



Guidelines for the Protection of Human Subjects in Research

1.0 Introduction

Union University, in accordance with its Multiple Project Assurance (MPA) filed with the Department of Health and Human Services, and 45 CFR part 46 establishes the Institutional Review Board for the Protection of Human Subjects (IRB).

The IRB is responsible for reviewing research involving human subjects to ensure that such research is consistent with the principles of (1) respect for persons, (2) beneficence, and (3) justice, as set forth in the Belmont Report (1979). Additionally, the IRB follows all applicable Federal, state, and university regulations. These include but are not limited to 45 CFR Part 46, 21 CFR parts 50 and 56 and the Union University Multiple Project Assurance (MPA) for research involving human subjects.

Non-compliance

In accordance with 45 CFR 46, the IRB is required to report instances of serious or continuing non-compliance, and any suspension or termination of IRB approval to the Vice Provost for Research, the Federal Office for Protection from Research Risks OPRR, and, in the case of Federally supported research projects, the appropriate Department or Agency head.

Additionally, non-compliance with this policy by faculty/staff members may result in one or more of the following:

- Official reprimand
- Removal from graduate faculty status
- Suspension of research privileges at Union University
- Termination of employment

Non-compliance with this policy by students may jeopardize awarding of the degree being sought.

2.0 Scope of Review

IRB review and approval is required for any research involving human subjects that is (a) conducted by University faculty, staff or students; (b) performed with or involves the use of facilities or equipment belonging to the University.

2.1 Research methods courses

Courses in research methods and all class assignments which involve research with human subjects require IRB approval even if the class exercise does not seem to qualify as “true research”: when, for example, the results are not intended for publication, will not advance work in another area, or will not contribute to generalized knowledge. For

such classes, the instructor should submit a generic protocol and consent form for IRB approval. Students should be required to complete the appropriate IRB form and use the consent form in gathering data for the class exercise. Individual student forms would be submitted to the IRB if their project falls outside the scope of the approved protocol, or if subsequent to the class, it was decided to use the data for generalized knowledge.

Research methods courses that collect data with invasive techniques or with ionizing radiation are required to be reviewed by the IRB even if the collected data is not intended to be generalized or publishable.

2.2 Research conducted by students

Students conducting research using human subjects or materials, either on or off University property, as part of the requirements for completing a degree are required to have the project reviewed by the IRB. A faculty advisor must mentor all student projects. The faculty advisor is ultimately responsible for all aspects of adherence to IRB policy. As such, the advisor should assist in the generation and review of all materials to be submitted to the IRB. The advisor will be responsible for all project termination documentation if the student leaves the University before the documentation is completed.

2.3 Theses and dissertation requirements

The University prospectus form required for initiation of thesis/dissertation work must indicate IRB approval if human subject data is used. A copy of the IRB approval document must be attached to the prospectus form. Failure to obtain IRB approval before collection or use of data for a thesis or dissertation will result in voiding all data collected prior to the approval date and may jeopardize awarding of the degree.

2.4 Research conducted at another institution

Research conducted at, or in affiliation with, another institution must be reviewed by the IRBs of both Union University and the other participating institution(s). Researchers must secure approval from both sites and a single unified protocol and consent document must be generated.

2.5 Research conducted in a foreign country

Research conducted in a foreign country must also be reviewed by the IRB. Although the culture of the country may require different levels of documentation the standards for ethical conduct are not changed and the principles of the Belmont Report must be met.

For projects requiring an informed consent document, both an English and a native language document must be generated.

The project must be approved by the Union University IRB before submission to the local equivalent to the IRB in the foreign country. If a local committee is not available the investigator must assemble a group of local experts and community leaders to provide approval. The makeup of the local committee and written documentation of their approval must be submitted along with Union University forms for the local approval process to begin.

3.0 **Levels of Review**

The IRB reviews each application with consideration for the rights and welfare of the individuals involved, the balance of risks and potential benefits of the study, and the methods used to secure informed consent.

There are three levels of review, as determined by the degree of risk to subjects. Applications may be screened for exemption from Federal regulations, require expedited IRB review, or full IRB review. The level of review is determined by the IRB.

3.1 Screening for exempt status

Exempt status is determined by the IRB chairperson or by one or more experienced reviewers designated by the chairperson. Investigators submit an Initial Review form. If the project is declared exempt by the IRB, a letter approving the basis for the exemption will be sent to the investigator. If the project is declared non-exempt, the protocol will be sent for expedited or full board review. An IRB approval document must be obtained prior to initiating the research. Any changes to the protocol must be submitted and approved by the IRB.

Research using existing or archived data, documents, records, or specimens only may be exempt from Federal regulations. Existing data means the items existed before the research was proposed or was collected prior to the research for a purpose other than the proposed research. The data, documents, records, or specimens must be recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Research using educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observational procedures and questionnaires may be exempt from Federal regulations. (Note: exemption is not allowed in surveys or interviews with children.) Information obtained must be recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects; and any disclosure of the human subject's response outside the research must not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

Other examples of research that may be exempt from Federal regulations include:

(a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(b) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(c) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food

ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level 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.

3.2 Expedited review

If the research meets the definition of minimal risk and involves only procedures listed in one or more of the categories below it may be reviewed by expedited procedures.

Expedited review consists of review by the IRB chairperson or by one or more experienced reviewers designated by the chairperson. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- Clinical studies of drugs and medical devices that do not require investigational new drug or investigational exemption application.
- Collection of blood samples by finger stick, heel stick, or venipuncture.
- Prospective collection of biological specimens for research purposes by noninvasive means (e.g., hair and nail clippings, sputum specimen collected after saline mist nebulization, to name a few).
- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves (e.g., body weight, electrocardiograph, ultrasound, moderate exercise when appropriate).
- Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as for medical treatment or diagnosis). Note: some research in this category may be exempt from HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.
- Collection of data from voice, video, digital, or image recordings made for research.
- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Note some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.
- Continuing review of research previously approved by the convened IRB when one of the following applies:
 - (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research related interventions, and (iii) the research remains active only for long term follow-up of subjects; or

- No subjects have been enrolled and no additional risks have been identified; or
 - The remaining research activities are limited to data analysis.
- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the above categories do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3.3 Full board review

Any research that involves more than minimal risk requires review by the full board. Further, research involving the following requires full board review:

- Research that involves vulnerable populations (i.e. children, prisoners, pregnant women, mentally disabled person, or economically or educationally disadvantaged persons)
- Research that involves experimental drugs or devices
- Research that involves invasive procedures
- Research that involves deception

3.4 Continuing review

All research is subject to continuing review at least every 12 months, but if the IRB feels that the research presents significant physical, social or psychological risks to subjects, more frequent review may be required. The required frequency of review will be detailed in the approval document. An application for continuing review is scrutinized at the same level as the initial review, unless it meets the criteria for expedited review.

Research activities that are exempt from Federal regulations are subject to additional review if there are any changes in the protocol at any time.

4.0 **Review Process**

After review at the appropriate level one of the following actions will be taken:

- Approved as submitted and research may begin
- Approved with conditions that must be met before final approval is granted
- Deferred, pending receipt of additional information or major revisions
- Not approved

Investigators will be notified in writing of any revisions that are required, or of other information needed before final approval can be obtained. Research may begin only after revisions have been made and approved by the IRB. Upon final approval (when all concerns of the reviewers have been satisfied), investigator will receive an approval document signed by the chairperson, or an experienced IRB member designated by the chairperson and, if applicable, the approved informed consent document that has been labeled by the IRB indicating the expiration date. A copy of all documentation is archived in the IRB Office.

All proposed changes to the approved research activity must be reported promptly to the IRB for review. Any changes to the approved research during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject. Any revised informed consent document must be re-stamped. Approval of the change is given for the same period as the most recent review.

There may be occasions where the IRB will require verification from sources other than the investigators that no material changes have occurred since previous IRB reviewed, such as the experience of the investigator or if an investigator has a history of non-compliance.

Initial review applications are submitted to the IRB, and are reviewed against the checklist to determine if they are complete. If they are not, they are sent back to the investigator to complete. Complete applications are assessed as to level of review (exempt, expedited or full) based on risks to subjects, subject population, or if medical equipment or drugs are used.

4.1 Exempt

Exempt status is determined by the IRB chairperson or by one or more experienced reviewers designated by the chairperson. Investigators submit an Initial Review form. If the project is declared exempt by the IRB, a letter approving the basis for the exemption will be sent to the investigator. If the project is declared non-exempt, the protocol will be sent for expedited or full board review. An IRB approval document must be obtained prior to initiating the research. Any changes to the protocol must be submitted and approved by the IRB.

4.2 Expedited Review

Expedited review consists of review by one or more IRB members. There is no deadline for submitting an application for expedited review. Investigators should allow 2 weeks for the review process, and longer if revisions are required. Any of the reviewers can require that an application be submitted to the full board for review if they feel the risks are more than minimal, or for any other reason. When comments are received from the reviewers, the investigator is advised in writing of the approval, or of any revisions required before final approval can be obtained. A list of all applications approved through the expedited process is submitted to the full board and documented in the minutes.

4.3 Full Board Review

Full board review consists of review by all members of the IRB. Applications are due by noon on the deadline date (usually 2 weeks prior to the meeting date), and are distributed to each member at that time to allow adequate time for review. At convened meetings of the IRB, applications are approved, approved with revisions, deferred, or disapproved. The investigator is advised in writing of the decision, of any revisions that are required, or of other information needed before final approval can be obtained. Full board actions require the presence of a quorum of the voting members, defined as a majority of the membership including at least one member whose primary concerns are in a nonscientific area. Regulations may require that a consultant or expert be added to the IRB when

reviewing some research. Meetings are scheduled on a regular monthly basis, and investigators are encouraged to attend. Investigators will be excused from the meeting prior to the vote of the IRB.

4.4 What to submit

- Initial Review form
- Copy of consent document, cover letter, or script
- Copies of any survey, questionnaire, or interview guides/scripts
- Copies of any recruitment advertisements
- Signed Assurances page which includes the signature for the investigator and the advisor
- Copy of the OHRP completion certificate
- Copy of the School of Education Research Review Committee approval

4.5 Continuing Review

All research is subject to continuing review at least every 12 months, but if the IRB feels that the research presents significant physical, social or psychological risks to subjects, more frequent review may be required. The required frequency of review will be detailed in the approval document.

Investigators and, when investigators are students, faculty advisors will receive e-mail notice of the date of expiration of their IRB approval three months in advance of that date. The investigator will be requested to submit an application for continuing review if any aspect of the research is expected to continue past the expiration date, or a final report if the research will be completed by the expiration date. A second notice will be sent to the investigator/faculty advisor and department chair or faculty advisor's department chair 45 days in advance of the approval expiration date if no request for continuing review or final report has been received. Failure to apply for continuing review or to provide written notification that the research will be completed by the expiration date will result in the following actions. The investigator will be contacted by telephone and given written notice to cease all research activities involving human subjects as of the expiration date. A copy of this notice will be forwarded to the Provost and OPRR will be notified.

4.5.1 What to submit

- Continuing Review form
- Copy of the most recent IRB approval letter
- Copy of the most recent IRB approved informed consent document
- Clean copy of the proposed informed consent document (to be re-stamped by IRB)

4.6 Final Report

A final report must be submitted when the research has been completed.

4.6.1 What to submit

- A summary of the results of the research (include a summary of any recent literature, findings, or other relevant information)

- The number of subjects enrolled since the last review and the total number of subjects enrolled
- Breakdowns of the subject population by gender and other demographics
- Any difficulties recruiting or retaining subjects, an explanation of the difficulties, and the number of subjects who withdrew from the study
- Any unanticipated risks or adverse outcomes
- Any early indication that one of the treatments under study is significantly better or worse than others

4.7 Adverse Events

New findings are unexpected problems whose nature, severity, and frequency are not described in the information provided to the IRB or to participants. Examples include unexpected complications in a subject, missteps in the consent documentation, or breaches of confidentiality. Adverse events should be reported to the IRB within 10 working days. These reports usually receive expedited review, but in some cases the full IRB is involved. Sometimes a study must be suspended to ensure subjects' safety. All reports of adverse events, and any suspension or termination of IRB approval will be reported to the Provost, the Federal Office for Protection from Research Risks, and, the appropriate Department or Agency head.

4.7.1 What to submit

- The facts of the case, including the date and a description of the subject
- Whether the event is related to the study's procedures or drugs or to the subject's underlying disease or condition
- The steps that have been taken to address the problem
- Whether the event is likely to recur; and whether the event provides new information about the study's risks that should be conveyed to participants, in a revised consent form

5.0 **Special Populations**

The Federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. In general, these special regulations allow IRBs to approve research that is of minimal risk or that will benefit the subjects directly.

5.1 Students as research subjects

In order to avoid coercion, instructors should not use their own students as research subjects. If class credit is offered to participate in research, it must be at a level appropriate to the degree of risk. Also, an alternative method of receiving the same credit must be listed and detail how credit will be pro-rated for early withdrawal. A copy of recruitment materials must be submitted with the application.

5.2 Children as research subjects

Any research that involves children as subjects must take into consideration the benefits, risks, and discomforts inherent in the research. Generally, research using children as subjects should involve no more than minimal risk. Permission of parents or guardians

must be obtained, as well as assent of the child. Failure to object to the research should not be construed as assent.

Note: The exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with children.

5.3 Prisoners as research subjects

The primary issue surrounding the participation of prisoners in research has always been whether prisoners have a real choice regarding their participation in research, or whether their situation prohibits the exercise of free choice. A secondary issue is whether confidentiality of participation and of data can be adequately maintained in the prison. Any study involving prisoners as subjects must be reviewed by an IRB that includes a prisoner or prisoner representative with appropriate background and experience to serve in that capacity.

6.0 **Consent**

The process of informed consent is central to the protection of human subjects involved in research. Informed consent involves more than signing a form, they must understand the study and what they are being asked to do. Therefore, consent documents should be written in language appropriate to the intended audience, avoiding jargon and technical or scientific terms.

6.1. Basic elements of informed consent

Federal regulations identify basic elements of informed consent, which must be addressed in consent documents. The following information must be provided to each subject:

- (a) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (b) a description of any reasonably foreseeable risks or discomforts to the subject;
- (c) a description of any benefits to the subject or to others which may reasonably be expected from the research;
- (d) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (e) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (Note: confidentiality can only be maintained within the limits allowed by law and should be stated as such. Do not promise strict confidentiality unless participation is anonymous);
- (f) 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 (Note: a statement must be included that The Union University does not have any funds budgeted for compensation for injury, damages, or other expenses);
- (g) an explanation of whom to contact for answers to pertinent questions about the research and whom to contact in the event of a research-related injury to the subject;
- (h) 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; and

(i) for an explanation for answers to questions regarding the research subjects' rights, the Chair of the Institutional Review Board should be contacted at 731-661-5580.

When appropriate, the IRB may ask that additional information be provided to each subject.

6.2. Alterations to informed consent

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (a) the research involves no more than minimal risk to the subjects;
- (b) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (c) the research could not practicably be carried out without the waiver or alteration; and
- (d) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

7.0 **Definitions**

ADVERSE EVENT An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy).

ANONYMOUS data collection means that even the researcher does not know the identity of the subjects.

CONFIDENTIAL data collection means that the researcher knows the identity of the subjects either directly or through the use of a master list used for coding but will not release identifying information when sharing the data with others.

HUMAN SUBJECTS Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the Federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information [Federal Policy §46.102(f)].

INTERACTION includes communication or interpersonal contact between investigator and subject.

INTERVENTION includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

MINIMAL RISK A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy §46.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults. [See 45 CFR 46.303(d) and Guidebook Chapter 6, Section E, "Prisoners."]

PRINCIPAL INVESTIGATOR is an employee, faculty member, or student who accepts responsibility for the research.

PROTOCOL The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

RATIONALE A statement, grounded in the pertinent body of research literature, that describes the purpose and importance of the proposed research project.

RESEARCH A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalized knowledge [Federal Policy §46.102(d)].

RETROSPECTIVE STUDIES Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

VULNERABLE POPULATIONS Special consideration is given to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, mentally disabled person, or economically or educationally disadvantaged persons.

CHECKLIST

1. _____ Has the OHRP tutorial been completed (and Certificate of Completion printed)?
2. _____ Is there approval from the School of Education Research Review Committee (if applicable)?
3. _____ Is the appropriate form completed (initial or continuing review)?
4. _____ Is there a complete protocol provided with the document?
5. _____ Is there more than minimal risk involved in this study? If yes, this project must be submitted for full board review.
6. _____ Do the project benefits outweigh the project risks?
7. _____ Is the informed consent written at a 6th grade level?
8. _____ If any compensation is associated with this study, is it pro-rated over the course of the study?
9. _____ Is the assurances page signed (not typewritten) by both the researcher and the advisor?
10. _____ Does the description of the project in the consent form match the protocol?
11. Are the following items present in the informed consent document?
 - a. _____ a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
 - b. _____ a description of any reasonably foreseeable risks or discomforts to the subject;
 - c. _____ a description of any benefits to the subject or to others which may reasonably be expected from the research;
 - d. _____ a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
 - e. _____ a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (Note: due to the Open Records Act, confidentiality can only be maintained within the limits allowed by law and should be stated as such. Do not promise strict confidentiality unless participation is anonymous);
 - f. _____ 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 (Note: a statement must be included that Union University does not have any funds budgeted for compensation for injury, damages, or other expenses);
 - g. _____ an explanation of whom to contact for answers to pertinent questions about the research and whom to contact in the event of a research-related injury to the subject;
 - h. _____ 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;
 - i. _____ an explanation that for answers to questions regarding the research subjects' rights, the Chair of the Institutional Review Board should be contacted at 731-661-5580.