Office of the Vice Chancellor for Research and Graduate Education
UNIVERSITY OF WISCONSIN–MADISON

Phased Resumption of Research Operations During COVID-19 Pandemic

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Summary

COVID-19 has dramatically changed how we conduct research on campus. We are now embarking on a limited expansion of on-site research and other scholarly activities, while ensuring we are following campus guidelines to minimize the impact of the COVID-19 pandemic.

In Phase 1, campus operations will be limited and activity on campus will look very different from that prior to COVID-19. This is a very infectious and complex disease. To reduce the spread of this virus, we must limit the number of researchers permitted to work in rooms and buildings during Phase 1. Only activities that cannot be performed at home will be allowed on site. Significant changes in workplace practices are expected from returning researchers. Restrictions will limit the number and density of people in campus buildings and rooms. New health safety protocols that follow government recommendations and best practices will be in place throughout campus operations.

- **Obtain Approval**
    - All Phase 1 on-site research and scholarly activities require advance approval. Contact your Associate Dean for Research or OVCRGE Center Director or SMPH Division Head for information on the approval process for your school, college or center.
    - All previously approved on-site research activities require re-approval for Phase 1 using the approval process described here.
    - Requests to conduct Phase 1 on-site research will use an online form, which will be evaluated by department chairs/section chiefs/center directors. Deans or the VCRGE, or their designee, will have authority for final approval of requests.
- **Reconfigure Work**
    - For Phase 1, maintain a maximum of one person per 350 square feet of research space and allow 6 feet of physical distancing for personnel *working* and *moving* within research spaces.
    - Limit the duration of time that researchers are working in the same room, even with physical distancing.
    - Research requests should take into account that some supplies and services in animal facilities and shared core facilities may be limited.
- **Reduce Transmission**
    - Stay home when you are sick.
    - Avoid contact with people who are sick.
    - Avoid touching your eyes, nose, or mouth with unwashed hands.
    - Cover your coughs and sneezes.
    - Wash your hands regularly throughout the day and when entering and before exiting all buildings; use hand sanitizer when hand-washing facilities are unavailable.
    - Disinfect all surfaces and equipment between shifts.
    - Follow campus guidelines on wearing face coverings while on campus.

In opening our campus for more on-site research and scholarly activities, we must work together and strive to keep all of us healthy. These guidelines will be reviewed and modified as our understanding of the transmission of this virus continues to improve.

Introduction

This document provides guidance and direction for restarting on-site research and scholarly activities, while ensuring we are following campus efforts to minimize the impact of the COVID-19 pandemic. **On-site activities** refer to those activities conducted on campus, at University-owned facilities, and at non-University field locations or leased spaces. Until further notice, on-site research and scholarly activities must be approved and follow the guidance in this document. Research that can be conducted remotely should continue to be done remotely (e.g., theoretical and computational work, or non-face-to-face human subjects research) and does not require review or approval to continue at home.

What is a research site?

A **research site** is an environmental setting or workplace in which any form of scholarship or inquiry takes place in controlled conditions by professionals in their field (e.g., faculty, scientists, technicians) and their trainees (e.g. students, fellows). Such inquiry can involve qualitative or quantitative analyses, such as (but not limited to) biological, ecological, environmental, behavioral, statistical, physical, engineering, historical, cultural, literary, linguistic, aesthetic, philosophical, and other kinds of assays; hypothesis testing, collection of data or preparation for collection of data; interpretation of data or cultural products; examination of literature in the field; data compilation and writing for the purpose of dissemination of results; theoretical or methodological innovation; and creative work in the literary, visual, plastic, and performing arts.

In a research site, there may be locations devoted to specific functions, such as imaging organisms (viruses, bacteria, animals and plants); studying genetic information encoded by DNA and RNA; monitoring plant growth and water quality; testing or interviewing human subjects; calling members of a sample from a population; preparing mailings to a sample of people; designing, building, testing and implementing physical systems and measurement instruments; analyzing data on computers; creating artworks in a wide range of materials and media; preparing artifacts for an exhibit; theatrical, dance, musical, or other forms of arts performance; interviewing human subjects; or other activities. Work in a research site can include the use of specialized instrumentation; physiological and behavioral measurements; computerized and graphical techniques; library, museum, and archival materials; or other specialized materials and equipment specific to that site.

A phased process

Campus research and scholarly activities were curtailed in response to the COVID-19 pandemic. This document provides guidance on the steps toward a gradual increase in these activities on campus. The restart will be phased, with a focus on restoring activities at research sites while minimizing the risk of transmission of the COVID-19 virus to our students, staff, faculty, and the larger Madison community. Controls on the spread of the infection need to be balanced with research needs to operate effectively and safely. During the start of Phase I we take a conservative approach in setting guidelines to reduce the chance of transmission of the virus. Additionally, we will learn how to operate safely in this new working environment.

COVID-19 is thought to spread primarily through respiratory droplets produced when an infected person coughs or sneezes. Other possible means of transmission include aerosols (e.g., from an infected person exhaling), and transfer of virus through touching the mouth, nose, or eyes after touching a contaminated surface. Symptoms may appear 2-14 days after exposure, and some infected individuals never exhibit symptoms. Infected individuals may transmit the disease even if pre-symptomatic or asymptomatic. It is critical that campus implements a plan to minimize the spread, consistent with our current understanding of how the disease spreads. These guidelines attempt to achieve that goal.

Phase I of the re-opening of campus activities will focus on projects that can move forward while successfully implementing requirements for physical distancing and other safety protocols to reduce transmission risk. As campus researchers learn to carry out their research in these new ways, while preventing spread of the virus, additional expansion of research activities will be possible.

Guiding Principles for On-Site Research Activities

The framework for increasing research activity at campus research sites must be informed by the following principles:

- Protect the emotional as well as physical health and safety of our workforce.
- Protect the health and safety of our clinical patients and human research subjects.
- Follow campus health directives (e.g., physical distancing, size limitations on gatherings.)
- Implement a fair, equitable, and transparent process for granting access to campus research facilities.

Safety

The best protection against spreading COVID-19 is to keep a distance of at least six feet between people (defined as physical distancing). However, there are other ways to help with reducing the spread (https://covid19.wisc.edu), including:

- Stay home when you are sick and avoid close contact with others. Stay home even if you have mild symptoms of illness. This helps to protect the health of your colleagues and your community.
- Wash your hands often with soap and water for at least 20 seconds. If water is not available, use hand sanitizer, with at least 60% alcohol.
- Avoid touching your eyes, nose, or mouth with unwashed hands.
- Avoid contact with people who are sick.
- Cover your mouth and nose with a tissue or sleeve when coughing or sneezing. Immediately throw the tissue in the garbage, and wash your hands.
- Limit duration of time that you are working in same room with others, even with physical distancing.
- Follow UW Madison guidelines on wearing face coverings on campus. (Campus resources, including face covering guidance, will be posted at https://facilities.fpm.wisc.edu/returning-to-campus-safely/).

- Disinfect work surfaces and "high-touch" surfaces.
- Do not come to campus or go to field sites if you have symptoms of COVID-19 or believe you have been exposed to it. Employees should review campus policies related to temperature taking, monitor their temperatures on days they are planning to work on-site, and stay home if they have a fever of 100.4°F (38°C) or higher (based on CDC guidance) or other symptoms (e.g.. shortness of breath, cough). Testing for COVID-19 through your health care provider or the free Dane County testing program (https://publichealthmdc.com/coronavirus/testing) is encouraged for those with symptoms.

Requests to begin on-site research and scholarly activities must follow current public health and university-wide safety protocols, **plus** any additional required safety procedures defined by the particular activity or research site. Any enclosed space in which a confirmed case of COVID-19 is identified will be closed until disinfection can be completed.

All requests to resume on-site research must:

- Take into account the Environmental Health and Safety (EHS) recommendations for bringing research laboratories back online from temporary shutdown, see: https://d1cjb8q1w2lzm7.cloudfront.net/wp-content/uploads/sites/22/2020/05/EHS-ADM-GUI-002.pdf.
- Provide a plan for how physical distancing will be implemented and describe what precautions will be made if physical distancing cannot be achieved for the work that is needed.
- Provide a plan for how to minimize the number of the people in a research site *at any given time* while meeting all the appropriate safety standards.
- Describe how access to shared offices and accommodations for work with higher risk populations (see CDC information below) or individuals with health and safety concerns will be handled. This applies to employees and human subjects research participants.
- Have a Continuity of Operations Plan (COOP) to respond to on-campus emergencies related to the research being conducted.
- Detail the PPE needed. PPE must be ordered centrally. Contact EOC_PPE_Supplies@lists.wisc.edu.
- Describe disinfection protocols for shared equipment or other surfaces exposed to contact or contamination during activities (e.g., surfaces in research sites, including labs or offices should be wiped down with bleach, alcohol, or other approved disinfectants before and after each user's session). Similarly, individuals should frequently clean "high-touch" surfaces (e.g., door handles, drawer handles, faucets, instruments, computers, touchpads, etc.). (Campus guidance is under development and will be posted at https://facilities.fpm.wisc.edu/returning-to-campus-safely/).
- Consider that there may be a need to pause or wind down on-campus activities in response to new information about COVID-19, new outbreaks, or changes in the capacity of our communities to respond. Include a plan for stepping back research activities in case of a resurgence of COVID-19. Do not start an activity in Phase I that might consume limited resources or cannot be reduced or ceased in an orderly way, either temporarily or permanently.

The CDC has identified the following individuals at a higher risk for severe illness from COVID-19:

- People 65 years and older;
- People with chronic lung disease or moderate to severe asthma;
- People who have serious heart conditions;
- People who are immunocompromised;
- People with severe obesity (body mass index of 40 or higher);
- People with diabetes;
- People with chronic kidney disease undergoing dialysis;
- People with liver disease.

These colleagues are strongly advised not to participate in on-campus research at this time. Supervisors should consult with their Human Resource offices to explore alternate work assignments for these employees, including graduate student employees.

Implementation Considerations

As we reconstitute on-site activities, we must maintain physical distancing and continue to prioritize the health and safety of our communities.

- We are living with this virus until a vaccine is developed. Strict physical distancing rules must remain in place, until a vaccine or other means to mitigate transmission is widely available.
- Research that can be accomplished remotely should continue to be done that way, until further notice, with access to campus only in the case of extenuating circumstances.
- Restarting on-site research activities impacts other units on campus - animal care staff, biosafety staff, custodial staff, PPE needs, research sites, and shared core facilities located in the same building. Limits on these essential services may necessarily impede some of our desired activities.
- PPE will be centrally distributed. PPE should be procured by emailing needs to: EOC_PPE_Supplies@lists.wisc.edu.
- June 1 is the earliest date for increased campus research activity. Higher risk groups —older or otherwise more vulnerable faculty, staff and students — may need to stay at home longer.
- On-site activity may be increased as we progress between phases (a separate document defining these campus phases is in preparation), but only if community health metrics remain favorable. Should an outbreak occur, we will return to a lower level of on-site research and scholarly activities.
- On March 15, 2020, face-to-face human subjects research interactions were paused until June 30, 2020, except for therapeutic studies involving drugs or devices or those studies where a hiatus in face-to-face interactions would negatively affect a participant's health, safety, or well-being. On **June 1, 2020**, at the earliest, some additional in-person human subjects research studies may resume as we begin to phase in these activities. Other studies may resume face-to-face human subjects interactions on **July 1, 2020**, at the earliest, provided that public health conditions are favorable at that time. Please see additional guidance for human subjects research below.

Requesting On-Site Research and Scholarly Activities

In most cases, on-site research activities that were previously approved during the COVID-19 campus shutdown from March to May 2020 will be allowed to continue, but must be registered and approved via the request form at the link below to facilitate safety coordination among groups within buildings.

Faculty, students, post-docs, technicians and other staff may not be compelled to engage in research travel or activities as a condition of employment or fellowship support while research activities are restricted due to the pandemic.

All PIs requesting to conduct on-campus activities must submit a **Research Activity Request** form through the OVCRGE portal <https://vcrge-uwmadison.smapply.io/prog/research_reboot/>, which will include a list of all research members who need to use on-site facilities, and the room numbers and names of buildings they will be working in. An email acknowledging receipt of the request will be sent to the individual, along with guidance on the next steps. The submitted form will automatically be forwarded to the relevant department chair, SMPH section chief, or center director. **The PI must submit a revised Research Activity request if the operations or activities of the research group subsequently change.**

When the PI needs to submit the Research Activity Request, depends on the process defined by the particular school, college or OVCRGE. The PI should check with the chair, section chief, or center director on processes to follow to submit a request. The requesting PIs has the responsibility to update the request form following revisions, including the approval status of the request, in the final question on the on-line form. Once the request form response indicates that approval has been granted, on-site research activities may commence in each of requested buildings only after verifying that the building has reopened for research activities.

Chairs, SMPH section chiefs, and center directors will work with PIs on how to balance the needs of different research and scholarly activities while minimizing the risk of transmission of COVID-19. Considerations must address the guidance below and that of their unit. There is a need to ensure that the density and scheduling of people in rooms, buildings, and facilities comply with current campus health guidelines and that PPE and sanitizing needs for requested activities can be met.

After review and discussion of the request, the request is forwarded on to the divisional Dean, Associate Dean for Research, or other designated representative of the college, division, or OVCRGE for final approval. Approval of the Research Activity Request does not provide immediate authorization to begin on-site work; please check on the status of your building prior to determining when your research team may enter the building and begin work on site.

Chairs, SMPH section chiefs, and center directors will collaborate with PIs to monitor compliance with approved plans. PIs will also ensure that personnel are informed of the need to self-monitor their health and stay home if they feel ill or have fever, shortness of breath, cough or other symptoms. PIs must inform personnel of what to do if they think they have been exposed to someone with COVID-19.

The Dean or VCRGE will ensure the division's HR office is consulted on the request for on-site activity to determine if relevant HR issues are identified and addressed.

Note that core facilities are required to follow the same process for requesting approval to continue or begin on-site work through the dean or VCRGE (for OVCRGE centers) having administrative responsibility for the core. Additional guidance regarding the process will be provided to core facility directors.

Prioritizing Research Facilities and Projects

During Phase 1 of campus activity, we seek to increase on-site research and scholarly activities while minimizing the risk of contamination. Phase 1 will serve to establish new patterns of behavior that enhance our ability to maintain physical distancing and other safety protocols to reduce transmission risk. There will be limitations on access to facilities, availability of support staff, and custodial services as we ramp up campus activities occurring in our buildings. Consequently, there will be limitations on the number of employees permitted to be in rooms and buildings.

During Phase 1 of restarting on-site research and scholarly activities, spaces should be staffed to maintain a maximum of one person (employees or other people on site) per 350 square feet of research space (or one person per room for rooms less than 700 square feet). Researchers should also maintain 6 feet of physical distancing for personnel working and moving within research spaces. Safe distances between individuals depends on several factors, including the nature and layout of specific rooms, HVAC systems, as well as research protocols.

Phase 1 limitations provide opportunities to test and refine new research site– and building-level procedures for maintaining physical distancing, minimizing the total number of people in research spaces at any given time, reducing contact duration, developing capacity for contact tracing, and monitoring for local instances of viral infection. Significant changes in workplace practices and behavior are expected from returning employees. A gradual approach will help establish appropriate patterns and guide the design of environment modifications to facilitate new modes of working while plans for large-scale campus testing and contact tracing are under consideration.

We recommend that chairs, division chiefs, and center directors take a conservative, equitable, and transparent approach to approval of the first requests so there is room for later requests that may have a high priority or need. To ensure greater equity, chairs, division chiefs, and center directors are encouraged to work with all faculty and staff to review needs and research plans. There should be a general expectation that requests may not be fully granted during Phase I (or in later phases) in order to keep the numbers of people on campus from growing too fast. Therefore, chairs, division chiefs, and center directors need to work with the PIs to prioritize on-site research and scholarly activities, remembering that conducting the activity safely is a requirement. Questions to consider in this discussion include (but are not limited to):

- If the activity is discontinued will it pose a safety hazard?
- If the activity is discontinued, would there be a significant data or sample loss?

- Does the activity involve graduate students who are near to graduation or postdocs who need to complete their projects?
- Are junior faculty at risk for not meeting promotion criteria?
- Does the activity maintain critical equipment in facilities and laboratories?
- Does the activity maintain critical samples, reagents, and materials?
- Does the activity maintain animal populations?
- Does the activity maintain critically needed plant populations, tissue cultures, bacteria, archaea, and other living organisms?
- Is the activity related to COVID-19, and does it have a timeline for deployment that could address the crisis?
- Does the activity support essential human subjects research?
- Is the activity a clinical trial that if discontinued would negatively impact the patient's care?
- Is the activity required to meet aims and goals of a funded grant or contract?
- Is the activity required to obtain data for an upcoming grant deadline?
- Is the activity required to meet delivery deadlines for a journal, press, or for a performance or exhibition?

Guidelines for On-Site Research and Scholarly Activities

Requests to conduct on-site activities must comply with both physical distancing and room capacity constraints. In opening our campus for more research, we must work together and strive to maximize the distance between each other at all times and everywhere. We must also minimize the time individuals spend together in an enclosed space.

The types of spaces needed to conduct research and scholarly activities vary widely among the different disciplines on our campus. Some guidance on conducting activities safely is provided below. We anticipate that you will identify examples and challenges relevant to your circumstances and research to which you will need to respond appropriately.

- All tasks that can be done remotely must continue to be carried out remotely. Examples include theoretical and computational work, manuscript preparation, analysis and interpretation of data and cultural products, grant and progress report preparation, non-face-to-face human subjects research, literature review, and creative work that can be safely carried out remotely.

Plans to restart must consider both the priority of the research tasks (see Prioritizing Research Facilities and Projects) and equity within and across projects. In developing schedules for use of space, consider the constraints and needs of all users in order to ensure equity. For example, those with caregiving responsibilities may only be able to come to campus at specific times. Proposed research personnel and schedules should take into account individual circumstances such as childcare, eldercare, other family care responsibilities, and ADA accommodations. Equity issues can also arise for those who need

accommodations. It could be, for example, that some staff might need more space in order to maintain their accommodations when physical distancing is being observed. Or the need for accommodations could restrict the types and timing of transportation available to staff with special transportation requirements.

- All face-to-face research meetings are prohibited from occurring on campus. These events must be conducted on-line.

- Follow guidelines in the section titled "Safety" above.

- If break rooms and lounges are open, coordinate with other research groups using the space to develop a schedule for staggered use (that meets distance and density requirements) and cleaning of common spaces such as breakrooms and lounge areas. Consider if rooms can re-purposed to allow greater distance among on-site staff.

- Casual visitors, such as researchers' friends and family members, are not permitted in university facilities.

- Suppliers (e.g., liquid He, N_2), service technicians or other delivery persons can come to campus by appointment and should be accompanied by a staff member when entering the building.

- Room occupancy must be reduced to ensure a minimum distance of 6 feet between individuals at all times. While the CDC recommends 6-foot physical distancing between individuals (~113 square feet/person), the maximum number of persons permitted per room is a function of the size of the room, the time individuals spend in the room, the activities conducted, as well as the air flow throughout the room. Thus, in Phase I the actual space per researcher sharing a room will need to be greater than 113 square feet. Steps to achieve this include limiting the number of people permitted in a facility at any one time, working in shifts, and scheduling shared facilities and equipment. Examples include:
    - Music practice rooms: Only one person per practice room. The room should remain empty between sessions in accordance with best practices and appropriate sanitization practices should be employed for shared instruments.
    - When a room has more than one occupant, all occupants should wear face coverings in keeping with campus guidelines.
    - Stagger shifts on alternating days and specific days of the week, and extend the time available for on-site activities beyond the normal 8-hour workday. However, **do not require prolonged work hours** for any one individual and provide time for cleaning crews to come into a building when significant numbers of staff in building are not present.
    - Consider foot traffic throughout rooms and buildings to minimize incidental contact.

- In some cases, working more closely than 6 feet may be necessary to conduct the activity safely (e.g., moving heavy equipment, using highly hazardous materials) and according to protocols.

All persons involved must wear appropriate PPE or face coverings. It is important to keep the time of contact between individuals as short as possible. Such activities may undergo additional review and restrictions by your Dean or the VCRGE.

- Incidental encounters with other people (e.g., passing in a hallway) are unavoidable, but should be reduced whenever possible, for example, by limiting the number of people sharing elevators and limiting the number of people in restrooms and other common areas. In general, minimize the number of people in the space at all times.

- Consider the potential movement of individuals throughout the building, the number of entrances and exits, and the number of restrooms in each floor. Consider how elevators can best be used while minimizing co-occupancy.

- Check bus schedules and campus parking restrictions in scheduling activities.

- Researchers proposing to conduct activities off-site must have permission from partners at the site for the work to be done at those sites and institute practices that control access to the site. The off-site activity must follow the campus density and duration guidelines that are the most stringent, unless expressly relaxed by the partner agencies.

- If the PI or other employees are traveling out of Dane County, they must obtain permission from the Dean or VCRGE (for VCRGE research centers). Guidance on travel through June 30 for research and scholarly activities can be found here: https://research.wisc.edu/uncategorized/2020/04/28/uw-madison-research-travel-guidance-in-response-to-covid-19/. If staff are traveling long distances, they should stop only for fuel and restroom breaks and sanitize hands before and after any such travel breaks.

- Graduate students and post-docs may participate in on-campus research consistent with these guidelines. Graduate students should consult as appropriate with their faculty supervisors or graduate program advisors before the research begins and throughout the research effort.

- During summer 2020, undergraduates can participate in on-campus research only if an exception is granted by the dean or VCRGE.

Face-to-face Human Subjects Research Restart Framework

This section presents a general framework for allowing resumption of IRB-approved face-to-face human subjects interactions for studies that provide the potential for direct and meaningful benefits to individual participants on or about **June 1, 2020**, at the earliest, while restarting remaining necessary face-to-face study interactions no earlier than **July 1, 2020**. These dates are tentative and subject to change. This document will refer to the two separate resumption dates as June 1 and July 1, 2020 as

the earliest possible dates for restarting face-to-face human subjects interactions. The actual dates may be later.

This framework is for schools, colleges, and centers to use in developing specific guidance for their study teams and for setting priorities in restart phases. Specific guidance and processes for individual study teams will be provided by the PI's school/college/center and research site.

Prioritizing the phase-in of IRB-approved research studies engaging in face-to-face human subjects interactions will be performed by department chairs, center directors, and deans, using the general framework presented here, and information provided by PIs. Authority for approvals will reside with deans (or VCRGE for its research centers.)

On March 15, 2020, a temporary hiatus was imposed on face-to-face (i.e., in-person) human subjects research interactions; that hiatus had an end date of June 30, 2020. Exceptions to the hiatus were therapeutic studies involving drugs or devices, or other research activities that are critical to the health and safety of patients or study participants. These studies continued using face-to-face interactions. Even for therapeutic studies, we recommended moving toward remote data collection methods to the extent possible (for instance, telephone or electronic methods for screening or follow-up). Human subjects research conducted online or using other remote data collection methodologies (email, mail, phone, etc.) continued.

To determine whether it is appropriate to restart particular IRB-approved in-person human subjects research interactions on June 1 or July 1, 2020 (at the earliest, provided public health conditions permit), department chairs, center directors, and deans will consider the risk/benefit ratio for the restart and determine the priority for individual projects in the re-start as described in this campus guidance. The particular authorizing official or body (such as use of a committee) will vary across administrative units across campus.

At any time after the restart, campus may revert to suspension of face-to-face human subjects interactions if events dictate the need to do so.

Human subjects research regulations are based on principles found in the Belmont Report.

- https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

- One of the three guiding principles is "beneficence;" specifically, that we must maximize possible benefits and minimize possible harms. Beneficence applies to particular research projects, but also applies in a larger sense to our entire research enterprise. With the COVID-19 situation, beneficence relates to how our institution and PIs are maximizing benefits and minimizing risks in face-to-face human subjects research interactions

Department chairs, center directors, and deans will prioritize the restart of IRB-approved treatment studies on **June 1, 2020** that have the potential of direct and meaningful benefits to individual study

participants relative to risks, including those imposed by possible COVID-19 exposure, and procedures in place to mitigate exposure to participants and study personnel.

Direct and meaningful benefit means that participation in the study has a good probability of having a direct benefit to the participant in a medical, psychological, social, or other dimension, and that these benefits outweigh the risk of COVID-19 exposure associated with in-person interactions.

- Studies without the potential of direct and meaningful benefit to individual study participants will have a target date for restart of face-to-face interactions on **July 1, 2020**. Steps for mitigation of risks due to COVID-19 must also be performed for these studies.
- Investigators should carefully consider their research, including the study population and study interventions and contact the IRB that originally reviewed their study protocol if there are changes in study-specific research activities since the hiatus in face-to-face human subjects research interactions was imposed on March 15, 2020.
- The risks of acquiring COVID-19 are not specifically a research risk; therefore, we do not believe at this time that it is necessary to require that all studies involving in-person interactions add risks related to COVID to their study or the consent document.
    i. Changes in research activities should be addressed both in updated consent forms and change of protocols
    ii. Study teams must provide subjects with information about what to expect during their face-to-face interaction, including screening, physical distancing, and measurements in place to minimize risks associated with the spread of COVID-19. These activities are not research specific activities and do not need to be submitted to the IRB for review.
        1. Some studies may have more perceived risk than others. For example, studies involving exercise equipment, MRI procedures, more than one simultaneous participant engaging in data collection, or use of manipulatives do not necessarily increase risk, yet participants may have a concern about possible surface contamination.
        2. It may be appropriate to discuss risks of acquiring COVID-19 with certain research participants, such as those in higher risk categories.

Restarting face-to-face human subjects research interactions is phased. It is expected that studies will adhere to the guidelines described below.

- All research tasks that can be performed remotely should continue to be performed remotely, even after the phase-in start date.

- No face-to-face group meetings should be held, even after the phase-in start date. Study team meetings should be held using technology-assisted methods such as Teams, WebEx, or other methods.

- All public health best practices must be used in face-to-face human subjects research interactions. These practices include physical distancing, frequent hand washing, staggered work schedules for employees, minimum necessary staff on site, use of cloth face coverings for both staff and participants, use of PPE when indicated, use of gloves, clear procedures for sanitizing, and other measures.
    - Please see https://covid19.wisc.edu for current public health best practices.
    - If appropriate, study teams should consider the use of screening questions based on COVID-19 symptoms prior to scheduling a study participant, such as those recommended by UW Health for patient care purposes. Please see https://coronavirus.uwhealth.org/symptoms-and-care/
    - Plans for monitoring staff health and safety should be developed.
    - Use of electronic consenting and recordkeeping can be a means of minimizing use of paper that can potentially become contaminated. Electronic devices will be sanitized after each use. Please see:
      Obtaining Informed Consent from COVID-19 Positive Patients and
      Documenting Consent Electronically or for Remote Subjects Guidance

All procedures for face-to-face human subjects research interactions, including re-start dates, are subject to rules, policies, standard operating procedures, and other restrictions found in particular research settings on and off campus.

Framework for research in non-healthcare sites:

- Use the same process for approval as other laboratory research. Use public health best practices (see above).
    - Other guidelines for human subjects laboratories may be implemented, according to changes in public health best practices.
    - June 1, 2020 is an estimated earliest start date for treatment studies that offer potential for direct and meaningful benefits to individual participants and are able to minimize risk (see above).
    - July 1, 2020 is the estimated earliest start date for all other studies using risk mitigation steps described in this document.

Framework for research in health care sites:

- June 1, 2020 is an estimated earliest start date for treatment studies that offer potential for direct and meaningful benefits to individual participants and are able to minimize risk (see above), especially those risks of working with particular high-risk populations.
- PPE should be procured by emailing needs to: EOC_PPE_Supplies@lists.wisc.edu
- UW Health facilities have the following considerations:
    - PPE found at UW-Health facilities are for clinical care use. PPE for research use should be procured as noted above.
        a. Department chairs, center directors, or deans will provide this information to study teams.

        b. Study teams should comply with PPE training requirements for particular research sites.
    - Infection Control considerations require limiting the presence of research staff in clinical areas; therefore, any activity that can be done remotely, must be done remotely.
        a. Infection control measures are determined by research sites.
    - Many of the ancillary support departments in UW Health (Pharmaceutical Research Center/Lab/Imaging) are on reduced staffing through the first week in July, so there will need to be consideration on whether there is capacity to provide support to research. These departments would not have capacity to open ***new studies*** to enrollment until the June 30, 2020 time frame.
- July 1, 2020 is the estimated earliest start date for all other studies using risk mitigation steps described in this document (see above).

As IRB-approved studies restart, population density within and the flow of traffic through facilities should be considered to ensure availability of adequate space for appropriate physical distancing.

- The same guidelines used for laboratory research will apply to human subjects research interactions.
- Communication with building managers about study needs, times and durations of room use, sanitation practices, ingress and egress, and best routes for participant access must be maintained.

Moving Forward for All Research

Progress toward the Phase 1 goal of establishing best practices for carrying out research while maintaining physical distancing will permit successive phases and increased levels of research that can be approved and safely carried out on campus.

Researchers should also be aware that during Phase 1, many normal campus operations will be limited. Reduced Madison Metro bus availability and changes in campus parking policy are expected during this time [https://transportation.wisc.edu]. Buildings will continue to be locked with access by card key, and on campus food service will be limited. Campus childcare centers are expected to resume operations during the summer, after the beginning of Phase 1. Campus operations will increase over time as the ability to manage the spread of COVID-19 improves, but in the meantime, research PIs are asked to be sensitive to the challenges their group members may be facing and accommodating as they work to adapt to this new campus environment.

Proposed research personnel and schedules should take into account individual circumstances such as childcare, eldercare, other family care responsibilities, and ADA accommodations.

Be aware that in the future there may be a need to pause, scale back, or wind down on-campus research and scholarly activities in response to new information about COVID-19, new outbreaks, or changes in the capacity of our communities to respond. Therefore, approved on-site activities should

also have in place a plan for the orderly reduction or cessation of on-campus activity on a temporary or long-term basis.

Campus leadership expects that all on-site activities will fully comply with these guidelines and any additional requirements provided by Colleges, Schools, and Centers. These guidelines seek to protect the health of our colleagues and our broader communities. PIs are responsible for compliance with these guidelines by their teams. Willful or repeated noncompliance can lead to termination of the privilege to carry out on-site research and scholarly activities.

These guidelines will be reviewed regularly to respond to changing conditions and new information about the spread of COVID-19. Individuals will be advised of any significant changes.