

# **EASTERN MICHIGAN UNIVERSITY**

# COVID-19 PREPAREDNESS, RESPONSE, AND SAFE RETURN TO CAMPUS OPERATIONS PLAN

#### **HUMAN SUBJECT RESEARCH**

#### I. PURPOSE

- **A. Goal:** The goal of the Eastern Michigan University ("EMU" or "University") COVID-19 Preparedness, Response, and Safe Return to Campus Operations Plan for human subject research, and exclusive to the EMU community, is to:
  - reduce the spread, and mitigate the impacts, of the COVID-19 virus on EMU's campus; and
  - 2. outline standards for a safe return to on-campus operations for human subject research.

This plan supplements the University's COVID-19 Preparedness, Response, and Safe Return to Campus Operations Plan.

- B. Compliance: This plan is designed to comply with applicable executive orders ("EO") from the State of Michigan, any other applicable government directives and guidelines, and suggestions from the "Guidance for Preparing Workplaces for COVID-19" ("OSHA Guidance") published by the Occupational Safety & Health Administration ("OSHA"). The information and protocols in this Plan are therefore subject to change.
- C. Minimizing risk exposure: All of the University's employees are classified as having either "low" or "medium" risk of workplace exposure to COVID-19 as defined by the OSHA Guidance. None of the University's employees are classified as having "high" or "very high" risk of workplace

exposure to COVID-19 as defined by the OSHA Guidance. This plan is therefore designed to meet the recommendations in the OSHA Guidance for mitigating "low" and/or "medium" risk exposures for employees. Although human research subjects are not employees, human subjects for in-person research studies will be given health screenings before arriving on campus; nobody considered to be high or very high risk, as determined by the most recently published CDC guidance (https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/inde x.html), will be permitted to participate in in-person research.

### II. SCOPE & APPLICATION

- **A. Application:** This plan applies to all employees, contractors, and students who conduct human subject research on behalf of EMU. This plan may also apply to human subjects in research and individuals accompanying human subjects (in particular, minors who are subjects).
- **B. Reopening phases:** The University has three\_phases of resuming human subject research. The President and Provost determine which phase the University is in. After a phase change, the new access conditions and requirements will be communicated as soon as feasible.
  - 1. Phase 0/1: Remote human subject research only.
  - 2. Phase 2: Low-risk in-person research with expanded safety requirements. Most activities can be resumed, but building or room occupancy is restricted and/or the level and frequency of cleanings is increased. Only subjects who are low-risk for COVID-19 and in good health may participate in in-person research. In-person interactions (i.e., interactions in which the investigator(s) and subject(s) are within 6 feet from each other, must be brief (less than 15 minutes, cumulative, in duration). Remote services must still be used "to the greatest extent possible". Community-engaged research (i.e., research conducted in collaboration with community stakeholders and that takes place within the community) may not be conducted during Phase 2. The Provost's Office will provide a list of additional criteria for who is and is not permitted to participate in in-person research (e.g.,

- minors, campus visitors, people over age 60, etc.
- 3. Phase 3: Full in-person research with expanded safety requirements: All in-person resumed with CDC hygiene protocols in place.

#### III. IMPLEMENTATION

- **A. Publication:** This Plan or a modified version of it will be published as follows. (Ref: EO 2020-161 Sec. 1(a))
  - Website: <a href="https://www.emich.edu/research/compliance/coronavirus\_hsr">https://www.emich.edu/research/compliance/coronavirus\_hsr</a>
  - Hard copy: Individuals may request a copy of this Plan by contacting Wade Tornquist, Interim Associate Provost for Graduate Studies and Research, at <a href="wtornquis@emich.edu">wtornquis@emich.edu</a>.
- **B. Supervision:** The following individuals are designated to implement, monitor, and report on the strategies developed under this plan. (Ref: EO 2020-161 Sec. 1(b))
  - Wade Tornquist, Interim Associate Provost for Graduate Studies and Research, at <u>wtornquis@emich.edu</u>, is responsible for compliance of all activities covered by this plan.
  - 2. The Assistant Vice President for Academic & Student Affairs and Dean of Students shall provide guidance and assistance to this Plan and unit plans for issues regarding COVID-19 reporting. The contact is Ellen Gold, Dean of Students, at <a href="mailto:emu\_deanofstudents@emich.edu">emu\_deanofstudents@emich.edu</a>.
  - 3. The Office of Wellness and Community Responsibility shall provide guidance and assistance regarding student non-compliance issues. The contact is <a href="mailto:emu\_owcr@emich.edu">emu\_owcr@emich.edu</a>.
  - 4. The Office of Environmental Health and Safety is responsible for receiving and reviewing complaints of unsafe working

conditions. The contact is Kathryn Wilhoff, Director of Environmental Health & Safety ("EHS"), at <a href="mailto:kwilhoff@emich.edu">kwilhoff@emich.edu</a> or 734-487-0794.

## **IV. POLICIES & PRACTICES**

## A. In-Person Human Subject Research Plan

- 1. All principal investigators whose research requires in-person contact with human subjects must develop a research plan. The research plan will consist of safety protocols for researchers and human subjects, including information about COVID-19 screening, use of PPE, physical distancing measures, cleaning/disinfecting procedures (including expanded time between subjects for proper cleaning/disinfecting), research procedure modifications, and how investigators will obtain subject information for potential contact tracing. Principal investigators must also describe how they will inform research subjects of COVID-19 risk and safety protocols in their research plan.
- 2. The principal investigator submits the plan to the Department Head/School Director for initial review and support, followed by the Dean. The DH/SD and Dean's Office will review to approve for resource availability. The Research Plan will use this form.
  - a) The DH/SD will review the research plan and determine whether the department/school can provide the resources and PPE required for the research.
  - b) The Dean's office will review the research plan to determine that there is sufficient space and that building procedures are in place to safely bring human subjects into the research spaces.
- 3. After the Dean approves the Research Plan, the principal investigator must submit the Research Plan as a modification to their previously approved IRB protocol in Cayuse for IRB approval. The IRB will review the Research Plan for human subject protections, including COVID-19 safety measures, and determine that remote procedures are not possible for the research.
- 4. IRB approval is required **prior** to initiation of in-person human subject research procedures.

#### B. Access:

1. Remote services must be employed to the greatest extent

- possible. (Ref: EO 2020-161 Sec. 1(q) and 9(k)). Only research procedures that cannot take place remotely can be conducted in person.
- 2. In-person human subject research must first receive written approval from their Dean and Provost. Such approval must designate the specific individuals who are authorized to conduct work on campus covered by this plan.
- 3. Students are only permitted to perform work covered by this plan if (a) they are conducting procedures that cannot be conducted remotely, (b) pre-authorized by their faculty adviser's dean, and (c) have a plan in place for supervision by their faculty adviser or a staff designee.
- 4. The number of in-person appointments must be limited to maintain physical distancing and to allow adequate time between appointments for cleaning and disinfecting. (Ref. EO 2020-161 Sec. 9(I))
- 5. Off-campus research at other sites must also comply with site-specific requirements. Documented permission from site administrators must be provided with the research plan and submitted to the Dean and to the IRB.
- C. Training: All individuals engaged in in-person human subject research covered by this plan must complete an online training that is offered through the University's Bridge training system, Canvas course shell, or videoconference. This training program covers, at a minimum, workplace-infection control practices, the proper use of protective equipment, steps an employee or student must take to notify the business or operation of any symptoms of COVID-19 or a suspected or confirmed diagnosis of COVID-19, and how to report unsafe working conditions. Each principal investigator is responsible for ensuring that individuals engaged in in-person human subject research covered by this plan have completed the training. (Ref: EO 2020-161, Sec. 1(c))

D. Daily Entry Self-Screening: All investigators, including students, engaged in in-person human subject research covered by this plan must complete a daily self-screening form each day before coming to campus or conducting research on site. The completed form is automatically sent to the employee's supervisor. Individuals who do not meet the criteria outlined on the form are not permitted to come to conduct in-person human subject research. (Ref: EO 2020-161 Sec. 1(d); EO 2020-161 Sec. 9(f))

# E. Building spaces:

- 1. Entry points: Space that is covered by this plan is located in multiple buildings across campus. Each building in which approved work occurs under this plan shall have signs posted at designated entry points instructing human subjects and other visitors to wear a face covering while inside and will have hand sanitizer at laboratory or research space entrances. If a research subject needs a face mask, then the investigator will meet the subject at the building entrance and provide a face mask to the subject. With the exception of minors and adults who are decisionally impaired, only the research subject(s) will be permitted to enter buildings.
- 2. **Waiting areas:** Occupancy of waiting areas must be limited to the number of individuals who can be present while staying six feet away from one another. Waiting areas must be marked to enable six feet of physical distancing.

# F. Physical distancing:

- Policy: All individuals engaged in activities covered by this plan must maintain physical distance of six feet or more from other individuals whenever practical. (Ref: EO 2020-161 Sec. 9(b), (c), and (l))
- 2. **Application to research spaces:** Physical space used on campus for activities covered by this plan may not be used until the space has been reviewed by the Office of Environmental Health & Safety

to ensure proper physical distancing protocols have been implemented. Such protocols in this instance include, but are not limited to, designating work areas and installing floor markings.

3. **Communication:** Signage to promote this policy has been developed by the Office of Research Compliance and will be installed by principal investigators.

## G. Face coverings and Personal Protective Equipment:

- 1. **Policy:** All individuals engaged in activities covered by this plan who are medically able to do so must wear a covering over their mouth and nose (such as a cloth face mask) when in an enclosed public space when another individual is present. Public space includes, but is not limited to: testing rooms, building corridors, stairways, hallways, and restrooms; conference rooms, waiting rooms, and offices; and vehicles with more than one occupant. (Ref: EO 2020-161 Sec. 1(f) and 1(g); EO 2020-161 Sec. 9(a) and (i)). Personal Protective Equipment (PPE) also must be used by the researcher(s) whenever physical contact with the subject is required by the research procedures, or in accordance with guidance from the CDC and OSHA. (Ref. EO 2020-161 Sec. 9(h)). PPE includes but is not limited to gowns, gloves, goggles, and face shields. If the research procedures preclude the subject from wearing a protective face covering (e.g., assessing oxygen consumption during physical activity), then the principal investigator must explain in their Research Plan how they will employ additional protective measures against COVID-19.
- 2. **Accommodation:** Minors under age 2 years or individuals who believe that they have a medical condition that prohibits them from wearing a face covering shall contact the following office to request an accommodation from this policy:
  - a) Students must contact the Disability Resource Center at drc@emich.edu.
  - b) Employees must contact the Office of University Human Resources at <a href="mailto:hr-employment@emich.edu">hr-employment@emich.edu</a>.
  - c) Research subjects: The subject or parent/guardian

must provide documentation from a physician of a medical condition that precludes wearing a face covering. The subject or parent/guardian will bring the medical issue to the attention of the principal investigator, who will consult with the Disability Resource Center for safety accommodations.

- 3. Availability: To promote compliance with this policy, the University shall make face coverings available to all students and employees engaged in work covered by this plan. Each principal investigator is responsible for securing face coverings for themselves and their research staff (including students) through this website. Research subjects must be informed prior to in-person interactions that face coverings are required. The investigator must make face coverings available for human subjects in the event that the subject does not bring a face covering.
- 4. Communications: <u>Signage</u> to promote this policy has been developed by the Office of Research Compliance and will be installed by principal investigators. Additional signage for work spaces can be found at this website: <a href="https://www.emich.edu/emu-safe/">https://www.emich.edu/emu-safe/</a>
- H. Discourage equipment sharing: Individuals performing work on campus that is covered by this plan shall, whenever possible, not share equipment between investigators. In all instances, equipment used for research that is covered by this plan is subject to cleaning standards outlined in Section IV(I).

# I. Pre-Review, Compliance, and Audit:

- Pre-Review: Before beginning any in-person human subject research or work covered by this plan, the principal investigator must:
  - a) Secure written approval from their Dean and Provost;
  - b) Ensure they have building access approved by the Office of the President; and

- c) Schedule a walk-through of the on-campus workspace with the Office of Environmental Health & Safety (www.emich.edu/publicsafety/ehs). (Ref: EO 2020-161 Sec. 5(c))
- 2. **Compliance:** Investigators must assure they have cleaned and disinfected all spaces and touch points immediately after research procedures with each human subject and as necessary and contacted Custodial Services at the conclusion of each day. (Ref: EO 2020-161 Sec. 9(n))
- 3. **Audit:** The Office of Environmental Health & Safety will periodically audit the Record of Daily Cleaning. (Ref: EO 2020-161 Sec. 9(ln)
- Hygiene protocols (e.g., hand washing, sanitizer, tissues, and respiratory etiquette): The individuals covered by this plan are subject to the following hygiene protocols. (Ref: EO 2020-161, Sec. 1(j); OSHA Guidance)
  - 1. **Policy:** The University encourages all students, employees, and visitors to regularly wash their hands with soap and water, use hand sanitizer when necessary, use tissues as needed to manage coughing and sneezing, and to use proper hygiene etiquette when coughing or sneezing pursuant to health guidelines.
  - 2. Availability: Employees and students are encouraged to regularly wash their hands, and the University shall make soap available at designated locations, including public restrooms and sinks in clinic spaces. Employees and students are encouraged to use hand sanitizer (but not in lieu of handwashing when soap and water are available), and the University shall make hand sanitizer available in designated locations, which vary between buildings. Employees and students are encouraged to use tissues to wipe/blow their nose, and clinic directors are responsible for procuring and providing tissue in their workspaces that are covered by this plan. Principal investigators may obtain hand sanitizer here.
  - 3. **Communications:** Signage to promote this policy has been developed by the Office of Research Compliance and will

be installed by principal investigators. Signs can be found at https://www.emich.edu/emu-safe/communication-resources/printable-materials/index.php

- J. **General cleaning standards:** Custodial Services cleans buildings on a regular basis, but principal investigators and research staff are responsible for disinfecting equipment, surfaces, and other areas in their research spaces. Each investigator approved to conduct in-person human subject research that is covered by this plan will be provided disinfectant supplies, will use gloves when using disinfectant products, and is required to clean and disinfect rooms after each subject's session. (Ref. EO 2020-161 Sec. 9(n)). Questions regarding custodial services may be directed to Dieter Otto, Director of Custodial Services and Grounds, at dotto@emich.edu. (Ref: EO 2020-161 Sec. 1(h))
- K. Notice of positive cases: EMU has implemented the following notification protocols when an individual tests positive for COVID-19. (Ref: EO 2020-161 Sec. 1(k))
  - 1. Employees and students who test positive for COVID-19 shall:
    - a) Notify their supervisor that they are ill (they do not need to inform their supervisor that they tested positive for COVID-19); and
    - b) Complete this form.
  - 2. The Office of the Assistant Vice President for Academic & Student Affairs and Dean of Students is responsible for maintaining records of positive cases of COVID-19 and notifying the Washtenaw County Health Department about all known cases of a COVID-19 positive test involving an employee or student on the University's campus.
  - 3. All notifications to co-workers, contractors, or suppliers who have come in contact with an individual who has tested positive for COVID-19 will be coordinated by the Office of the Assistant Vice President for Academic & Student Affairs and Dean of Students and completed in coordination with, and at the direction of, the Washtenaw County Public Health Department.

- L. Cleaning standards in the event of a COVID-19 positive test: EMU has implemented the following protocols to disinfect areas where an individual who has tested positive for COVID-19 is known to have visited during relevant time periods as identified through contact tracing. (Ref: EO 2020-161 Sec. 1(i) and 9(o))
  - 1. Employees and research subjects: If the University is notified that an employee has tested positive for COVID-19, the University's Custodial Services office disinfects the research, space all touch points in the building that the investigator or human subject accessed, and any other areas where the investigator or human subject recently visited on campus as identified through contact tracing that is coordinated by the Assistant Vice President for Academic & Student Affairs and Dean of Students Office. This cleaning process includes, where applicable, fogging of entire rooms or buildings.
  - 2. Students: If the University is notified that a student has tested positive for COVID-19, the University's Custodial Services office disinfects the student's residence hall room/apartment (if applicable), and any other areas (e.g., lab or classroom) where the student recently visited as identified through contact tracing. This cleaning process includes, where applicable, fogging of rooms, hallways, or buildings.
- M. **Staying home if sick:** The University has established the following protocols to ensure that employees who are sick stay home, and that employees with a confirmed or suspected case of COVID-19 return to the workplace only after they are no longer infectious. (Ref: EO 2020-161 Sec. 1(I), 1(m); OSHA Guidance)
  - 1. Employees who are sick should stay home until symptoms pass and isolation times, if applicable, have passed.
  - 2. If an employee is sick or becomes sick at work, they should notify their supervisor immediately and make arrangements to go home as soon as possible. They should avoid contact with other individuals as much as possible.

- 3. The vast majority of EMU's workforce has access to paid sick time as outlined in Board Policy 3.2.5 (for non-bargained-for employees) and the collective bargaining agreements (for employees employed in a collective bargaining unit).
- 4. The University does not retaliate against employees (through discharge, discipline or otherwise) who stay home or leave work when they are at particular risk of infecting others. University Human Resources is responsible for ensuring compliance with this policy and investigating allegations that this policy has been violated.
- 5. Any employee conducting work as part of this plan who works on campus with a pre-approved external contractor shall encourage those contractors to instruct their employees who may be assigned to work on-site at the University to stay home if they are sick and to immediately report to their University contact any instance when an employee assigned to work on-site at the University has tested positive for COVID-19.
- N. Response plan for COVID-19 positive cases: The University has established the following protocols for dealing with a confirmed infection in the workplace. (Ref: EO 2020-161 Sec. 1(n))
  - As outlined in Section IV(H) of the University's COVID-19
     Preparedness, Response, and Safe Return to Campus Operations
     Plan, the University has established cleaning protocols for when the University learns that an employee, student, or visitor tests positive for COVID-19.
  - As outlined in Section IV(I) of the University's COVID-19
     <u>Preparedness</u>, <u>Response</u>, <u>and Safe Return to Campus Operations</u>
     <u>Plan</u>, the University has established protocols for employees to remain at home in the event they test positive for COVID-19.
  - 3. The University will close certain buildings and/or the campus in the

event of a COVID-19 positive case based on the scope of any outbreak of COVID-19 and in consultation with the Washtenaw County Health Department. The decision to close a building and/or the campus in this context is made by the President of the University.

- O. **Travel:** The University has established the following protocols regarding travel. (Ref. EO 2020-161 Sec. 1(o))
  - In March 2020, the University prohibited all University-sponsored air travel by employees and students in response to the outbreak of COVID-19. Requests to travel by air for essential work must be reviewed and approved by the Chief Financial Officer and/or Executive Vice President. That policy remains in effect.
  - 2. **Public transit protocol:** Students and employees who use public transportation (e.g., buses) are encouraged to: always wear a face covering; practice physical distancing at all times; and wash their hands after their trip or, if that is not feasible, carry and use hand sanitizer immediately after their trip. (Ref: EO 2020-161 Sec. 1(p)).
- P. **Unsafe working conditions:** Employees who believe they are subject to unsafe working conditions, or who have concerns regarding compliance with the COVID-19 plans as applied, should immediately contact their supervisor, followed by, if needed, that individual's supervisor. Campus safety concerns should be reported to Environmental Health and Safety (kwilhoff@emich.edu or 734-487-0794).

Date: September 24, 2020