The University of Mount Union Institutional Review Board (IRB) Human Subject(s) Handbook

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Mission of the University of Mount Union Institutional Review Board (IRB)

At the University of Mount Union, the primary purpose of the Institutional Review Board (IRB) is to protect the welfare of human subjects in research. Federal and state regulations mandate that research involving human participants must be reviewed and approved by an IRB and may be subject to continuing review by the IRB. As an institution, the University of Mount Union is committed to fostering the growth of human subjects' research by faculty, staff, and students for the greater good of humanity and for the pursuance of knowledge. The University of Mount Union's, President's Council, grants authority to the IRB to approve of research involving human subjects.

Federal Governance

The University of Mount Union, has committed to the U.S. Department of Health & Human Services (HHS) that it will comply with the requirements outlined in the HHS Protection of Human Subjects regulations at 45 CFR part 46. The University of Mount Union's IRB has been reviewed and approved by HHS and issued a Federalwide Assurance (FWA). The HHS regulations, 45 CFR part 46, include four subparts: subpart A, also known as the Federal Policy or the "Common Rule"; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and, subpart D, additional protections for children.

What is Considered Human Subjects Research?

Research is considered to involve human subjects when a researcher (1) obtains information or biospecimens through intervention or interaction with a living individual and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (45 CFR part 46).

1. Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

   Research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication. Research that never is published is still research. Participants in research studies deserve protection whether the research is published or not.
   - Systematic Investigation: is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

2. Intervention: physical procedures by which information or biospecimens are gathered (for example, venipuncture) or manipulations of the subject or the subject's environment are performed for research purposes.

3. Interaction: communication or interpersonal contact between the researcher and the subject.

4. Identifiable: for which the identity of the subject is or may readily be ascertained by the researcher or associated with the information or biospecimen.

5. Identifiable Private Information: private information for which the identity of the subject is or may readily be ascertained by the researcher or associated with the information.

6. Identifiable Biospecimen: specimen for which the identity of the subject is or may readily be ascertained by the researcher or associated with the information.

What is Not Typically Considered Human Subject Research?

1. Scholarly and journalistic activities: including the collection and use of information that has already been published and is being examined, and information is collected. Examples include: journalism, biography, and literary criticism.

2. Public health surveillance activities: limited to those activities conducted, supported, requested, ordered, required, or authorized by a public health authority.

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for criminal justice or investigative purposes: for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. This does not include social and behavioral studies of the causes of criminal behavior.

4. Authorized operational activities for national security purposes: authorized operation activities in support of intelligence, homeland security, defense, or other national security missions.

University of Mount Union IRB Organizational Structure

The IRB is a University Committee and functions administratively under the President's Council. The Vice President for Academic Affairs (VPAA), or designee, serves as the IRB Administrator, the Office of Institutional Effectiveness serves as the Office of Record, and the Compliance Oversight Committee (COC) serves as the reporting body for the IRB in matters of federal regulatory compliance and adherence to IRB policy by the university community, non-university researchers, and third-party research entities.

The chair of the COC is the point of contact for the IRB in all compliance-related matters and concerns. The IRB Chair is also a part of the COC in an ex-officio capacity. This structure provides for administrative coordination of the IRB with the various academic and administrative units in the university. The IRB committee, and/or the IRB Chair, advise and make recommendations to the COC, the University President, and to policy/administrative bodies, as well as to any member of the university community on all matters related to the use of human subjects in research. All recommendations involving policies and procedures will be submitted to the respective administrative parties and/or faculty committees for review and approval.

University of Mount Union IRB Composition Requirements

IRB membership is comprised of appointed faculty from the University and volunteers from the community.

The IRB at the University of Mount Union will:

1. Consist of at least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;
2. Be sufficiently qualified through the experience and expertise of its members (professional competence);
3. Make every effort to ensure the diversity of its members, including race, gender, and 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;
4. Include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
5. 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; and,
6. Not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Positions and Appointments

IRB Chair

The current IRB committee members, together with the IRB Administrator, will recommend the name of a prospective IRB chair to President's Council for approval. There is no specified time limit for serving as an IRB Chair; however, the IRB Chair is expected to hold the position for a minimum of 3 years. The IRB Chair may be replaced by President's Council or may resign their position by submitting a letter of resignation to the IRB Administrator. Newly recommended and approved IRB Chairs will serve one year in waiting with the current IRB chair to mentor. Once the year in waiting has ended, the chair in waiting will assume the official IRB Chair role.

Internal University of Mount Union IRB Members

The IRB Chair and the IRB Administrator are responsible for selecting Internal Members to serve on the University of Mount Union's IRB. The selection process is conducted with prior consultation with the current IRB committee members.

The IRB Chair will take the selection from consultation with the current IRB committee members and provide the nominations to the IRB Administrator, for an official offer of appointment to be sent out via email. Internal IRB Members receive an appointment letter after their appointment is confirmed/accepted. The letter states the terms of service. Internal IRB Members serve a three-year term, which is consecutively renewable once, at the discretion of the IRB Chair and the IRB Administrator. Internal IRB Members may resign at any time by submitting a letter of resignation to the IRB Chair. The IRB Chair *may* remove an Internal Member from the committee if the member is not able to complete his/her responsibilities as an IRB Member, and an official letter via email will be sent by the IRB Administrator.

External IRB Members

The IRB Chair and the IRB Administrator are responsible for selecting External Members to serve on the IRB. The selection process may be conducted in consultation with the other IRB Members.

The IRB Chair will appoint the External IRB Members. The External IRB Members receive an appointment letter after their appointment is confirmed/accepted. The letter states the terms of service. The External IRB Members serve a three-year term. The External IRB Members have no term limits, and their renewal is at the discretion of the IRB Chair and the IRB Administrator. The External IRB Members may resign at any time by submitting a letter of resignation to the IRB Chair. The IRB Chair may remove an External Member from the committee if the member is not able to complete his/her responsibilities as an IRB Member.

Alternate IRB Members

Up to three Alternate IRB Members may be appointed by the IRB Chair and the IRB Administrator. Alternates are appointed and function in the same manner as the primary IRB Members. The alternate's expertise is comparable to those of the primary member. The role of the Alternate Member is to serve as a voting member of the IRB when the regular member is unable to attend a convened meeting. When an Alternate Member substitutes for a primary member, the Alternate Member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The IRB minutes will document when an Alternate Member replaces a primary member.

Ad Hoc Consultant

At times, the IRB may not have the necessary expertise to judge the scientific soundness of a research application and may be unable to make a fair and accurate determination of the risk- benefit ratio. For these applications, the IRB Chair, may call upon an Ad Hoc Consultant for assistance. The Ad Hoc Consultants are not considered IRB members, are utilized only for expert scientific review, have no voting rights, and must disclose any conflicts of interest with the application.

IRB Administrator

The VPAA (or designee) serves as the IRB Administrator as designated by President's Council. The IRB Administrator does not have a term limit and is a non-voting member.

IRB Administrative Assistant

The IRB Administrative Assistant is designated by the President's Council and is identified as the Chair to the Compliance Committee (COC). The IRB Administrative Assistant does not have a term limit and is a non-voting member.

Position Responsibilities

IRB Overall

1. Safeguards the rights and welfare of human subjects.
2. Has the responsibility and authority to review, approve, disapprove or require changes in appropriate research activities.
3. Will review all proposals involving test articles and medical research, and it will also review non-invasive proposals involving social and behavioral research.
4. Conducts review of initial application submissions, continuing reviews, and all revisions to applications of human subject research conducted by the researchers.
5. Approves, requires modifications to secure approval, defers (tables), or disapproves research activities overseen and conducted under the auspices of the university, regardless of location of the research activities.
6. Analyzes applications systematically for benefits in relation to the potential risks involved in the research.
7. Reports in writing (email) the findings and actions of the IRB to the researchers, OIE/COC, and to federal regulatory agencies or departments, as necessary.
8. Determines the interval at which ongoing studies need to be reviewed by the IRB.
9. Ensures prompt reporting of any changes in research activities to the IRB by researchers.
10. Ensures prompt reporting of adverse events to the IRB and federal agencies, where applicable, including:
    - Unanticipated problems involving risks to subjects or others.
    - Serious or continuing noncompliance with regulations.
    - Suspension or termination of IRB approval.
11. Suspends or terminates research not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects.

IRB Chair

1. Serves as public spokesperson for the IRB.
2. Convenes meetings of the IRB.
3. Updates the full committee at first AY meeting of who is serving as *IRB Administrator and IRB Administrative Assistant*
4. Ensures adequate expertise for the review of applications.
5. Completes required human subjects research CITI training.
6. Appoints and evaluates IRB Members, Alternate Members, and Ad Hoc Consultants with assistance from the IRB Administrator.
7. Logs IRB applications, assigns application number, and sends applications with all submitted material to IRB members for review.
8. Reviews and checks incoming IRB applications for completeness, as needed; submits review comments.
9. Reviews applications, continuing review reports, unanticipated problem and deviation reports, and other documentation submitted to the IRB.
10. Reviews, requests any necessary revisions, and approves exempt applications.
11. Delegates review responsibilities as necessary and applicable.
12. Sends sixty-day courtesy expiration notice emails to all researchers.
13. Records meeting minutes.
14. Maintains IRB files.
15. Maintains up-to-date knowledge of human subject regulations and pertinent events.

16. Consults with researchers as necessary.
17. Suspends the conduct of research when individuals are placed at an unacceptable level of risk.
18. Collaborates with the Institutional Official and IRB Administrator to provide continuing education for IRB Members.
19. Collaborates with the IRB committee members to develop a list of internal member nominations and provides them to the IRB Administrator for the appointment.
20. Collaborates with the Institutional Official and IRB Administrator to resolve IRB-related issues with faculty or subjects.
21. Recognizes and supports partnership with Institutional Official to assure IRB efficiency and effectiveness.
22. Ensures that IRB Members with a conflict of interest are not present for any discussion and vote on research where he/she has a conflict.
23. Reviews copies of all IRB meeting minutes containing reports of IRB deliberations on human subject applications, the results of quality improvement audits, and noncompliance findings.

IRB Members (Internal & External)

1. Are familiar with IRB policies, procedures and federal, state, and local regulations, policies or guidelines relating to human subject research.
2. Completes all offered and required human subjects research CITI training.
3. Reviews submitted proposals as assigned by IRB Chair, within 2 weeks from being assigned.
4. Attends a minimum of 75% of the meetings and participates in the review of research applications.
5. Reviews meeting materials and minutes in advance of IRB meetings and are prepared for discussions, voting, and deliberations.
6. Acts as a primary or secondary reviewer of applications when assigned.
7. Works with researchers to resolve issues related to IRB review.
8. Maintains confidentiality of IRB proceedings.
9. Discloses conflicts of interest, if applicable.

IRB Administrator and IRB Administrative Assistant

1. Are familiar with IRB policies, procedures and federal, state, and local regulations, policies or guidelines relating to human subject research.
2. Maintain required human subjects research CITI training certification.
3. Facilitate federal reporting, trainings, and quality improvement.
4. Disclose conflicts of interest, if applicable.
5. Represent the institution in matters regarding human subject research and is the signatory authority for all the Federalwide Assurance to the Office for Human Research Protections.
6. Sign all correspondence and reports sent to federal regulatory agencies regarding researcher or institutional noncompliance.
7. Collaborate with the Office of Institutional Effectiveness and IRB Chair to provide continuing education for IRB Members.
8. Collaborate with the IRB Chair and IRB Administrative Assistant (COC) to resolve IRB-related issues with faculty or subjects.
9. Maintain the IRB's federal registration and Federalwide Assurance Number.

10. Address all Survey policy and other University policy questions.
11. Maintain confidentiality of IRB proceedings.

IRB Records

The IRB shall prepare and maintain the following documentation of IRB activities on file for the time period set forth below:

1. Copies of all research proposals received, scientific evaluations, if any, that accompany the proposals, copies of all internal and external correspondence related to each submitted proposal, approved sample consent forms, progress reports submitted by researchers, and reports of injuries to subjects, if any.
2. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
3. A list of IRB Members.
4. Written procedures for the IRB.
5. Copies of all correspondence between the IRB and the principal investigator of any study.
6. Statements of significant new findings provided to subjects as required by the consent forms.
7. Records of continuing review activities.
8. The rationale for an expedited reviewer's determination that research appearing on the expedited review list is no more than minimal to moderate risk to the subject(s).
9. Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of 45 CFR part 46.

The foregoing records shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.

IRB Website

The IRB website should (UMU IRB WEBSITE) contain up-to-date information including:

1. Human subject research definitions;
2. Steps to completing the IRB process;
3. Link to Application and Application working document forms;
4. Training requirements;
5. Policies and procedures
6. IRB personnel names and contact information (UMU Email for IRB Only);
7. Helpful information; and,
8. Frequently asked questions.

Corresponding with the IRB

The IRB will communicate with researchers via email. Letters detailing required changes to a submitted IRB application and documentation approving an IRB application will be emailed to all researchers identified on the IRB application. Researchers can contact the IRB via email (irb@mountunion.edu). IRB personnel's information is located on the IRB website (UMU IRB Website).

IRB Meetings

The IRB meeting will be held when deemed necessary by the IRB Chair. The IRB Chair may convene additional meetings the IRB Chair deems necessary to handle the business of the IRB, with notice of any meetings of the IRB requiring being provided to each member of the IRB no less than seventy-two (72) hours before each meeting.

Required quorum for any IRB meeting shall be a majority of the members of the IRB, including the IRB Chair or a committee member appointed by the chair to chair such meeting. The agenda for any IRB meeting shall be determined by the chair, and may include (a) a review of, and action on minutes of a previous meeting(s), (b) old and new business related to IRB functioning, (c) review and discussion of, and action on new proposals (in order of submission), continuing proposals, and substantive changes to previously-approved proposals, and (d) other business. Proposals shall be approved, approved with conditions, disapproved or tabled until a specified future date by a majority vote of the IRB members present.

To preserve autonomy of the IRB and its decisions, IRB meetings are typically closed, provided that such closure is not in conflict with 45 CFR Part 46 or other, applicable Federal, State, or local laws and regulations. Anyone may speak for or against a proposal, provided that remarks are based only on the criteria for approval stated for each criterion of the IRB paperwork. The chair of the meeting may limit the duration of comments or number of speakers for and against a proposal to serve the best interests of IRB committee functioning. Written comments received by the IRB chair prior to the meeting will be read into the minutes or distributed and appended to the minutes, insofar as they address the criteria for approval. The IRB Chair may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that represented by the members of the IRB.

IRB members and persons speaking or submitting written comments must declare any potential conflicts of interest in advance. Members of the IRB may speak for, but may not vote on their own proposals, proposals for students that they are sponsoring, or any proposal in which an IRB member is or is likely to be a participant. Written comments shall specifically address any conflict of interest or its absence in the event of a perceived conflict of interest.

IRB Review of Research

Research reviewed by the IRB will fall into one of three categories based upon the risk level to the human subjects involved in the research:

1. Exempt research contains minimal risk to human subjects.
2. Expedited research contains minimal to moderate risk.
3. Full board research contains moderate to high risk to human subjects.

Exempt Research

For research to be deemed exempt, it must fall into one of the following eight categories and contain minimal risks to the human subject participants. *BE ADVISED that all exempt research must still meet basic ethical standards and must still come through the UMU IRB Committee for review to determine whether it meets the federal criteria for exemption.*

Exemption 1: Research conducted or established in commonly accepted educational settings that involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. For this exemption, the party requesting exemption must certify in writing that the research activities will (a) not differ in any significant way from the normal range of activities of the classroom; (b) involve only customary and non-controversial instructional goals; (c) not deny any student's educational benefits that they would otherwise receive; (d) provide direct benefits (at least in the form of evaluation information) to the classroom; (e) incorporate adequate safeguards to protect privacy of all individuals who might participate in the research; and (f) involve only existing data on students which is not identity-specific.

Exemption 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures (excluding research involving children), or public behavior observations, provided that (a) the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to them, or (b) disclosure of the human subjects' responses outside of the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement or reputation, or (c) the identity of the human subjects can readily be ascertained and the IRB conducts a limited IRB review (excluding research involving children).

Exemption 3: Research involving benign behavioral interventions and data collection through verbal or written responses, including audiovisual recordings if the adult participants agree prospectively, if one of the following applies: (a) the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to them, or (b) disclosure of the human subjects' responses outside of the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement or reputation, or (c) the identity of the human subjects can readily be ascertained and the IRB conducts a limited IRB review. This exemption is not to be used when the research is with children. For purposes of this exemption, "benign behavioral intervention" shall mean (i) brief in duration, (ii) harmless, painless, not physically invasive, no long adverse impact, and (iii) the researcher has no reason to think that the subjects will find the interventions offensive or embarrassing.

Exemption 4: Secondary research involving the collection or study of existing, identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information or specimens) data, documents, records, pathological specimens, or diagnostic specimens, if (a) the identifiable information or specimens are publicly available, (b) the information is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects, (c) the researcher's use of identifiable health information (not biospecimens) is, where HIPAA applies, for purposes of "health care operations," "research," or

for “public health activities or purposes” (as such terms are defined under HIPAA), or (d) the research is conducted by, or on behalf of a federal department or agency using government-generated or government-collected information obtained for non-research activities and federal privacy regulations apply.

Exemption 5: Research designed to study, evaluate or otherwise examine (a) public benefit or service programs, (b) procedures for obtaining benefits or services under those programs, (c) possible changes in or alternatives to those programs or procedures, and/or (d) possible changes in methods or levels of services under those programs.

Exemption 6: For taste, food quality and consumer acceptance studies, if (a) wholesome foods without additives are consumed, or (b) if a food consumed contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exemption 7: Storage or maintenance of identifiable materials for secondary research with a broad consent form and if the IRB conducts a limited IRB review.

Exemption 8: Research using identifiable private information or biospecimens for secondary research use if (a) a broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained, (b) documentation of informed consent or waiver of documentation of consent was obtained, (c) the IRB conducts a limited IRB review, and (d) the investigator does not include returning individual research results to subjects as part of the study plan.

For purposes of the foregoing, a “limited IRB review” shall mean a review process conducted by designated reviewers, the IRB chair, or other members of the IRB Committee in accordance with applicable federal regulations.

Vulnerable Populations

Research containing a vulnerable population typically requires expedited or full board review. The U.S. Department of Health & Human Services (HHS) regulations, 45 CFR part 46, specifies vulnerable populations that require additional protections when involved in human subject(s) research. These populations included: pregnant women, human fetuses, and neonates (subpart B); prisoners (subpart C); and children (subpart D).

Expedited and Full Board Research

The IRB Chair determines if the research contains moderate or high risk and designates the application as requiring an expedited or full board review (see IRB Review Process).

Steps to Complete the IRB Process

1. All faculty, staff, students and external researcher(s) must complete and pass the Collaborative Institutional Training Initiative (CITI) course in human subject(s)

research prior to submitting an IRB application. Applications submitted to the IRB are not considered complete until appropriate training is completed. A copy of all CITI training completion certificates must be included with the IRB application.
2. Download the application working document and complete.
3. Take the working document and copy/paste over the information into the appropriate IRB Wufoo application link.
4. Wait for response regarding the IRB online application submitted which may be up to 2-3 weeks from submission.

Application Forms

There is a working document application form linked on the IRB Website. All new IRB applicants should use this form to work off. Once fully completed, applicants will take the information within the working document and copy over into the IRB application link located on the IRB website.

Required Consent Form Elements

Before involving a human subject in research, a researcher shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative. The Common Rule (45 CFR part 46) outlines the required elements of a consent form. The University of Mount Union IRB has developed a sample consent form template for researchers to use and is found on the IRB Website.

The required consent form elements include but are not limited to:

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. Any additional costs to the subject that may result from participation in the research;
5. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
6. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
7. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies;
8. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
9. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what

conditions

10. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
11. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
12. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
13. If applicable, a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
14. If applicable, for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);
15. If applicable, a statement that the treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable; and,
16. If applicable, anticipated circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's or the legally authorized representative's consent.

IRB Review Process

1. IRB applications are accepted and reviewed on a rolling basis.
2. Exempt and Expedited applications are reviewed by one or two IRB Members, with the IRB overseeing the reviews.
3. Exempt and Expedited reviews are generally returned within two to three weeks, not including time for requested revisions.
4. If minor revisions or a revise and resubmit are required, an email is sent to the researchers detailing the required revisions needing to be addressed within their IRB application, consent form, and supporting documents.
5. Applications that are ineligible for Exempt or Expedited review are presented to the IRB for full committee review by the IRB Chair.
6. The IRB Chair assesses whether an application can be deemed as exempted or expedited. The IRB Chair then deems if an application requires a full board review, and this cannot be determined until a complete application is submitted.
7. Full board applications must be received two weeks in advance of the IRB meeting dates to be considered that month (See IRB Website for scheduled Meeting Dates).
8. If a researcher's application requires a full board review, the researcher may be invited to attend the meeting to answer any questions/concerns to keep the process moving forward.

IRB Approval

IRB approval letters are emailed to lead the researcher and advisor identified on the IRB application. The approval letter will include:

1. The application name and number.
2. The date of the IRB approval.
3. If the application is exempt, the exemption category is provided.
4. If the application requires subsequent reviews. Exempt and Expedited applications per 45 CFR part 46 do not require annual review*; however, the University of Mount Union's IRB does require it*.
5. Full Board applications are required per 45 CFR part 46 to have at least annual reviews.
6. The letter specifies that any changes to the application will require a formal revision application to, and approval of, the IRB prior to implementation of the change(s). The IRB may ask for a full application submission if changes are found to be excessive enough to have possibly changed the original application information.
7. The date of research completion as identified in the IRB application. Prior to this date, the researcher may amend the application to extend the date of the project via an Amendment of Changes to an Approved Application form. A sixty (60) day courtesy expiration notice is emailed to all researchers. If an application expires, a new initial IRB application is required before the research can begin.
8. All research that has extended beyond a two-year period, requires a new application to be submitted (See Ongoing IRB Requirements)
9. A Final Report/Closeout form is due within 30 days of the research being completed. The courtesy expiration reminder email (#7) notes the date that the Final Report/Closeout forms are due.
10. IRB letters may contain provisional approval with elements that are required prior to full research commencing.

Ongoing IRB Requirements

Amendments or Changes to an Approved Application

Any changes to an approved IRB application require a formal revisions application, and approval of, the IRB prior to implementation of the change(s). Changes include but are not limited to a change in:

1. Principal or co-investigators/researchers;
2. Approved application;
3. Risk level;
4. Consent form;
5. Project materials; or,
6. Research sites.

Amendments or Changes to an Approved Application are completed under the revisions form link, found on the University of Mount Union's IRB Website.

Continuing Review Application

Approved applications requiring subsequent IRB review, as outlined in the IRB approval letter, must complete a Continuing Review Application prior to the expiration of the project. If an application expires

prior to the Continuing Review Application approval by the IRB, *OR* the research is anticipated to be conducted beyond one continuing review application process (two-years of research), a new Application for Initial Review will be required before the research can begin. The Continuing Review Application form link can be found on the University of Mount Union's IRB Website.

Unanticipated Adverse Event
Researchers must report all adverse events to the IRB within 48 hours of the event. Unanticipated problems are defined as any incident, experience or outcome that meets one or all, of the following criteria:

1. Unexpected (unforeseen by the researcher or the research participant) in terms of nature, severity, or frequency, given the research procedures and the subject population being studied;
2. Related or probably related to participation in the research, or if the event or problem probably or definitely affects the safety, rights and welfare of current participants; and
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

The Unanticipated Adverse Event form link can be found on the University of Mount Union IRB Website. The IRB Chair and IRB Administrator/Assistant Administrator will review any submitted Unanticipated Adverse Event forms to determine next steps.

Final Report/Closeout
Within 30 days of research completion, a Final Report/Closeout form must be submitted to the IRB. The IRB Final Report Closeout form can be found on the University of Mount Union's IRB Website.

Resources

The University of Mount Union Website: https://www.mountunion.edu/

The University of Mount Union IRB Website: https://www.mountunion.edu/about-mount/leadership/administration/office-of-academic-affairs/institutional-review-board

Federal Regulations (45 CFR 46): https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

Office for Human Research Protections (OHRP) Human Subject Regulations Decision Charts: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

Collaborative Institutional Training Initiative (CITI): https://www.citiprogram.org

Questions and Concerns

Questions or concerns related to the IRB or research approved by the IRB can be directed to the IRB via email (IRB@mountunion.edu).