

UMSON Application to Initiate/ Resume In-Person Contact Human Subjects Research (and Non-Human Subjects Research Projects that Involve Participant Contact)

7-1-21

Contents

Introduction/Background	2
UMSON Resumption Guiding Principles	2
UMSON Process of Applying to Initiate/Resume Human Subjects Research (See also UMB Guidance)	3
UMSON Researcher Plan to Reduce COVID-19 Transmission in the Research (or NHSR) Setting.....	4
UMB Checklist for Initiating/Resuming Human Research (or NHSR).....	5
Campus Operations Proposal Assessment Questions for COVID-19 Recovery Task Force Teams.....	11

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 initiating/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 6/21/2021 Guidelines for resumption of research (<https://www.umaryland.edu/hrp/>).

UMSON Resumption 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. Masks should be worn by research staff and participants/ visitors during all contact.
3. 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.
4. Each research proposal can be submitted directly to IRB. For projects that were approved by the IRB prior to COVID-19 but are just now being restarted, submit the required forms in CICERO as an RNI. For new studies, submit the required forms in CICERO as Additional Files at the end of the CICERO application.
5. Notify the ORS that you have submitted the request to the IRB by sending all of the following documents (as appropriate to your study) to Email notification of the plan and appropriate checklists to be sent to UMSON Research Resumption Committee ([DL- NRSResearchResumptionCommittee@umaryland.edu](mailto:DL-NRSResearchResumptionCommittee@umaryland.edu)):
 - a) Initial submission for research not previously IRB approved, OR
 - b) Reportable New Information (RNI) submission, for research previously approved and then halted
 - c) UMSON Researcher Plan to Reduce COVID-19 Transmission in the Research Setting,
 - d) UMB Checklist for Initiating/Resuming Human Research checklist, and
 - e) Campus Operations Proposal Assessment Questions for COVID-19 Recovery Task Force Teams
 - f) Include in your human subjects document [COVID-19 Risk Statement for Human Research Participants](#)
 - g) Although submissions are no longer reviewed by the UMSON Research Resumption Committee, consultations may be requested via email at DL-NRSResearchResumptionCommittee@umaryland.edu.

UMSON Process of Applying to Initiate/Resume Human Subjects Research

(See also [UMB Guidance](#))

Note: *If a study has previously been approved to initiate/resume post COVID-19, no additional action is required.*

- 1) PI of human subjects research (on CICERO application) must complete the:
 - a) Initial submission application or Reportable New Information (RNI) submission with forms relevant to COVID-19 protocols included in the “Additional” documents tab (All studies),
 - b) UMSON Researcher Plan to Reduce COVID-19 Transmission in the Research Setting (signed by the PI)
 - c) UMB Checklist for Initiating/Resuming Human Research checklist (or NHR) form (All studies),
 - d) Campus Operations Proposal Assessment Questions for COVID-19 Recovery Task Force Teams (Studies that are conducted in campus buildings only)
 - e) Inclusion of [COVID-19 Risk Statement for Human Research Participants](#) and
 - f) Approval from the site to conduct research there. Note if the UMSON is a research site, submission of #3 below allows you to state that the UMSON is aware the research will be taking place in the building.

Note: Many of the questions on the *UMB Checklist for Initiating/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 jdohertry@umaryland.edu.

- 2) PI of NHR must complete the:
 - a) UMSON Researcher Plan to Reduce COVID-19 Transmission in the Research (or NHR) Setting (signed by the PI)
 - b) UMB Checklist for Initiating/Resuming HSR form (All studies)
 - c) UMB Checklist for Initiating/Resuming HSR (or NHR) form (All studies),
 - d) UMB Campus Operations Proposal Assessment Questions for COVID-19 Recovery Task Force Teams (Studies that are conducted in campus buildings only) and
 - e) Approval from the site to conduct research there. Note if the UMSON is a research site, submission of #3 below allows you to state that the UMSON is aware the research will be taking place in the building.
- 3) Email completed packets from #1 or 2 above to the UMSON Research Resumption Committee (DL-NRSResearchResumptionCommittee@umaryland.edu). The UMSON committee includes: Associate Dean for Research, Center Directors, and the Research Quality Manager.

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

For studies approved prior to COVID19, in-person research must not resume until the UMB HRPO/IRB acknowledges the RNI.

UMSON Researcher Plan to Reduce COVID-19 Transmission in the Research (or NHR) Setting

Name of PI: _____

Email Address: _____

Study Title: _____

CICERO Protocol Number: HP-_____

I hereby attest to the following while conducting my research:

1. Masks will be worn by research staff and research participants/visitors during all contact. Within our campus community, when masks are not required, we will be mindful to wear masks around research participants, young children and parents with young children out of respect for them and their families.
2. We will be mindful to maintain cleanliness of all contact surfaces, to a daily minimum.
3. For social distancing, crowding will be avoided (strive for 6ft between persons)
4. For meetings held longer than 30 minutes, a larger space will be utilized to support adequate air flow and filtration. In addition, rooms will be free between participants.
5. Research visitors/participants will be screened for COVID-19 symptoms prior to arrival on-site.
6. Research visitors/participants will provide government issued ID upon entry to building.
7. The [UMB COVID-19 Visitors Guidance](#) will be followed.
8. For long procedures, extra precautions will be taken to maintain safety of everyone.
9. Contact information will be provided to research visitors/participants to contact should they need to reschedule if not feeling well.
10. Sufficient PPE is/will be in place for potential aerosol/bodily fluid contact.
11. 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 will be reported to the UMB COVID- 19 Hotline (800-701-9863).
12. The [COVID-19 Risk Statement for Human Research Participants](#) will be completed as it is required to be submitted in the HRPO application for all in-contact HS research.
13. Prior to submission, IRB will be informed that an email notification of the plan and appropriate checklists has been or will be sent to UMSON Research Resumption Committee (DL-NRSResearchResumptionCommittee@umaryland.edu) along with the CICERO RNI or initial application.
14. For questions and clarifications, the resumption committee will be contacted at DL-NRSResearchResumptionCommittee@umaryland.edu.

PI Signature: _____

Date: _____

Please submit this document to the UMSON Research Resumption Committee at:

DL-NRSResearchResumptionCommittee@umaryland.edu

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UMB Checklist for Initiating/Resuming Human Research (or NHSR)

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.***

HUMAN RESEARCH OPERATIONS

ITEM	COMPLETE	N/A	NOTES
Develop a work schedule to minimize onsite personnel.	<input type="checkbox"/>	<input type="checkbox"/>	
Enroll all study personnel (except students) in SAFE screening tool	<input type="checkbox"/>	<input type="checkbox"/>	
Confirm that student research team members are enrolled in Castlebranch	<input type="checkbox"/>	<input type="checkbox"/>	
Plan to maintain physical distancing according to current UMB guidelines whenever possible and promote use of face coverings when physical distancing cannot be maintained.	<input type="checkbox"/>	<input type="checkbox"/>	
Ensure you have sufficient Personal Protective Equipment (PPE) supplies to conduct research safely. Take inventory and order well in advance.	<input type="checkbox"/>	<input type="checkbox"/>	
Cross-train research staff to fill in for others who may be sick or unable to come to work.	<input type="checkbox"/>	<input type="checkbox"/>	
Develop a plan for cleaning and disinfection of high-touch surfaces within the clinic and ensure supplies are available.	<input type="checkbox"/>	<input type="checkbox"/>	

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

CLINICAL FACILITIES

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.	<input type="checkbox"/>	<input type="checkbox"/>	
Waiting and clinical areas have been reconfigured to promote physical distancing (see EHS Guidelines).	<input type="checkbox"/>	<input type="checkbox"/>	
Physical distancing signage in place.	<input type="checkbox"/>	<input type="checkbox"/>	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.	<input type="checkbox"/>	<input type="checkbox"/>	
Plexiglass or clear barriers are installed between reception and waiting areas.	<input type="checkbox"/>	<input type="checkbox"/>	

ITEM	COMPLETE	N/A	NOTES
Protocols are in place for custodial service cleaning.	<input type="checkbox"/>	<input type="checkbox"/>	
Adequate IT is available for telemedicine visits.	<input type="checkbox"/>	<input type="checkbox"/>	

PARTICIPANT MANAGEMENT

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

ITEM	COMPLETE	N/A	NOTES
Protocols in place to limit the use of nebulizers.	<input type="checkbox"/>	<input type="checkbox"/>	
Requirements for the use of facemasks and other PPE are in place.	<input type="checkbox"/>	<input type="checkbox"/>	
Procedures are in place to prohibit visitors, children, or guests	<input type="checkbox"/>	<input type="checkbox"/>	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.	<input type="checkbox"/>	<input type="checkbox"/>	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.	<input type="checkbox"/>	<input type="checkbox"/>	

COMMUNICATIONS

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

ITEM	COMPLETE	N/A	NOTES
List of critical contacts has been compiled and provided to all team members.	<input type="checkbox"/>	<input type="checkbox"/>	
Expectations and roles have been communicated to all personnel to avoid potential confusion and conflicts.	<input type="checkbox"/>	<input type="checkbox"/>	
Personnel have access to materials and resources that may be needed to work from home.	<input type="checkbox"/>	<input type="checkbox"/>	
Meetings have been transitioned to remote formats, such as Zoom, Webex, or Microsoft Teams whenever possible.	<input type="checkbox"/>	<input type="checkbox"/>	<p>Zoom: https://www.umaryland.edu/cits/services/zoom/</p> <p>Webex: https://www.umaryland.edu/cits/services/webex/</p> <p>Microsoft Teams: https://www.umaryland.edu/office365/teams/</p>

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.	<input type="checkbox"/>	<input type="checkbox"/>	
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.	<input type="checkbox"/>	<input type="checkbox"/>	

SECURITY

ITEM	COMPLETE	N/A	NOTES
Personnel have been provided the following contact information: <ul style="list-style-type: none"> • Emergency – 911 • UMB Police Non-Emergency and Safe Walk/Safe Ride – 410-706-6882 • EHS – 410-706-7055 • UMB COVID Hotline – 800-701-9863 	<input type="checkbox"/>	<input type="checkbox"/>	
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).	<input type="checkbox"/>	<input type="checkbox"/>	
Guidance to all personnel to properly store valuables (e.g., laptops are out of sight and in locked drawers) has been provided.	<input type="checkbox"/>	<input type="checkbox"/>	
Clinical doors will be locked at the end of each day.	<input type="checkbox"/>	<input type="checkbox"/>	
Ensure windows are closed, if applicable.	<input type="checkbox"/>	<input type="checkbox"/>	
Guidance to all personnel to take needed personal belongings home at the end of each day has been provided.	<input type="checkbox"/>	<input type="checkbox"/>	

ENERGY REDUCTION

ITEM	COMPLETE	N/A	NOTES
Any non-essential equipment will be unplugged when not in use, even if it is turned off.	<input type="checkbox"/>	<input type="checkbox"/>	
Fume hoods will be closed when not in use and at the end of each day.	<input type="checkbox"/>	<input type="checkbox"/>	
Lights will be turned off when personnel leave.	<input type="checkbox"/>	<input type="checkbox"/>	
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).	<input type="checkbox"/>	<input type="checkbox"/>	

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
<p>Location – Please provide building and floor, PI name if applicable (address).</p>	
<p>Hours and days of operations requested; please be detailed, including needs for weekend support.</p>	
<p>Purpose – What will you be doing in the space requested (laboratory research, experiential teaching/learning, etc.).</p>	
<p>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.</p>	
<p>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.</p>	
<p>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.</p>	
<p>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.</p>	