COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD

EMERGENCY PREPAREDNESS PLAN FOR THE HUMAN RESEARCH PROTECTION PROGRAM

I. BACKGROUND

This Emergency Preparedness Plan (**Plan)** for the Human Research Protection Program (**HRPP)** provides guidance on the management and oversight of the HRPP of Columbia University (**Columbia** or the **University)** before, during and after disasters or public health emergencies (collectively, **Disasters).** Disasters can include, but are not limited to, extreme weather events and natural occurences such as hurricanes, tornados, and earthquakes, military conflicts and other man-made disasters, infectious disease outbreaks or terrorist attacks. These events can cause major disruptions in the conduct of human subjects research at the University. As a result, research may be interrupted and any component of the University's HRPP, including the University's Human Research Protection Office **(HRPO),** rendered unable to function, possibly for an extended period of time.

This Plan is specific to the HRPP and is intended to interface with and supplement, not replace, emergency response planning by University leadership and/or University-wide response measures, such as the University's policies and procedures relating to Emergency Management Operations Teams that function during Disasters. Because the impact of a Disaster on the University's schools, institutes and departments (each, a **University Unit)** may vary, this Plan establishes a set of recommendations of the HRPO that should be considered by the University Units in developing more specific guidelines for their researchers. It is also for this reason that the Plan is based on an "all hazards" approach to disaster preparedness. Any guidelines developed by University Units must be consistent with the principles articulated in this Plan.

The Plan will be invoked once the University's Executive Vice President for Research (**EVPR)** has determined that an emergency has occurred or that preparations are needed for an imminent emergency, and human research at the University is or is likely to be adversely impacted.

Further information can be obtained in (a) the U.S. Office for Human Research Protections' Effects of Disasters on Human Research Protections Programs Guidance, (b) the U.S. Food and Drug Administration's Guidance on Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies and (c) the Emergency Preparedness Tip Sheet of the Association for the Accreditation of Human Research Protection Programs, Inc. (**AAHRPP).**

II. EFFECTIVE DATE: April 1, 2025

III. ROLES AND RESPONSIBILITIES

A. General Management of the Plan

The University's Institutional Officials (i.e., the individuals who are the signatories on the applicable Federalwide Assurance) (**IOs)**, the Institutional Review Boards (**IRBs),** the Chairs of the IRBs (**IRB Chairs),** the Vice President for Research Operations and Policy (**VPROP),** the Associate Vice President for Human Research Protection (**AVP HRP)** and the IRB Executive Committee (IEC**)** are responsible for carrying out the procedures described in this Plan.

The EVPR is responsible for designating a HRPP Emergency Advisory Committee (**Committee)** to advise on the emergency responses, composed of key personnel in the HRPP, such as the VPROP, the AVP HRP, the IOs, the IEC, the Medical Director of NewYork-Presbyterian Hospital, up to three researchers and others as appropriate, provided that the exact composition of the Committee may change based on the types of emergencies that the Plan addresses.

A. Periodic Evaluation of the Plan

The VPROP and the AVP HRP, in consultation with the Committee, are responsible for evaluating this Plan and making changes, when appropriate. This evaluation shall occur at least annually and may include tabletop exercises. The evaluation and recommendations shall be communicated to the University's research community. The University may use AAHRPP's guidance on emergency preparedness as a framework to revise and expand the Plan.

B. Training and Education

The AVP HRP is responsible for preparing, reviewing and updating educational and training materials relating to emergency preparedness, based on the outcome of the periodic evaluations of the Plan, and ensuring that key personnel are educated about the Plan. Examples of information that may be presented include alternate mechanisms of delivering investigational drugs; remote study visits; remote monitoring; and providing or arranging for the provision of care in the event of a research-related injury.

IV. EMERGENCY RESPONSE IMPLEMENTATION

During an emergency, the AVP HRP has the authority to stop or postpone certain types of research to protect the safety and wellbeing of staff and research subjects or to prioritize resources. The termination or revisions of studies shall be considered actions of the University and not suspension or termination of IRB approval. The IRBs will continue to have authority to approve new studies and modification of studies or suspend or terminate open and ongoing studies.

The AVP HRP, with advice from the Committee, will be responsible for determining which studies will continue, which studies will be stopped and which new studies may be submitted for IRB review. The review should consider temporarily not accepting submissions of new research studies that are non-interventional in nature or which present no prospect of direct benefit to

participants. The AVP HRP shall also determine which studies that involve in person interactions with research subjects may be conducted in accordance with the study protocol, as adjusted to take into account the emergency. In general, the following triage guidelines may be used:

- Studies that present a likelihood of direct benefit to participants (or conversely, studies that include interventions that may be harmful to subjects if discontinued), as well as those with ongoing data analysis only or no in person contact, or those that relate to the emergency at hand, should not be postponed to the extent possible.
- Research involving direct interactions or interventions may continue via alternative mechanisms (such as remote visits) to the extent possible.
- Studies requiring in person contact, without prospect of direct benefit to participants, should be paused.
- Studies that may have an adverse impact on resources required to address the emergency should be postponed.

If the emergency may prevent one or more IRB meetings from occurring, the AVP HRP in consultation with the IRB Chairs will determine whether to cancel or reschedule the meetings, or to hold meetings virtually. If the HRPO staff will be unable to complete protocol processing and review responsibilities, or if capacity will be limited, the AVP HRP will work with the HRPO staff to prioritize reviews and to use remote computers to continue processing protocols in Rascal, the University's electronic research administration system.

If electronic records are unavailable, the AVP HRP will consult with the University IT staff to implement alternative procedures.

If necessary, the HRPO and the Committee shall develop alternative mechanisms for safety monitoring. If participants are not able to come to the investigational site for protocol-specified visits, the IEC and the HRPO staff shall evaluate whether phone contact, virtual visits or alternative locations can be utilized. In addition, the HRPO may consider more widespread use of waivers of documentation of consent for minimal risk research.

The AVP HRP, in consultation with the VPROP and the Committee, has the authority to transfer studies to an external IRB for review, pursuant to an approved reliance agreement. There should be a written plan on how such research will be returned to the University.

If the emergency affects normal communications, alternative communication strategies should be identified, including telephone, email, mobile telephone, text messaging and website messaging. In all situations, the AVP HRP and the HRPO staff shall provide timely updates to investigators. When the emergency impacts University operations beyond the HRPP, efforts to consolidate communications should be undertaken.

This Plan shall be posted on the HRPO website and on the websites of the relevant Emergency Management offices of the University.