Division of Research and Innovation

Human Subjects Research Restart

University of Memphis | 2020

Human Subjects Research

Research must be conducted under IRB approved procedures to protect human subjects from research and unnecessary exposure to COVID-19.

The Office of Human Research Protections (OHRP) requires that the IRB prioritize public health and safety. Even where interactions with subjects are not under FDA guidelines, the OHRP refers to FDA Guidance issued April 2, 2020: **https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html**

The IRB will review protocols following guidance from the OHRP, FDA, and the CDC based on the context of each protocol. The IRB advises that UofM departments consider the specific context of their research and plan for the protection they can provide to their research participants.

Because this is a rapidly changing environment, the IRB cannot predict the guidelines that will be in place when our campus reopens; however, minimizing contact, handwashing, sanitizing surfaces, and PPE have been consistent practices.

To assist with this process the Division of Research and Innovation has published **COVID-19 Research Guidelines**.

General Guidelines For Return to Work

- Online form to be submitted by PI to department Associate Dean for Research (ADR)
  - List all personnel who will be on campus and their building location
  - Confirm all personnel have completed online COVID19 training
- Review Employee Heath & Safety Guidance on Returning to Work
- Confirm facility access with ADR
- Review updates to campus operations
- University travel restrictions remain in place
- CDC guidelines should be followed –social distancing, sanitization, cough etiquette, PPE
- Masks must be worn by faculty, staff, students, visitors who will be working within 6 feet of others
- Self-health checks prior to coming to work; stay home if any symptoms checked
- Review COVID-19 Reporting requirements
- Document Contact and facilities use for tracing
- No gathering in common areas (kitchens, etc.)

Working in Research Spaces

- Provide 200 sq ft of space for each desk with researcher desks 10 feet apart
- Stagger work schedules when possible with no overlaps
- Minimize face-to-face lab meetings, maintain social distancing or use online meetings
- Disinfect common research areas, frequently touched surfaces for each work shift and equipment between individual uses
- PPE – masks/gloves must be available in shared areas and used when in close proximity/using shared equipment. Obtaining PPE is the responsibility of the PI.
- Review safety precautions when only one individual is in a lab normally populated by more

Reactivating Paused Research Activities

- Review and follow social distancing protocols in research laboratories, clinic environments and shared office spaces
- Survey the laboratory and clinical facilities for unsafe conditions and address them before the start of research activitiesSanitize all surfaces including computer keyboards and phones daily
- Review your inventory to properly manage supply and properly dispose of any expired, outdated, or limited shelf life items
- Review laboratory safety protocols to include
- Revised PPE guidelines
- Standard operating procedures
- Review equipment safe startup instructions / review calibration requirements

Employee and Subjects Daily Health Screening

Do not come to campus, or allow subjects to come to campus if they have received a diagnosis of COVID-19 in the past fourteen days or if researchers or subjects 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° Fahrenheit
- Have had close contact with a person who is lab confirmed to have COVID-19 within the past 14 days

Additional considerations

- UofM and the IRB, will continue to consider risk/benefit ratio for subjects participating in research
- Conduct pre-screening health checks of subjects before interactions
- Conduct remote interactions whenever possible
- When activities are conducted in person, additional precautions to protect both research team members and human subjects apply

Of note: *IRB approval to conduct human subjects activities may change on a day-to-day, or week-to-week basis, based on the current county/city/state or federal outlook. Please keep a close attention to EVPR/IRB emails.*

Submit Protocol Modifications to the IRB when:

- Any procedures have changed to your protocol.
- Your timeline has changed, or your protocol has expired.
- The number of subjects have changed.
- Your subjects have additional vulnerabilities due to age (over 65) or medical conditions. Depending on the current conditions, research with COVID19-vulnerable populations may not be approved.
- Your settings (i.e. classroom) to conduct research have changed

Modifications Required Due to COVID 19

When interacting in-person with human subjects, modifications to procedures should include:

- Plans for PPE (researchers and subjects) and additional protections of subjects based on specific interactions.
- Plans for sanitizing the clinic environment
- Plans to stagger visits to the clinic limiting the number of subjects present at a time
- The maintenance of identifiers in order to conduct contact tracing, and how this data will be protected.

Research Compliance and the IRB

Remain open, accessible and fully operational.

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Email **researchcompliance@memphis.edu** for a prompt response.

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