Protocol for the University of Mount Union IRB

What is an IRB?

An IRB is a committee with the authority to review and approve research involving human subjects. An IRB is composed of a diverse group of men and women with expertise in science, ethics, and other non-scientific areas. This diversity is important as it fosters a comprehensive approach to protecting the rights and safeguarding the welfare of subjects. In addition to their individual skills, experience and perspectives, members are recruited to serve on an IRB based on their independence, professional integrity and willingness to perform a public service.

An Institutional Review Board ("IRB") is the formal name for a Human Subjects Committee. The IRB is a committee that reviews all proposed UMU human subjects research to ensure that the safety and welfare of subjects are protected. All human subjects research requires review and approval by an IRB prior to subject recruitment and data collection, and prior to the use of extant data or private information. IRB members have the responsibility for reviewing all research involving human subjects conducted by UMU faculty, students, or staff, regardless of the source of funding.

Appointment to Mount Union's IRB

In accordance with the US Department of Health and Human Services (PART 56 - INSTITUTIONAL REVIEW BOARDS; subpart b - ORGANIZATION AND PERSONNEL; 56.107 - IRB membership).

> *(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.*
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> *(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of*

both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

[46 FR 8975, Jan 27, 1981, as amended at 56 FR 28028, June 18, 1991; 56 FR 29756, June 28, 1991]

The University of Mount Union appoints members to serve on the IRB. Members are appointed for three-year renewable terms. IRB members include faculty, staff and community members, scientists and non-scientists, who, in the aggregate, possess a broad range of interests and expertise that correspond with the areas of research reviewed. Members of the committee should be familiar with the ethical principles of *The Belmont Report* of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979) (see Appendix A). In summary, these principles are:

- Respect for persons - which includes the requirement of a voluntary informed consent process
- Beneficence – which entails an obligation to protect persons from harm by minimizing risks and maximizing benefits
- Justice – which requires that selection of subjects be fair and equitable and that particular care be taken when working with populations (i.e. children, those with impaired decision making abilities) whose status puts them in a vulnerable position.

IRB Meetings

The IRB holds meetings as necessary for the timely and effective review of proposed research projects. The IRB chairperson schedules and presides over the meetings. Historically, the IRB convenes meetings of the full membership monthly during the academic year. However, intermittent e-meetings can be called if committee member collaboration is needed prior to the official meeting.

Meetings do not proceed unless quorum exists. A quorum exists when a majority of the IRB members are present and those present include at least one member whose primary concerns are in a non-scientific area.

CORRESPONDENCE WITH THE IRB

Correspondence to and from the IRB is done electronically via email. All requests for review and approval are submitted to the IRB chairperson electronically as an email attachment sent to irb@mountunion.edu.

Timing of Submissions
All requests for IRB review and approval must be completed in advance of the start of the proposed research project. When funding is sought from sponsors to support the proposed research, the chairperson of the IRB shall be notified of any applicable grant proposal deadline at the time the IRB Request for Review and Approval form is submitted.

Timing of Responses
Investigators will receive prompt notification of IRB decisions. The chairperson notifies the investigator who submitted the IRB Request for review of the decision of the IRB conferring approval, approval with minor revisions, or disapproval of the proposed research project within 48 hours of the IRB decision. In the case of approval with minor revisions or disapproval, the notification will include specific citation of the reason(s) for the outcome.

IRB REVIEW

Initial Review
All proposed research projects submitted for review are directed to the IRB chairperson who conducts an initial review to determine whether the research is categorized correctly, and confirms that all necessary materials are included with the application (e.g., signatures, materials, etc). Upon confirmation of the complete application, the chairperson assigns the application for review to the appropriate Committee member(s), who then use the IRB Protocol Review Standards (see Appendix B) to complete the IRB Reviewer Response Form (see Appendix C). All IRB Human Subject Applications (see Appendix D) and corresponding materials are made available electronically via links that are included in the appendices, and reviews are shared electronically as well, in an effort to facilitate the review process.

Exempt Review Category:
- Research that is anonymous, does not involve minors, and the collection of data poses no greater risk than normally expected on a typical day.
- One member of the Committee reviews these proposals.

Expedited Category:
- Research that may have confidential collection of data, and exposes participants to risk that is no greater than what they would normally be exposed to on a typical day.
- Two members of the Committee review these proposals.

Full Category:
- Any study involving **greater than minimal risk** requires a review by the convened IRB. This includes studies with vulnerable populations and sensitive questions as well as studies with the possibility of physical risk.
- Studies assigned to full board review are reviewed by all members of the IRB committee and then discussed at the meeting. At the meeting, the committee votes on whether or not to approve the study.

IRB DECISIONS

Approved
The research may proceed as described.

Approved with Minor Revisions
In this case, revisions requested by the IRB are straightforward and easily verified. Proposals in this category will not need to be reviewed again by the full IRB. The IRB Secretary or Chairperson will do verification that required revisions have been made, in consultation with reviewers. Upon verification that satisfactory revisions have been made, formal written approval will be granted to the project. Data collection may not begin until formal written approval is received.

Revise and resubmit
This status indicates that, in the view of the reviewers from the IRB, the required revisions are significant and important to the ethical assessment and/or acceptance of the research project. Upon verification by the initial reviewers that satisfactory revisions have been made, formal written approval will be granted to the project. Data collection may not begin until formal written approval is received.

DUTIES OF THE IRB CHAIRPERSON

The duties of the IRB chairperson include, but are not limited to, the following:

Work with the committee to prepare for the academic year:
- Establish meeting dates
- Update application material
- Update iRaider portal information

Review all incoming IRB proposals:
- Check proposals for completeness
- Assign materials to committee member(s) for review
- Post materials to application link for committee review
- Notify research of review outcome
- Review revisions and resubmissions
- Track all proposals throughout the review process

Meeting oversight:
- Prepares and agenda that lists all proposals under review
- Emails agenda to committee members at least 24 hours prior to meeting
- Assigns member to track meeting minutes, and distributes minutes prior to next meeting

Maintains committee records
- Tracks all proposals
- Maintains copies of all correspondence related to proposals

Appendix A

The Ethical Principles of The Belmont Report

The Belmont Report -- Ethical Principles and Guidelines for the Protection of Human Subjects -- was published in 1979 and provides the philosophical underpinnings for the current laws governing human subjects research. The Belmont Report establishes three fundamental ethical principles that are relevant to all research involving human subjects: Respect for Persons, Beneficence, and Justice. Although other important principles sometimes apply to research, these three provide a comprehensive framework for ethical decision-making in research involving human subjects.

1. The principle of Respect for Persons acknowledges the dignity and autonomy of individuals, and requires that people with diminished autonomy be provided special protection. This principle requires that subjects give informed consent to participation in research. Because of their potential vulnerability, certain subject populations are provided with additional protections. These include children, prisoners, the mentally disabled, and people with severe illnesses.

2. The principle of Beneficence requires us to protect individuals by maximizing anticipated benefits and minimizing possible harms. Therefore, we must examine carefully the design of the study and its risks and benefits including, in some cases, identifying alter- native ways of obtaining the benefits sought from the research. Research risks must be reasonable in relation to the expected benefits, if any, to the subjects and the importance of the knowledge that may be expected to result.

3. The principle of Justice requires that we treat subjects fairly. For example, subjects should be carefully and equitably chosen to insure that certain individuals or classes of individuals -- such as prisoners, elderly people, or financially impoverished people -- are not systematically selected or excluded, unless there are scientifically or ethically valid reasons for doing so. Also, unless there is careful justification for an exception, research should not involve persons from groups that are unlikely to benefit from subsequent applications of the research.

Each of these principles carries strong moral force and difficult ethical dilemmas arise when they conflict. A careful and thoughtful application of the principles of The Belmont Report by IRB members will not always achieve clear resolution of ethical problems. However, it is important to understand and apply the principles, because doing so helps to assure that people who agree to be experimental subjects will be treated in a respectful and ethical manner.

Appendix B

IRB PROTOCOL REVIEW STANDARDS	
Review requirements	**Suggested questions for IRB discussion**
1. The proposed research design is scientifically sound & will not unnecessarily expose participants to risk.	(a) Is the hypothesis clear? Is it clearly stated? (b) Is the study design appropriate to prove the hypothesis? (c) Will the research contribute to generalizable knowledge and is it worth exposing participants to risk?
2. Risks to participants are **reasonable** in relation to anticipated benefits, if any, to participants, **and** the importance of knowledge that may reasonably be expected to result.	(a) Is the risk to participants reasonable, in relation to the expected gain in knowledge? (b) Are there reasonable levels of risk/discomfort/inconvenience? (c) Is there prospect of direct benefit to participants?
3. Participant selection is equitable.	(a) Who is to be enrolled? Men? Women? Ethnic minorities? Children (rationale for inclusion/exclusion addressed)? Seriously-ill persons? Healthy volunteers? (b) Are these participants appropriate for the protocol?
4. Additional safeguards required for participants likely to be vulnerable to coercion or undue influence.	(a) Are appropriate protections in place for vulnerable participants, e.g., pregnant women, fetuses, socially- or economically-disadvantaged, cognitively impaired?
5. Informed consent is obtained from research participants or their legally authorized representative(s).	(a) Is the consent document understandable to participants? (b) Who will obtain informed consent (PI, nurse, other?) & in what setting? (c) If appropriate, is there a children's assent? (d) Is the IRB requested to waive or alter any informed consent requirement?
6. Risks to participants are minimized.	(a) Does the research design minimize risks to participants? (b) Would use of a data & safety monitoring board or other research oversight process enhance participant safety?
7. Participant privacy & confidentiality are maximized.	(a) Will personally-identifiable research data be protected to the extent possible from access or use? (b) Are any special privacy & confidentiality issues properly addressed, e.g., use of genetic information?

Appendix C

Human Subject Application Reviewer Form

https://irbumu.wufoo.com/forms/irb-application-review/

Appendix D

Human Subject Application Form

https://irbumu.wufoo.com/forms/irb-application/