

01 Jul 2020

Re: Plan to Resume Human Subjects Research at Greenebaum Comprehensive Cancer Center

This plan represents the comprehensive plan for ensuring staff and patient safety for all clinical research happening at University of Maryland Greenebaum Comprehensive Cancer Center. Each PI performing research at UMGCCC will submit this plan in addition to the UMB Environmental Health and Safety Checklist via CICERO, to gain permission to fully resume clinical trial activities. Given the gravity of a cancer diagnosis, it is recognized that even during this pandemic, UMGCCC has continued to enroll patients onto therapeutic trials on a case-by-case basis, upon review of the case by Dr. Ashkan Emadi (Associate Director of Clinical Research).

During Stage 0 and 1 clinical research as defined by UMB's Guidelines for Resuming Human Subjects Research published 6/23/2020, essential UMGCCC personnel involved with clinical research include: **Research Medical Assistants** – patient facing personnel who interact with patients to complete all research related procedures (phlebotomy, ECG, VS etc.) – on site five days per week. **Study Coordinators** – patient facing personnel who interact with patients for all study related visits – on site activities are limited to days when patients visits may occur as well as one additional day for administrative purposes; **Data Managers** – administrative support responsible for managing paperwork generated during research visits – on site activities will not exceed more than two days per week as scheduled by manager; **Managers and Administrative staff** – on site activities will be limited to as needed for proper support and management of team members; **Regulatory team members** – including those responsible for printing and managing hard copies of regulatory paperwork associated with trials – on site activities will not exceed more than three days per week as scheduled by manager; **GCRC nurses** who may be needed for completion of scatter visits/after hour research procedures. These activities require access to existing office spaces, computers, printers, copiers, binders and clinical spaces including Stoler out-patient pavilion, Weinberg Breast Center, Allogenic transplant clinic on 9th floor B wing, in-patient units N8W, N9W and BMT unit on Gudelski 9, research lab space in Stoler pavilion and 9th floor of Bressler building.

This review took into consideration the alternative available options for the patient and the staff availability to complete study related procedures in a safe manner.

Health Monitoring & Training for Staff

- Since all Medical Oncology trials for UMGCCC occur in the University of Maryland Medical Center, all faculty and staff will continue to abide by the current practices in place to screen and monitor research team members. These include:
 - o Must wear a mask or appropriate Personal Protective Equipment (PPE) while on UMMC premises at all times in open area (hallways, waiting rooms, etc.) or clinical spaces (in patient units, out-patient clinics, etc.).
 - o Must be afebrile
 - o Must not be exhibiting or report any symptoms of COVID-19 or Flu-like symptoms
 - o Must display UMMC badge at all times while on the premises
- Complete the UMB Environmental Health and Safety COVID-19 Clinical Research Safety Guidance at <https://www.umaryland.edu/ehs/>
 - o The modules explain research requirements for all UMB faculty, staff and students. Please note that SAFE on Campus applies only to those reporting to UMGCCC who DO NOT work in the UMMC space (ie. Regulatory and IT staff). Those working in UMMC space are required to follow UMMC policies relating to screening upon arrival and reporting COVID symptoms.

Reporting Requirements for Staff

- Any staff person who comes into contact with a known COVID-19-positive person (in any setting) must notify their supervisor as well as the UMMC COVID hotline and follow the instructions provided.
- Any staff person who tests positive for SARS-CoV-2:
 - o Must immediately notify their supervisor as well as the UMMC COVID hotline and follow the instructions provided.
 - o Must NOT report to work until given clearance to do so by a member of the COVID hotline.

Social Density Requirements for Staff

- All staff will adhere to social distance requirements in place at UMMC. Hallways, elevators and other common gathering spots in UMMC have clear markings on the floor to notify staff a proper/safe proximity. These indicators must be followed at all times.
- Staff will be expected to be on-site for only the required time needed to perform research related activities that cannot be performed remotely.
- If research staff share an office with others, the management team will ensure a schedule is put into place to ensure offices are not occupied in a manner that does not allow for the minimum of 6 feet between work stations. This written schedule for each staff person on the team will be drafted by the team manager and submitted to the Director of Clinical Research Operations for approval prior to implementation with the team.
- Hand sanitizer stations are placed strategically throughout UMMC and readily available for all staff. All staff are expected to wash their hands frequently throughout the day, including but not limited to at the conclusion of any patient facing interaction.

- PPE (masks and face shields) is provided by UMGCCC clinical team leaders. If N95 masks are provided, the research team members are to follow UMMC's Employee Health Teams instructions on fit testing procedures, to ensure proper fit of the mask is obtained. Masks are also being provided by UMB School of Medicine via iLabs. Each clinical research team is provided a supply of face masks by the Research Lab Manager.

Cleaning practices for Staff Areas

- o Disinfectant wipes or a comparable cleaning solution for wiping down work stations, phones, door knobs etc. is readily available and supplied by UMMC EHS. Staff are instructed to wipe down their work area upon arrival to work, prior to departure for the day as well as frequent disinfecting of door knobs, faucet handles, copier buttons and other high traffic areas.
- o UMMC EHS is performing a deep cleaning of all spaces at the end of every day

Health Monitoring for Oncology Research Participants

- All Oncology research participants will be screened following UMMC guidelines, which include the following activities at the time of development of this plan:
 - o Contacted via phone 24 hours prior to scheduled visit to ensure the patient has no reported symptoms of COVID-19 (fever, cough, shortness of breath, etc.)
 - o Must not be exhibiting or report any current symptoms of COVID-19 upon questioning. This questioning is completed by UMMC employees upon entry into the building – before patients are allowed to proceed into clinical spaces.
 - o Must have temperature checked upon arrival to UMGCCC facilities and be afebrile. If patient is exhibiting a fever (which is fairly common in cancer patients), they will be escorted to one of the isolation exam rooms in the Stoler Pavilion for a full work-up by their treating oncologist as well as consultation with infectious disease team member, as deemed necessary by medical oncologist.
 - o Strict adherence to the No-Visitors policy in place at UMMC

Reporting Requirements for Research Participants

- All research participants who test positive for SARS-CoV-2 are restricted from entering Stoler Pavilion until they have 2 consecutive negative tests that are at least 24 hours apart.
- Any Oncology patient that tests positive for SARS-CoV-2 have daily telephone visits with nurses to get updates on their clinical status and ensure their safety.

Social Density Requirements for Patients

- All research participants will be instructed to adhere to UMMC social distancing requirements, which include the following activities at the time of development of this plan:

- All waiting room areas have had at least 50% of seating removed to reconfigure the space to allow for at least 6 feet between patient waiting room chairs
- Any patient able to have a telemedicine visit (in lieu of an in person visit) have been shifted to telemedicine visits with providers, to lessen the numbers of people on site at any given time. This accounts for ~20% of out-patient clinic activities.
- Infusion stations have been modified to allow the required 6 feet between each person. Nine total infusion stations were closed, with a current capacity of 16 chairs at a time.
- Hand sanitizer stations are placed strategically throughout UMMC and readily available for all patients.
- Masks must be worn at all times by patients while on the premises.

Cleaning Practices for Patient Areas

- Waiting room chairs and exam rooms are being disinfected after each patient by UMGCCC staff. High touch areas (door knobs, elevator buttons etc.) are being disinfected hourly by UMGCCC staff.
- UMMC EHS is performing a deep cleaning of all spaces at the end of every day.