

Research Advisory Task Force (COVID-19)

Committee Topic: Clinical Research

Committee Members: S. Davis; P. Crino; K. Cullen; J. Doherty; E. Friedmann; S. Kottlilil; R. Rosenthal

Policy Effective Date: March 18, 2020

Final UMB policy based upon the committee report and recommendations

- 1) The Decision to Enroll/Continue on research protocol should be based initially on level of risk as determined by the IRB.
- 2) Minimal Risk studies:
 - a. Participants may not be present at UMB or UMMC for follow up except for urgent conditions.
 - b. Participants may be enrolled or continue to be followed if all activities can be completed through telemedicine or other remote mechanisms.
 - c. Participants may be enrolled in minimal risk studies directly if the condition to be studied is part of routine care, and that enrollment/follow up is performed **ONLY** by clinical staff who are providing clinical care and thus designated as clinically essential for pandemic conditions.
- 3) Greater than Minimal Risk (Potential for Direct Therapeutic Benefit to Research Subject):
 - a. Subjects already enrolled may continue in the trial if removal from the trial would negatively impact the safety or welfare of the research subject.
 - b. Continuing new enrollment in clinical trials is permitted **ONLY** if there is potential for **CRITICAL** therapeutic benefit for specific disease processes. An example is cancer chemotherapy type trials. Investigators who believe their studies meet such criteria require approval of Chairperson, Academic Dean of Research, Program director or his/her designee to affirm appropriateness of **EACH** trial. **New trials for critical therapeutic trials may be initiated under the same approval process.**
 - c. Continuing new enrollment in and initiation of new clinical trials is not permitted for **NON-CRITICAL** therapeutic benefit.

- d. **Therapeutic trials for coronavirus will receive priority in ethical review.**
- e. **Emergency Use of a Test Article, or Single Use Expanded Access related to covid-19 (OR OTHER INDICATIONS AS APPROPRIATE) may still be used. Please Contact IRB Chair, Dr. Robert Rosenthal, rosenthal@som.umaryland.edu, 301-461-3969.**
- f. It is important to stress that clinical research should not continue unless there are adequate personnel, designated clinically essential for pandemic conditions, not only to enroll subjects but to perform appropriate follow up, taking into account that the staff available may decrease with time as infection/quarantine will undoubtedly affect research staff.

4) Greater than Minimal Risk, (No Potential for Direct therapeutic Benefit to Research Subject):

- a. This category of research is not permitted.

5) Community Research: nursing home, senior centers and other community facilities:

We will pause UMB research projects in those locations or other locations where populations vulnerable to COVID exist—except

- a. If subject safety is endangered by not performing a necessary intervention, monitoring a treatment, etc. in an ongoing trial; OR
- b. Where the research intervention is performed by the permanent staff of the facility under the guidance of UMB research staff but which does not require the UMB staff to enter the facility.

6) Research coordinators should follow up frequently with research subjects to determine feasibility of continuing in individual protocols.

7) For all studies the PI needs to communicate with study sponsor regarding interruption or changes to any aspects of currently approved research.

Please note: Everything detailed above applies to protocols approved by the UMB IRB as well as all external IRB's.

If studies require distribution of investigational products, please contact the Investigation Drug Service for guidance: mlee1@umm.edu.

For international research, the above guidance applies. Directives from local ethics committees or Ministries of Health may supersede this guidance. Follow local in-country directives but keep the UMB IRB informed.

Questions or concerns regarding human subjects research may be addressed to HRPO Director, Dr. Julie Doherty: hrpo@umaryland.edu, 410-706-5037 or IRB Chair, Dr. Robert Rosenthal: rosenthal@som.umaryland.edu, 301-461-3969.

The following applies only to protocols approved through the University of Maryland IRB.

Note: For protocols relying on other IRB's please check with the appropriate external IRB for guidance.

- 1) Modifications to previously approved research should be submitted only if changes in proposed research activities will result in increased risk to research subjects. Any changes taken to eliminate immediate apparent hazards to research subjects or staff should be documented locally and reported in aggregate at continuing review.
- 2) Reportable New Information: Any reportable new information that meets current reporting guidelines should be submitted appropriately. Please see HRPO website for further guidance: "HRP-105, Reportable New Information"
<https://www.umaryland.edu/hrp/for-researchers/study-conduct>

It is understood that the situation is changing rapidly and may require modifications in the near future.

The Clinical Research Taskforce considers the health and safety of researchers and staff as well as research participants to be of the greatest importance. No one with signs, symptoms of COVID or a recent high risk exposure should be involved in clinical research. Students and trainees are not permitted to participate in any research that exposes them to COVID-19 risk and must follow UMB's [Step 2 Policy](#) and [Clinical Activities Guidance](#).