NEOMED RESEARCH POLICY	Policy No: 3349-R-657
RESEARCH POLICY TITLE: Roles and Responsibilities of the Institutional Review Board (IRB)	EFFECTIVE DATE: June 4, 2019
RESPONSIBLE DEPARTMENTS: Office of Research and Sponsored Programs	Approval Authority: V.P. for Research Responsible Office: Research and Sponsored Programs

(A) PURPOSE

The purpose of this policy is to describe the roles and responsibilities of Northeast Ohio Medical University (NEOMED or University) Institutional Review Board (IRB) in the effort to protect the rights and welfare of human subjects based on local, state, and federal regulations.

(B) SCOPE

This policy outlines responsibilities for the protection of human subjects by the NEOMED IRB, institutional officials, and the University.

(C) DEFINITIONS

(1) "NEOMED IRB" refers to the independent standing committee established under University policy and federal regulations. NEOMED's IRB is administratively housed in the Office of Research and Sponsored Programs (ORSP) under the direction of the Vice President for Research.

(2) "Federal Wide Assurance (FWA)" refers to the agreement between NEOMED and the Department of Health and Human Services, where NEOMED agrees to be responsible for adhering to the guidelines of human subject research. The Vice President for Research provides oversight of all administrative functions required for research at NEOMED and is the signatory official for the FWA.

(3) "Institutional Official (IO)" refers to the Vice President for Research, who has administrative and operational authority to enforce policies, secure resources, and authorize administrative action toward research compliance. The IO communicates with federal and state authorities on matters of protection and welfare of human subjects and investigator and institutional compliance.

(4) "Human Protections Administrator (HPA)" refers to the person responsible for serving as the primary point of contact for NEOMED's system for protection of human subjects. The HPA plays a key role in ensuring that NEOMED fulfills its responsibilities under the FWA.

(5) "IRB Coordinator" refers to the person who receives applications from faculty, reviews each application for completeness, and distributes applications for purposes of review. The IRB Coordinator is responsible for keeping the institutional record of the research protocol. He or she will coordinate activities for purposes of continuing review, completion of studies, audits, consultations and maintenance of the database. The IRB coordinator works with the IRB Chair and Vice-Chair in determining which applications require full IRB review, prepares a written agenda for the meeting, is responsible for all logistics and prepares the IRB meeting minutes. The IRB Coordinator has been delegated limited signatory authority of IRB correspondence (protocol change memos, approval memos, consent forms) by the NEOMED IRB Chair.

(D) POLICY STATEMENT

(1) Human subject research at NEOMED must be reviewed by one or more federally registered IRBs at NEOMED or its affiliates. Additional federally registered IRBs outside of NEOMED may also be designated under the appropriate FWA to review collaborative human research on an as needed basis. An IRB has the regulatory authority to take any action necessary to protect the rights and welfare of human subjects at NEOMED including:

(a) To approve, required modifications to secure approval, disapprove, all research activities overseen and conducted by the organization;

(b) To suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm to participants;

(c) To observe, or have a third party observe, the consent process and the conduct of research.

(2) Review by NEOMED

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of NEOMED. Those officials, however, may not approve the research if it has not been approved by an IRB.

(3) Membership of the NEOMED IRB

(a) IRB Chair: The IRB Chair is responsible for setting the agenda for each meeting, determining what applications will be exempt, expedited, or require full IRB review, and is authorized to represent the IRB in communicating with investigators, administrators, legal advisors, and community representatives. The IRB Chair may approve applications that qualify for exempt, expedited, or limited review; disapproval requires full IRB review at a convened meeting. The IRB Chair serves as a mentor for IRB members, investigators and ORSP staff.

(b) IRB Vice Chair: The Vice Chair is responsible for providing a review of applications that may fall under the categories of exempt, expedited, limited, or full IRB review. The Vice Chair may approve applications that qualify for exempt, expedited, or limited review; disapproval requires full IRB review. The Vice Chair serves as a mentor for IRB members, investigators, and ORSP staff and assumes.

(c) Consistent with federal regulations and the local research climate, a minimum of five members, whose profile is maintained with the U.S. Office for Human Research Protection to include:

(i) include both men and women;

(ii) include at least one member who is not affiliated with the University;

(iii) are nominated by the Vice President for Research in consultation with Office of Research and Sponsored Program personnel;

(iv) are appointed by the University President;

(v) serve for a three-year, renewable membership; and

(vi) consultants and experts may be invited to assist in the review of research relevant to their field of study.

(4) Expertise of the NEOMED IRB

IRB membership is a composite of experience and expertise reflecting the research climate of NEOMED and its partnering universities, clinical, and research centers. All IRB Members are required to have human subjects training certification and continuing education on matters of IRB review and responsibilities. Training certification must be updated every three (3) years. Members of the IRB must:

(a) Have the professional knowledge to review human subjects research activities, including the accuracy of scientific and medical methods and information, the informed consent process, the recruitment, inclusion, and exclusion of individual subjects and diverse subject populations, the research environment(s), and other factors that contribute to risk-benefit determinations toward the protection of human subjects;

(b) Have knowledge of the subject populations, subject vulnerabilities, and those factors that contribute to determinations of how risks and benefits are distributed among subjects; and

(c) Have the skills to evaluate the accuracy of information presented by the Principal Investigator including the scope of research activities, the consent process, among other documentation and corresponding information including, but not limited to, consent documentation, advertisements, data use agreements, and other materials.

(5) The NEOMED IRB shall:

(a) Follow the three basic principles outlined by the Belmont Report (1979)

(i) Respect for persons;

(ii) Beneficence; and

(iii) Justice.

(b) Approve, require modification, or disapprove proposed human subjects research activities.

(c) Have the authority to modify, suspend, or terminate human subjects research that is not being conducted in accordance with institutional policies, local or state laws, or federal regulations (21 CFR 56.113 and 45 CFR 46.109), particularly research that may seriously harm or disrespect human subjects without proper safeguards and written and approved justification. Its decisions may only be modified by other institutions, groups, or individuals to be more restrictive, not less so.

(d) Approve research according to federal regulations and standard criteria, which may include:

(i) Minimizing risks as far as possible by sound research, safeguards against risks, and avoidance of unnecessary risks.

(ii) Ensuring the risks are reasonable in relation to the benefits of the subject or the importance of the knowledge to be gained for humanity;

(iii) Ensuring the selection of subjects is equitable and fair;

(iv) Verifying the informed consent of subjects will be obtained and documented;

(v) Providing that there will be monitoring of the data to protect subjects;

(vi) Protecting the privacy and confidentiality of the subjects, as well as their rights and welfare, unless the subject consents to their loss of privacy and confidentiality.

(e) Convene meetings for the review of full board research proposals. Full Board meetings require:

(i) the majority of IRB members be present to meet quorum, including one non-scientific member;

(ii) no action that requires voting be taken unless quorum is fulfilled;

(iii) actions are passed based on simple majority voting;

(iv) scheduling every other month based on the frequency of submitted proposals. Unscheduled meetings may be called at the IRB Chair's discretion;

(v) the ability to be held via audio (telephone) or video conferencing; and

(vi) Meeting minutes taken and maintained.

(f) Provide guidance and contribute to continued education and training to all investigators of the NEOMED community who conduct human subjects research.

(g) Conduct audits of investigator activities of human subject research to further safeguard the rights and welfare of human subjects and create a respectful culture of human subject research.

(h) Provide continuing review of approved ongoing research at least annually if required to do so by federal regulation or institutional policy. Continuing review will include receipt of a progress report (Continuation Form or Closure Form) from the Principal Investigator.