

Checklist for Resuming Clinical Research

The following checklist outlines actions to consider for resuming clinical 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.

CLINICAL OPERATIONS

ITEM	COMPLETE	N/A	NOTES
Develop a work schedule to minimize onsite personnel.			
Enroll approved personnel in SAFE on Campus screening tool or create alternate screening plan for any personnel unable to access SAFE on Campus.			
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.			
Cross-train research staff to fill in for others who may be sick or unable to come to work.			
Train all research personnel on appropriate use of PPE and safety precautions.			
Develop a plan for cleaning and disinfection of high-touch surfaces within the clinic and ensure supplies are available.			
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 clinical staff or participants.			

CLINICAL FACILITIES

ITEM	COMPLETE	N/A	NOTES
Secure approval from EACH clinical 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.			
Adequate alcohol-based (60% or more) hand sanitizers are available.			
Plexiglass or clear barriers are installed between reception and waiting areas.			
Protocols are in place for custodial service cleaning.			
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.			

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.			
COVID-19 procedures applicable to the clinical site have been reviewed with all members of the team.			

List of critical contacts has been compiled 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.			

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: <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 Hotline – 866-594-5220 • 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).			
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).			