UMSON Application to Resume Human Subjects Research (7.14.20)

Contents

Introduction/Background

This document 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 projects that involve in person interaction with participants. It is intended to complement the UMB June 23, 2020 Guidelines for Phased Resumption of Research (https://www.umaryland.edu/hrp/).

UMSON Guiding Principles

The following is a set of guiding principles for resuming 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 researchers, research staff, and participants involved in human subjects research to the minimum necessary for the research visit.

3. PhD students whose dissertation data collection had not started before 3-18-20 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 for 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 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 with a previously IRB approved dissertation proposal that has been defended and approved by the dissertation committee (before 3/18/20);
   c. NIH funded R-level or federally/foundation funded R-equivalent studies in no-cost extensions;
   d. NIH funded R-level or federally/foundation funded R-equivalent studies;
   e. MPower or other campus internally funded studies; and
   f. Studies not included above.

7. The least (minimal) number of faculty and 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. Students should be encouraged to conduct or staff only human subjects research that minimizes their personal risk (including dissertation research).

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.

Process of Applying to Resume Human Subejcts Research (See also UMB Guidance)

PI (on IRB application) must complete the

1) SON Research Information Page,
2) Study Plan,
3) UMB Checklist for Resuming HSR form, and
4) UMB Campus Operations form – note that forms may need to be edited and there may be many NAs, especially for off-site studies.

This packet will be submitted to the UMSON (DL-NRSResearchResumptionCommitte@umaryland.edu) and examined by the UMSON committee: Associate Dean for Research, Center Directors, and Research Quality Manager.

After UMSON approval, PI must submit as Reportable New Information (RNI) to IRB.

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

Research must not resume until IRB acknowledges the RNI.

Research Information Page
SON Human Subjects Research Study or Non-Human Subjects Research (NHSR) Project with Direct Contact with Participant

(For questions about this form, please contact DL-NRSResearchResumptionCommitte@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. Name of study: _____
7. IRB protocol number: _____
8. Does this study involve international sites? ☐Yes ☐ No
   If yes, provide information about location and local regulations

9. 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
   ☐ Other (describe) _____

   If on UMB campus, building/room #: _____
10. Does study require entry into UMB facilities for study participants? ☐Yes ☐ No
    If yes, provide purpose of the access, location, duration, frequency and complete Campus Operations Proposal Assessment Questions for COVID-19 Recovery Task Force Teams
    Purpose of access: _____
    Location: _____
    Duration: _____
    Frequency: _____

    NOTE: access form must be completed (Click below for form)
    Campus access form (Link TBD)
    UMSON access form

11. Does study require entry into UMB facilities for study staff? ☐Yes ☐ No
    If yes, provide purpose of the access, location, duration, frequency and complete Campus Operations Proposal Assessment Questions for COVID-19, note access form must be completed
    Purpose of Access: _____
    Location: _____
    Duration: _____
    Frequency: _____

12. Names /addresses for locations of study:

Facility	Address	Room	Contact Person Name/Email/Phone

13. Are any of the locations high risk (e.g., senior center)? ☐Yes ☐ No
    Does the study target at risk population (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. Study Personnel (on IRB protocol who will have in person contact with research participants or staff)

Name	Type: student, staff, trainee, faculty	In person contact > 6 ft or No in person contact	In person contact < 6 ft	In person contact + aerosolizing procedure or biospecimen	Enrolled in SAFE	Completed COVID-19 Research Safety Training

22. Documentation (e-mail or letter) that site agrees to allow study to resume/occur.

_____

23. Statement of any additional requirements by site.

_____

24. What is your estimate of the PPE required for this study? Please 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:		

Study Plan for Resuming Research

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

1. Plan for monitoring COVID-19 status of study personnel and study participants

   SON Personnel and Participant Expectations

   - Study personnel must complete SAFE (Campus REDCap monitoring system used by UMB (see Appendix for instructions) if they will be doing research on campus.

   - Temperature of participant, medically required escort (if needed), and participant will be checked upon arrival at study site and participation canceled if it is above 100^{0}F for participant or personnel.

   - If employee answers indicate potential COVID-19 positive notify PI, Employee COVID -19 hotline (800-701-9863) and Employee Health Services.

   - All participants, escorts, and other individuals involved in the research visit will be pre-screened for COVID-19 within 24 hours of study visit ((See *COVID-19 Symptom Screening Form in Appendix*) and not participate in research if COVID-19 is suspected.

   - If participant's answers indicate possible COVID-19 notify PI and refer participant to seek advice from their health care provider

2. Patient care considerations

   SON Expectation
   Ensure that researchers and research staff will not disrupt patient care by research activity. For example, if staff enters a room to provide patient care, leave and resume research after patient care finishes.

3. 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 below. Or research at other sites, please provide similar information.

4. Identify the social density of both research personnel, 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.

5. Identify essential personnel for conducting research activities, including any persons who may have contact with participants (Please see UMB's COVID-19 hotline information at https://www.umaryland.edu/coronavirus/hotline/).

   SON Expectations:
   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 (Affiliates), 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/).

   Determine actions for responding to potential COVID-19 infection in research personnel,

participants, and required escorts, including communication plan for providing notice to anyone in contact with potential or actual infected persons.

If an employee is found to have COVID-19, or is exposed to an infected individual, the incident must be reported to the Employee COVID- 19 Hotline (800-701-9863).

6. Plan for appropriate and frequent disinfection and cleaning of spaces and equipment, including shared spaces that are accessed by participants and research personnel (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/

7. Encourage all active members of the research team to receive a Flu vaccine upon availability prior to or during flu season;

8. 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.

   SON 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.

9. Provide training to all research personnel on the appropriate use of PPE and safety precautions;

10. Communicate with all members of the research team on the use of the UMB Hotline for reporting safety concerns

Note: Many of the questions on the *Checklist for Resuming Human Research* and the *Campus Operations Proposal Assessment Questions for COVID-19* will not apply exactly to many research projects that are conducted 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. For questions

regarding completion of these forms or your plan, please contact Dr. Julie Doherty at jdoherty@umaryland.edu.

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.

HUMAN RESEARCH OPERATIONS

ITEM	COMPLETE	N/A	NOTES
Develop a work schedule to minimize onsite personnel.	☐	☐	
Enroll all personnel in SAFE screening tool	☐	☐	See instructions on page 28
Plan to maintain physical distancing (6 feet of separation) whenever possible and promote use of face coverings when physical distancing cannot be maintained.	☐	☐	
Ensure you have sufficient Personal Protective Equipment (PPE) supplies to conduct research safely. Take inventory and order well in advance.	☐	☐	BIORESCO: • https://cf.umaryland.edu/freezer/index.cfm?
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
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).	☐	☐	
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.478931
Adequate alcohol-based (60% or more) hand sanitizers are available.	☐	☐	Disinfectants (Selected EPA-Registered Disinfectants): • https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants
Plexiglass or clear barriers are installed between reception and waiting areas.	☐	☐	
Protocols are in place for custodial service cleaning.	☐	☐	How Buildings Are Cleaned and Disinfected: • https://www.umaryland.edu/corona virus/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.	☐	☐	
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.	☐	☐	

ITEM	COMPLETE	N/A	NOTES
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.	☐	☐	
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	☐	☐	
Protocols are in place for transporting participants with respiratory symptoms to home or to the local hospital.	☐	☐	
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.	☐	☐	1-800-701-9863
COVID-19 procedures applicable to the clinical site have been reviewed with all members of the team.	☐	☐	
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.	☐	☐	

ITEM	COMPLETE	N/A	NOTES
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 Hotline – 866-594-5220 • COVID-19 hotline - 866-594-5220 • Employee COVID-19 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).	☐	☐	

ITEM	COMPLETE	N/A	NOTES
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).	☐	☐	

PERSONAL PROTECTIVE EQUIPMENT (PPE)

ITEM	COMPLETE	N/A	NOTES
Estimate PPE required for this study. Please assume that you will need to bring your own PPE to all sites. This will also include PPE for participants.	☐	☐	
If your study is not in a clinical site, estimate 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.	☐	☐	
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.	☐	☐	See number 8 of page 9 for SON PPE Expectations.

ITEM	COMPLETE	N/A	NOTES
Train all research personnel on appropriate use of PPE and safety precautions.	☐	☐	

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

(If ANY campus access note access request needed)

Current State w/Operational Questions	Need Being Requested
Location – Please provide building and floor, PI name if applicable (address).	
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 requests by Work Order, 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 need to be present for building during open hours; current operations support 8 a.m.-4:30 p.m. Please outline additional weekly and/or weekend needs.	

Campus Access – Procedure requires advance approval via temporary campus access form on UMB's COVID-19 site. Will those requesting access be staff/faculty, students, or contractors?	
Other Comments:	

Committee Review Sheet

Title_____
Principle Investigator_____ **Date/Time Completed**_____

Committee Discussion Date: _____

Comments/Changes Requested:

Committee Decision:

Committee Discussion Date: _____

Comments/Changes Requested:

Committee Decision:

Appendix

COVID-19 Symptom Screening Form

Study # HP-_____
PI _____ Date/Time Completed_____ Screener_____

Please check: ☐ Participant ☐ Escort Participant ☐ Staff (Name) _____

24 hours prior to scheduled visit: If any answer is yes, please reschedule and refer as per study plan

☐ YES	☐ NO	Have you been in close contact, personally or professionally, with a confirmed case of the coronavirus/COVID-19 within the past 2 weeks?
☐ YES	☐ NO	Have you traveled to a country with the spread of coronavirus or out of state within the last 30 days? If yes, then where? _____
☐ YES	☐ NO	Do you work in a healthcare center or hospital where patients with coronavirus or persons under investigation are being treated? If yes, then where? _____
☐ YES	☐ NO	Do you reside in a home or retirement community setting where community spread of COVID-19 is occurring? If yes, then where? _____
☐ YES	☐ NO	Have you been to an Emergency Room or Urgent Care Center within the past 48 hours?
☐ YES	☐ NO	Are you experiencing a new/unusual cough or had within the last 24 hours?
☐ YES	☐ NO	Are you experiencing new/unusual shortness of breath or had within the last 24 hours?
☐ YES	☐ NO	Are you experiencing new/unusual loss of taste and smell?
☐ YES	☐ NO	Are you experiencing new/unusual difficulty breathing or had within the last 24 hours?
☐ YES	☐ NO	Are you experiencing a sore throat or had within the last 24 hours?
☐ YES	☐ NO	Have you had a fever in the past 24-48 hours?
☐ YES	☐ NO	Do you have new/unusual diarrhea?
☐ YES	☐ NO	Do you have new/unusual muscles aches?
☐ YES	☐ NO	Do you have a general feeling of not feeling well/malaise?

COVID-19 Symptom Screening Form

Study # HP-_____
PI _____ Date/Time Completed_____ Screener_____

At entry to study location:_____ Date/Time: _____

Temperature: _____ If temperature is above 100^{0}F, reschedule and refer as per study plan

Action taken: _____

Signature: _____

Welcome to REDCap!

REDCap URL (Works best in Internet Explorer Browser:
https://redcap-secure.igs.umaryland.edu (***copy and paste url)***

REDCap is a secure, web-based application for building and managing online surveys and databases.
You may create and design projects using

- The online method from your web browser using the Online Designer
- The offline method by constructing a 'data dictionary' template file in Microsoft Excel, which can be later uploaded into REDCap
- Both surveys and databases can be built using these methods.

REDCap provides automated export procedures for data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, real- time reporting tools, and branching logic, file uploading, and calculated fields.

REDCap data sits behind SSL and requires a UMID to logon to the REDCap-SOM **VPN** for use inside and outside of the University of Maryland.

How to Gain Access to REDCap?

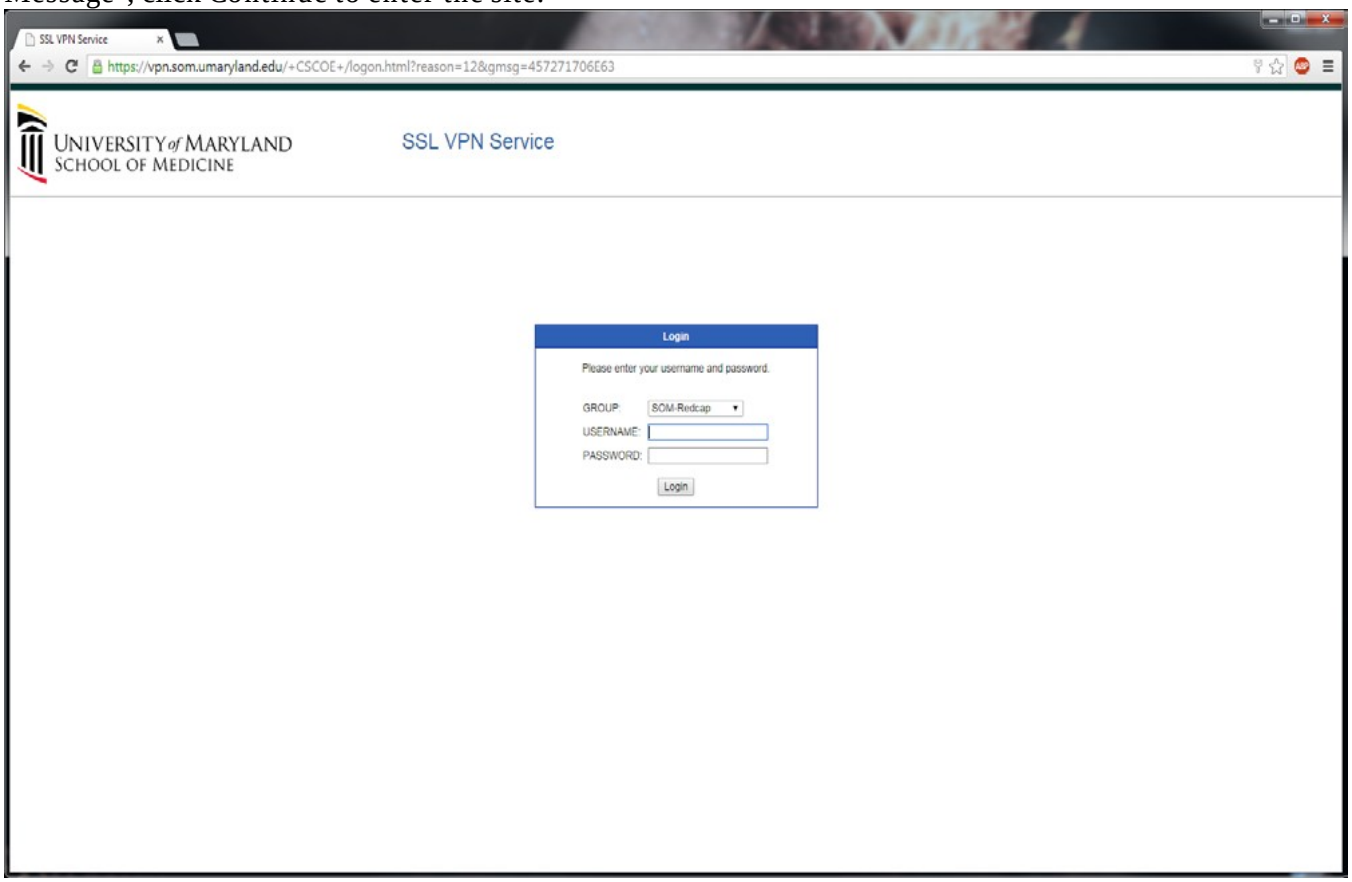
1. Send your UMID username to (CTRIC) research@som.umaryland.edu, so it can be added to the REDCap-SOM VPN system by the SOM HelpDesk and to the REDCap system by CTRIC. Subject line should read "Request access to REDCap"
   a. **If you are having trouble finding your UMID or password, please go to: https://directory.umaryland.edu/**
2. Once appropriate permissions have been applied you will receive an email from CTRIC.

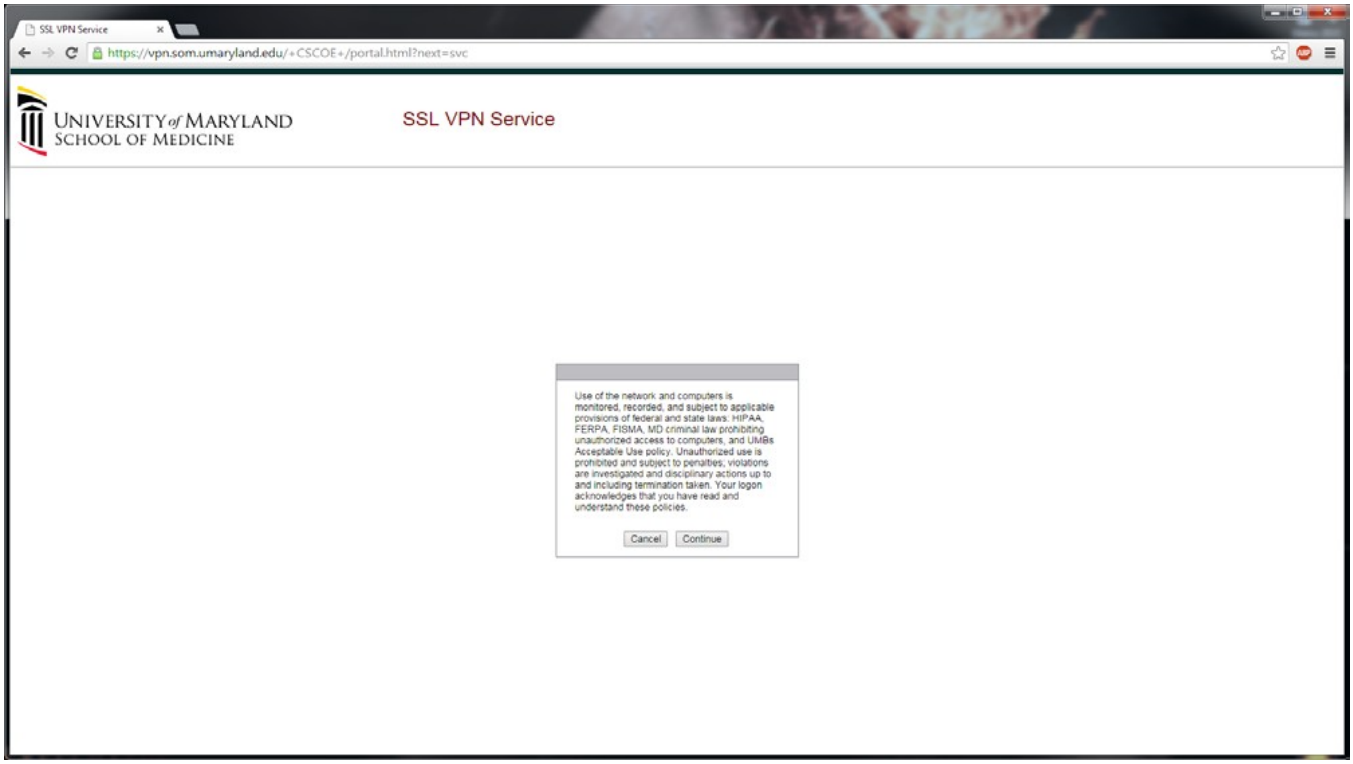
**** If you do not have an SOM account, please email research@som.umaryland.edu. Subject line should read:* REDCAp SOM VPN account needed**

Download and Installing the Cisco AnyConnect VPN Client: *You may not be able to download the VPN onto your computer, because you don't have Administrators rights. If so, you should contact your IT Department, because they will need to download the VPN for you.*

****If you have already downloaded this, you do not have to download it again; just choose your Group and login using your UMID credentials.****

1) Point your browser to: https://vpn.som.umaryland.edu
2) Choose VPN **Group**: SOM-Redcap
3) Enter UMID Username
4) Enter UMID Password
5) Click **Login**
6) Authentication to SOM VPN is successful if you receive the below "Successful Logon Message", click Continue to enter the site:





7) Click the **Start AnyConnect** link in your browser window to begin installation the AnyConnect program. If you receive a certificate warning, click **Yes** to accept the certificate and continue.

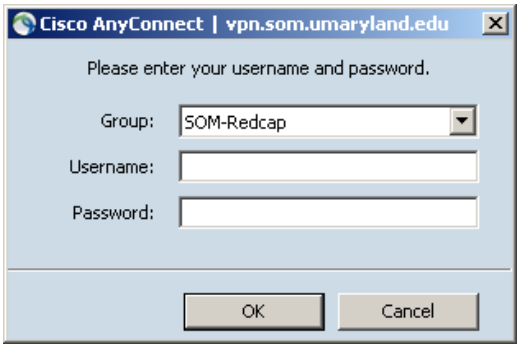
How to Log on

Check to see if you are connected using the VPN.

Click on the little icon near the bottom right corner of your screen for Cisco Anyconnect. When you do, a box will open.

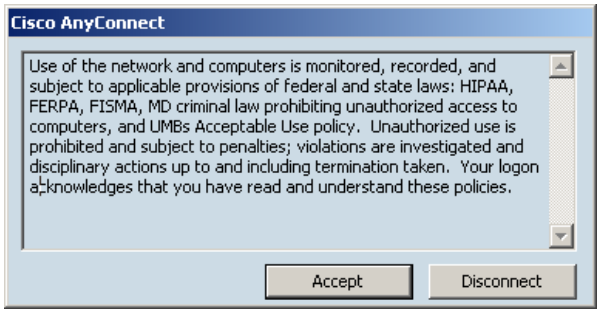
If you are not connected, it looks like this:

To connect:
Make sure that vpn.som.umaryland.edu is in the box as pictured above. If not, see if it is in the dropdown. If it is not there, type it in. Then click on "Connect"
You will get a logon screen:



Your UMID should be in the Username box. If it is not, type it in. Type in your password for your UMID and click "Ok".

You will see the following screen:



Click "Accept".

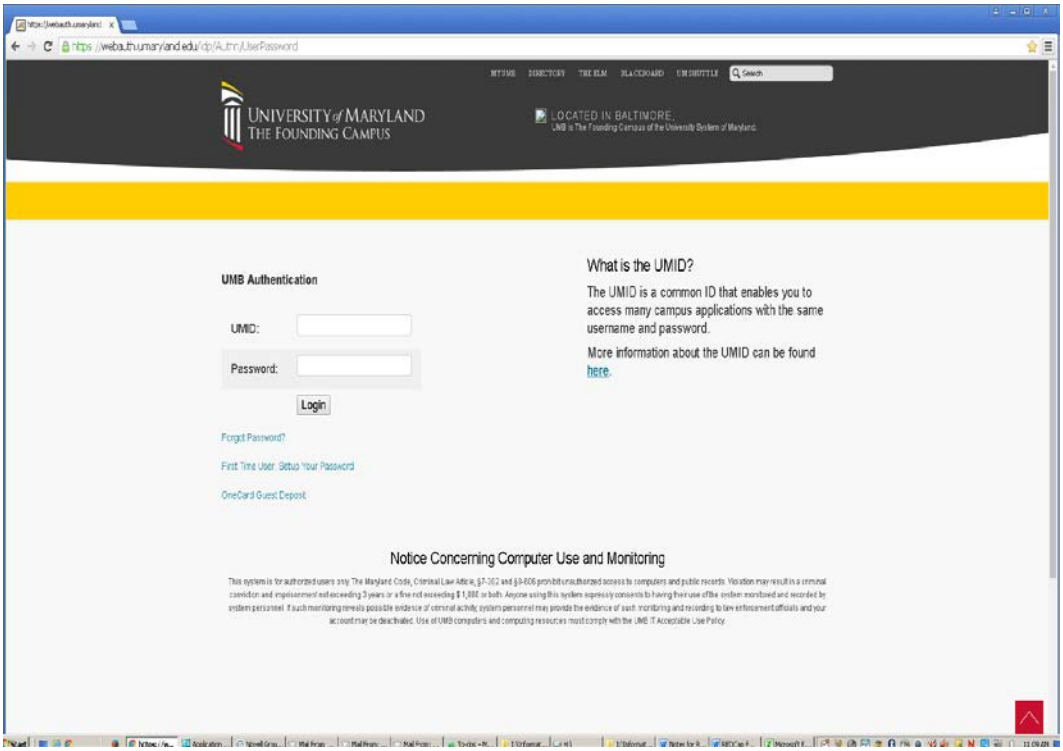
You are now connected to the server via the VPN.

To get into REDCap

Once you are connected to the server using the VPN, open your browser (Please use Explorer or Chrome; Firefox won't work) and go to https://redcap-secure.igs.umaryland.edu/

Make sure you are using the **secure server**; there is an old address that does not have "secure" in it.

You will be directed to the University Authentication page.



Type in your UMID and password, click on "Login" and you will be in REDCap.

Working with REDCap

1. Learn and review REDCap training videos:

    - Brief Training video: http://redcap.vanderbilt.edu/consortium/videoplayer.php?video=redcap_overview_brief01&title=Brief%20Overview%20of%20REDCap&referer=redcap.igs.umaryland.edu
    - Training Resources: https://redcap.vanderbilt.edu/index.php?action=training

2. Request access and create your REDCap project online
3. Define your data variables and their properties (text boxes, drop down menus, radio buttons, and etc.)
4. Preview your project content and add study member permissions, and test functionality
5. Revise your database as needed
6. Launch your project into production and begin collecting data

Additional notes about UMB REDCap

- **UMB REDCap is HIPAA compliant.**
- **With good security and privacy practices setting up your study, UMB REDCap can also be compliant with FDA CFR 21 Part 11**
- **The server for UMB REDCap is maintained by the Institute for Genome Sciences in the School of Medicine.**
- **Survey data is maintained on a separate, but equally secure, server.**
- **The server is backed up nightly, and backups are kept for a year.**
    - **Backups are handled by an enterprise grade tape StorageTek backup system that performs periodic and incremental backups to LTO4 tape libraries. The data on the backup tapes is encrypted with 128-bit encryption as well to safeguard the data in the event a tape is compromised or lost.**
- **Additional information about server security is available at:**
    - **http://confluence.igs.umaryland.edu/display/ENG/Security+Write-up**

NOTICE: Please remember that if you are collecting data for the purposes of human subject's research, review and approval of the project is required by your Institutional Review Board; you could get audited.

If you need assistance, please email us at: research@som.umaryland.edu

UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

SAFE

Symptom Assessment for Employees

This letter describes the UMB Employee COVID-19 Symptom Monitoring Program. Your participation is important for keeping our people safe while we work to re-open our facilities. The goal of the Employee Monitoring Program is to give our on-campus employees the ability to self-report any symptoms they may be experiencing daily, while keeping supervisors informed about the status of their employees.

Here is how it will work.

1. When you identify employees who need to be on campus, you will send them a link to register in the monitoring system. Please scroll to the end of this for email language you can copy and paste to instruct your employees to register.

2. Opening the link will take the employee to a demographics form registering them in the system.

3. This will then trigger a daily email to the employee asking them to complete a short form that asks about plans to be on campus that day, with one reminder if not completed within two hours.

    a. If the employee does not plan to be on campus that day, the questionnaire ends. (No need to report symptoms if not planning to be on campus.)

    b. If yes, they are asked about presence of symptoms of COVID-19

        i. If no symptoms are reported, they receive a note that they are cleared to work on campus.

        ii. If symptoms are reported, they receive an email with guidance about calling the hotline, informing their supervisor and staying home. The hotline, in collaboration with employee health, will provide guidance on testing and return to work.

    c. Supervisors may request pauses in email reminders for employees who are expected to be off campus for prolonged periods of time by emailing Dr. Marianne Cloeren.

4. As the program evolves, we will develop reports to use for dashboards to monitor cooperation and results. If you have ideas for a specific report please contact Dr. Marianne Cloeren.

As a PI or supervisor to one or more employees, you can help keep our campus community safe by remaining up to date on the status of your employees. To assist you with this, you will be receiving the following pieces of information regularly:

1. A copy of the email sent to your employee confirming registration in the system.
2. A copy of the email sent in response to an employee reporting symptoms or exposure.
3. A weekly report that describes which of your employees have been on campus for work and which have experienced symptoms, completion data, and other critical information.

We hope that the information we share helps you better manage your employees during these challenging times. Our system is flexible and can adapt to your needs. Your questions about this process are welcome.

Please continue to follow the appropriate safety guidelines, and we thank you for doing your part in keeping our campus healthy and safe.

Use this email to instruct employees to register:

Please follow this link to register in the UMB Symptom Assessment For Employees On Campus (SAFE on Campus) Program: https://rs.igs.umaryland.edu/surveys/?s=YPYPNMDCKL. This will set you up to receive a daily reminder to log any symptoms that may relate to COVID-19 on days you are coming to campus, and provide you with instructions if you do develop symptoms.

Note: For issues getting into SAFE, please contact Joni M. Prasad at JPrasad@som.umaryland.edu.

Helpful and Important Links:

Checklist for Resuming Clinical Research:

- https://www.umaryland.edu/media/umb/oaa/hrp/documents/Clinical-Research-Resumption---Checklist-for-Resuming-FINAL-UMB-EDITS-6-24-20-3.pdf

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

EH&S 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

Getting COVID-19 Test/Testing Locations:

- https://www.umms.org/coronavirus/what-to-know/diagnosis-symptoms/test
- https://www.umms.org/coronavirus/what-to-know/diagnosis-symptoms/test/testing-locations

Optimizing use of PPE:

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

Phone Number to Report Any Concerns about Health Safety:

- https://www.umaryland.edu/coronavirus/faq-content/who-can-i-talk-to-if-i-have-a-concern-about-health- safety.php

PPE Supplies/Local Contact:

- https://www.umaryland.edu/coronavirus/faq-content/how-can-i-purchase-ppe-through-umb-for-employees.php
- https://cf.umaryland.edu/freezer/promo_ppe.cfm
- https://health.maryland.gov/mdpcp/Documents/Emergency%20PPE%20Request%20Form.pdf

Researchers Safety Plan and Enhanced Hygiene:

- https://www.umaryland.edu/coronavirus/content/testing-hygiene-and-health/researchers-safety-plan.php

- https://www.umaryland.edu/coronavirus/content/testing-hygiene-and-health/enhanced-hygiene.php

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 COVID-19 Research Safety Plan (PDF):

- https://www.umaryland.edu/media/umb/af/ehs/laboratory-safety/Lab-COVID19-safety-plan-05212020.pdf

UMB Coronavirus Info:

- https://www.umaryland.edu/coronavirus/