****

**Newman University Institutional Review Board (IRB)**

**Policy and Procedures**

9/27/2018

Purpose of the Policy

This policy details the definitions, regulations, and procedures governing any research done at Newman University (NU) that involves human participants. This policy applies to all research involving human participants at Newman University regardless of the source of funding including research conducted by individuals outside of the University either using human participants or pre-existing or unpublished data gathered from Newman University. The intended audience for this policy includes research administrators, principal investigators, students, and IRB members.

Authorization of the IRB

Newman University has authorized the IRB to provide oversight of human research protections. The committee ensures proper protection of the rights, privacy and welfare of the individuals involved, with consideration of the methods used to gain informed consent and the justification of risks in terms of the potential benefits to be gained. The IRB has the authority to review, approve, require modifications or deny research activities proposed by faculty, staff or student investigators. This Policy applies to all research involving human subjects, regardless of sponsorship, if one or more of the following apply:

1. The research is sponsored by NU, or
2. The research is conducted by a NU employee or agent of NU, or
3. The research is conducted by a NU student, or
4. The research requires participation of NU students or employees, or
5. The research involves the use of NU’s non-public information to identify or contact research subjects or prospective subjects.

Purpose of the IRB

The role of the IRB is to ensure the welfare, rights and privacy of all human participants in research conducted by NU faculty, staff or students, or research done on NU faculty, staff, or students. The IRB works to educate investigators and research staff about their ethical responsibility to protect research participants as defined in The Belmont Report issued in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The IRB aims to meet the minimal criteria of these principles as established by the Department of Health and Human Services, Code of Federal Regulations (Title 45, Part 46 of the Code of Federal Regulations, “The Revised Common Rule” effective July 19, 2018) for all human subject research, regardless of sponsorship. When appropriate, the IRB will intervene in research and/or respond directly to concerns of research participants.

IRB Membership

IRB membership is determined per Part A: 45 CFR 46.107. The IRB will have five members. These members will consist of:

1. Both men and women
2. At least one member whose primary concerns are in scientific areas
3. At least one member whose primary concerns are in non-scientific areas
4. At least one member who is not affiliated with NU nor is a family member of anyone affiliated with NU
5. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB

The Director of Institutional Research will chair the IRB and will be responsible for recommending members to serve on the IRB to the Vice-President of Academic Affairs. Members will serve terms of three years and may serve for more than one term. All members complete the training in human participant research module provided by the National Institutes of Health (NIH).

Determination of Human Subjects Research

The IRB must approve all research involving human participants prior to the research beginning. Research investigators should refer to the following definitions to determine if their activity constitutes human subjects research.

Per Part A: 45 CFR 46.102:

(l) *Research* means a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**. Activities that meet this definition constitute research for purposes of this Policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research (1) Obtains information or biospecimens through **intervention** or **interaction** with the individual, and users, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates **Identifiable private information or identifiable biospecimens**.

*Intervention*includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes.

*Interaction* includes communication or interpersonal contact between investigator and subject.

*Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Application for IRB Approval

Faculty, staff, or students who will engage in research of human subjects must submit an application for IRB approval regardless of funding source (federal, state, local, private, or unsponsored). The IRB can assist research investigators in determining whether their proposed activity constitutes research of human subjects.

**Independent Faculty research** involving human participants: The principal investigator must submit the “**APPLICATION FOR PROJECT/PROPOSAL APPROVAL”** and wait for IRB approvalbefore beginning research. IRB approval from a previous institution does not constitute IRB approval at Newman University.

**Faculty-Student Collaborative research** involving human participants intended to result in generalizable knowledge: The IRB must approve any research or activity involving intervention or interaction of human participants that will be shared outside the class (including presentations at NU Scholar’s Day, conferences, or public symposiums). The principal investigator must submit the “**APPLICATION FOR PROJECT/PROPOSAL APPROVAL”** and wait for IRB approval before beginning research.

**Non-research Class Projects** involving human participants but not intended to result in generalizable knowledge: Faculty should submit a **“Non-Research Class Project – Request for Clearance Form”** for any class activity that cannot be generalized, the activity involves intervention or interaction of human participants, and the activity will be shared within the class only.

**Non-NU researchers** conducting research that will impact the NU community, including faculty, staff or students: Documentation of IRB approval from another institution should be submitted to the NU IRB before research begins. Once the NU IRB receives the documentation, the IRB will determine if further approval from the NU IRB is required.

The applications are located on the NU website, <https://newmanu.edu/academics/academic-information/institutional-review-board> and the NU Intranet (*location to be determined*).

Exemptions, Expedited and Full Reviews

When submitting the APPLICATION FOR PROJECT/PROPOSAL APPROVAL, the primary investigator can request that their research activity be exempt from IRB review or request an Expedited or Full review. The IRB will have final determination of the type of IRB review necessary in accordance with the 45 CFR 46. The IRB chair initially evaluates all applications to determine the type of review required by the IRB.

The IRB will require documentation of informed consent or waive documentation in accordance with 45 CFR 46.117.

**Exempt from IRB Review:** The exempt category covers research of minimal or no risk.There are eight categories, such as de-identified survey, interviews, or existing data or normal educational practices (for more detailed descriptions and limitations consult 45 CFR 46.104). If no limited review is required, the IRB chair informs the principal investigator in writing that their research activity is exempt from further review. The principal investigator may begin research any time after receiving notification.In some cases, a limited IRB review is required, such as in the case of a privacy and confidentiality review. The IRB will treat these cases as an Expedited Review.

**Expedited Review:** The IRB conducts an expedited review for research that involves no more than minimal risk or for review of minor changes in previously approved research protocols. A subcommittee of the IRB conducts the review. The IRB chair may request that committee members meet face-to-face to discuss the application; however, discussions may also take place via emails or through other secure discussion platforms. The IRB either approves the application unconditionally through a majority vote of its members, or requires modifications needed to secure IRB approval, or denies approval. The IRB chair notifies the principal investigator of the IRB decision in writing. If the IRB does not approve the research, the IRB will include a statement of reasons for its decisions and give the investigator an opportunity to respond.

**Full Review:** Full committee review is required for all research involving greater than minimal risk to subjects. In addition, full review is required for all research activities involving vulnerable subject populations, including fetuses, pregnant women, human in vitro fertilization, prisoners, children, elderly, and psychiatric patients. Approval of the research requires agreement by a majority of the IRB members present.

In all cases, the IRB will follow the criteria for IRB approval of research per 45 CFR 46.111. The IRB may suspend or terminate approval of research that is not conducted in accordance with the IRB’s requirements or that is associated with unanticipated harm to participants. Any suspension of termination of approval shall include a statement of reasons for its decisions and shall be reported promptly to the research investigator and appropriate NU officials.

IRB Resources

The Office of Human Research Participant Decision Charts are available as a reference and resource for research project planners. The Decision Charts as well as an Informed Consent template, the NON-RESEARCH CLASS PROJECT – REQUEST FOR CLEARANCE form, and the APPLICATION FOR PROJECT/PROPOSAL APPROVAL are available on the NU Intranet (*location to be determined*).