# IRB Policies and Procedures

I. Background and Administration

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IRB Policies and Procedures

Chapter 1. Background and Principles

Background for Development of Human Research Participants Protections

Examples of inhuman and unethical treatment of humans in the name of research have been documented throughout recent history. The Nuremberg trials documented the unethical behavior of Nazi physicians, but there have been ethical lapses in the United States as well. American researchers from the Public Health Service studied 400 African American men with syphilis in the Tuskegee syphilis study between 1933 and 1972. These men were not asked for their informed consent or authorization to be in the study and they were, in fact, given misinformation about their treatment. Even after penicillin became available and was known to be effective in the treatment of syphilis in the 1950s, it was withheld from these subjects because the researchers were interested in the natural history of the disease. The study only ended when a journalist broke the story of the study. In another example, researchers from Harvard and MIT formed a "science club" of 19 mentally impaired boys at the Fernald State School between 1946 and 1956. These boys were fed forms of radioactive iron or calcium, sometimes in their milk, to enable the researchers to study the body's ability to digest minerals. Doctors at the Jewish Chronic Disease Hospital conducted studies of human transplant rejection using cancer cells. The subjects were not asked for informed consent or authorization or told that they were being injected with live cancer cells. Between 1963 and 1966, children at the Willowbrook State School, a state school for "mentally defective" youths, were purposely infected with the hepatitis virus in a study of that disease. During the course of this study, the institution closed its doors to new clients, claiming overcrowding. However, the wing housing the hepatitis program was willing to admit new clients if their parents agreed to allow their children to participate in the ongoing studies.

Behavioral and social science researchers have exposed other humans to severe trauma and psychological stress in investigations of power. The participants in Milgram's "obedience" studies, conducted in the early 1960s, were told that they had to continue to participate in the study and shock another person at increasingly intense voltages. Studies supported by the Human Resources Research Office of the U.S. Army introduced severe stress to Army recruits by threatening them with death from errant artillery rounds or by causing the recruits to think that they, by making a mistake in wiring an instrument, had caused the injury or death of others in their units. Despite potentially important knowledge gained from such studies, the risks to the participants were extreme.

Codes of Research Ethics

Codes of research ethics have been developed, in part to address the disregard for human safety and dignity that these research projects reflect. The Nuremberg Code of 1947 was the first
international code of research ethics. Its first principle is "The voluntary consent/authorization of the human subject is absolutely essential." The accompanying text made it clear that this voluntary consent/authorization should also be informed consent/authorization: "...the person involved ... should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." This principle of "free and informed consent/authorization" remains the basic foundation of ethical research with human participants.

Another early code was the Helsinki Declaration, adopted by the World Medical Assembly at its meeting in Helsinki, Finland in 1964. Its second principle, "The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor..." established the concept of ethical review.

The first ethical code covering social and behavioral research was a set of 10 ethical principles adopted by the American Psychological Association in 1972. The bases for these principles were critical incidents. Psychologists were asked to submit examples of research that they deemed unethical or of questionable ethicality. The committee charged with developing ethical standards for psychological research then developed principles that would guide the conduct of researchers when conducting research that could pose ethical problems. The American Psychological Association's principles were the first to recognize the principle of confidentiality. Principle 10 states: "Information obtained about the research participants during the course of an investigation is confidential. When the possibility exists that others may obtain access to such information, ethical research practice requires that this possibility, together with the plans for protecting confidentiality, be explained to the participants as a part of the procedure for obtaining informed consent/authorization." Most professional organizations have ethical codes, and most require authors of manuscripts submitted to the journals of these organizations to state that they have followed these ethical principles in their research.

The U. S. Department of Health, Education, and Welfare issued ethical guidelines in 1971 which were codified into Federal Regulations in 1974. However, the primary impetus for current government ethical regulation began with the establishment of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research under the aegis of the Department of Health, Education, and Welfare in 1974. The Commission was charged with identifying the basic ethical principles that should underlie research with human subjects. The report of the Commission, called The Belmont Report because it was based on deliberations held at the Smithsonian Institution's Belmont Conference Center, was published in 1978.

**Belmont Principles**

The Belmont Report identified three basic ethical principles that now serve as the foundation all human research participant protection programs. They are:
(1) Respect for Persons (autonomy): This principle acknowledges the dignity and freedom of every person. It requires obtaining informed consent/authorization from all potential research subjects (or their legally authorized representatives).

(2) Beneficence: This principle requires that researchers maximize benefits and minimize harms or risks associated with research. Research-related risks must be reasonable in light of expected benefits.

(3) Justice: This principle requires the equitable selection and recruitment and fair treatment of research subjects.
Chapter 2. Governmental Oversight and Regulations

The University of Northern Iowa (UNI) is committed to ensuring that the rights and welfare of human research participants are adequately protected in all research activities conducted under its auspices. In addition, UNI strives to comply with all relevant federal and state regulations pertaining to the involvement of individuals in research activities. This includes maintaining and authorizing an Institutional Review Board (IRB) to oversee human participants research at UNI.

**Federal Regulations on Human Participants Research**

In order for the University to fulfill its responsibility and to comply with the laws and regulations, all human participants research conducted under University auspices must receive appropriate IRB review and approval. In its Federal-wide Assurance (FWA), on file with the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services (DHHS), the University assures compliance with all requirements of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) for all human participants research, regardless of source of support. This law serves as the federal policy for the protection of human research participants. Although DHHS was directed to exercise authority over 45 CFR 46, this policy has nevertheless also been adopted by more than 16 other federal departments and agencies, including the National Science Foundation and the Department of Education. This federal policy, sometimes called the Common Rule, is codified as the Common Federal Policy for the Protection of Human Subjects and was published in the Federal Register in 1991. It requires that each institution at which federally funded research is conducted adhere to the principles of The Belmont Report and set forth in writing its ethical principles, policies, and procedures. It also requires that all institutions conducting such research file an Assurance of Compliance (such as the FWA) and register each IRB operated by the institution.

Periodic audits conducted by the federal departments that are responsible for human subject protections and the performance of IRBs have resulted in temporary injunctions of research with humans at institutions that are not in compliance with the regulations. The IRB is also required to report to the OHRP serious problems and adverse events that occur in particular research projects at the institution, including serious noncompliance with IRB requirements.

**Other Related Federal Regulations**

The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a federal law that protects the privacy of student education records. The law applies to all institutions and schools that receive funds under an applicable program of the U.S. Department of Education. Generally, FERPA requires that schools have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to certain parties under certain conditions, as outlined in the regulations (such as to other schools or for certain research purposes). Schools also may disclose to anyone, without consent, "directory"
information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance.

The Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98) applies to programs that receive funding from the U.S. Department of Education (ED). Among other things, it seeks to ensure that schools and contractors obtain written parental consent before minor students are invited to participate in any ED-funded survey, analysis, or evaluation that reveals information concerning:

Political affiliations;

Mental and psychological problems potentially embarrassing to the student and his/her family;

Sex behavior and attitudes;

Illegal, anti-social, self-incriminating and demeaning behavior;

Critical appraisals of other individuals with whom respondents have close family relationships;

Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; or

Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

Health Information Privacy and Portability Act (HIPPA). The Office for Civil Rights enforces the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; and the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety. The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” See 45 CFR 164.501. A covered entity may use or disclose for research purposes health information that has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule).

In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule, which include obtaining IRB approval.

Relevant State Regulations
**Iowa Code Chapter 232.2(5) Definition of Child.** "Child" means a person under eighteen years of age.

**Iowa Code Chapter 599.1 Definition of Minority Age.** The period of minority extends to the age of eighteen years, but all minors attain their majority by marriage. A person who is less than eighteen years old, but who is tried, convicted, and sentenced as an adult and committed to the custody of the director of the department of corrections shall be deemed to have attained the age of majority for purposes of making decisions and giving consent to medical care, related services, and treatment during the period of the person’s incarceration.

**Iowa Code Chapter 235B.3: Dependent Adult Abuse.** This section lists the types of individuals who are mandated to report dependent adult abuse, primarily service professionals and police officers. It also provides the option for others to make reports. Dependent adult" is defined in §235B.2(4) as follows: "Dependent adult" means a person 18 years of age or older who is unable to protect the person's own interests or unable to adequately perform or obtain services necessary to meet essential human needs, as a result of a physical or mental condition which requires assistance from another, or as defined by departmental rule.

**Iowa Code Chapter 232.69(1) Child Abuse Reporting.** This section lists the individuals who are mandated to report child abuse within 24 hours, primarily service professionals, school employees, and police officers. This section also refers to permissive reporters ("any other person (i.e., other than on the list) who believes that a child has been abused may make a report"). When it is possible that identification of a reportable abuse may occur in the research setting, investigators must include this information in the informed consent document.

**Iowa Code Chapter 147.111 Reporting Injuries.** The general licensing provisions for a number of health care professions (see Iowa Code Chapter 147) require reporting a wound or "other serious injury" that is being treated by the person licensed under that chapter and that appears to have been received in connection with the commission of a criminal offense.

**Iowa Code Chapter 139A.3 Reporting Diseases.** This section requires health providers and laboratories to make a report to the local or state health department when they become aware of possible communicable and infectious diseases, and conditions. The section also provides for immunity from prosecution for individuals who report, and for confidentiality of the identifiable data in the records. Of note, in Iowa reportable conditions include cancer and birth defects with reporting to the State Health Registry located at UI. When it is possible that identification of a reportable condition may occur in the research setting, investigators must include this information in the informed consent document.
Chapter 3. IRB Scope and Authority

Regulatory Authority of the IRB

The requirements in this document apply equally to all research involving human participants conducted under the auspices of the University of Northern Iowa. The conduct of research with human beings raises fundamental ethical and civil rights questions; thus, no distinctions in the monitoring of research are drawn between funded and non-funded research; between research conducted on or off campus or internationally; or between various kinds of individuals associated with the institution. All UNI faculty members, staff, students and affiliated researchers who anticipate conducting research projects involving human participants are responsible for familiarizing themselves and complying with IRB requirements.

The IRB is formally designated by UNI to review and approve or disapprove the initiation and ongoing conduct of research involving human participants. The primary purpose of this review is to assure the protection of the rights and welfare of human participants, although risks to the researcher and to nonparticipants may be considered as well. The IRB also has the authority to disapprove a proposed research activity if in its judgment, appropriate and reasonable mechanisms are not in place for the protection of the participants and/or the potential benefits to the research do not outweigh the risks. The IRB may request that the investigator modify proposed study procedures in order to receive approval.

Review and approval of the IRB must be secured prior to the initiation of any aspect of the research involving individual human participants. (See Chapter 10 for a discussion of acceptable methods for making initial contacts with research sites and potential participants.)

Definition of UNI Affiliation

This policy applies to all research involving human participants, and all activities which even in part involve such research, regardless of sponsorship, if the research:

- is sponsored by this institution, or
- is conducted by or under the direction of University of Northern Iowa faculty, staff, or students in connection with the fulfillment of institutional responsibilities or academic requirements; or
- is performed with or involves the use of University records, facilities or equipment belonging to the University.

Research Conducted in Foreign Countries

Research conducted in a foreign countries by a UNI-affiliated researcher must be reviewed by the IRB and adhere to University and federal guidelines. The standards for ethical conduct in research as well as considerations regarding cultural differences must be incorporated into the research design.
Performance Sites

The University is responsible for ensuring that all performance sites cooperating in the conduct of research to which the University’s Federal Wide Assurance applies does so only under an appropriate Federal assurance and/or satisfaction of UNI IRB requirements.

Research Involving More than One Institution

The University will ensure that all collaborating institutions (including subcontractors and subgrantees) engaged in the conduct of research involving human participants will have mechanisms to protect human subjects that are at least equivalent to those procedures provided for in the ethical principles to which this institution is committed. Collaborating institutions are those engaged in human participants research by virtue of subject accrual, transfer of identifiable information, and/or in exchange of something of value, such as material support (e.g., money or identifiable materials), co-authorship, intellectual property, or credits.

The University will comply with the requirements set forth in 45 CFR 46.114 regarding cooperative research projects. When research covered by this institution’s Federal Wide Assurance (FWA) is conducted at or in cooperation with another entity, all provisions remain in effect for that research.

The UNI IRB may, at its discretion, enter into a joint review arrangement, rely upon the review of another qualified IRB that adheres to similar standards of human participant protections, or make similar arrangements for the purpose of meeting the IRB review requirements and avoiding duplication of effort. These arrangements may be entered into on a case-by-case basis, if an arrangement is needed for the review of a single research project. Or, for ongoing cooperative research, a more formal arrangement may be entered into, such as a memorandum of understanding detailing the joint review mechanism(s). Use of a single, consolidated informed consent form for such studies is strongly encouraged. In addition, copies of all correlative protocols and consent documents required at collaborating institutions must be kept on file at the University of Northern Iowa.

Research Not Affiliated with UNI

When individuals from other institutions or organizations conduct research involving participants who are UNI students, staff, or faculty, the UNI IRB does not oversee that research unless the study is more than minimal risk. In minimal risk research, external investigators are expected to seek the permission of the unit or administrative head that provides the closest oversight for the study sample (e.g., coach or department head), as appropriate, and notify the IRB of the intention to conduct the study. If someone affiliated with the institution serves as a co-investigator, or otherwise performs study tasks (beyond simply forwarding or collecting anonymous study materials, or providing mailing lists), then the study must be reviewed at UNI as well.

Research Begun Prior to Affiliation with UNI
When a faculty member, staff, or student comes to UNI with a research project already underway, the study must be reviewed by the UNI IRB prior to any further activities taking place on the project. If all data collection is completed, and data analysis is the only activity still planned, then the review will be accomplished using the Application for Use of Existing Data. If the only remaining activity is to write up the results of analysis already completed, then UNI IRB review is not necessary.

An exception to this general rule is that if the study was reviewed by an IRB at a prior institution and was found Exempt, the only requirement for transferring the study to UNI is that the Exempt approval/determination be provided to and accepted by the UNI IRB office. In the event changes are subsequently needed in study procedures or other details, the investigator must request approval of the modifications from the IRB prior to implementing the changes (see Modifications).
Chapter 4. Noncompliance

Non-compliance with IRB guidelines is a violation of UNI’s Federal Wide Assurance (FWA00002159) and federal regulations for the protection of human participants. Any incident of serious or continuing non-compliance with IRB guidelines must be reported to the IRB Administrator or the Chair of the IRB immediately. Incidents of non-compliance must be reported both to ensure the protection of the rights of human participants and to uphold UNI’s Assurance to the federal government.

Definitions

Non-compliance is defined as significant failure by an investigator to abide by Federal, State, or University regulations governing the protection of human participants in research, including the requirements or determinations of the IRB.

Serious Noncompliance.

Serious non-compliance is defined as an action that potentially places participants at more than minimal risk and involves deliberate disregard for the regulations or the determinations of the IRB. Examples may include, but are not limited to:

- beginning or continuing more than minimal risk research without IRB approval;
- serious misuse or non-use of approved consent forms;
- failure to secure IRB approval before introducing changes in an on-going protocol, when those changes potentially constitute more than minimal risk to the participants;
- not reporting Adverse Events or Unanticipated Problems consistent with UNI policy (see Chapter 16)

Continuing Noncompliance. In the event that an investigator engages in multiple occurrences of any level of noncompliance (serious or otherwise) and the IRB believes that the noncompliance involves deliberate disregard for IRB regulations, that will constitute Continuing noncompliance.

Federal regulations require that instances of serious or continuing noncompliance be reported to the Office of Human Research Protections (OHRP). Sponsors, administrators, and others may also be notified. Noncompliance involving no or minimal risk to participants or first occurrences that are believed to be the result of ignorance or misinterpretation of the IRB regulations will not result in a report to OHRP, although other sanctions or requirements for education may be applied. Examples include:

- not submitting Continuing Review/Project Closure form as a final report on the study;
- failure to secure IRB approval before beginning research or introducing protocol changes, when those changes constitute minimal or no risk to the participants.

OHRP does not require reporting on Exempt projects, but the IRB may choose to do so, depending on the circumstances.
Procedures for Monitoring and Addressing Noncompliance

All faculty, staff, students, and administrators are responsible for supporting the ethical conduct of research involving human participants at UNI. This includes reporting possible noncompliance promptly to the IRB Chair or IRB Administrator so that it can be addressed, and educational and other corrective actions taken, if needed. In addition, IRB members and staff monitor the research that goes on at UNI, including the day to day conduct of research as well as the reporting and dissemination of results. If a question arises as to whether a particular project was reviewed by the IRB or whether particular procedures were approved, the IRB Administrator informally inquires about it, as necessary, and reports any unresolved questions to the Chair. A letter or email describing the IRB’s concern is then prepared by the IRB Chair and/or IRB Administrator offering the investigator an opportunity to respond via email, in writing, at an informal conference, or at an IRB meeting, and specifying a time period within which the response must be provided. If the investigator offers a timely and satisfactory explanation for the concern, the process will be terminated and the researcher will be notified in writing. If the investigator offers an explanation that fails to satisfy the complaint, or if the investigator fails to respond within the specified time period, the IRB Chair, in consultation with the IRB Administrator, will make a determination of whether the action appears to have involved deliberate disregard or lack of knowledge/awareness and whether the noncompliance is Serious and/or Continuing. Consideration will be given to the length of time the individual has been engaged in research, the extent and nature of previous involvement with the IRB, and any previous communications with the IRB. If a consensus determination cannot be reached, the matter will be discussed and voted on by the full IRB. All instances of noncompliance will be kept confidential, except when reporting within the University, OHRP, and/or sponsors is necessary.

Possible Actions by the IRB

Federal regulations (45 CFR 46.113) provide the IRB with the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements. Depending upon the nature and seriousness of the non-compliance activity, the IRB may take the following actions:

1. Require a response from the investigator with a plan for corrective actions
2. Require the investigator to complete additional human participants protection training
3. Initiate audits of the active protocols
4. Require that research participants previously enrolled in the study be contacted and provided with additional information and/or re-consented
5. Suspend or terminate the study
6. Freeze sponsored research grant account
7. Determine that data collected during non-compliance cannot be used for publication
8. Require that data collected during non-compliance be destroyed
9. Require that a statement be included with all publications or research reports indicating that the research was not approved by the IRB
10. Report to the sponsor, university officials, and governmental agencies, (e.g., NIH, OHRP)
11. Disqualify the investigator from conducting research involving human participants at the university.

As noted above, the IRB is required by Federal Regulations to report incidents of Serious or Continuing noncompliance to the Office of Human Research Protections (OHRP), and in some cases, to the research sponsor. All UNI projects are covered by these reporting requirements, regardless of funding source. Initial reports to OHRP will be made as soon as possible, and at least within 4 weeks of the IRB making a determination as to the nature of the concern.

In the case of serious or continuing non-compliance, the IRB and the University will address the question of the investigator's qualifications to conduct human participant research. The IRB will also take remedial action, as necessary, regarding the welfare of the participants and the research data gathered in non-compliance. Further, the IRB may refer instances of Serious or Continuing non-compliance to the Department Chair, Dean, and Provost who may decide whether to impose disciplinary sanctions. Non-compliance may also be referred to the UNI Research Integrity Officer if it involves potential violations of the institutional policy on research misconduct. The distinction between remedial action taken by the IRB and disciplinary action taken by an administrator is: Remedial action is action that the IRB takes or may require on behalf of present or future human participants in research. Disciplinary action, in this context, is a penalty imposed by administrators on an investigator for non-compliance with human subjects or related research regulations.
Chapter 5. Roles and Responsibilities

Most of the functional tasks, roles, and responsibilities of the various individuals and components of the IRB system are based on guidance from the Office of Human Research Protection (OHRP), as outlined in the OHRP Human Subject Assurance Training.

Role of the Institution

Consistent with federal regulations, the University as an institution is responsible for providing administrative oversight, support, and sufficient resources to maintain an effective IRB system. This includes at a minimum designating individuals to serve as Institutional Official and IRB Administrator, promoting an ethical research culture at the institution, and providing space and adequate staff support to the IRB to support its functions and maintain institutional compliance with regulations.

The University must provide the necessary resources so that the IRB Chairperson(s), IRB members, investigators, and relevant administrative personnel have access to and complete appropriate initial and continuing education related to the protection of human participants before reviewing or conducting research.

The University encourages and promotes constructive communication among research investigators, the IRB, and human participants as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the participants.

As put forth in the federal regulations, to assure independence, and to avoid potential administrative influence, the IRB as a committee functions independently of the administrative authority of the institution. However, the institution may and should exercise appropriate administrative oversight to ensure that the procedures being implemented for the protection of the rights and welfare of human participants and records are in compliance with the requirements of 45 CFR 46 and the IRB’s own policies and procedures. The IRB’s role is to exercise independent judgment in the review of research; the institution’s role is to ensure that the IRB follows the rules and has the resources it needs to function.

Federal regulations do allow that the institution may disapprove or terminate a project that an IRB has approved. However, the institution may not approve projects or procedures for individual projects that have been disapproved by the IRB.

Role of the Institutional Official

The Institutional Official (IO) is the individual authorized to act for the institution and obligates the institution to the Terms of the Assurance. Responsibilities include:

- Designating one or more IRBs that will review research covered by the institution's FWA;
• Providing sufficient resources, space, and staff to support the IRB's functions;
• Making available training and educational opportunities for the IRB and investigators;
• Setting the "tone" for an institutional culture of respect for human participants;
• Ensuring effective institution-wide communication and guidance on human participants research;
• Ensuring that all staff engaged in the conduct or oversight of human participant research receive training in human participants research ethics; and
• Serving as a knowledgeable point of contact for OHRP, or delegating this responsibility to the IRB Administrator or other appropriate individual.

The Institutional Official makes appointments to the IRB, based on consultation with the IRB Chair, Administrator, and members. The latter receive suggestions from the campus and recommend possible members, based on the regulatory requirements for certain qualities and types of members, and their understanding of the expertise available at the institution and in the community. Based on those recommendations, the IO then makes appointments to the Board for varying terms. The IO may also elect not to renew an appointment for a member that is not contributing effectively to IRB activities, or in unusual circumstances, to withdraw an appointment if an individual is not participating appropriately. The Institutional Official may not appoint a member over a formal vote by the IRB objecting to the appointment.

Roles and Responsibilities of the IRB Administrator

The IRB Administrator is an individual designated by the Institutional Official to oversee and manage the IRB system and its operations, including working in collaboration with the Board in the development and maintenance of appropriate policy, procedures, processes, and records.

Communication & Education Responsibilities

• Promoting communication among research administrators, department heads, investigators, human participants, and institutional officials to maintain a high level of awareness regarding the ethical conduct of research and to safeguard the rights and welfare of participants.
• Maintaining access to the institution's Assurance, copies of pertinent Federal regulations, policies, and guidelines related to the involvement of human participants in research, and institutional policies and procedures.
• Educating the members of its research community in order to establish and maintain a culture of compliance with Federal regulations and institutional policies relevant to the protection of human participants.

Record Keeping & Reporting Responsibilities

• Ensuring that IRB records are being maintained per federal regulations and that the records are accessible, upon request, to authorized federal officials. The IRB Administrator shall oversee procedures for the retention of University IRB records and documents for at least three (3) years past completion of the research activity.
• Ensuring certification of IRB approval of research to the appropriate federal agency, as required.
• Ensuring that changes in approved research, during the period for which IRB approval has already been given, are not initiated without IRB review and approval, except when necessary to eliminate apparent, immediate hazards to the participant.
• Ensuring prompt reporting to the IRB of all proposed changes in a research activity.
• Ensuring the prompt reporting to the IRB, appropriate institutional officials, OHRP, and any sponsoring Federal department or agency head of:  a) any unanticipated problems involving risks to participants or others; b) any serious or continuing noncompliance with the regulations or requirements of the IRB, and c) any suspension or termination of IRB approval for research.

Monitoring & Oversight Responsibilities

• Ensuring that appropriate oversight mechanisms have been implemented to ensure compliance with the determinations of the IRB.
• Ensuring that all cooperating performance sites conducting research primarily under the direction of the institution have appropriate OHRP-approved assurances and provide certifications of IRB approval to the appropriate federal authorities.
• Ensuring that cooperative IRB review arrangements are documented in writing, in accordance with OHRP guidance.

Board (IRB) Responsibilities

• Reviewing proposed research at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in non-scientific areas, except when exemption or expedited review procedures are applicable. In order for the research to be approved, it must receive the approval of a majority of those members present at the meeting.
• Reviewing, approving, requiring modifications in (to secure approval), or disapproving all research activities, including changes in previously approved human participants research.
• Requiring that information given to participants as part of the informed consent process is in accordance with 45 CFR 46.116. The IRB may require that information, in addition to those required elements specified in 45 CFR 46.116(a), be given to participants when in the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of the participants.
• Requiring documentation of informed consent or waiving documentation in accordance with 45 CFR 46.117.
• Notifying investigators in writing (via email or letter) through the IRB Administrator, of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of research activity. If the IRB formally disapproves a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
• Certifying IRB review and approval for all Federally-sponsored research involving human participants that will be submitted by the IRB Administrator to the appropriate Federal department or agency, as required. Compliance will occur within the time and manner prescribed for forwarding certifications or IRB review to DHHS or other Federal department or agency.

• As its discretion, inviting 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.

IRB Member Responsibilities

• Being familiar with the requirements of the Federal regulations, applicable state laws, the University’s Assurance, and institutional policies and procedures for the protection of human participants.

• Having effective knowledge of subject populations and other factors involved in determinations of risks and benefits to participants as well as informed consent.

• Being able to judge the adequacy and accuracy of information in the informed consent document, recruitment, advertising, and any other materials to be presented to participants.

• Having the professional competence necessary to review the specific research activities presented for approval.

• Preparing for and actively participating in the review processes in full board meetings as well as participating in expedited and exempt reviews as assigned.

• Promoting positive communication and awareness on campus of the role of the IRB and ethical research principles in regard to human participant research.

IRB Chair Responsibilities

The Chair of the IRB is designated by the Institutional Official, based on the recommendations of the IRB members and the IRB Administrator. The Chair’s responsibilities include all of those listed for IRB members in general, and in addition, include:

• Maintaining an in-depth knowledge of the regulations and regulatory guidance, and expertise in the review of human participants research.

• Providing leadership and oversight, in partnership with the IRB Administrator, for the policies, procedures, practices, and functioning of the IRB and human participants research at the institution.

• Designing and leading training for IRB members, and supporting orientation for new members.

• Providing campus training and educational events coordinated by the IRB office for faculty, staff, and students.

• Facilitating Board meetings and serving as the lead reviewer for full board reviews;

• Serving as the lead reviewer for Expedited and Exempt reviews, in concert with the distributed review process involving other members of the IRB.

• Appointing the individuals designated to serve in special roles, including for Continuing Review, Survey Reviews, and Reviews of Existing Data. The Continuing Review appointment must be in writing and on file in the IRB office.
Please refer to Chapter 6 for additional information on IRB composition and member qualifications.

**Investigator Responsibilities**

All members of the UNI community are responsible for promoting good ethics in research. Principal investigators are responsible for overseeing and maintaining ethical procedures in all projects under their purview.

Researchers contemplating research involving human participants are required to submit an application to the IRB for review and approval before initiating each project. This requirement encompasses a variety of research activities that can range from the simple use of surveys or interview procedures to more complex activities such as treatment interventions. All research must be conducted in accordance with the following documents.

- **The Belmont Report.** This report is a summary of the basic ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

- **Federalwide Assurance - FWA00002159.** This contract between UNI and the Office of Human Research Protection (OHRP) of the Department of Health and Human Services assures that Investigators conducting human participant research at UNI will follow the ethical principles outlined in the Belmont report.

- **The Code of Federal Regulations for the Protection of Human Subjects, Title 45, Part 46, and Title 21 CFR Part 50 and Title 21 CFR Part 56.** These are federal regulations that describe general standards for the composition, operation, and responsibility of an Institutional Review Board. Compliance with these regulations is intended to protect the rights and welfare of human participants involved in research projects.

- **UNI IRB Policies and Procedures** – This document outlines all of the requirements for human participants research at UNI, and is largely, although not exclusively, based on the three documents above.

**Faculty Advisor Responsibilities**

Faculty Advisors are jointly responsible with student investigators for the conduct of student research projects. This responsibility includes assisting students in becoming familiar with ethical principles and IRB rules and processes. Advisors are expected to assist students in the design of their protocols, carefully review their applications for IRB review to ensure they are complete and appropriate, and help the student resolve any questions or concerns that arise during the review. Subsequently, they are responsible for ensuring that the student complies with ethical principles and IRB requirements throughout the study. This includes monitoring to
ensure that the student submits modification requests to the IRB prior to initiating changes as well as the timely submission of renewal and/or closure forms. Advisors are encouraged to instruct their students to submit a closure form for each completed study before they leave campus.
Chapter 6. IRB Composition & Meetings

Compositional Requirements

The University has established its IRB in accordance with the compositional requirements of 45 CFR 46.107. These regulations require that an IRB:

Must be comprised of at least 5 members from diverse backgrounds to promote complete and adequate review of research activities commonly conducted at the University;

Must be sufficiently qualified through the experience and expertise of its members, and the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes and issues related to vulnerable populations, to promote respect for its advice and counsel safeguarding the rights and welfare of human participants;

Must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice and shall, therefore, include persons knowledgeable in these areas; and

Must include qualified persons of both genders so long as no selection is made on the basis of gender.

In addition:

At least one member must be someone whose primary concerns are in a non-scientific area and at least one member whose primary concerns are in a scientific area;

At least one member must be not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University;

Members may not 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;

The IRB may, at 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; and

Studies that are more than minimal risk and propose to involve youth or adults confined or at risk for confinement in the correctional or involuntary mental health system may only be reviewed when a member designated as a “prisoner advocate” is present and eligible to vote.

A current membership roster for the UNI IRB is posted online.
Alternate Members

Individuals who are appointed to the IRB as alternates may not contribute to the quorum or vote on applications under review at a given IRB meeting unless s/he is replacing a regular member. A nonscientist regular member can only be replaced by another nonscientist (because one must always be part of the quorum).

Appointments to the IRB

The Institutional Official (IO), in consultation with the IRB Chair and IRB Administrator, makes formal appointments of full-time UNI faculty, staff, and community members to the IRB for terms not more than 3 years in length. Terms are renewable.

The Institutional Official, with input from the IRB Administrator and IRB members, appoints the Chair of the IRB for a 3-year renewable term.

Special roles that may be established by the IRB, such as Continuing Reviewer, Survey Reviewer, and/or Advocate for Children with Special Needs, are assigned by the IRB Chair, in consultation with the IRB Administrator. The Continuing Reviewer role will be documented in writing, as required by regulation.

Member Files and Qualifications

The names and affiliations of all regular and alternate members of the IRB shall be on file with the U.S. Office for Human Research Protections (OHRP), in accordance with the requirements of the University/PHS Federal Wide Assurance, and in the IRB Office in East Bartlett Hall. All changes in IRB membership are reported to OHRP as appropriate.

Member files include: 1) a letter of appointment showing the specific term of appointment, 2) curriculum vitae, and 3) documentation of human protections training.

The following are some of the characteristics that are given consideration in identifying and recruiting new Board members and renewing appointments of existing members.

1. Commitment to regular monthly meeting attendance
2. Availability of at least 8-10 hours/month for monthly meetings, training in protocol review and regulations, and protocol reviews as appropriate
3. Interest and willingness to learn regulations and guidelines
4. Experience in research involving human participants and oversight of student research
5. Recognition of the value in and need for institutional oversight and support of research
6. Interest in ethics and ethical decision-making in research
7. Cross-campus representation and membership diversity

Meeting Minutes
Minutes are taken at each IRB Committee review meeting. Minutes include a list of all studies that were voted on at the meeting, and include separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB. The vote on all IRB actions include the number of persons voting for, against, and abstaining, in order to document the continued existence of a quorum. The minutes include the documentation of risk as well as the names of any members not participating in the review due to actual or perceived conflicts of interest. The minutes also include documentation of all expedited and exempt applications that were reviewed since the last meeting, and their current status (e.g., approved, pending).

**Meeting Schedule**

The UNI IRB meets monthly on the 2nd Thursday of the month in East Bartlett Hall. The agenda includes approval of minutes, announcements, review of protocol applications requiring full board review, review of any expedited, exempt, or continuing protocols that members believe need full board discussion, education/training activities for Board members, special topic discussions, and IRB operational business. If no protocols are pending review by the full IRB and no other pressing business is on the agenda, the Chair and IRB Administrator may elect to cancel a meeting. Special meetings may also be called as needed to attend to urgent matters.

**Investigator and Visitor Attendance**

Protocol reviews are considered confidential, but visitors who wish to address the Board or discuss a particular issue should notify the IRB Administrator of their desire and request to be placed on the agenda for a specific time. Investigators with applications under review by the Board are very welcome and encouraged to attend their portion of the meeting. They should likewise inform the IRB Administrator of their intention to attend the meeting. Attendance by the PI often moves the review along more quickly and increases the likelihood that the protocol can be approved following minor adjustments (rather than needing to be taken up again at the next monthly meeting). Investigators or visitors arriving to participate in a discussion of their application or issue should be seated in the reception area and wait to be called into the meeting at the appropriate time. In the event that the PI chooses not to attend, the IRB member facilitating that review (typically the Chair) will send an email to the PI following the meeting, outlining the discussion and any requests made by the IRB for edits or procedural adjustments.

**Quorum**

A quorum is required in order to take formal action on a given application in a convened IRB meeting (voting to approve or disapprove). Quorum is comprised of a simple majority of members eligible to participate in that particular review. All regular members count towards the quorum unless they have a conflict of interest with a particular application, in which case they are requested to leave the room during final discussions and voting. If there is no regular nonscientist present and eligible to participate, an alternate nonscientist may be considered in the quorum count. Similarly, scientist alternates may substitute for scientist regular members. If the study requires the presence of a prisoner advocate, the individual designated to serve in that capacity will be counted in the quorum, whether s/he is a regular or alternate member.
Timing of Submissions

A meeting schedule is posted for the convenience of the campus which shows the IRB meeting dates, along with the dates by which a protocol should be submitted to the IRB office in order to leave sufficient time for IRB members to consider it before the meeting date. Minimal risk protocols may be submitted at any time during the month.
Chapter 7. Which Projects Require IRB Review

All projects defined by the IRB as “research” involving “human participants” must be reviewed and approved by the IRB before any research activities involving potential participants are initiated. This includes honors theses, culminating graduate research papers, and Masters or Doctoral theses involving human participants, and the IRB reviews projects that involve more than minimal risk samples, topics, or procedures (see below).

Exempt versus Research Needing Review

As will be discussed further in Chapter 9, some projects that the IRB reviews fit into the federal category of “Exempt”. This status should not be confused with “Not Research.” In the former case, the study meets the IRB’s definition for research needing review, but the review has determined that the study meets the criteria for Exempt(ion) from Continuing Review. In the latter case, “Not Research,” the project does not need IRB review in the first place because, in the judgment of the IRB, it does not fit the definition of human participants research.

Criteria for Research Needing Review

Please note that the process of determining whether or not a given project is “research” is often a nebulous undertaking. The IRB has spent considerable time working to define “research” as clearly and consistently as possible, in light of the federal regulations and balancing the need to oversee potential risks for human participants with the desire to avoid over-regulation of minimal risk projects. In some cases, the question simply requires a judgment call, which according to regulation, must be made by the IRB. In questionable cases, investigators are encouraged to simply email the IRB Administrator and ask if review is required.

The considerations involved in determining if a project needs review are: 1) does it meet the IRB’s definition of research; 2) does it involve interaction with or information about living human beings; and/or 3) does the project involve more than minimal risk or vulnerable populations?

1. How does the IRB define “research”?

The first criterion for assessing if a given project requires review involves determining if the project meets the regulatory definition of “research”. Research is defined in the federal regulations at 45 CFR 46.102(d) as “a systematic investigation, including research development, pilot studies, testing and evaluation, designed to develop or contribute to generalizable (or transferable) knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”

Generalizable knowledge is typically interpreted by the IRB to include research findings or data that are intended to contribute to the existing body of knowledge on the topic. A strong indicator of the intention to contribute to general knowledge is when the results are intended for public
dissemination or presentation. Public dissemination of knowledge may involve many formats, including broadcast email, poster presentation, scholarly paper, public bulletin board, web publication, or report to external sponsor.

Data collection activities that are conducted solely for institutional purposes, even if the results will be accessible by the public, are not typically considered research by the IRB, unless there is a dual, scholarly purpose involved or the researcher believes there may be in the future.

Research projects involving human participants that are conducted by students for the purpose of independent research papers, culminating graduate research papers, master’s theses, and dissertations are all considered research and must be reviewed by the IRB.

2. How does the IRB define human participants involvement?

The second criterion for determining if review is required is whether or not the project involves obtaining private information from or about living human beings. This may include obtaining information through interventions or interactions, or by accessing datasets or private records.

A. Obtaining private data FROM human beings. According to 45 CFR 46.2102 (f), “Intervention includes both physical procedures by which data are gathered (for example, venipuncture) 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....”

Thus, for example, if you are planning to observe children in a public park but not expecting to interact with them in any way, the study does not need review. If you are planning to observe adults in a public restroom, those individuals are obviously expecting some degree of privacy and your study does need review.

B. Obtaining private data ABOUT human beings. This involves obtaining individual-level information from datasets or records that may have been compiled for some other purpose and now are going to be used for research purposes. There are several considerations involved in regard to secondary data studies, including individual level vs. aggregate data, identifiable data vs. de-identified, and publicly-available vs. privately-held datasets.

Individual level data means that the information is recorded for each individual, rather than compiled into aggregate statistics. And it means that the data is actually about the individual, not some other entity (such as the organization they may work for). For example, if you are asking school districts to provide you with the number of school psychologists they employ and what percentage have master’s degrees, IRB review is not needed. If you are asking principals what their opinion is about the number of school psychologists they employ, the data is now about the individual principals and the study does need review. If you want to ask the districts to provide you with private information about each psychologist (e.g., Birthdate, degree, number of years employed), then the study does need review.
Identifiable information is that which can either directly or indirectly identify an individual. **Direct identifiers** include name, address, telephone number, social security number, identification number, medical record number, license number, photographs, voice recording, and biometric information. **Indirect identifiers** are those items that taken together might enable a reasonably informed and determined person to deduce the identity of the participant, and include race, gender, age, zip code, IP address, and college major. Projects involving “de-identified” **private datasets** (e.g., a dataset you obtain from a state agency or another investigator) are commonly found Exempt from continuing review by the IRB, but they are considered research that must be reviewed. See Chapter 8 for a full discussion of exempt determinations.

**Publicly-available datasets** are defined by the IRB as data that have already been compiled and are now available in a library or on the internet, and no permissions are required to access them. Privately-held datasets are those for which some type of permission is necessary to access the data and studies involving these typically require IRB review. (The IRB has made an exception for a few well-known, commonly used repositories of secondary data, such as the InterUniversity Consortium for Political and Social Research-ICPSR.) Research involving data that is both completely de-identified and **publicly available** without permission is not reviewed by the IRB. If you do not need permission from anyone to access the data and the data is completely “de-identified,” you do not need to seek review.

3. **Does the study involve more than minimal risk or vulnerable populations?**

If a research project involves more risk than an individual might expect to encounter in the course of daily life, or involves groups or procedures that require special precautions, the study may need to be reviewed even if it does not fall within the above guidelines for “research”. For example, if your study involves children or other vulnerable populations, or you will be asking about sensitive topics that may cause psychological harm or embarrassment, or you will need to deceive the participants about the nature of the research, your study must be reviewed by the IRB even if it is a class project or other situation that would not normally be seen as formal research.

**Examples**

Examples of projects **that the IRB does not typically review** because they do not fit any of the above criteria are:

- Teacher and student evaluations used solely by the institution
- Class-related data collection projects (with adults and of no more than minimal risk) conducted solely for didactic purposes where the results are not disseminated outside the classroom
- Activities conducted for quality improvement/quality assurance intended solely for internal use and not designed to contribute to generalizable knowledge – these may include “institutional” surveys or other assessment projects that are less than minimal risk and are only intended for purposes of benchmarking or institutional assessment and are not publicly disseminated
• Data collection activities performed as a commercial service to inform business decisions regarding a specific process or product if the results will not be made public by the researchers, the business, and/or the sponsor (if other than the business)
• Journalism articles
• Theatrical productions
• Art exhibits
• Self-ethnographies
• Secondary datasets available online without permission (e.g., IPEDS data accessed through the National Center for Education Statistics website), or data obtained from well-known secondary public data sources that anyone can access but involve a standard registration process (e.g., data obtained from the ICPSR).

Examples of projects that typically are considered research needing review include:

• Oral history projects
• “Action” research conducted by graduate students or faculty in education settings
• Class or institutional projects that will be disseminated for a scholarly purpose, or that involve data collection on sensitive populations or subjects (e.g., minors and/or substance abuse, mental health, sexual identity), involve deception of potential participants, or otherwise present more than minimal risk to participants
• Taking blood or other biological samples from any person other than oneself, unless it is clearly for non-research purposes
• Secondary datasets obtained from a state agency, nonprofit organization, other university researchers, or other private source which are then going to be used for faculty or student research

It is possible that some activities will begin as non-research activities (such as course evaluations) and later spark a research question or otherwise evolve into research, at which time they fall under IRB jurisdiction, and it becomes necessary to obtain IRB approval to use data that has already been collected. When the intent of the activity becomes dissemination to a wider audience and contribution to the general knowledge base in a field, IRB approval is necessary.

Please note that retrospective approval cannot be granted for research studies that have already begun. Investigators must seek a determination and/or IRB review of projects that may fit the definition of research as described above, or risk being found in regulatory noncompliance, which typically results in a finding that the data be destroyed.

Class Projects

The University recognizes that some student projects conducted to fulfill course requirements involve activities that, in a different context, might be viewed as research. As a general rule, when those activities are conducted solely to fulfill a course requirement, an element of the definition of research (the intent to develop or contribute to generalizable knowledge) is lacking. However, it is also the case that some classroom research assignments could place participants at risk. Therefore, recognizing its role in the protection of human participants, the IRB has determined that some classroom assignments may require review by the IRB.
UNI considers classroom assignments involving research activities to be educational in nature, and not subject to IRB review, when all of the following criteria are true:

1. The project is limited to surveys, questionnaires, interview procedures, observation of public behavior, minimal risk experimental studies, or standard educational exercises directly related to the topic(s) being studied in an official University course. In general, audio and video recordings made as part of the interview procedure for the sole purpose of accuracy are allowed.

2. Surveys/questionnaires/interviews, if used, contain no sensitive personal questions (e.g., no questions about alcohol/drug use, sexual behavior/attitudes, criminal activity, medical history, grades/test scores) or other personal information that could "label" or "stigmatize" an individual.

3. The participants are not from a special population that requires extra protections (e.g., pregnant women, people in the criminal justice system, children under age 18, cognitively impaired individuals).

4. Either the information is recorded:
   a) without any direct or indirect (e.g., race, gender, code number) identifier linking the participant to his/her data; or
   b) no direct identifiers are recorded and any indirect identifiers could not be combined to ascertain the identity of some or all the participants; or
   c) if direct or indirect identifiers are retained in the dataset, then the other data contained in the dataset could not reasonably harm the participant's reputation, employability, financial standing, or place the participant at risk of criminal or civil liability.

5. The results of the classroom assignment, including audio and video recordings, either do not leave the classroom, or, if the project involves gathering data from or about a company, agency, or organization, the data/results are shared only with that company, agency, or organization, and the company will not share the data or results with anyone else.

If any one of the foregoing criteria is not true, then the project must be sent to IRB for review. It is the responsibility of faculty to determine whether an assigned project involving human participants can be classified as a course-related student project. Faculty should contact the IRB Office if assistance in making this determination is needed. It is also the responsibility of faculty to discuss general principles of research ethics with the class prior to the initiation of the project and ensure that those are followed.

The IRB is willing to review class research projects submitted by students individually or in groups, in order to support the educational process, but please recognize the traffic issues involved. The reviewers cannot always respond to applications from multiple classes during the
two or three week window that may have been planned by the instructor for IRB review. Therefore, please do take into account the volume of applications that may be under review at a given time, particularly at certain points in the semester.
Chapter 8. Review Process

The IRB strives to process all applications for IRB review as quickly and efficiently as possible. This is accomplished by the IRB office working with principal investigators to ensure that the applications are complete prior to being forwarded to a reviewer, by conducting as much communication as possible by email, by reviewers striving to complete their initial reviews of applications within 2 weeks of receiving all materials, and by investigators responding to reviewer comments within 2 weeks whenever possible.

Application Forms

To initiate an IRB review, the PI must select, download and complete the correct IRB application from the IRB website. There are three application forms: 1) the Application for Use of Existing Data should be used for studies that only involve review and analysis of data and records that already exist; 2) the Survey Application should be used only for survey research; and 3) the Standard Application should be used for all other studies, including mixed methods. Please note that forms are periodically revised and thus investigators should download a fresh form from the website each time they prepare an application. All applications must be typed; handwritten applications are not accepted.

Supplementary Documentation

Several of the questions on the application forms require the Principal Investigator (PI) to develop and attach supplementary documents. Applications missing items required to begin the review will be held at screening until those items are provided.

Supplementary documents that are required in order to begin the review are:

- **Recruitment materials** for each sample and method, including scripts, flyers, letters, emails, etc. (See Chapter 10 for further detail.)

- **Consent materials** for each sample and method, including scripts, forms, letters, electronic display text, etc. Depending on the sample, these may include materials for consent (for adults), assent (for minors), and/or permission (for parents or guardians). (See Chapter 10 for further detail.)

- **Data collection instruments**, including interview questions, questionnaires, and tests, regardless of how well known they are. Qualitative interviews can be approved even if all of the questions cannot be specified in advance, as long as likely questions for each topic are provided. Links to an online test or survey will be accepted (provided there are no access issues) but it is preferred that they be included with the application materials.

- **Training documentation** for the PI, Co-Investigators, and Faculty Advisor (if applicable). Certificates of training for all other key personnel must be on file before that individual
becomes involved in the project. The UNI IRB accepts documentation from any legitimate training for this purpose, including those sponsored by UNI, which are provided online by a known training provider or training obtained while employed at another institution. For those who take the CITI training, a certificate will be automatically emailed to the IRB office from the CITI program. Training options offered or sponsored by UNI, such as the CITI program, are described on the IRB training page, along with instructions on how to access them.

**Key personnel** are those who have authority or responsibility for the design or management of the project, as well as those involved in recruitment, data collection and management activities, including those responsible for maintaining data privacy and confidentiality processes. Individuals who typically do not require training are staff involved only in the analysis or management of de-identified datasets, individuals providing video services, or individuals in the community who distribute written materials or make announcements about the study according to written script(s) provided by the research team. Any person who actually explains the study for recruitment purposes or attempts to answer questions about the research must receive training before doing so.

“On file” means the training certificate is in the IRB office, not in faculty or departmental offices. “On file” also does not refer to being in the database of a training provider, although the CITI training program automatically notifies the IRB office when someone has completed that program.

*Previous IRB documentation* for this project. When applicable, copies of IRB applications and/or IRB approval letters from other institutions for the current project are required at the time of submission.

Second language materials are required at the application stage. This refers to recruitment materials, consent documents, data collection instruments, or any other text that will be seen or heard by the participants. If participants are not fluent in English, these materials must be developed in (or translated into) the participants own first language, and must be made available to the IRB for review. The IRB may or may not choose to consult a speaker of that language for assistance, if the reviewer is not fluent.

Supplementary documents that are not required in order to begin the review but *must be on file in order for the study to be approved* are:

*Letters of cooperation* from any external research site or cooperating organization will be required. These may come in during the review but at least one must be on file with the IRB before the application can be approved. These should not be confused with consent documents from individual participants (see Chapter 10). A letter of cooperation serves as documentation from the research site that the investigator has permission to conduct the research at that location. The letter typically must be from someone in authority at the organization, not a group counselor or teacher. Although the PI is encouraged to likewise have contact with others in the organization whose cooperation will be needed to

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carry out the research (e.g., teachers who will be distributing consent forms to students), only the top individual needs to document permission. An exception to this rule is that letters are occasionally permitted from coaches or professors in large or international institutions, when it makes more sense to seek the permission of someone closer to the research rather a central administrator. PIs are cautioned to check with central administration at colleges and universities, however, because they sometimes have their own rules about oversight of research conducted at their institutions.

When the research is being carried out at UNI, letters are only required from special departments or areas, primarily coaches of sports teams, directors of student clubs, and individual faculty or departments who are providing a dataset to the PI for analysis. Please note that some departments, such as the Registrar, may themselves require documentation of IRB review (or that IRB review is not needed) prior to providing a mailing list or contact information for potential participants.

A letter of cooperation may be submitted to the IRB as a formal signed hard copy letter or as an informal email or fax from the organization. Regardless of format, the letter must show the individual’s name, title, organization, and contact information. If by email, the email must show the originator’s email address (in the case of forwarded emails). The letter should also say something about what is being permitted (e.g., to allow the investigator access to recruit participants, to allow the investigator to carry out the data collection on site, to allow posting of a flyer, or to serve as a “conduit” for distributing recruitment materials). If the letters do not contain the required contact information or are not from a person in authority, the PI will be requested to seek another letter or email.

If the study requires multiple sites, the PI has the option to draft the “letter” of cooperation as a form and simply request signatures from the research sites. Also, the study may be approved as a multi-site project with only one letter of cooperation on file. The PI is then required to ensure that letters from each additional site are provided to the IRB before initiating any research at those locations. When an additional letter is received for a multi-site study, the IRB Administrator will send a confirmatory email to the PI authorizing the research to begin at that location.

**Submission and Screening**

When the application and all necessary attachments are complete, the application may be submitted by email or by hard copy to the IRB Office in the Office of Sponsored Programs, in 213 East Bartlett Hall.

*Submission by Hard Copy:* If by hard copy, the application must be signed by the PI, and if the PI is a student, it must also be signed by the Faculty Advisor. Only one copy is needed, which can be mailed or dropped off at 213 East Bartlett Hall, campus mail code 0394.
Submission by Email: If by email, it is preferred that the application and all its attachments be submitted as one pdf or Word file. The application must be emailed to the IRB Administrator by the Principal or Co-Investigator. If the PI is a student, the email must include a copy to any co-investigators and the student’s Advisor to indicate that the Advisor and other members of the team are aware of the submission and have approved its contents.

After submission, each new application is given an IRB protocol number for tracking purposes. Please use this number in all correspondence with the IRB whenever possible. The applications are then screened for completeness by the IRB Office in the order in which they are received. If questions are not answered or required supplementary documents are not attached, the application will be placed in a temporary file and an email will be sent to the PI requesting those additional items. The application will not be forwarded to a reviewer until the necessary documents are in place for the review to take place.

The items most commonly missing from submitted applications, thus requiring communications with the PI at the screening point, are:

- Training certificate for PI and/or Advisor
- Letter of cooperation from at least one research site (including schools)
- Additional consent or assent forms called for by the research design
- One or more of the data collection instruments listed in the application
- Recruitment materials that match procedures (e.g., verbal script)
- Written justification for requested waiver of documentation of consent

It is possible, under special circumstances, to request review of a study for which some of the materials are not yet available, because the project development is scheduled to take place over a period of time. In those cases, the PI may request a “concept” review or a review of all procedures except X, and receive approval to proceed with initial activities only. If this situation is approved by the IRB, the PI will be required to submit the materials for subsequent phases of the study as a modification request and receive approval for those components prior to implementation.

When the application is complete, it will be forwarded to the IRB Chair or other designated IRB member for initial review.

Status Determination

When the IRB Chair or designated reviewer receives the protocol, s/he conducts an initial review and makes a determination of whether the study requires full board approval. Studies that require full board review are typically those that are deemed to involve more than minimal risk, that do not meet the regulatory criteria for Expedited or Exempt review, and/or involve sensitive issues that the primary reviewer would like to have considered by the full board. If the study is referred for full committee review, the PI is so notified, the application is forwarded to all IRB members, and the protocol is scheduled for review at the next regularly scheduled IRB meeting.
Expedited and Exempt Reviews (No more than Minimal Risk)

If the study does not require full board review, the initial reviewer will undertake the review individually, consulting with other IRB members or special experts as needed and appropriate. Reviewers strive to complete the initial reading of each application within two weeks of receiving it, although this is not always possible, depending on schedules and volume. After initial review, the reviewer will email any questions, comments, or requests for adjustment to the PI, and if a student PI, to the Faculty Advisor. The PI is expected to respond within two weeks with answers to the questions posed by the reviewer, any questions the PI may have, further discussion as needed, and/or edited documents. It is not required that all changes requested by the reviewer be made exactly as requested without discussion. If the PI has questions or concerns, they should be shared with the reviewer, so that reviewer can help find solutions whenever possible.

Communications between the PI and the reviewer are most efficient if the following guidelines are followed by the investigator:

1. Respond directly to the reviewer, by “Reply All” email, not by starting a new email string.
2. Insert (or keep) the IRB protocol number in the Subject line.
3. Only return the items requested, not the entire application.
4. Respond to ALL items, not just some, and preferably in the same email, in the same order as listed in the review.
5. Mark any changes made to edited documents – don’t just edit them and return a clean copy (because then it takes so much extra time to find the changes made).
6. Always, always, copy the IRB Administrator on ALL communications.
7. If you have not heard from your reviewer in 2-3 weeks, check in with the IRB Administrator. Likely the cause is work overload, but it may be possible that a communication has gotten missed.

The primary reviewer may review and approve a study that does not require full board approval under one of two categories: Expedited or Exempt. The criteria for approving studies as Expedited or Exempt are outlined in the Federal regulations (45 CFR 46.110 or 45 CFR 46.101). Expedited approval means that the study must be reviewed again periodically, at least annually. Exempt approval means the study does not need standard continuing review and approval. In all cases, whether Full Board, Expedited, or Exempt, the PI must report any serious adverse events that arise during the study and must request review of any changes to the protocol before implementing them.

When the review and any discussion is complete, the reviewer will send an approval email to the PI and the Faculty Advisor, if the PI is a student, indicating that the study may proceed. It is highly unusual for a study at UNI to be disapproved. Most often, the reviewers have resolvable concerns regarding the procedures or participant materials and will recommend changes to the PI during the review process. In the rare event that the reviewer and PI cannot reach an agreement
on the changes needed, the PI may request that the application be forwarded to the entire IRB for further review and discussion.

**Full Board Review (More than Minimal Risk)**

In the event that a study is reviewed by the full committee, the investigator will be invited but not required to attend the meeting. Investigators are encouraged to accept the invitation in order to save time in the process by discussing the study at the meeting and answering any questions that the IRB members have. Investigators who wish to attend the meeting must inform the IRB Administrator. Upon arrival, investigators or visitors should be seated in the reception area and wait to be called into the meeting at the appropriate time.

For full IRB review, a complete set of documents is sent to each IRB member who will review the protocol and supporting documentation in detail prior to the meeting. In preparing for the meeting, the Chair or other primary IRB reviewer may contact the investigator, co-investigators, other IRB members, or outside sources as necessary to insure a thorough evaluation of risks and benefits of the proposed research. The protocols undergoing initial review are presented and discussed individually by the IRB, in addition to those protocols undergoing continuing review.

After complete and individual discussion, each protocol is voted upon for one of four possible dispositions. The Board may vote to approve a study, table a study, approve a study with explicit conditions, or disapprove a study. A study may be tabled either because the Board did not have sufficient time, or expertise, or appropriate personnel present (i.e., absence of prisoner advocate for a study involving prisoners) to vote on the study or because the Board needed substantive clarification or modifications regarding the protocol or informed consent documents to determine whether to approve or disapprove the study. A study may be approved with explicit conditions when the convened IRB is able to stipulate specific revisions that require simple concurrence by the investigator. If the IRB approves a study with explicit conditions, then the primary IRB reviewer or Chair may subsequently approve the revised research protocol on behalf of the Board, after determining that the investigator has incorporated the specified explicit conditions into his or her project. In a rare circumstance, the study may be disapproved because the protocol describes a research activity that is deemed to have risks which outweigh potential benefits or the protocol is significantly deficient in several major areas. A principal investigator has the right to appeal the disapproval of his research protocol to the Board and asked to have the decision reconsidered.

**Special Determinations**

If the protocol disposition is "Approved" or "Approved with Explicit Conditions" and the protocol requests inclusion of a vulnerable population(s), special determinations for the vulnerable population(s) may be made during the meeting as well. These will be documented in the minutes and communicated to the investigator(s).

The minutes will also document if the study was determined to be More than Minimal Risk or No More than Minimal Risk. Studies reviewed by the full board initially that are determined by the
IRB to be no more than minimal risk may be subsequently reviewed through an expedited process if the IRB so decides.

If a waiver of consent or waiver of documentation of consent (see Chapter 10) is granted, whether by the full board or through Expedited or Exempt review, this will be noted in the IRB minutes (for full board studies), in the IRB database, and in the protocol file.

**Administrative Closure** (study closed by the IRB)

If an application remains pending for 30 days with no action or communication by the PI, the PI will be sent an email notification of the intent by the IRB office to close the file. The PI may respond at this point and request that the file be kept open longer if additional activity on the application is expected. If no response is received, the file is closed. If the PI subsequently decides to pursue the study at a later date, a new application for review must be submitted.

**Notification of Approval**

When a study is approved, the primary reviewer or Chair on behalf of the full committee will so notify the PI and Advisor, and the study may begin immediately upon receipt of the email. Subsequently, a formal letter of approval will be issued by the IRB Office to the PI, any Co-Investigators, and Faculty Advisor, if applicable. The letter will indicate the duration of approval, if applicable, and remind investigators they must report serious adverse events as they occur and request approval for modifications prior to implementing them. No portion of a study involving the participants, including recruitment/invitational activities or data collection, may be initiated prior to the email notification of approval from the IRB.

**Duration of Approval**

All Full Board and Expedited studies must be periodically reviewed again at least annually (see Chapter 13). There are times when the risks associated with a particular protocol are such that continuing review should take place more frequently than annually. In these cases, the IRB will specify that the PI report to the IRB either at a shorter time interval or after a specified number of participants (e.g., after each participant or after 3 participants) are enrolled. The PI's report must describe the observed effects of the research activities and/or how the participant(s) responded to the research interventions. Such a determination will be recorded in the IRB files (e.g., minutes), along with whether the reports will be reviewed by the full board or primary reviewer.

**Appealing an IRB Decision**

If the IRB makes a decision that an investigator believes to be unfair, unsubstantiated, or unduly restrictive on his/her proposed research, the investigator should first discuss the matter with the Chair of the IRB and the IRB Administrator. The investigator should be prepared to present reasons that he/she believes that the proposed research is in compliance with University policy and Federal regulations for the protection of human participants.
If the issue cannot be resolved satisfactorily by negotiation, the investigator may appeal the decision, in writing, to the IRB. In developing his/her appeal, the investigator is encouraged to seek the advice or opinion of an objective, qualified consultant (or consultants) to support the claim that the proposed research is in compliance with human participants policy and regulations.

The investigator must appear before the IRB to present his/her appeal and any supportive material or documentation obtained through consultation. Based upon this appeal, the IRB will issue a final determination on the proposed research.
Chapter 9. Key Review Considerations

General Principles of IRB Review

The IRB is responsible for protecting the rights of human participants engaged in research. This is achieved through a careful review of the proposed study, including the scientific design, methodology, study procedures, participant population, recruitment procedures, and consent processes. Through this review, the IRB seeks to balance the risks to the participants against the scientific knowledge to be gained and the potential benefits to society.

Federal guidelines grant the IRB autonomy in the interpretation of regulations for review of research studies. Thus, each IRB must apply its own discretion when deciding how a research proposal will be judged to meet the ethical criteria provided in the regulations. And, in the case of informed consent, 45 CFR 46 allows the IRB to waive the requirement for written consent in special circumstances. This means that each IRB must independently determine the nature of research risks and research benefits, the extent to which risks to participants are "reasonable" in relation to anticipated benefits, when research risks and benefits justify modification of the informed consent requirement, and what constitutes equitable participant selection.

No involvement of human participants in research, including initial contact and recruitment, is permitted until the IRB has reviewed and approved the planned procedures. It is the responsibility of the investigator to obtain approval from the IRB prior to the initiation of any research, including recruitment activities and pilot or pre-test studies.

IRB review is grounded in the following essential principles for participant rights and protections:

- All activities involving humans as research participants must provide for the safety, health, and welfare of every individual. Rights, including the right to privacy, must not be infringed. No participant in a research activity shall be exposed to unreasonable risk to health or well-being.
- An individual does not abdicate any rights by consenting to be a research participant. A participant has the right to withdraw from a research project at any time or can refuse to participate without loss of benefits to which the subject would otherwise be entitled. Further, a participant has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue embarrassment, discomfort, anxiety, and harassment.
- The direct or potential benefits to the participant, or the importance of the knowledge to be gained, must not preclude consideration of the inherent risks to the individual.
- The confidentiality of information received from participants in experiments or respondents to questionnaires or surveys shall be fully protected, both during and after the conduct of a research activity, within the limits of the law.
- Participation in projects must be voluntary. Informed consent must be obtained from all participants and must be documented (unless the requirement for documentation of consent is specifically waived by the IRB). Methods in accordance with the requirements
of 45 CFR 46.116 and 46.117, appropriate to the risks of the research, must be used to obtain the participants’ informed consent.

- In research involving more than minimal risk or substantial stress or discomfort, such risk, stress, or discomfort shall be carefully explained to the participant before his or her participation and justified by the expected benefits of the research. The investigator shall be satisfied that the explanation has been understood by the participant; and the written consent of the participant (unless otherwise waived by the IRB), containing the substance of the explanation, shall be obtained and kept as a matter of record for 3 years.

**Risks and Benefits**

Most investigators are able to readily identify the potential benefits of their proposed research to the knowledge base in their discipline as well as to society, since those are often the underlying motivations for undertaking the research. Identifying the potential benefits and risks to participants can be a little more challenging, and it is not uncommon for our judgment as researchers to become clouded by a strong desire to realize those benefits to society. It is also helpful to recognize the personal advancement that is the intended product of most research endeavors in an academic setting. With that in mind, it is particularly important to carefully consider the possible participant benefits and risks to ensure appropriate procedures and protections are established. All research can be said to carry some risk, including inconvenience at the very least, but much of the research done has little direct personal benefit to participants. Payments or incentives provided to participants who consent to the research are not considered benefits to the research – they are considered compensation for efforts. (See Chapter 11.) We seek their involvement primarily as volunteers in the hope that their contributions will lead to the broader benefits to society.

Benefits are only likely to accrue directly to participants if something beneficial is being provided to them as an aspect of the research. Experimental medical treatments may be of benefit to patients who are ill, as may new counseling services to those who are in need of psychological care. Children may likewise benefit from involvement in an experimental new approach to education. But some research does not involve experiments with new services or interventions, but instead are designed to simply examine outcomes of existing programs or methods. There may therefore be no benefits to participating in the research at all. However, if the risks from the research activities are likewise low, nonexistent, or sufficiently mitigated, the study can still be approved.

Risks of potential harm to participants can sometimes be subtle, and should involve an assessment of both the magnitude (severity) and likelihood (risk) of the potential harms. Death would be a very serious harm, for example, but the risk of its occurrence in relation to a given research project may be extremely low or nonexistent. More common are potential psychological or privacy harms that actually do have a reasonable chance of occurring as a result of research participation. Discussion of sensitive topics may cause emotional or psychological concerns, particularly in individuals with particular vulnerabilities. Employability or reputational harms could result from individuals sharing negative opinions or private information, and they could actually have a reasonable risk of occurrence if the data were to become known, unless the PI takes precautions to mitigate the risk of a potential breach of
confidentiality. Mitigation of risks does not render potential harms nonexistent or less harmful; it merely reduces the likelihood they may occur. In almost all studies, participants run the risk that they will be inconvenienced and their valuable time used profitably or wasted, making it all the more important that the PI develop a sound design that has a reasonable chance of at least benefitting society through an increase in knowledge.

Further reading on this topic can be found in the IRB Guidebook, published by the Office of Human Research Protections (OHRP).

Participants

Who actually are the participants in a research project? The answer is obvious in most studies, but there are some interesting nuances that investigators should be aware of. Below are examples of when individuals are and are not considered participants in a study. This is important in part because anyone who is considered a participant must provide assent or consent in order to be included in the study.

1. When individuals provide any kind of information about themselves, they are obviously participants.

2. When individual-level information is included in a dataset (whether they can be identified or not) the individuals are typically participants. (See Chapter 7 to determine when IRB review is required.)

3. When an individual provides information about other individuals, the others are the participants. For example, when a principal provides information about individual teachers, such as their age, gender, and college degree, the teachers are the participants, not the principal. However, if the principal offers opinions about how well-prepared each of the teachers is, then the principal also becomes a participant. If the principal only provides aggregate data about the teachers (e.g., 50% have MA degrees), then there are no participants involved at all – it is not human subjects research.

4. Somewhat similar criteria as shown in item 3 can be applied to parents and children. If parents provide individual information about their children, the parents are only informants and the children are the participants. If they provide opinions about each of their children, both the parents and the children are participants. Providing aggregate data about the children would depend on how large the family is – if a small family, all would be participants. For a very large family, it could be argued that only the parents are the participants if no individual data could be inferred.

5. Multi-phase studies involving “helpers” versus participants can be a little tricky. Here are some examples:

   a) In phase 1, a panel of teachers with special expertise is invited to review and suggest further developments for a new curriculum developed by the researchers. These teachers would be considered expert “helpers”. In phase 2, a second larger group of teachers is
recruited to use the curriculum, likewise provide a critique and suggestions for development, and share outcome data from the children in their classes. This one is in a grey area - teachers are both expert commentators (helpers) as well as participant teachers, because their performance using the curriculum is being assessed as well as the curriculum. Unless the student outcome data provided by the teachers to the researchers is in aggregate (e.g., 50% of the students got A’s), the students are also now participants. In phase 3, another group of teachers are invited to use the curriculum and provide attitudinal data (opinions) about how well the curriculum worked as well as student outcome data. These teachers are only participants, not helpers.

b) In phase 1, a group of individuals is taped speaking English. In phase 2, these videos are shown in systematically varied ways to ESL students learning to speak English, and the students are asked to rate the confidence level of the speakers as well as take language tests assessing their own speaking abilities. The individuals taped in phase 1 are providing stimuli for the study – they are not participants. The students who are rating them and providing data about themselves are the participants in the study.

The purpose of this discussion has been to distinguish when individuals involved in a research project are or are not serving in the role of participants because participants must typically provide formal consent. However, there is some overlap between this discussion and the question of whether or not a given data collection activity involves participants at all and thus needs review by the IRB. That question is answered more fully in Chapter 7 – Which Projects Need Review.

**Privacy and Confidentiality**

In most research projects, it is incumbent upon the researcher to protect the privacy and confidentiality of those who volunteer to serve as participants in the study. First, it is important to understand the difference between the two concepts. *Privacy* is defined by Merriam-Webster as: a) “the quality or state of being apart from company or observation”, and b) “freedom from authorized intrusion”. Thus, privacy has to do with the privacy of the person. *Confidentiality* has more to do with the private or secret nature of information.

In regard to privacy, researchers must consider whether or not others are present when individuals are invited to participate in a study as well as when they are actually participating. During the recruitment process, it is important to provide ways for individuals to say “yes” or “no” to the study without others being aware of their choices. This is particularly important when the study topic is somewhat or very sensitive and/or when others’ knowledge might influence the decision that the potential participant might make. Recruiting potential participants in individual situations helps avoid this issue. Inviting participation by phone (if others are not in the background listening to the conversation) or by email may be good options. Researchers must strive for the degree of privacy that matches the sensitivity of the study. It would be completely inappropriate to recruit domestic abuse victims by visiting their homes. On the other hand, it is typically acceptable to ask students who are interested in participating in a study about reading habits to simply drop their surveys in a box at the front of the room. Similarly, if the study topic or population has the potential to harm an individual’s reputation or might simply
embarrass them if they were overheard, obviously then interviews must be conducted in a private setting. Likewise, participants must not fill out sensitive questionnaires and then drop them in a box, or even sometimes hand them directly to the researcher. A better option is to have them sealed in an envelope first.

As noted, confidentiality pertains to what happens to the data or information collected or analyzed during the study. The fact of an individual’s participation should be kept confidential, as well as the data provided, unless there is a reason to do otherwise (see below). There are a variety of methods that researchers use to maintain confidentiality, which again should be tailored to the study’s potential risks. At the very least, if the study is at all sensitive, the names of participants should be kept in a separate electronic or physical file from the other data provided, and a password-protected master code list maintained to connect them. Researchers should always consider whether they actually need the names of participants in the first place – if not necessary for future contact or research purposes, the data should be anonymous.

It is beyond the scope of this discussion to examine all of the procedures that can be used to track, connect, and/or protect the privacy of individuals and confidentiality of data. It is simply important to note that all potential participants have a right to know what steps, if any, are being taken by the researchers to protect their privacy and confidentiality, in order to make an informed decision about whether or not to participate.

In some cases, even in sensitive studies, it may be appropriate for participants’ identities to be known. In some qualitative studies, for example, participants may be considered partners in the research and the researchers may wish to offer the option for participant names to be associated with the results. This is certainly acceptable – it simply needs to be documented one way or the other by each participant. Similarly, the researcher may wish for some reason pertinent to the study to NOT protect the identities of participants. This then needs to be clearly stated in the consent information for potential participants to consider when deciding whether or not to participate.

One final issue in regard to privacy and confidentiality is the question of direct versus indirect identifiers. Direct personal identifiers include information such as name, address, telephone number, social security number, identification number, medical record number, license number, photographs, and biometric information. Indirect personal identifiers include information such as race, gender, age, zip code, IP address, and major. Researchers must be aware that, even in anonymous studies with no direct identifiers, indirect identifiers can sometimes be combined to ascertain the identity of a participant. This is most common when one or more of the identifiers is relatively rare in the population (e.g., some racial/ethnic groups in some geographic areas in the state). When this is the case, caution must be used to guard that information to prevent identification, particularly in higher-risk studies. Different fields have various methods for doing this, but a common procedure is to not report certain information in the study results when identification becomes possible.

**Investigator Qualifications**
Researchers and the members of their team must be qualified to carry out the procedures outlined in their research design or obtain the oversight and/or participation of others who do have the qualifications. If questions arise, the IRB may request that the researchers document that they or their key personnel have the appropriate qualifications. This is typically only an issue when special procedures are being undertaken that require particular expertise, such as certain therapeutic procedures. All key personnel, however, should be trained in human subjects protections and research procedures that they are responsible for (e.g., how to invite participation in a study without introducing undue influence).
Chapter 10. Recruitment and Consent

Initial Contact with and Recruitment of Participants

Participant recruitment is the process of inviting individuals from the target population to consider participating in the research project. The process begins with the initial contact with potential participants, whether that be in person, by email, over the telephone, or on the web, and whether it be directly by the investigator or by someone else acting on behalf of the investigator. During the recruitment process, potential participants receive information about the study that will help them decide if they wish to learn more and possibly become involved in the study. Therefore, the IRB must review these procedures before they are implemented and as a general rule, investigators may not have any contact whatsoever with potential participants prior to IRB review of the study.

In order to review the procedures, the PI must provide a copy of the information being provided to potential participants as part of the recruitment process. The recruitment language, whether it is the form of an email, an oral script, a letter, or a flyer, must be provided with the IRB application. The information provided at recruitment is typically not as extensive as that provided at the consent phase. Sometimes, the recruitment and consent processes occur simultaneously (such as in telephone interviews), in which case, this must be explained in the IRB application. Missing recruitment information, such as the recruitment email or script, is a common cause of delay in the review process.

In oral history projects or other studies in which the sample is very targeted and relatively small, the investigator may wish to have very preliminary contact with potential participants in order to determine the feasibility of the research prior to fully developing the study design and IRB application. In this situation, the investigator should first contact the IRB Administrator or Chair and confirm the appropriateness of the preliminary contact.

In service or educational programs, the service provider (who may also be the researcher) may sometimes need to invite participation in the program prior to inviting participation in the research aspects of the project. This is permissible, provided that a) the program is not part of the research; in other words, the service or training would take place with or without the research component; b) any information about the research is only referred to in the most general terms (e.g., “at a later date, you will receive an invitation to participate in research associated with this program, but your involvement in the program will not be affected by whether or not you decide to participate in the research”). Please refer to Chapter 11 for other special considerations pertaining to program evaluation, services research, workshops, and educational assessment activities.

Contact with and Recruitment of Research Sites

It is permissible, and in fact advisable, for researchers to have contact prior to IRB review with cooperating organizations and research sites regarding their willingness to play a role in the project. If external sites are involved in the study, the IRB will require documentation of
permission from at least one research site prior to approving the study. See Chapter 8 for further
details.

If the individual in authority at the prospective site is also a possible participant in the study,
investigators should be careful not to confuse requesting permission to conduct the study at that
site with inviting the individual’s participation as a possible subject in the study. This can
happen, for example, when the purpose of the study is to interview school administrators,
including superintendents and principals. In this case, the PI should wait and first submit for
IRB review a special letter of invitation for the top administrator in each school or system that
requests permission to conduct the study as well as a personal solicitation to participate as a
subject. The IRB would then approve the study contingent on receiving letters of cooperation
from each of the sites, and after receiving authorization to proceed from the IRB Administrator,
the PI would then proceed to seek formal consent and otherwise collect data from that individual
and all of the other administrators in that location. As with all consent documents, the consent
form signed by the participant-administrators would not be provided to the IRB, only that initial
letter/email of cooperation on behalf of the organization. A parallel situation could arise for
studies involving other organizations or companies, and the same process should be considered
in those circumstances as well.

Informed Consent

An underlying ethical principle of the federal regulations is that human participants enter into
research voluntarily and with adequate information. (See The Belmont Report on Ethical
Principles and Guidelines for the Protection of Human Subjects of Research, 1979.) Thus,
consent must be informed and voluntarily given. A participant’s consent is “informed” if he/she
has a reasonable comprehension of that to which he/she is consenting. The investigator must use
language appropriate to the participant’s ability to comprehend. Generally, consent information
should be provided at no more than an 8th grade reading level. Information may not be withheld
from participants simply to assure their participation in the research.

Consent should be considered a process, not an event. Although consent is typically documented
by the participant signing a form, the form itself is not the consent (although it is often referred
to in that way). The consent is the individual’s decision to participate and/or to continue
participation. It is the researcher’s responsibility to ensure that the participant is consenting
throughout the study procedures. Participants have the right to withdraw consent and terminate
participation at any point, and researchers must be attuned to the participants’ state of mind and
allow for this to occur, particularly when participants may find it difficult to express their
feelings if they believe it will make the researcher unhappy.

Coercion and Undue Influence

Any legally competent adult can give consent; but said adult cannot give valid consent if he/she
is under the influence of alcohol or drugs, or if the consent is obtained under duress or undue
influence. To ensure that participants’ consent is voluntary, the IRB considers whether any
undue pressures or coercion will be brought to bear on potential participants. Excessive
compensation or no payment for withdrawals can be viewed by the participants as pressure to
participate or continue participation. Other pressures may be more subtle as, for example, when individuals request that family members, friends, or colleagues participate in a study they are conducting. An indirect method of recruitment (e.g., email) may be best in these situations.

Undue influence occurs most commonly when the researchers is in a formal position of power over the potential participants – supervisor/employee, counselor/client, teacher/student. It is best to avoid these situations whenever possible. For example, investigators should try to avoid using their current students in their research projects. If current students must be used, it must be made clear to the participants that the decision to participate will have no effect upon their grades or other standing in the course. Typically this means that someone other than the investigator must recruit the participant and/or collect the data so that the investigator has no knowledge of who did or did not participate, or that consent to use student work be obtained after the close of the semester or school year when the instructor no longer has a differential power relationship with the participants. Investigators should be aware that the IRB will not approve a study when coercion or undue influence is present - even if no adequate alternative design is available - unless the IRB is satisfied that voluntary consent can be obtained and undue influence or coercion to participate has been mitigated by the study procedures.

Consent Process

The consent process involves the researcher or key personnel providing the consent information – the information participants need to make an informed decision – and then the individual decides whether or not to proceed. There are several “elements” of consent that reviewers are looking for in consent materials, which are all listed on an Informed Consent Checklist. Sample consent forms are also available to assist investigators in the preparation of their own consent materials. The samples reflect both requirements of the federal regulations and customary language adopted by the IRB. Use of the Checklist and samples will facilitate IRB review.

Consent information may be provided orally, in written form, and/or by electronic text or display, according to the nature of the study. Providing consent information in written form is the standard, preferred method, and thus researchers must provide a justification when proposing other methods. The justification is often inherent in the method, however. For example, oral consent makes more sense in telephone interviews, rather than mailing the consent information or asking participants to return a signed form. Likewise, online or email surveys will typically provide the consent information in the email text or on the webpage (electronic display). There are other situations, however, when a written consent process is not best for the participants, such as when language or literacy issues are present. Oral consent (assent) is obviously more appropriate for young children and for individuals with certain significant communication problems. In some communities and countries, there may be cultural concerns. In these cases, the investigator must explain the justification on the IRB application form when proposing an alternative to written, signed consent.

Waiver of Consent

Certain studies can only be undertaken if the potential participants are not aware of the nature of the study, or that the study is even taking place. In these cases, the PI must request a waiver of
consent (or some of the elements of consent). It is also possible to request that the consent requirements be waived in cases where the research is important but consent would be impossible or highly impractical to obtain. This type of waiver is unusual and must not only be justified by the requirements of the study design, but also well-balanced by its benefits. Waivers can be requested by checking the appropriate box on the application form and providing a written justification on the form as to why the waiver is appropriate.

**Documentation of Consent (Consent Forms)**

The standard consent process is for the PI to develop and provide a written informed consent document to a potential participant that includes signatures lines for participants as well as the PI and Advisor (if the PI is a student). If the individual is interested in participating in the study, s/he signs the form as well as the PI (or other key personnel), the participant is provided a copy, and the PI or Advisor keeps it in a secure location, separate from the data, for at least 3 years. Each participant must be offered a copy of the consent form when written consent is obtained.

Researchers should not provide signed consent forms to the IRB. They should be kept in a private, locked filing cabinet and not provided to anyone outside of the study team, unless specifically requested by the IRB as part of a study audit or other review process. PIs should notify the IRB if an outside agency or court of law requests to see the consent forms.

**Waiver of Documentation of Consent**

The standard written informed consent agreement provides the PI with documented proof that participants gave informed consent, and it partially protects the PI and the University of Northern Iowa from later charges of misconduct. The IRB recommends that written documentation of informed consent be obtained whenever it is appropriate and possible to do so. However, if in the PI’s judgment obtaining signed consent is inappropriate or risky in itself, and thus the consent method being proposed is oral, electronic, or by mail, the PI may request a waiver of documentation of consent by checking the appropriate box on the IRB application and providing a justification as to why the alternate method is more appropriate. Note that this is not a waiver of consent, but a waiver of the standard requirement to obtain documentation of consent from the participant (the signatures on a form).

When a waiver of documentation of consent is granted, it is nevertheless highly advisable for investigators to document in some other fashion that consent was obtained. One alternative is to tape record the interview, or at least the informed consent procedures. A second procedure is to have a witness (e.g., a research assistant) record in written notes that the participant was fully informed, and gave consent. Under some circumstances the IRB will accept the most minimal documentation: a note in the PI’s own records stating that he/she followed informed consent procedure and obtained fully informed consent. If the researcher chooses to use this minimal documentation procedure, he/she should explain why no other form of documentation is appropriate. The greater the risk is to the participant, the greater the burden on the researcher to justify a less conventional means of documenting consent.
Chapter 11. Compensation of Participants

General Ethical Principles[1]

A primary principle in human participants research is that a participant's decision to become involved in the research must be voluntary and free of undue influence or coercion, including potential undue influence through payments or rewards for participation. On a practical level, it is probably impossible for an IRB to determine what amount of money or type of reward would unduly influence a particular individual to accept a given degree of risk. Although our society generally accepts the premise that those assuming risk deserve reward, the application of this rule in establishing payment for participants in biomedical and behavioral experiments is still being debated. The appropriateness of proposed payments is therefore a matter each IRB must address for each study.

Clear cases of coercion (e.g., actual threats) are readily identifiable; it is more difficult to recognize undue inducement. An offer one could not refuse is essentially coercive (or "undue"). Undue inducements may be troublesome because: (1) offers that are too attractive may blind prospective participants to the risks or impair their ability to exercise proper judgment; and (2) they may prompt participants to lie or conceal information that, if known, would disqualify them from enrolling or continuing as participants in a research project.

When determining the appropriate level of renumeration, the principal investigator (PI) should take into consideration the participants' medical, employment, and educational status, as well as their financial, emotional and community resources. These considerations should be applied regardless of the form of payment, which may be offered by cash, gift card, gift (e.g., T-shirts or books), entry into a drawing, travel or child care reimbursement, course credit, or no-cost services or treatment.

Record Keeping and Payment Process When University Funds are Involved

Following approval of the study protocol by the IRB, the PI will need to work with the Office of Business Operations (OBO) and/or the Office of Sponsored Programs (OSP, for externally funded projects) to set up the participant payment process, if the study involves direct payments to individuals from university funds. The appropriate process will depend on which type of compensation is planned and the dollar value of the compensation.

I. If individual payments to participants will not exceed $75 AND any recurring payments to individuals will not exceed $599 in any one year, investigators may choose to pay participants by cash, gifts or gift cards, or entry into a drawing. If the PI wants to pay cash to participants, or purchase gift cards to use for participant compensation, a cash advance should be requested using the OBO Cash Advance form. Purchase of gift cards with personal money for which the PI then requests reimbursement is acceptable, but not encouraged, particularly if the exact number of participants is not certain. The PI should not request that University checks be issued to pay participants because doing so requires that participant identity and contact information be
revealed to others outside of the research team, which is not required for payments under the $75 individual - $599 annual threshold. If the PI wants to provide a gift, those should be purchased using standard departmental processes for doing so, and then provided to the participants after they complete the study task for which they are receiving payment.

When requesting a cash advance or reimbursement for purchase of gift cards, the cash advance or reimbursement form must be accompanied by the IRB Approval letter and the page from the IRB application that documents the number of planned participants. Investigators will not be limited to payments for the exact number of participants originally planned. The number may vary over the course of the study, but if significant changes to the sample size or a new sample population should be necessary, the PI must send an email to the IRB Administrator requesting approval for a study modification before proceeding further.

Investigators are cautioned to use appropriate financial tracking procedures when managing participant payment processes. If cash or gift cards are lost or stolen, the PI will be required to reimburse the University for the loss. In addition, in all cases, including anonymous studies, the PI must maintain a tracking list or spreadsheet with individual code numbers and payments to ensure that no one individual receives a total of $599 or more, which would require following the procedures listed below. If the study is not anonymous, the PI must also keep a master list linking code numbers and individual participant names and contact information, which must be kept in a password protected computer and/or locked filing cabinet. The tracking spreadsheet or other documentation with study and individual code numbers must be kept indefinitely to allow for an audit of expenditures if required. If the PI is a student, the tracking spreadsheet and master list must be turned over to the student’s Advisor for storage long-term.

II. If individual payments will exceed $75 OR any recurring payments to individuals may exceed a total of $599, investigators may choose to pay participants by University check, gifts or gift cards, or entry into a drawing. The use of cash payments is not allowed for these studies.

If compensation is by gift or gift card, the researchers must record the individual’s name, UNI ID#, address, and signature at the time of payment, using the OBO Acknowledgement of Payment Receipt form. The PI then retains this information in a confidential manner, except that a copy of all signed forms must be sent to OBO at the end of the study. If the compensation is by University check, participant name, ID, and contact information must be provided to OBO on a Request for Payment form and then checks will be issued.

As above, the PI must maintain a tracking spreadsheet of individual and study code numbers and payments to track how much individual participants are being paid for the study. The PI must also keep a master list linking code numbers and individual names, which must be kept in a password protected computer and/or locked filing cabinet. Tracking information must be retained per the document retention schedule. These items should be kept for the length of time identified for Request for Payments in order to allow for an audit of expenditure documentation if necessary.

In the event a PI wishes to propose a study that may include compensation that will go over the $75 - $599 thresholds, and will be either anonymous or include a waiver of consent signatures,
the PI must request special approval for this in the IRB application. It is likely the request will only be approved if providing signatures will pose a significant risk to participants, compensation is strongly indicated for study success, and the study benefits are expected to be quite high. The IRB will also confer with the OBO before approving such a request.

**UNI Employees and Students as Study Participants**

In the event the participants are employees or students at UNI, regardless of the value or type of compensation, all names and contact information and UNI ID# of participants who elect to receive compensation must be provided to OBO, so that the dollar amount (or value) can be included in the individual’s tax statements as required by IRS. Participant signatures will also be required for any payments made over the $ 75 - $ 599 thresholds. This policy is applicable even if the actual payments to UNI employees or students come from another organization and UNI is just a co-sponsor of the study in some way (e.g., someone at UNI is a co-investigator). Again, a special request can be made for a waiver of this policy, but significant justification will be necessary for approval.

**Informed Consent about Payments**

In those studies where names, contact information and UNI ID# (but not their research data) must be submitted to OBO (all university employees and students and all non-employees who are eligible to receive an individual payment exceeding $ 75 and/or receive more than $ 599 in one year, either in one study or through multiple studies) the participants must be informed about this policy during the consent process, and that they will receive a tax form from the institution at the end of the year. They must also be informed that the business office has careful procedures in place to keep such information confidential, and that they may elect not to receive payments if they prefer not to have their identifying information provided to anyone outside the research team.

[1] The language in this section draws heavily on written guidance from OHRP, which can be found at: [http://www.hhs.gov/ohrp/](http://www.hhs.gov/ohrp/)
Chapter 12. Special Methods

Research Using Existing or Secondary Data

Research that involves the use of existing data, documents, records and pathological specimens, or diagnostic specimens must be reviewed in advance of receiving or analyzing the data. If the data contain individual identifiers, the research may be eligible for an Expedited review. If the data are recorded so that participants cannot be identified, either directly or through identifiers linked to the subject, the research may be reviewed by the IRB through Exempt procedures. See Chapter 4 for a discussion of direct versus indirect identifiers as well as which secondary data projects require review (most do).

Consent issues require special attention in secondary data projects. Ordinarily, when a person uses data collected by someone else for another purpose, the consent of the participants must be sought again. For example, if researcher A has interviewed a number of persons for project A, the interview cannot be released later to researcher B for project B. The participant who consented for his or her data to be used in project A might disapprove heartily of project B and thus might refuse to cooperate. The wording of the original consent form is critical. If a participant consented to allow his or her blood sample to be available to persons studying blood diseases, his or her sample could be shared with many researchers without additional consent. The original researchers who received consent can re-work the data without new consent provided it is for a related purpose and the original consent form informed participants of this possibility.

Having said that, if the data from the original research are truly anonymous or the data are pooled in a form ensuring anonymity, then consent for secondary use may be waived by the IRB. It is also possible to request that the IRB waive consent when it will be impossible or highly impractical to go back and obtain consent. Issues pertaining to waivers of consent and documentation of consent are discussed in Chapter 10.

Use of Biological Samples

The use of biological samples in research has become very sensitive due to the rapidly increasing technology available that allows identification of individuals through their DNA. Unless the biological samples are drawn from the researcher alone, informed consent will be required in most cases and the consent information must address how the biological samples will be drawn, handled, and stored, and for how long. Unless the participant consents to future research using them, the samples should be destroyed as soon as possible after data analysis is complete.

Ethnographic Research

The IRB recognizes that ethnography and participant observation are different from experiments conducted in a laboratory or classroom, and that the standard written consent form may be inappropriate. The IRB also recognizes that such qualitative methods often involve casual conversations with dozens or hundreds of participants in various settings. The researcher should simply describe in the IRB application what methods will be used under which circumstances for
disclosing that research is taking place and how other elements of the consent process will be addressed. Often a waiver of documentation of consent may be granted if written consent is inappropriate in a given situation.

**Deception**

Deception should be employed only when there are no viable alternative procedures. Where deception is a necessary part of a study, the IRB may require that a preliminary consent be obtained, if possible, in which the investigator informs the participant that the study activities or purpose cannot be described fully in advance. After the study, the participant should be informed of the deception and its purpose. The IRB recognizes that there are rare instances in which no consent can be obtained or debriefing done: for example, where debriefing would cause more harm to the participant than the deception itself.
Chapter 13. Special Populations

Protections for Vulnerable Populations

Vulnerable populations include individuals who may be vulnerable to coercion or undue influence to participate in research projects. They may also include research populations, or be associated with populations, that are simply unable or have limited capacity to provide "consent." Thus, Federal Regulations require additional protections for special participant populations, such as: (1) pregnant women (2) prisoners (3) children (4) physically or mentally impaired persons (5) economically or educationally disadvantaged persons (6) other potentially vulnerable groups, and (7) activities involving fetuses and human in vitro fertilization.

It is important to note that, in some cases, state and local laws will also be relevant in these considerations.

Children

Children are defined as persons who have not yet attained the legal age for consent to treatment or procedures involved in research as determined by local law. Generally, the law considers any person under 18 years old to be a minor. Persons aged 18 and older may consent to participating in research and parental permission is not required. For participants aged 17 and under, however, the permission (consent) of at least one parent or guardian is required. Permission from parents is usually indicated in a form similar to a participant consent form, constructed to request "your child" to participate.

If a minor is age 7 or older, the minor's assent must also be obtained. An assent is defined as a minor’s affirmative agreement to participate in research. (Failure to object should not be construed as assent.) The aims and general nature of the project must be described in language that is appropriate to the minor’s age, experience, maturity, and condition. This explanation should also include a discussion of any discomforts and inconveniences the child may experience if he or she agrees to participate. Parental permission overrules a minor’s decision not to participate in therapeutic settings.

There are no particular requirements to obtain assent from children under age 7, provided parental permission is secured. However, early childhood professionals have developed appropriate methods for seeking the assent of young children in research that should be considered in the design. Sample assent and consent forms are available on the IRB forms page.

In certain cases where risk would be increased if parental permission is sought (e.g., studies of abuse) and where it would be unreasonable to require parental permission, the IRB may waive the requirement. Research on minors which involves more than minimal risk will be approved only if it is (i) of direct benefit to the participant or (ii) yields useful knowledge about a participant's problem or disorder. In the latter case, both parents must give consent. If a child is
a ward of the state, the IRB requires that there be an advocate appointed to function as a guardian in the child's behalf.

Children are considered a vulnerable population because their physical and intellectual capacities are limited and as such, special considerations are necessary. The IRB reviewing research involving children as participants must consider the benefits, risks, and discomforts inherent in the proposed research and assess their justification in light of the expected benefits to the child-participant or to society as a whole. Thus, when the IRB reviews research involving children, it is required to classify such research as involving children in one of four categories. The four categories are:

- Research not involving greater than minimal risk.
- Research involving greater than minimal risk, but presenting the prospect of direct benefit to the participant.
- Research involving greater than minimal risk with no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant’s disorder or condition.
- Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

If the IRB determines that the research involves greater than minimal risk, signatures from both parents are necessary. However, in some cases, the IRB may determine that it is acceptable for only one parent to provide permission when one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

**Prisoners**

According to 45 CFR 46.303(c), a prisoner is defined as any individual involuntarily confined or detained in a penal institution. This term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. It is important to note that this category of special protections also includes situations where a research participant may become a prisoner after the research has commenced.

Only certain types of research may be conducted utilizing prisoners as participants: (1) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants; study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants; (2) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; (3) and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults). (4) Research on practices, both innovative and accepted, which
have the intent and reasonable probability of improving the health or well-being of the participant.

Coercion is the IRB’s main focus when reviewing studies involving prisoners. Many factors will be taken into account regarding this issue before a study may be approved. When prisoner research is reviewed by the IRB, IRB membership in attendance at that meeting will include a prisoner representative with appropriate background and experience to serve in that capacity.

Pregnant Women
Research involving women who are or may become pregnant receives special attention from IRBs because of women’s additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus. Pregnancy is defined as the period from confirmation of implantation of a fertilized egg within the uterus until the fetus has entirely left the uterus (i.e., has been delivered). In studies involving pregnant women, IRBs must also determine when the informed consent of the father is necessary. Additionally, because of the involvement of the fetus (who cannot give consent), the IRB must consider the need to prevent harm or injury to future members of society. At the same time, IRBs must also recognize that the inclusion of women in research study populations is important so that research findings can be generalizable and of benefit to all persons at risk of a disease, disorder, or condition under study. Therefore, pregnant women may be involved in several kinds of research which present differing IRB duties for each kind of research.

The three basic types of research are:

- Studies in which pregnancy is coincidental to participant selection. Any study where women of childbearing potential are possible participants could inadvertently include pregnant women. Depending on the research procedures, these participants may need to be notified that a particular treatment or procedure "may involve risks to the participant (or to the embryo or fetus if the participant is or becomes pregnant) that are currently unforeseeable." Non-pregnant participants may need to be advised to avoid pregnancy or nursing while involved or following the research.

- Studies directed primarily toward the mother’s health. As women’s health can be positively or negatively affected by pregnancy, some research may be undertaken to explore these issues. As such, a woman’s needs generally take precedence over those of the fetus. The IRB will, however, attempt to ensure that the risks to the fetus are minimized.

- Studies directed toward pregnancy. Many studies are directed to examine the normal and abnormal processes of pregnancy, labor, and delivery. In these cases, the IRB must determine that the risk to the fetus is "minimal." "Minimal" is defined as where the risk to the fetus is no more than that from established procedures routinely used in an uncomplicated pregnancy or in a pregnancy with complications comparable to those being studied. If the IRB cannot conclude that the risk is minimal, it can consult with the experts for advice. Basically, it must then be determined that the risks are far outweighed by the benefits to the participant and the importance of the knowledge to be gained.
Fetuses
A fetus is defined as the product of conception from the time of implantation until delivery. Once the fetus is delivered or expelled and is viable (likely to survive to the point of sustaining life independently, given the benefit of available medical therapy), it is designated as an infant and is thus subject to Federal Regulations governing research with children. The fetus should be treated respectfully and with dignity and its genetic heritage and vulnerability should be recognized, regardless of its life prospects. Because the fetus shares a unique relationship with its mother and cannot consent to be a research participant, special Federal Regulations are in place to guide fetal research.

In research, risks to the fetus may not be more than minimal (e.g., risks from ultrasound or changes in maternal diet) and if the risk to the fetus is deemed more than minimal, it must be justified by the anticipated benefit for the health of the mother or the particular fetus. It can be problematic, however, to determine what exactly is minimal risk for a fetus as compared to a child or adult; and the IRB will work closely with investigators to make this determination. However, if risk to the fetus is more than minimal and without anticipated medical benefit to the mother or fetus, special provisions apply, and the IRB must determine that data gained from such a study is not obtainable in any other research design or format.

Basic types of research involving fetuses include:

- Research directed toward the fetus in utero. The IRB can approve this kind of research if the purpose of the research is to meet the health needs of the fetus and will be conducted in such a way to minimize risk or if the research presents no more than minimal risk to the fetus and the purpose of this activity is the development of new knowledge that is unobtainable by any other way. As always, risks should be justified by a consideration of potential benefits.

- Research involving the fetus ex utero. If the fetus is judged viable outside of the uterus, then it is considered an infant and is thus governed by research regulations involving children. If a fetus is judged nonviable (unable to survive to the point of sustaining life independently), then research is forbidden.

- Research with dead fetuses, fetal material, and placenta. Research with dead fetuses, fetal material, or cells, tissues, or organs removed from a dead fetus are governed by state laws and regulations. Ethical considerations commonly held about respect for the dead should be observed if proposing such research.

Persons with Cognitive Impairment
A cognitively impaired person is defined as having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia), or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. In addition, persons under the influence of or dependent on drugs or alcohol, suffering from degenerative
diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

Thus, the major ethical concern in research involving individuals with psychiatric, cognitive, or developmental disorders, or who are substance abusers is that their disorders may affect their capacity to understand the information presented and their ability to make a reasoned decision about participation. Also, many individuals with such disabilities may be residents of institutions responsible for their total care and treatment and this factor may have an impact on or further compromise these individuals’ ability to exercise free choice (voluntariness) in participating in research. (For example, these individuals may agree too readily to requests for their "cooperation" or may be vulnerable to perceived or actual pressures for fear of being denied services.) It is for these reasons that special protections must be considered by the IRB when reviewing research involving cognitively impaired persons.

When reviewing research involving cognitively impaired persons, the IRB must consider several issues:

Do such individuals comprise the only appropriate participant population? In other words, do the research questions focus on issues unrelated to their disorders or institutionalization?

Are there sufficient protections for privacy and confidentiality of information gathered?

How are issues of consent and competence addressed? As a general rule, there should be specific evidence of individuals’ incapacity to understand and to make a choice before they are deemed unable to consent. If cognitive impairment cannot be judged a priori, then mental status testing should be included in the research design. If a person is capable of understanding the nature of the project, consent should be obtained from both the participant and a parent, guardian, or advocate as appropriate. In instances where the person is not competent to consent, parental or guardian consent alone is sufficient. When individuals are deemed unable to consent, investigators and IRBs must consider state and local laws governing the selection of an appropriate representative to consent on behalf of these individuals. The IRB will consider the possibility of obtaining "assent" (see the discussion on involving children in research) from potential research participants when they are cognitively impaired.
Chapter 14. Continuing Review and Project Closure

All Expedited and Full Board studies must be reviewed at least annually by the IRB. Investigators are also required to close the project out with the IRB when the study ends. Exempt studies are exempt from these requirements, although as noted in a previous chapter, approval is required before modifications are made for all studies, including Exempt projects.

The purpose of continuing review is to determine whether the risk/benefit ratio previously assessed has changed, to ensure that the measures taken to safeguard participants are adequate, that the approved IRB application/protocol is being followed, and that the project reflects any changes that have been made in the regulations for human subjects research since the last approval. In the event of Project Closure, the form provides a final report of how the study progressed and whether or not any problems arose.

Continuing Review of Ongoing Research

Continuing reviews are performed by the IRB Chair or one or more experienced reviewers designated by the IRB chairperson from among the IRB members (45 CFR 46.110(b)). The IRB chairperson or IRB members designated by the chairperson can approve or require modification in (to secure approval of) research, but may not disapprove research using the expedited procedures (45 CFR 46.110(b)). Disapproval of continuing research can only occur after review by the IRB at a convened meeting. All IRB members must be advised of research that has been approved under an expedited review procedure (45 CFR 46.100(c)).

Form and Attachments

The form for requesting continuing review and for closing out a project is the same, posted on the IRB forms page. The Continuing Review/Closure form and any required attachments must be submitted prior to the expiration date designated at last review. A current copy of all assent and consent forms must be attached for all Active studies (except those in data analysis only), even if no changes have been made. For project closure, the form may be submitted at any point prior to expiration. For continuing reviews, the form should not be submitted more than 60 days in advance of the expiration date.

Project Status

The researcher must check the appropriate box on the form that reflects the current status of the study. Studies cannot be closed if any activity, including data analysis, is still underway or planned. If all data collection is complete, but the researcher is still analyzing data, the box “Active-Post-Enrollment” should be selected. A study may become exempt from future continuing review if all data is de-identified.

Approval Period

Federal regulations require that the IRB conduct ongoing reviews of all non-Exempt protocols at intervals appropriate to the degree of risk, but not less than once per year. The interval is set for
each protocol. Most protocols at UNI are approved for one year minus one day, although the approval period may be less if the IRB deems more frequent reviews necessary. Modifications that may have occurred during the year do not change or advance the approval period. The phrase “not less than once per year” means that the research must be reviewed within one year of the date of the Expedited approval date or in the case of Full Board studies, the date of the IRB meeting at which the research was approved (with or without conditions) even though the research activities may not begin until after the IRB has given final approval. Factors to be considered by the IRB in determining the appropriate interval for periodic review include the following:

- involvement of vulnerable populations;
- research conducted internationally;
- the involvement of recombinant DNA or other types of gene transfer protocols;
- any waivers of informed consent procedures;
- research for which participants would be exposed to additional serious risks, such as breach of confidentiality;
- previous suspension of the research due to compliance, record-keeping, or other concerns; and
- studies that pose a very high level of risk to individual participants or some risk to a large number of participants;

In addition, at its discretion the IRB may require review more frequently than annually for studies conducted by investigators that have not been compliance with IRB requirements in the past or studies being conducted by new investigators.

The frequency of continuing review may be changed at any point in the future. Examples of reasons for a change in the length of the approval period may include the following: (a) a large number of participant withdrawals, (b) participant complaints, (c) new information that indicates a change in the participant risk/benefit ratio, (d) unanticipated adverse events/complications that would affect the risk/benefit ratio, (e) a change in primary investigators, and (f) notification of changes in the consent process, research plans, the procedures, or the data collection methods. This list should not be considered exhaustive. However, should a more frequent review be required, the researcher will be provided with a statement of the reasons for the change.

Approval Dates and Communications

The approval and expiration dates for the study will be printed in a formal letter of approval sent to the investigator. Investigators will be informed if a continuing review is required and that s/he is responsible for submitting a Continuing Review form in sufficient time for review to occur prior to the study’s expiration date. For expedited studies, Continuing Review forms should be submitted 2 weeks prior to the expiration date. For full board studies, continuing review requests should be in to the IRB office at least 45-60 days prior to expiration, or otherwise in sufficient time to be distributed prior to the next scheduled Board meeting.

Reminders. Approximately 45-60 days prior to the expiration date for all open non-exempt studies, a Continuing Review/Closure form will be emailed to investigators as a reminder that
the study is about to expire. If no email is available for the investigator (typically a student who has left campus), the form is emailed only to the Advisor. If a faculty investigator has left campus, the IRB office attempts to locate a forwarding email or mail address for the faculty member. If there is no response to the initial email and form, a second reminder email is sent to the same individual(s), noting that study expiration is pending and that the study file will be closed upon expiration. If still no response occurs, the file is closed with a notation that the investigator was non-responsive to the IRB renewal/closure requirements. If the study was approved by the full board, a third and final email is sent, notifying the investigator that the study has in fact expired and reminding him or her once again that no further research is permissible without a new review.

**Study Expiration**

It is the investigator’s responsibility to ensure that his or her research is submitted for review in time for continuing approval. If the continuing review form is not received by the IRB office at least by the study expiration date, the study approval automatically expires and new application for review will be required in order to continue the study.

In the event that the study is not approved either through continuing review or via a new review process by the study’s expiration date, all research activities must stop at that point until approval is again obtained. The only exception to this is if stopping the research would cause harm to participants (e.g., by removing them from a clinical trial), in which case the IRB needs to be notified of this immediately.

**Review Process for Active Projects**

For most projects that need ongoing approval, the reviewer will receive a copy of the past protocol and modifications from the study file, as well as the current Continuing Review/Closure form and materials. (For active projects in which no participants have been enrolled, or participant enrollment has been completed, reviewers may simply choose to review the Continuing form and materials without examining the overall file.) During the review, the reviewer may email any questions or concerns to the investigator. If it is an expedited study, the reviewer may simply approve the study for continuation by sending an email to the investigator, which will be followed by a more formal letter of approval from the IRB office. If the study required full board review, one member of the IRB will receive all past materials and all IRB members will receive all current materials plus a summary of the protocol provided by the member facilitating the review. The investigator(s) (and advisors if applicable) are invited but not required to attend the meeting as well. Full board continuing reviews are in other ways similar to initial reviews, in that materials are reviewed, any concerns raised, and a vote taken on the protocol.

**Continuing Approval Category**

Most studies will be approved at the continuing review point in the same regulatory category under which they were originally approved. However, there are exceptions to this when the circumstances, including risks/benefits for participants, have changed. For example, a study
originally approved as Expedited may be reviewed by the full board at the continuing review point if new components have been added such that Expedited review is no longer allowed, or simply because the lead reviewer wishes to consult with the other members of the Board.

As another example, studies that were originally reviewed by the full board may be subsequently reviewed under Expedited procedures (i.e., by one reviewer) under the following conditions: a) no participants have yet been enrolled; b) the study is inactive; c) the study is completed; or d) participant enrollment is closed and the study is in data analysis only. The results of expedited reviews for original full board studies are reported to the committee members on the IRB monthly status sheets.

Studies that are in the Active-Post-Enrollment phase may be approved as Exempt at the continuing review point if the study now meets the criteria for Exempt studies, including that all identifiers and/or links to identifiers have been removed from the dataset.

**Project Closure**

Submitting the Continuing Review/Closure form prior to the expiration date is not optional. As noted above, investigators are required to return the form even if the study is completed and renewal is not needed. The form serves both purposes.

Investigators may return the Continuing Review/Closure form at whatever point the project is complete, rather than waiting until the end of the approval period to close the study. Student researchers and all others completing projects in the middle of the approval period are encouraged to do this to avoid having to subsequently receive reminder materials after the end of the study. Students are often difficult to contact at the expiration point since they may have left campus by that time, in which case Advisors are expected to complete materials on their behalf and will receive multiple requests to do so. Upon receipt by the IRB, the form will be forwarded to an IRB committee member for review, who will either share any questions or concerns s/he may have about the study with the investigator, or will approve closure of the study and the file will be closed by the IRB office without further communication with the investigator.
Chapter 15. Study Modifications

Policy Regarding Study Modifications

When changes are needed in a previously approved protocol, the investigator is responsible for requesting and receiving IRB approval for the changes before the changes are implemented. However, when changes are made to eliminate an immediate hazard or serious potential risk to participants, review of those changes may be requested after it occurs, provided the request is made within 10 days of occurrence. If non-emergency changes are introduced without advance approval, the investigator will be considered to be out of compliance with IRB regulations. This policy applies to all projects, regardless of funding source, and including those originally determined to be Exempt from ongoing review.

Which Modifications Need Review

Changes or additions that require review and approval by the IRB are those that may affect the assessment of risks and benefits for participants from the research, including the potential legal, social, economic, health, and privacy risks.

Examples of modifications that need review include:

- any revisions to consent materials beyond minor editorial or grammatical changes;
- adding a new measure or instrument, or changing current measures or instruments;
- adding or changing the sample(s) of participants;
- adding or changing the review of academic or medical records;
- involvement with participants again for follow-up research that was not originally included in the protocol;
- adding a site for recruitment or data collection;
- changing key personnel on the study (individuals involved in decision-making, recruitment, or data collection);
- changing the procedures for how participants are invited/recruited into the study;
- changing the data collection procedures.

Examples of modifications that do NOT require review are:

- dropping a measure or instrument (unless it is used to screen or monitor the welfare of study participants);
- making minor editorial or grammatical revisions to approved documents that are unrelated to the sensitivity of the questions or the privacy of the participants;
- removing a research site from the study;
- changing the strategy or procedures for data analysis.

If in doubt whether or not a proposed change requires review, the investigator should simply send in an email describing the change to the IRB Administrator.

Review Process
• Modifications are typically reviewed fairly quickly without the use of a special form. The investigator should simply send an email to the IRB Administrator describing the proposed changes and attach any consent forms or other participant materials that must be changed as well. The communication should include a reference to the original IRB protocol number. The request will be forwarded to an IRB Chair or other reviewer for expedited review, unless the study is being monitored by the full board, in which case the request will be reviewed at the next regularly scheduled meeting of the IRB. In either case, the investigator will receive an email from the primary reviewer noting questions or concerns about the modification, or approving the changes as requested and allowing the study to continue with the modification. A formal letter of approval is not issued for modifications. Documentation of all modifications is entered into the IRB database and the study file.

• Certain modifications may be authorized immediately by the IRB office staff, without being reviewed by a designated IRB member. These include: a) adding a site, when the study was approved to include multiple sites; and b) adding or changing key personnel. If multiple sites for a study are planned, at least one site must provide a letter of cooperation before the study can be approved by the IRB. Subsequent letters of cooperation should be forwarded to the IRB Administrator, preferably with the protocol number and/or investigator name noted on the letter. (See Chapter 8 regarding requirements for letters or emails documenting cooperation.) When each letter is received, the IRB Administrator will send an email confirming receipt of the letter and authorizing recruitment and data collection to commence at that site. If the study was originally approved for only one site, and the investigator now proposes to add or change sites, the request will be forwarded for formal review by a designated IRB member.

• If the study was originally reviewed by the full board, modifications may also require full board review. If the changes proposed are minor (e.g. changes to student personnel, minor revisions to participant materials, addition of study sites), regulations allow these to be approved under an expedited process.
Chapter 16. Reporting Problems

Requirements for Reporting

All problems or adverse events that occur during the course of an approved research project must be reported to the IRB. According to federal regulations, problems or potential adverse reactions that were anticipated by the researcher at the time of approval must be reported at periodic review or closure. Problems or adverse events related to the research that were not anticipated must be reported promptly after being discovered by the investigator, either within 7 or 14 days, depending on the seriousness of the event, as outlined below. Unfortunately, these regulations are somewhat complex, so a good rule of thumb is if anything unexpected occurs during your project, such as data being lost or stolen, a participant becoming upset, or a research procedure not being carried out as approved, simply send an email to the IRB Administrator and report it.

Definitions

Anticipated (expected) problems are those that involve potential risks previously described to the IRB, and to participants in the consent form and other participant materials. Anticipated problems should be reported in summary form at the time of IRB continuing review or project closure, whichever comes first. For example, emotional distress is a possible outcome of the research anticipated at the outset, this event should be reported at the time of the next review.

Unanticipated problems are those that have not previously been noted as potential risks of the research to the IRB and the participants, and which suggest that the research places participants or others at a greater risk of harm (physical, psychological, social, or economic) than was previously known or recognized. When unanticipated problems occur, the investigator should assess whether or not the incident, experience, or outcome is related to the research. If not, the problem should be reported in summary form at the time of continuing review. If, in the opinion of the investigator, the problem or event is possibly, probably or definitely related to the research procedures, it must be reported to the IRB within 14 days of when the investigator learns of it.

Adverse Events are defined as any untoward or unfavorable medical occurrences in one or more human participants, including any abnormal sign, symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. Adverse events include both physical and psychological harm, but not social, economic, or other kinds of harm. Instances of serious harm (death, disability, or hospitalization) that are unexpected are referred to as Serious Adverse Events.

In summary, Unanticipated Problems are unexpected, related to the research, and involve risk. Those that involve physical and psychological harm are called Adverse Events. (Only Adverse Events that were unexpected are considered Unanticipated Problems.) Thus, the following guidelines must be followed for reporting Unanticipated Problems and/or Adverse Events:

- Adverse Events (involving psychological or physical harm) that were not expected must be reported to the IRB within 7 days of the investigator learning of it, whether or not they are related to the research.
• **Other Unanticipated Problems** (involving social, economic or other harm) that were *not expected* must be reported to the IRB within 14 days of the investigator learning of it, *if they are related* to the research. If they are not related, these can wait until the continuing review or closure point.

• **Serious Adverse Events**, which involve death, hospitalization, and disability, that were *not expected* must be reported within 7 days to the IRB, whether related to the research or not.

• **Any problems or events** that were *anticipated* should be reported at continuing review or closure.

For example, the following events are considered Unanticipated Problems which must be reported within the 7 day time frame, using the Problem-Event Reporting form:

- Any event, which in the opinion of the local investigator, was unanticipated, involved risk to participants or others, and may have been related to the research procedures;
- Any accidental or unintentional change to the IRB-approved protocol that involves risk or has the potential to recur;
- Any deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research subject;
- Any publication in the literature, interim result, or other finding that indicates an unexpected change to the risk/benefit ratio of the research;
- Any breach in confidentiality that may involve risk to the subject or others;
- Any complaint of a subject that indicates an unanticipated risk or that cannot be resolved by the research staff; or
- Any other possibly related event which in the opinion of the investigator constitutes an unanticipated risk of physical or psychological harm.

**Review Process**

When an investigator has an Unanticipated Problem or Adverse Event to report, he or she must complete the [Problem-Event Reporting Form](#), sign it, and mail or drop it off at the IRB office. The IRB Administrator will review it and forward it to the IRB Chairperson. If the Chair determines it warrants full board consideration, it will be presented to the committee at its next regularly scheduled meeting, unless an immediate meeting is called for. The Chair and/or the Board will determine what, if any, action should be taken in response to the problem or event.

Examples of corrective actions or substantive changes that might need to be considered in response to an unanticipated problem or adverse event include:

- review/approval of changes to the research protocol that were initiated by the investigator prior to obtaining IRB approval to eliminate apparent immediate hazards to participants;
- modification of inclusion or exclusion criteria to mitigate the newly identified risks;
- implementation of additional procedures for monitoring participants;
- suspension of enrollment of new participants;
- suspension of research procedures in currently enrolled participants;
• modification of informed consent documents to include a description of newly recognized risks; and
• provision of additional information about newly recognized risks to previously enrolled participants.

**IRB Reporting to Others**

The IRB is required by Federal Regulations to report incidents to the Office of Human Research Protections (OHRP) when one of the following occurs: a) Unanticipated Problem (unexpected, related to research, and involving risk); b) Serious or continuing noncompliance by an investigator; or c) Suspension or termination of a protocol. Unanticipated Problems must be reported “promptly”, which is to be defined by the institution according to the nature and severity of the problem, but reports to OHRP are encouraged within 4 weeks of the IRB receiving the information. All UNI projects are covered by these requirements, regardless of funding source. Upon receipt, the OHRP will assess the adequacy and timeliness of the institution’s response to the problem. When a report is sent to the OHRP, a copy will also be sent to the investigator, and possibly his/her department head, the dean of the college, and the Provost.

**Examples**

**Example of an Unanticipated Problem that is not an Adverse Event. Investigator must report promptly and IRB must report it to the OHRP.**

An investigator conducting behavioral research collects individually identifiable sensitive information about illicit drug use and other illegal behaviors by surveying college students. The data are stored on a laptop computer without encryption, and the laptop computer is stolen from the investigator’s car on the way home from work. This is an unanticipated problem that must be reported because the incident was (a) unexpected (i.e., the investigators did not anticipate the theft); (b) related to participation in the research; and (c) placed the participants at a greater risk of psychological and social harm from the breach in confidentiality of the study data than was previously known or recognized.

**Examples of Adverse Events that are not Unanticipated Problems. Investigator reports these to the IRB at continuing review and IRB does not report to OHRP.**

An investigator is conducting a psychology study evaluating the factors that affect reaction times in response to auditory stimuli. In order to perform the reaction time measurements, participants are placed in a small, windowless soundproof booth and asked to wear headphones. The IRB-approved protocol and informed consent document describe claustrophobic reactions as one of the risks of the research. The 20th subject enrolled in the research experiences significant claustrophobia, resulting in the participant withdrawing from the research. This example is not an unanticipated problem because the occurrence of the claustrophobic reactions in terms of nature, severity, and frequency was expected.
An investigator performs prospective medical chart reviews to collect medical data on premature infants in a neonatal intensive care unit (NICU) for a research registry. An infant, about whom the investigator is collecting medical data for the registry, dies as the result of an infection that commonly occurs in the NICU setting. This example is not an unanticipated problem because the death of the subject is not related to participation in the research, but is most likely related to the infant’s underlying medical condition.

**Example of Adverse Event that is an Unanticipated Problem. Investigator must report it promptly to the IRB and the IRB must report it to OHRP.**

A behavioral researcher conducts a study in college students that involves completion of a detailed survey asking questions about early childhood experiences. The research was judged to involve no more than minimal risk and was approved by the IRB chairperson under an expedited review procedure. During the completion of the survey, one participant has a transient psychological reaction manifested by intense sadness and depressed mood that resolved without intervention after a few hours. The protocol and informed consent document for the research did not describe any risk of such negative psychological reactions. Upon further evaluation, the investigator determines that the participant’s negative psychological reaction resulted from certain survey questions that triggered memories of physical abuse as a child. The investigator had not expected that such reactions would be triggered by the survey questions. This is an example of an unanticipated problem that must be reported in the context of social and behavioral research because, although not serious, the adverse event was (a) unexpected; (b) related to participation in the research; and (c) suggested that the research places participants at a greater risk of psychological harm than was previously known or recognized.

**References**


45 CFR 46.103

45 CFR 46.111

45 CFR 46.109(e)

45 CFR 46.113