

Emergency Preparedness Guidelines

The purpose of these emergency preparedness guidelines is to ensure sustainability of the HRPP and continuing protection of research participants during emergencies.

Emergency Preparedness Plan Training

The Office of Human Research Affairs (OHRA) provides education about the emergency response plan for IRB members, staff, researchers, and other members of the HRPP, specific to the role within the HRPP. OHRA staff members are trained upon hire regarding their role during an emergency.

All investigators have access to emergency preparedness planning information via Einstein and Montefiore's websites. Training mechanisms such as in-person meetings, webinars, and project-specific training are dependent upon the ongoing and changing needs of the institution.

Emergency Actions

In the event of an emergency, OHRA leadership will contact the Dean's Office for institutional-level emergency plans. The OHRA will defer to institutional leadership and institution-wide disaster and emergency response planning.

- Infectious diseases: In the case of an infectious disease outbreak, institutional leadership may decide to limit on-site operations and face-to-face contact.

 Determinations of which categories of studies may proceed (e.g. studies that can be conducted remotely, or studies that offer direct benefit to subjects) are made by institutional officials in coordination with academic departments. Studies that involve contact with Montefiore patients will follow Montefiore's policies on limiting exposure.
- Extreme weather or disasters (e.g. tornadoes, major earthquakes, or human-caused disasters): The possible impact of such emergencies, in relation to human subjects research, will be considered in determining the extent of emergency preparedness implementation needs at the time of the emergency categorization.

OHRA Operations

In the case that HRPP leadership is incapacitated or unavailable, HRPP decision making and responsibility for emergency procedures will follow the "Delegation of Authority" Policy (OHRA-POL-2019-002).

OHRA committee meetings may be conducted remotely. If the need arises (e.g. for treatment use of investigational drugs), the Executive IRB can serve as a rapid, ad hoc IRB review. OHRA staff may transition to fully-remote work if necessary.



Montefiore's Research Compliance may conduct remote safety monitoring if in-person access is restricted.

Periodic Review

The OHRA will periodically review these emergency preparedness guidelines and adjust as necessary ensure continuity of operations. The periodic review will follow the "HRPP Quality Improvement Procedure" (OHRA-SOP-2020-024).