UMSON Application to Resume/Initiate In-Person Contact Human Subjects Research

(and Non-Human Subjects Research Projects that Involve Participant Contact)

3-1-21

Contents

Introduction/Background

This application was developed by the University of Maryland School of Nursing (UMSON) Organized Research Center Directors and Office of Research and Scholarship to assist SON researchers with the process of resuming Human Subjects Research and Non-Human Subjects Research (NHSR) projects that involve in person interaction with participants. This application does not apply to research and NHSR projects conducted without in-person contact or DNP projects. It is intended to complement the UMB 6/23/2020 Guidelines for Phased Resumption of Research (https://www.umaryland.edu/hrp/). This document also includes updated guidance related to adding students to the research team.

UMSON Guiding Principles

The following is a set of guiding principles for resuming in-person human subjects and not human subjects research for UMSON researchers:

1. Follow all applicable local, state and national directives regarding required safety measures that must be taken during the COVID-19 pandemic and check frequently for updated guidance.

2. Limit close physical interactions for research staff and participants involved in human subjects research to the minimum necessary for the research visit. Only one participant per researcher is allowed unless a second study team member is justified (i.e. bio-specimen collection).
3. PhD students are encouraged to design their studies to use non-contact, remote data collection.

4. Human subjects research with a direct benefit to the participant must meet one of the following requirements:
   a. The approved IRB protocol specifies that there is a benefit to the participants enrolled in the current study;
   b. The researcher must justify how the currently enrolled subjects will obtain a direct benefit from participating in the study

5. Researchers must prioritize their studies in terms of restart within each phase. Only one study per Principal Investigator (PI) will be evaluated at a time. A period of 2 weeks should elapse between submission of successive protocols.

6. Prioritization for human subjects research studies in areas with limited space shall be evaluated as follows:
   a. Collection of preliminary data in support of a faculty member's first R-level or R-equivalent grant submission;
   b. PhD students in the dissertation phase and post-doctoral trainees; NIH funded R-level or federally/foundation funded R-equivalent studies in no-cost extensions;
   c. NIH funded R-level or federally/foundation funded R-equivalent studies;
   d. MPower or other campus internally funded studies; and
   e. Studies not included above.

7. The least (minimal) number of research staff should be in the space where the research is being conducted at any given time, to minimize unnecessary risk. Justification and rationale for the number of staff planned for each participant visit must be provided and cannot include matters of convenience.

8. Student research team members are encouraged to conduct human subjects research that minimizes their personal risk and receive guidance and consultation from their faculty advisor.

9. Research staff who are in a COVID-19 vulnerable group, feel uncomfortable to return to face-to-face work, or have family issues that would preclude a return to human subjects research should contact the UMSON Human Resources Department to arrange suitable accommodation.

10. Students are permitted to participate as research team members in human subjects research that requires contact with research participants so long as the research does not include contact with individuals with COVID-19 symptoms, who are COVID-19 positive, or persons under investigation for COVID-19. The following criteria must also be met:
    a. UMSON Resumption committee must first review and approve the resumption plan inclusive of student research staff participation details. The plan must include an amendment of their protocols/CICERO application to indicate inclusion of students and any revisions to procedures, space utilization, and all other aspects of the research affected by the change.
    b. Students must be provided with the opportunity to opt out of participation and may not be penalized or delayed in their educational programs for opting not to participate in research-required direct contact.
    c. The study must be approved for research resumption by the UMB Institutional Review Board/Human Research Protections Office (IRB/HRPO) prior to student research staff involvement.

UMSON Process of Applying to Resume Human Subjects Research

(See also UMB Guidance)

1) If there are any changes in personnel or procedures that has been approved by the process of UMSON research Resumption, the PI must submit an addendum (appendix B of this document) to the UMSON research resumption committee for review. Once approved, the PI may submit their modification and additional RNI to the IRB and be approved prior to implementing the changes.

2) PI (on CICERO application) must complete the:
   1) UMSON Research Information Form,
   2) Study Plan,
   3) UMB Checklist for Resuming HSR form, and
   4) UMB Campus Operations Proposal Assessment Questions for COVID-19 Recovery Task Force Teams

   Note: Many of the questions on the *UMB Checklist for Resuming Human Research* and the *Campus Operations Proposal Assessment Questions for COVID-19 Recovery Task Force Teams* will not apply exactly to many research projects that are conducted in non-clinical context or off campus. You may modify the forms as needed or indicate not applicable (N/A). Be sure to cover the relevant portions in your plan. You may reference your plan in providing answers to the UMB Checklist and the Campus Operations Proposal. For questions regarding completion of these forms or your plan, please contact Dr. Julie Doherty at jdoherty@umaryland.edu.

3) Submit completed packets to the UMSON Research Resumption Committee (DL-NRSResearchResumptionCommittee@umaryland.edu) for review. The UMSON committee includes: Associate Dean for Research, Center Directors, and the Research Quality Manager. Reviews occur weekly on Wednesdays. Applications are due Friday by noon for review on the following Wednesday.

After UMSON approval, the PI must submit this approved packet as a Reportable New Information (RNI) submission through CICERO to the UMB HRPO/IRB. Once the UMB HRPO/IRB acknowledges the RNI., in person research can resume. If the research requires the presence of research staff or participants on the UMB campus, appropriate access forms must be completed prior to the presence of research staff or participants on campus.

4) If the research requires access to a UMB campus building, appropriate building access forms must be submitted for the UMB research staff and participant at each visit. Forms must be submitted 48 hours prior to the campus visit. Research staff who will be conducting research in the UMSON building should complete the UMSON building access form. If research participants will be in the UMSON building, the PI or PI's designee must submit the UMSON building access forms for participants /visitors. If research participants will be in other campus buildings, the PI or PI's designee must submit the UMB building access form. The UMSON building access form (UMB research staff), the UMSON building access form (participants/visitors), and the UMB Building Access Request Form are all available on the SON COVID webpage under "Information for Researchers".

Note that circumstances may change, so it is possible that campus may change guidance as the COVID-19 pandemic continues.

In-person research must not resume until the UMB HRPO/IRB acknowledges the RNI.

*For NHSR Research Projects that Involve Participant Direct Contact, submission of the RNI is not necessary, and research can resume after UMSON approval.

UMSON Research Information Form

Human Subjects Research Study or NHSR Project - with Participant Contact

(For questions about this form, please contact DL-NRSResearchResumptionCommittee@umaryland.edu)

1. Date submitted to UMSON:_____
2. Version (check box): ☐ original/revision 1 ☐ /revision 2 ☐/other:_____
3. Name of PI: _____
4. Phone Number: _____
5. Email Address:_____
6. CICERO protocol number: HP-_____
7. Name of Study:

8. Does this study involve international sites? ☐Yes* ☐ No
*If yes, provide information about location and local regulations

9. Does study require entry into UMB facilities for study participants or study staff? ☐Yes ☐ No

10. Study Staff (on approved CICERO application who will have in person contact)

Name	Type: student, staff, trainee, faculty	**A)** In person contact >6 ft **or** B) No in person contact	In person contact <6 ft (Y/N)	In person contact + aerosolizing procedure or biospecimen (Y/N)	Enrolled in SAFE (Y/N)	Completed COVID-19 Research Safety Training (Y/N)

***Please note all study staff must follow the most current COVID-19 testing requirements and produce a negative result prior to in-person project engagement. Antibody tests do not count.

11. Type of location where study occurs (check all that apply)
☐ UMB campus
☐ UMMC building
☐ UMB/UMMC affiliate
☐ Participant home
☐ Public Location

☐ Community Facility
☐ Other Health Care Facility
☐ VA
☐ Outdoors
☐ Other (describe)_____

12. Names /addresses for locations of study (campus and other sites):

Facility	Address	Room	Contact Person Name/Email/Phone

13. Do any of the locations include a high risk community (e.g., senior center)? ☐Yes ☐ No
Does the study target at risk population(s) in terms of staging (e.g., immune suppressed)? ☐Yes ☐ No
Click here for CDC website for high risk populations

14. Which high risk population is targeted? _____

15. Are participants recruited because they have COVID-19 or recently had COVID-19? ☐Yes ☐ No

16. Types of human participants in the study (check all that apply):
☐ Inpatients
☐ Outpatients
☐ Community members without COVID-19 symptoms
☐ Community members with COVID-19 symptoms or COVID-19 positive
☐ Vulnerable populations without COVID-19 symptoms
☐ "Healthy controls" without COVID-19 symptoms
☐ Other (specify): _____

17. Category:
☐ A. Human subjects research that can be performed remotely or research during routine clinical care that does not increase risk to participant, clinician, or personnel
☐ B. Human subjects research with the potential for direct benefit to participants in this study
☐ C. Research with no potential for direct benefit to participants in this study
☐ D. Community based human subjects research in high risk facilities
☐ E. Other (if not addressed, please state reason) _____

18. Level of risk of study to study/project participants (IRB criteria):
☐ A. Minimal risk (The probability of harm/discomfort anticipated in this project are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination/tests.)
☐ B. Greater than minimal risk
☐ C. Compassionate use

19. Current UMB Research Phase (Phase 0, Stage 1, Stage 2, Stage 3): _____

20. Justification of why study should be permitted under this phase based on categories of research, risk level, and population being studied.

21. Documentation (e-mail or letter) that site agrees to allow study to resume/occur. For nursing research at the UMMC, approval of the appropriate director is required. See Appendix D for contact list.

22. Statement of any additional requirements by site.

23. Please describe any device(s) used in the study that will touch participants, including information around length of contact time (<6') involved. Also, include details on general use and cleaning procedures.

24. What is your estimate of the PPE required for this study? Please attach the form you submitted for this study. If there are changes since then, please complete the table below. Assume that you will need to bring your own PPE to all sites. This will also include PPE for participants.

Type	Quantity/Sizes	# (per month)/Duration
Surgical Mask		
N95 Masks	(not available except pt. care)	(not available except pt. care)
Face Shields		
Disposable Gowns		
Gloves (Non-Latex)		
Thermometers		
Other:		
Other:		

25. If your study is not in a clinical site, what is your estimate of the disinfectant required for this study? Please assume that you will need to bring your own cleaning supplies to all sites. Check with clinical sites about availability of cleaners and your use of them.

Type	Quantity/Sizes	# (per month)/Duration
Surface Cleaner Spray		
Surface Wipes		
Hand Sanitizer		
Microfiber Towels		
Other:		
Other:		

UMSON Study Plan for Resuming or Initiating In-Person Contact Human Subjects Research

(Submit as a word document attachment)

The required elements of plans for resuming human subjects research are as follows:

A. Short summary of purpose and procedures of study (3-5 sentences)

B. Plan to minimize disruption of patient care

C. Plan for conducting study activities/procedures to minimize contact between individuals (participants, staff, others)

D. Plan for use of facilities to minimize contact between individuals (participants, staff, others), including detailed location/description of facilities

E. Plan for screening for COVID-19 (participants, staff, others)

F. Plan for action if positive screening (participants, staff, others)

G. Plan for PPE use to maintain safety (participants, staff, others)

H. Plan for maintaining cleanliness of facilities and equipment. Provide detailed information around space (such as room dimensions), overall procedures, and cleaning procedures.

I. Plan for training for study personnel related to COVID-19 guidance/precautions

J. If the research requires access to UMSON building or another UMB building (excludes UMMC), provide plan for campus visits, including visitor classification and actions required for that classification

K. If you are conducting research at facility that has a plan for COVID -19 operations, please attach or include the plan.

UMSON Expectations to reference when developing plan (please include portions as appropriate to this study in your plan).

1) SON Research Staff and Participant Expectations

- Study staff must complete SAFE (Campus REDCap monitoring system used by UMB) if they will be doing research on campus. If you are unable to use SAFE, please utilize the *COVID-19 Symptom Screening Forms* (see Appendix A & B) until you are able to get access to SAFE (all research staff should be enrolled in SAFE).
- Study staff must adhere to the UMB mandatory COVID-19 testing requirements.
- If the study staff's SAFE or COVID-19 Symptom Screening Forms answers indicate potential COVID-19 positive: notify PI, COVID -19 hotline (800-701-9863), and Employee Health Services or Castlebranch (student research team members).
- All participants, escorts, and other individuals (non-UMB/UMMS employees/students) involved in the research visit will adhere to the appropriate UMB COVID-19 Visitor's Guidance and recommendations.
- If the research requires access to a UMB campus building, appropriate building access forms must be submitted for the UMB research staff and participant for each visit. Forms must be submitted 48 hours prior to the campus visit. UMB research staff who will be conducting research in the UMSON building should complete the UMSON building access form. UMB research staff who will be conducting research in any other UMB campus building should complete the UMB building access form. If research participants will be in the UMSON building, the PI or PI's designee must submit the UMSON building access forms for participants /visitors. If research participants will be in other campus buildings, the PI or PI's designee must submit the UMB building access form. The UMSON building access form (employees/students), the UMSON building access form

(participants/visitors), and the UMB Building Access Request Form are all available on the SON COVID webpage under "Information for Researchers".

- All participants, escorts, and other individuals (non-UMB/UMMS employees/students) involved in the research visit will be pre-screened for COVID-19 within 24 hours of study visit (See *Day before Visit COVID-19 Symptom Screening Form* in Appendix A). These individuals may not participate in research if COVID-19 is suspected.
- If participant's answers during screening indicate possible COVID-19, notify PI and refer participant to seek advice from their health care provider.
- Temperature of participant, medically required escort (if needed), and study staff will be checked upon arrival at study site (See *Day of Visit COVID-19 Symptom Screening Form* in Appendix A). Research visit must be canceled if temperature above 100^{0}F is recorded.
- Statement that the PI will encourage all active members of the research team to receive a Flu vaccine upon availability prior to or during flu season.
- Communicate with all members of the research team on the use of the UMB Hotline (800-701-9863) for reporting safety concerns.

2) Patient Care Expectations

Ensure that research staff/activities will not disrupt patient care. For example, if staff enters a room to provide patient care, leave and resume research after patient care finishes. Assess and describe the physical facilities and infrastructure necessary to resume human subjects research while maintaining physical distancing and other infection mitigation activities (include any special accommodations that will be needed). For research that requires access to UMB facilities, use the *Campus Operations Proposal Assessment Questions for COVID-19 Recovery Task Force Teams* form. For research at other sites, please provide similar information.

3) Location Description and Risk Minimization Expectations

- Describe purpose of site access, rationale for in-person contact, duration of site attendance per day, frequency (# days per week) of site attendance
- Description of location where there will be in-person contact (density, number of people present at a time, description of space (i.e. size of room)) and plan for minimizing contact/social distancing.
- Identify the social density of research staff, participants and medically required escorts that is anticipated upon resumption of research activities, plan for scheduling and staffing to minimize social density while maintaining adequate supervision and safe practices in the course of research.
- Identify essential personnel for conducting research activities, including any persons who may have contact with participants
- Require all individuals who may have contact with participants to complete COVID-19 research safety training. Employees can access it at COVID-19 Research Safety Training. If you are a Non-UMB Employee (affiliate), you can access UMB COVID-19 Training here. PLEASE NOTE: This link is NOT for UMB Student Access. Students will need to access the course through Blackboard.
- Require all individuals to read and be aware of UMB's COVID-19 hotline information (https://www.umaryland.edu/coronavirus/hotline/). Note the current phone number for UMB (non-UMMC) employees is: 800-701-9863.
- Determine actions for responding to potential COVID-19 infection in research staff, participants, and required escorts, including communication plan for providing notice to anyone in contact with potential or actual infected persons.

☐ **If a UMB research staff member is found to have COVID-19, has indications of possible COVID, or is exposed to an infected individual, the incident must be reported to the UMB COVID- 19 Hotline (800-701-9863).** If a COVID-19 test is recommended suggest that the individual go to University Immediate Care ((667) 214-1899) 408 W. Lombard Street) which has walk in testing and is less crowded. If a research staff member has

signs indicating possible COVID-19 they are excluded from campus and off campus research sites for 7 days. Student research staff will need to be cleared by the UMB COVID-19 hotline or in writing by student health prior to returning to the research site. If a participant's responses indicate potential COVID-19 refer them to their own primary health care provider for evaluation and reschedule at least 7 days after date of screening.

4) PPE and Cleaning Expectations:

- Plan for appropriate and frequent disinfection and cleaning of spaces and equipment, including shared spaces that are accessed by participants and research staff (include additional disinfection and decontamination procedures for areas which were occupied by persons who test/tested positive for COVID-19). For information in preparing this see: https://www.umaryland.edu/coronavirus/testing-hygiene-and- health/
- Identify and catalog Personal Protective Equipment (PPE) needs for research staff, participants, and required escorts for resuming and continuing research for the duration of the study. (Refer to the *Personal Protective Equipment PPE form*)
- Provide training to all research staff on the appropriate use of PPE and safety precautions (UMB COVID-19 Research Safety Website)

UMB Checklist for Resuming Human Research

The following checklist outlines actions to consider for resuming human research. This checklist is meant as guidance for assessing safety for clinical studies and sites. When working at non-UMB clinical sites, safety procedures for the host site should be followed. Concerns that the host site does not have adequate safety procedures in place should be reported to the clinical site leader. Some items may not apply to every clinical site. Check N/A, or customize this form, as needed. Feel free to refer to your plan sections as appropriate in the notes column (i.e. "see plan section B", etc.).

HUMAN RESEARCH OPERATIONS

ITEM	COMPLETE	N/A	NOTES
Develop a work schedule to minimize onsite personnel.	☐	☐	
Enroll all study personnel (except students) in SAFE screening tool	☐	☐	SAFE screening tool links: https://www.umaryland.edu/coronavirus/safe-on-campus/ https://safe.umaryland.edu/surveys/?s=SmoEyKgBww
Confirm that student research team members are enrolled in Castlebranch	☐	☐	
Plan to maintain physical distancing according to current UMB guidelines whenever possible and promote use of face coverings when physical distancing cannot be maintained.	☐	☐	See UMSON Research Information Form
Ensure you have sufficient Personal Protective Equipment (PPE) supplies to conduct research safely. Take inventory and order well in advance.	☐	☐	See PPE form (Appendix B)
Cross-train research staff to fill in for others who may be sick or unable to come to work.	☐	☐	
Develop a plan for cleaning and disinfection of high-touch surfaces within the clinic and ensure supplies are available.	☐	☐	How to Clean and Disinfect Your Research Space: https://www.umaryland.edu/coronavirus/content/testing- hygiene-and- health/researchers-safety-plan.php

ITEM	COMPLETE	N/A	NOTES
Routinely back up critical research data.	☐	☐	
Make a plan for the sudden cessation of operations, such as in the event of COVID-19 infections of human research staff or participants.	☐	☐	

CLINICAL FACILTIES

ITEM	COMPLETE	N/A	NOTES
Secure approval from EACH research site(s) for resumption of research activities (e.g., UMB, UMMS, FPI). UMMC requires department director approval.	☐	☐	UMMC Contacts to request approval (See Appendix D)
Waiting and clinical areas have been reconfigured to promote physical distancing (see EHS Guidelines).	☐	☐	
Physical distancing signage in place.	☐	☐	COVID-19 Digital Signage Toolbox: https://www.umaryland.edu/corona virus/testing-hygiene-and-health/signage/#d.en.478 931
Adequate alcohol-based (60% or more) hand sanitizers are available.	☐	☐	Disinfectants (Selected EPA-Registered Disinfectants): https://www.epa.gov/pest icide-registration/selected-epa-registered-disinfectants
Plexiglass or clear barriers are installed between reception and waiting areas.	☐	☐	

ITEM	COMPLETE	N/A	NOTES
Protocols are in place for custodial service cleaning.	☐	☐	How Buildings Are Cleaned and Disinfected: https://www.umaryland.edu/coronavirus/testing-hygiene-and-health/
Adequate IT is available for telemedicine visits.	☐	☐	

PARTICIPANT MANAGEMENT

ITEM	COMPLETE	N/A	NOTES
Participants advised to make appointments online or call before arrival.	☐	☐	See Appendix A
Measures are in place to limit participant contact with computers, keyboards, or other equipment.	☐	☐	
Measures are in place to promote continued use of telemedicine.	☐	☐	
Protocols are in place to promote online or telephone participant check-in.	☐	☐	See Appendix A
Updated screening protocols are in place for COVID-19 symptoms.	☐	☐	
Communication plan for informing participants of any potential contact with suspected COVID-19 infected person(s).	☐	☐	
Protocols are in place for managing participants with acute respiratory symptoms.	☐	☐	

ITEM	COMPLETE	N/A	NOTES
Protocols in place to limit the use of nebulizers.	☐	☐	
Requirements for the use of facemasks and other PPE are in place.	☐	☐	
Procedures are in place to prohibit visitors, children, or guests	☐	☐	Please note that patients within the hospital are not considered visitors. Caregivers follow hospital visitor's policy.
Protocols are in place for transporting participants with respiratory symptoms to home or to the local hospital.	☐	☐	Note caregivers would follow hospital visitor's policy.
Communication messages have been developed and implemented to inform participants on scheduling appointments and which visits should be in person or virtual.	☐	☐	

COMMUNICATIONS

ITEM	COMPLETE	N/A	NOTES
Personnel are subscribed to receive UMB alerts.	☐	☐	
Communication plan for informing research personnel or other exposed persons of any potential contact with suspected COVID-19- infected person(s).	☐	☐	
Communicate with all involved persons the availability of the UMB Hotline for reporting safety or other non-compliance concerns.	☐	☐	800-701-9863
COVID-19 procedures applicable to the clinical site have been reviewed with all members of the team.	☐	☐	

ITEM	COMPLETE	N/A	NOTES
List of critical contacts has been complied and provided to all team members.	☐	☐	
Expectations and roles have been communicated to all personnel to avoid potential confusion and conflicts.	☐	☐	
Personnel have access to materials and resources that may be needed to work from home.	☐	☐	
Meetings have been transitioned to remote formats, such as Zoom, Webex, or Microsoft Teams whenever possible.	☐	☐	Zoom: https://www.umaryland.edu/cits/service s/zoom/ Webex: https://www.umaryland.edu/cits/service s/webex/ Microsoft Teams: https://www.umaryland.edu/office365/t eams/

CLINICAL SUPPLIES

ITEM	COMPLETE	N/A	NOTES
Ongoing inventory plan for clinical materials, particularly those that are controlled, high value, and/or high risk is in place.	☐	☐	
As possible, a plan to maintain backup stocks of materials (e.g., cell lines) to ensure any disruption to operations does not result in their loss is in place.	☐	☐	

SECURITY

ITEM	COMPLETE	N/A	NOTES
Personnel have been provided the following contact information: • Emergency – 911 • UMB Police Non-Emergency and Safe Walk/Safe Ride – 410-706-6882 • EHS – 410-706-7055 • UMB COVID Hotline – 800-701-9863	☐	☐	
System for monitoring for life-threatening emergencies is in place (due to fewer people in the workplace, life-threatening emergencies may go undetected, consider implementing a "text- in/text-out" or similar system).	☐	☐	
Guidance to all personnel to properly store valuables (e.g., laptops are out of sight and in locked drawers) has been provided.	☐	☐	
Clinical doors will be locked at the end of each day.	☐	☐	
Ensure windows are closed, if applicable.	☐	☐	
Guidance to all personnel to take needed personal belongings home at the end of each day has been provided.	☐	☐	

ENERGY REDUCTION

ITEM	COMPLETE	N/A	NOTES
Any non-essential equipment will be unplugged when not in use, even if it is turned off.	☐	☐	
Fume hoods will be closed when not in use and at the end of each day.	☐	☐	
Lights will be turned off when personnel leave.	☐	☐	
In UMB facilities, plans to avoid working 7 p.m.-7 a.m. are in place (most UMB buildings are on energy setbacks during this time and non- research buildings are also on energy setbacks on weekends and holidays).	☐	☐	

Campus Operations Proposal Assessment Questions for COVID-19 Recovery Task Force Teams

Feel free to refer to your plan sections as appropriate in the notes column (i.e. "see plan section B", etc.).

Current State w/Operational Questions	Need Being Requested
Location – Please provide building and floor, PI name if applicable (address).	See UMSON Research Information Form
Hours and days of operations requested; please be detailed, including needs for weekend support.	
Purpose – What will you be doing in the space requested (laboratory research, experiential teaching/learning, etc.).	
Parking/Transportation needs? (24-hour access available in Pratt, Grand, Plaza, and Lexington garages). Consider who may need access to garages and which garages you would like to access (e.g., re-assignment may be required). Consider whether existing parking access to requested garages is already in place.	
Utility Needs – Detailed list of HVAC, water, electricity needs by location (floor, room, etc.). Please consider laboratory equipment, lunch room use, etc. Goes toward energy reduction plans currently in place and which may need to be altered.	
Custodial Services – What custodial needs are you requesting – e.g., trash bag disposal, cleaning common rooms (bathroom, lunch rooms)? Current hours of operation are Monday-Friday, 7 a.m.-3:30 p.m. (EVS cleans by Work Order request. For labs, only after EHS decontaminates lab and clears it for EVS cleaning.) Please identify if the needs apply to laboratory, office, or common spaces. Two-week lead time for deep cleaning of space is required.	
Public Safety – Security Officers will be present during open hours; current operations support 8 a.m.-4:30 p.m. Please outline additional weekly and/or weekend needs, if necessary.	

Other Comments:

UMSON Committee Review Sheet

(To be completed by SON Research Resumption Reviewers)

Principal Investigator_____**Date/Time Completed**_____
Study Title_____
Version (check box): ☐ **original** ☐ **revision 1** ☐ **revision 2** ☐ **modification** ☐ **other:**_____
Approval Date: _____ **Prior Approval Date:** _____
CICERO Protocol#: HP-_____

1. Committee Discussion Date: _____

Comments/Changes Requested:

Committee Decision:

2. Committee Discussion Date: _____

Comments/Changes Requested:

Committee Decision:

3. Committee Discussion Date: _____

Comments/Changes Modification Requested:

Committee Decision on Modification Requested:

Appendix

UMSON COVID-19 Symptom Screening Form
(Day before visit)

Study # HP-_____
PI_____Date/Time Completed_____Screener_____
Please check: ☐ Participant ☐ Participant Escort
☐ Research Staff_____
Contact Phone Number_____Email Address_____

Please select Yes for any of these symptoms you have had in the last 24 hours, unless they are symptoms of another condition not related to COVID-19, which has been evaluated and confirmed unrelated.

If any answer is yes, please re-schedule and refer as per study plan. If a staff member is completing this form for themselves, send completed form to the PI prior to visit.

☐ YES	☐ NO	Fever (defined as ≥ 100F or ≥ 38C) or feeling feverish
☐ YES	☐ NO	Chills
☐ YES	☐ NO	Cough
☐ YES	☐ NO	Trouble Breathing
☐ YES	☐ NO	Sore Throat
☐ YES	☐ NO	Decreased sense of taste
☐ YES	☐ NO	Decreased sense of smell
☐ YES	☐ NO	Nausea
☐ YES	☐ NO	Vomiting
☐ YES	☐ NO	Diarrhea
☐ YES	☐ NO	Muscle or body aches
☐ YES	☐ NO	Headache
☐ YES	☐ NO	Congestion or runny nose
☐ YES	☐ NO	Other (Please do not include symptoms with other explanations)
☐ YES	☐ NO	Have you been in close unprotected contact with anyone sick with COVID-19 in the past two-week period (and have NOT already reported)? This includes household or intimate contact, and encounters without face mask protection, lasting more than 15 minutes at less than 6 feet apart
☐ YES	☐ NO	Are you under current quarantine or isolation recommendations by any health professional (and have NOT already reported)?
☐ YES	☐ NO	Have you returned from multiple days of travel outside the state of Maryland (and have NOT already reported) (Please do not include regular commuting out-of-state or day trips.)

UMSON COVID-19 Symptom Screening Form (Day of visit)

Study # HP-_____
PI_____Date/Time Completed_____Screener_____

Location of site entry:_____ Date/Time: _____

Temperature:_____*If temperature is above 100⁰F, reschedule and refer as per study plan*

Action taken: _____

Signature: _____

UMSON RESUMPTION PLAN ADDENDUM FORM

Principal Investigator (PI)_____Date submitted to UMSON_____
PI Email Address_____
Study Title_____
Version (check box):☐revision 1 ☐revision 2 ☐modification ☐other:_____
Approval Date:_____ Prior Approval Date:_____
CICERO Protocol#: HP-_____

Please provide your originally approved study plan with revisions in tracked changes pertaining to the addendum (increase in in-contact procedures, increase in study staff, change in contact location, etc.), as well as the updated Research Information Form.

Should your addendum include student researchers, describe in detail the inclusion of students and any revisions to procedures, space utilization, and all other aspects of the research affected by the change. State your awareness that students must be provided with the opportunity to opt out of participation and may not be penalized or delayed in their educational programs for opting not to participate in research-required direct contact.

UMSON PERSONAL PROTECTIVE EQUIPMENT (PPE) and CLEANING SUPPLIES

(Please complete a separate form for each study that includes in person contact with a study participant in any location)

Please send completed forms to DL-NRSResearchResumptionCommittee@umaryland.edu

PI: _____
Study ID: HP- _____
Grant Funded? Yes/No Grant agency/ number/ name

In completing the information below, please consider needs of staff and participants (and medically required escorts as needed) during both recruitment and study participation

1. What is your estimate of the PPE required for this study? Please assume that you will need to bring your own PPE to all research sites. This will also include PPE for participants.

Type	Quantity/Sizes	One time or # (per month)/Duration
Surgical Mask		
N95 Masks	(not available except pt. care)	(not available except pt. care)
Face Shields		
Disposable Gowns		
Gloves (Non-Latex)		
Thermometers		
Other:		
Other:		
Other:		
Other:		

2. If your study is not in a clinical site, what is your estimate of the disinfectant required for this study? Please assume that you will need to bring your own cleaning supplies to all sites. Check with clinical sites about availability of cleaners and your use of them.

Type	Quantity/Sizes	One time or # (per month)/Duration
Surface Cleaner Spray (Bleach based)		
Surface Wipes (Bleach based)		
Hand Sanitizer		
Alcohol-based Equipment Wipes		
Microfiber Towels		
Hand Wipes		
Other:		
Other:		
Other:		

Identify and catalog Personal Protective Equipment (PPE) needs for research personnel, participants, and required escorts for resuming and continuing research for the duration of the study.

We expect that face shields will be sanitized and reused. We also expect that participants and personnel will arrive and leave wearing their own cloth masks,

We anticipate that the UMSON will purchase PPE in bulk from BIORESCO and charge costs back to

departments, grants, or ORS as appropriate.

NOTE: It may take several weeks for supplies to arrive. Be sure you have supplies in hand before resuming research activities.

UMSON PPE Expectations
For individuals pre-screened negative for COVID-19 (if study with COVID-19 separate guidance)

Study Personnel and required escorts if personnel -
Greater than 6 ft from participants at all times: cloth masks
Less than 6 ft from participants at ANY time: face shield and surgical mask
Less than 6 ft from participants at ANY time and aerosolizing activities: face shield, surgical mask plus gloves and disposable gowns during aerosolizing activities

Study Participants and required escorts if not personnel -
Greater than 6 ft from study personnel at all times: cloth masks
Less than 6 ft from study personnel at ANY time: surgical mask
Plan for rescheduling if inadequate PPE

For COVID-19 Positive Participants:
Personnel/Participants, if in health care setting, adhere to practices of that setting; researchers may be required to provide PPE, check with the site and indicate needs in the plan

If not in a health care or clinical research setting, limit time within 6 feet to minimum for essential activities, Face Shield, cloth mask,

If not in a health care or clinical research setting, with aerosolizing procedures
Face Shield, surgical mask, disposable gown, and gloves required

Note special guidance for studies that involve exercise and use of masks.

UMB Expectations for Cleaning Spaces
https://www.umaryland.edu/coronavirus/content/testing-hygiene-and-health/researchers-safety-plan.php

UMMC Nursing Director Contact List

Midtown Campus (MTC)		
Ambulatory Clinics	Julie Kubiak, Director	julie.kubiak@umm.edu
Inpatient	Tonja Marell-Bell, Director	tonjabell@umm.edu
Perioperative/Procedural Services	Wanda Walker-Hodges, Director	wandawalkerhodges@umm.edu
Downtown Campus (DTC)		
Ambulatory	Cathy Widmer, Director	cwidmer@umm.edu
Cardiac Surgery	Cindy Dove, Director	cdove@umm.edu
Cardiology	Shawn Hendricks, Director	shendricks@umm.edu
Emergency Medicine	Megan Lynn, Director	mlynn@umm.edu
Medicine	Shawn Hendricks, Director	shendricks@umm.edu
Neuro/Behavioral Health	Greg Raymond, Vice President	graymond@umm.edu
Oncology	Suzanne Cowperthewaite, Director	suzannecowperthwaite@umm.edu
Patient Access	Simone Odwin-Jenkins, Director	sodwin1@umm.edu
Patient Experience	Kerry Sobol, Director	ksobol@umm.edu
Perioperative	Jim McGowan, Vice President	james.mcgowan@umm.edu
Procedural Services	Jeff Knox, Director	jknox@umm.edu
Surgery	Cindy Dove, Director	cdove@umm.edu
Trauma	Claudia Handley, Director	chandley2@umm.edu
Women's/Children's	Monika Bauman, Director	mbauman1@umm.edu

COVID-19 Risk Statement for Human Research Participants

University of Maryland Baltimore
Statement of Risk
Notice to Research Subjects Prior to Enrollment or Continued Participation in Research Activities

The novel coronavirus, COVID-19 is extremely contagious and is believed to spread mainly from person-to-person contact. Infection may result in personal injury, illness, permanent disability, or death. Despite having put in place preventive measures to reduce the spread of COVID-19, UMB cannot guarantee that any individual will not become infected with COVID-19 when on the UMB main campus or at related off campus sites.

The University of Maryland, Baltimore ("UMB") employees conduct research that involves participation by individuals who voluntarily enroll in studies after completing a process of informed consent approved by the UMB Institutional Review Board (IRB). UMB programs have begun controlled re-opening of research activities in accordance with campus guidelines as approved by the UMB President, acting in consultation with Deans, health and safety experts and academic advisors. Decisions to resume research take into account the measures needed to limit risk to research subjects, staff, and others. Participation in a clinical trial or other research will potentially increase an individual's risk of contracting COVID-19. Before enrolling in, or continuing enrollment in research, individuals should inform themselves fully of the risks to themselves, and potentially to family members and close contacts.

As a condition of participation in UMB approved research during the COVID-19 emergency, you are required to follow safety rules in your daily life which include:

- Keep a safe distance (at least 6 feet apart) from others.
- Avoid touching your mouth and eyes.
- Wash your hands often, using soap and water (for 20 seconds) or hand sanitizer.
- Wear a mask to cover your nose and mouth.
- Always cover your cough using your shirt or elbow, not your hand.
- Stay home when you are feeling sick.
- Monitor yourself daily for symptoms and report symptoms to the principal investigator, study coordinator or other UMB contact as instructed before coming to the UMB campus.

If you are sick, have any symptom(s) of COVID-19, or have had any recent contact with COVID-19 case(s), you must inform a member of the research staff and receive authorization before being present on the UMB campus or at any remote location where UMB approved research is conducted.

STUDY RESEARCH STAFF CONTACT FOR COVID-19 SYMPTOMS:

[NAME]
[PHONE]
[EMAIL]

If you wish to receive more information about enrolling or continuing to participate in UMB research during the COVID-19 pandemic, please contact the study staff listed above or the UMB Office of Human Research Protections (410)706-5037 to discuss your options.

_____ I understand the above risks and would like to enroll or continue to participate in the study.

_____ I do not wish to enroll or to continue to participate in the study.

_____ I wish to speak with someone about COVID-19 risk and enrollment or continued participation in the study.

[INSERT STANDARD IRB INFORMED CONSENT SIGNATURE BLOCK]

AND/ OR UTILIZE DOCUMENT CONTENTS AS PART OF VERBAL NOTIFICATION TO PARTICPANT/LAR

**See the UMB Research Community - COVID-19 Risk Statement for Human Research Participants posted on the HRPO website to access this form and for more information.

Helpful and Important Links

Building Access Forms (under “Information for Researchers”):
https://www.nursing.umaryland.edu/covid19/

COVID-19 Digital Signage Toolbox:
https://www.umaryland.edu/coronavirus/testing-hygiene-and-health/signage/#d.en.478931

COVID-19 Partner Toolkit:
https://www.cms.gov/outreach-education/partner-resources/coronavirus-covid-19-partner-toolkit

EHS COVID-19 Research Safety Training for UMB Research Staff (Login Info Needed):
https://www.umaryland.edu/ehs/research-safety/covid-19-research-safety/

EPA-Registered Disinfectants (Selected EPA-Registered Disinfectants):
https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants

Optimizing use of PPE:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html

PPE Supplies:
https://cf.umaryland.edu/freezer/promo_ppe.cfm

SAFE Screening Tool:
https://www.umaryland.edu/coronavirus/safe-on-campus/

Sample Laboratory Re-occupancy Plan:
https://files.constantcontact.com/504da196201/463a39cd-10ac-4565-8074-088015ddf3fb.pdf

Tracking Employee Exposures to COVID-19 (includes REDCap) PPTX:
https://tools.niehs.nih.gov/wetp/public/hasl_get_blob.cfm?ID=11902

UMB Coronavirus Info:
https://www.umaryland.edu/coronavirus/

UMB Research Community - COVID-19 Risk Statement for Human Research Participants:
https://www.umaryland.edu/hrp/announcement-cv19-hrpo-participant-language.php

UMB Visitors Guidance:
https://www.umaryland.edu/coronavirus/content/campus-operations/covid-19-visitors-guidance.php

UMSON COVID-19 Response:
https://www.nursing.umaryland.edu/covid19/