectant. A list of approved disinfectants can be found at the following link: https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19

Additional precautions should be utilized where possible:

- A system and appropriate signage for one-way flow of people should be implemented.
- Minimize staff and volunteers in the research space.
- Increase ventilation in the facility using HVAC, fans, open windows, etc.
- Conduct study in an efficient manner to minimize the amount of time study investigators and subjects are physically in research space.

COVID-19 plan

All investigators who intend to engage in in-person HSR must submit and receive approval of a COVID-19 plan. This plan must include:

- Completion of a checklist for daily monitoring of investigator and research team for signs and symptoms of COVID-19 (see below). This form should also be completed by subjects **before** arriving for in-person research testing.
- Distribution of the study informed consent document to all potential subjects via email or physical mail **before** meeting with them in person.
- Temperature check of potential subjects when they report to the research space.
- To facilitate rapid contact tracing if needed, a daily log must be kept of all individuals – investigators, assistants, and subjects – who engage in in-person research activities. The log must be securely kept, to protect the privacy of participants.
    - This log should include name, date, contact information, and study location.
    - Because this involves the collection and (short-term) storage of identifiable participant information, this will require additional signature of agreement from the participants.
- Measures to ensure social distancing of ≥6 feet between all individuals in a research space, limitation of number of persons in small spaces, and minimizing time study investigators and subjects spend in the research space.
- Facemasks or other face coverings required for all subjects and all members of the research team.
- Increased cleaning and disinfecting measures – disinfecting of all furniture and equipment participants come in contact with required before and after each subject's participation in the study.
- Changing of gloves and/or handwashing are required before and after each subject's participation in the study.
- Affirmation from the investigator, and from each member their research team who will interact with subjects, that they have completed the college's COVID-19 training.
- Subjects will be required to report any new information about potential or known COVID-19 exposure and/or any COVID-19 symptoms experienced **after they've** participated if it is within a 14-day window of the research activity.
    - In such an event, subjects should contact the study's Principal Investigator, whose contact information is available in the informed consent form.
    - The principal investigator will contact the following individuals:
        - Anne Lambrecht (lambrechtak@alma.edu, (989) 463-7225), Director of Counseling, Health and Wellness at Alma College.
        - Alex Montoye (montoyeah@alma.edu, (989) 463-7923), Chair of Alma College's Institutional Review Board.
- Investigators are encouraged to monitor the IRB website (https://www.alma.edu/offices/provost/institutional-review-board/) to stay informed on changes to this guidance.

COVID-19 health screening form

This must be completed by all research staff and subjects **before** arriving at the place in-person research is to be conducted.

Name (first and last):	
Date:	
Email address:	
Phone number:	
Subjective fever (felt feverish):	YES NO (bold/highlight/circle one)
New or worsening cough:	YES NO (bold/highlight/circle one)
Shortness of breath:	YES NO (bold/highlight/circle one)
Sore throat:	YES NO (bold/highlight/circle one)
Diarrhea	YES NO (bold/highlight/circle one)
Chills	YES NO (bold/highlight/circle one)
Muscle pain	YES NO (bold/highlight/circle one)
New loss of taste or smell	YES NO (bold/highlight/circle one)
In the past 14 days, have you had close contact with an individual diagnosed with COVID-19?	YES NO (bold/highlight/circle one)
In the past 14 days, have you traveled internationally or taken a cruise?	YES NO (bold/highlight/circle one)
Current temperature (degrees F)	

If you answer "yes" to any of the above questions or have a current temperature of 100.4°F or higher, do not participate in in-person human subjects research. Additionally, it is strongly recommended that you contact your health care provider for direction as to the necessity to self-isolate. For questions, visit www.mmdhd.org or contact Mid-Michigan District Health Department at Clinton County: 989-224-2195, in Gratiot County: 989-875-3681 and in Montcalm County: 989-831-5237.

Health history form

The risk for developing severe symptoms from COVID-19 is partly dependent on age and health status. If you are aged 60 years or older or if you have a medical or other condition which you feel increases your risk of severe symptoms if you were to acquire COVID-19, please answer (circle, bold, or highlight) YES below. Otherwise, please answer NO. For reference, a list which includes medical conditions known to increase the risk of severe COVID-related symptoms can be found on the following page.

I am aged 60 years or older or have a medical or other condition that may increase my risk of severe COVID-related symptoms:

YES NO

Conditions known to increase the risk of severe COVID-related symptoms:

- Chronic obstructive pulmonary disease (COPD)
- Cystic fibrosis
- Pulmonary fibrosis
- Moderate or severe asthma
- Emphysema
- Diabetes (type I or II)
- Obesity (BMI 30 kg/m2 or higher)
- Cardiomyopathy
- Pulmonary hypertension
- Congenital heart disease
- Heart failure
- Coronary artery disease
- Peripheral artery disease
- Uncontrolled high blood pressure (hypertension)
- Previous heart attack or stroke
- HIV/AIDS
- Organ transplant
- Current or past cancer treatments (e.g., radiation, chemotherapy)
- Bone marrow transplant
- Medications with weaken immune system (e.g., prednisone, steroids, immunosuppressants)
- Chronic kidney disease
- Chronic liver disease
- Hepatitis
- Sickle cell disease
- Thalassemia
- Pregnant
- Parkinson's disease
- Multiple sclerosis
- Other autoimmune disease (e.g., rheumatoid arthritis, Hashimoto's disease, scleroderma, Celiac disease, Crohn's disease, colitis)
- Cerebral palsy
- Alzheimers or dementia

Daily log of laboratory visitors

Name	Study location	Date	Time In	Email	Phone

Example language for Informed Consent form (in-person research is required to include information related to COVID-19)

Inclusion/exclusion criteria

In addition to the normal inclusion and exclusion criteria, there are additional exclusion criteria imposed due to COVID-19. If you are ≥60 years of age or have any serious underlying medical conditions, you will not be able to participate in this study. You will complete a health history form to determine if you have a medical condition with warrants your exclusion from the study. Additionally, if you are sick or have potential exposure to individuals to have COVID-19, you will not be able to participate until you have self-quarantined for at least 14 days and no longer have symptoms.

Risks

In addition to the normal risks of involvement in this study, there are additional risks due to COVID-19. COVID-19 is a respiratory disease that is often mild but can cause severe symptoms that can, in the worst case, result in permanent impairment or death.

COVID-19 is thought to spread by air or on solid surfaces. To minimize risks of COVID-19 exposure to you while you are participating in this study, we require that you wear a facemask or other facial covering when you arrive and through the entirety of the study. Additionally, you will maintain a physical distance of at least 6 feet from any research staff or other subjects at all times during the study. The research staff will also wear facial coverings at all times, and before your participation they will disinfect all surfaces, equipment, supplies, and furniture with which you may come into contact during the study.

We require that you complete this form, a health history form, and a health screening form **before** you arrive at the research setting so that, if you do not feel comfortable participating, are at high risk of COVID-19 related complications, or have potential COVID-19 symptoms, you will minimize your risk and the risk to others. Finally, we will have you complete a log form which includes your name and contact information so that, if someone in the research team or a subject is diagnosed with COVID-19, we can perform contact tracing to locate others who may need to self-quarantine.

Confidentiality of information

In addition to keeping your research data confidential, due to COVID-19, we will keep a daily log for each visit you make to the research setting for up to 3 months following your completion of the study. This log contains your name and contact information. It will be kept within a lockable filing cabinet inside of a locked office space.

Signature

I have read the above information about the research study titled "Study title here" and have been given an opportunity to ask questions. I agree to participate in this study and I have been given a copy of this consent document for my own records. I agree to accurately answer questions for subject health screening, and I accept the entry and short-term maintenance of my name, contact information, the date, and location in a log to facilitate contact tracing if needed. I agree to immediately report to the study's principal investigator if I experience symptoms of, or receive a positive diagnosis of, COVID-19.