

Utah State Board of Education Institutional Review Board Policy

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CHAPTER 1: INTRODUCTION

The Institutional Review Board (IRB) at Utah State Board of Education (USBE) is a committee designated to review and approve research involving human participants prior to the initiation of such research, and to conduct periodic reviews of such research. The IRB operates according to Title 45 Code of Federal Regulations (CFR) part 46, Federal and State guidelines, and the Belmont Report (<http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html#>).

Mission Statement

Utah State Board of Education's partners conduct research designed to create new knowledge and promote an improved quality of life for citizens of Utah, the nation, and the world. The IRB furthers the Utah Data Research Center's (UDRC) research mission by:

- Reviewing proposed research involving human participants, in order to protect them against potential risks of research participation while promoting high-quality studies that can provide benefits to participants and/or society;
- Educating the larger community about ethical issues in human participants research; and
- Overseeing compliance with federal and state regulatory requirements for human participant research.

Authority and Responsibility of the IRB

USBE IRB operates under a Federal Wide Assurance (FWA). A FWA is a document which formalizes an institution's commitment to protect human participants and is required by any institution that participates in federally supported human participant research. This is an agreement between the IRB and the Department of Health and Human Services (DHHS) outlining the responsibilities of the IRB in upholding the ethical principles of research involving human participants. These principles are outlined in the report of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research entitled, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, known as the "Belmont Report" (<http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html#>).

Research activities are overseen for DHHS by the Office for Human Research Protections (OHRP; <http://www.hhs.gov/ohrp/>). The Grant Manager is responsible for administering the program, ensuring compliance with the Public Health Service Act, Protection of Human Participants, and 45CFR46. Parts of this handbook that are not specific to IRB are taken directly from the regulatory language (<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>).

The IRB is established to protect the rights and welfare of human participants in research and has the authority to approve, disapprove, or require modifications of research activities that fall within its jurisdiction. The IRB may work in conjunction with other universities or institutional

committees; however, it independently reviews research projects based upon the principle that human participants must be adequately protected. Any risk to participating in research should be outweighed by the potential benefits of the research.

IRB Members

The State Superintendent of Public Instruction recommends members of the IRB, including the Chair. The State Superintendent of Public Instruction approves the appointment of the USBE members and chair. Appointments to the USBE IRB have three-year terms. IRB members may serve no more than two consecutive terms or six years. Federal requirements mandate that the IRB have a minimum of five members with varying backgrounds to review research activities commonly conducted at UDRC. IRB members must be knowledgeable about institutional commitments and regulations, applicable laws, standards of professional conduct, and practice. The IRB membership must be diverse in race, gender, and cultural background; and include at least one person in each of the following categories:

- A member's primary concern is the social science area.
- A member's primary concern is in workforce areas.
- A member is not affiliated with UDRC and is not an immediate family member of a person who is affiliated with UDRC.

The USBE IRB comprises seven members - two members representing State Board of Education or Public Education, two members representing Utah System of Higher Education, one member representing Utah System of Technical Colleges, one member representing Department of Workforce Services, and one public at large member representing students' interests.

No member of the IRB may participate in the initial or continuing review of any project in which that member has a conflict of interest, except to provide information requested by the IRB. Common conflicts of interest may include but are not limited to scenarios where the reviewer (a) is principal or co-investigator for the project under review, (b) has a financial or other compelling interest in the project or its outcomes, or (c) is directly supervised by or supervises the principal or co-investigator.

The State Superintendent of Public Instruction may, at his/her discretion, invite additional individuals with competence in specialized areas to assist in the reviews that require expertise beyond or in addition to that available on the IRB. These individuals do not vote with the IRB.

The board roster is listed online at USBE Website.

Responsibilities of the IRB

The USBE IRB is responsible for the following:

- Reviewing and either approving, exempting, requiring modifications to, or disapproving all research activities involving human subjects that are to be conducted by researchers;

- Conducting continuing reviews of ongoing projects at least annually, but sometimes more frequently, commensurate with the degree of risk to human subjects that is posed by the project;
- Reviewing and approving all requested modifications to ongoing research activities prior to the incorporation of these modifications by investigators;
- Requiring informed consent as part of the proposed research activities;
- Requiring or waiving the documentation of informed consent or the entire informed consent process in rare cases when it is appropriate
- Notifying investigators and the institution in writing of its decisions to either approve or disapprove proposed research activities and/or informing investigators of the modifications necessary to secure approval (If a research activity is disapproved, the IRB must provide written notification to the investigators that includes the reason(s) for the disapproval, and then allow the investigator to reply in person or in writing.);
- Monitoring and requiring additional safeguards when vulnerable populations (i.e., minors, mentally incompetent individuals, prisoners, economically disadvantaged individuals, or pregnant females) are included in research activities;
- With the exception of expedited and exempt reviews, reviewing all proposed research activities at convened meetings of the IRB;
- Approving research at convened meetings only with a majority of IRB members votes (a quorum);
- Reporting to the USBE's Human Protections Program administrator and to the OHRP any continuing or serious matters of noncompliance by investigators with the requirements and determinations by the IRB; and
- Suspending or terminating approval of research that is not in compliance with the IRB's determinations or has been associated with unexpected harm to subjects.

IRB Record Keeping

The IRB maintains a series of written records including the following:

- Copies of all research proposals reviewed including all accompanying materials (e.g., evaluation proposals, sample instruments, approved sample consent forms, study advertisement/recruitment materials, progress reports submitted by investigators, and reports of injuries to subjects);
- Minutes of all convened IRB meetings, which include sufficient written detail to (a) show attendance at meetings; (b) document actions taken by the IRB; (c) document the number of members voting for, against, and abstaining for a given action; (d) explain the basis for the IRB requiring changes in or disapproving research activities; and (e) summarize any controversial issues discussed as well as their resolution;
- Continuing review documents;
- Correspondence between IRB and investigators;
- A current roster of IRB members including each member's (a) name, (b) earned degrees, (c) representative group, (d) indications of experience sufficient to establish potential contribution to the IRB, and (e) relationship to UDRC;
- A manual detailing the IRB's written procedures; and
- A statement of any significant findings that have been presented to research subjects.

All IRB records must be maintained for at least 3 years following the completion of a research activity and must be available for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner. All records are maintained by the Grant Executive Assistant.

Education Requirements for IRB Members and Investigators

Ongoing education is required to ensure that IRB members, investigators, and coinvestigators are aware of the historical foundations that underscore the importance of protections for human subjects who participate in research, the relevant codes and regulations that apply to government-supported human subjects research activities, and the application of the guiding principles of respect, beneficence, and justice in human subjects research.

Education requirements for IRB members

All IRB members must complete the three Human Subjects Assurance Training modules available via the OHRP website (<https://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>) listed below:

1. HHS Regulations and Institutional Responsibilities
2. Investigator Responsibilities and Informed Consent
3. Human Research Protections Program

Additionally, IRB members must complete the seven-module course titled “Protecting Human Research Participants” available via the National Institutes of Health (NIH) Office of Extramural Research (<https://phrp.nihtraining.com/users/login.php>). These modules include:

1. Introduction
2. History
3. Codes and Regulations
4. Respect for Persons
5. Beneficence
6. Justice
7. Conclusion

Both sets of training modules must be completed by IRB members every 3 years. The IRB secretary maintains a database of research staff that have satisfied the education components noted above. No IRB member may serve on the IRB without first providing documentation of this certification.

In addition, IRB members are also recommended to be familiar with the following documents (available via the UDRC website):

- Ethical Principles and Guidelines for the Protection of Human Subjects—The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (The Belmont Report)

- Terms of the Federalwide Assurance (FWA) for the Protection of Human Subjects—United States Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP)
- Code of Federal Regulations Title 45, Part 46, Protection of Human Subjects, Subparts A, B, C, and D—United States Department of Health and Human Services
- Code of Federal Regulations Title 34, Part 97, Protection of Human Subjects, Subparts A & D—United States Department of Education
- Code of Federal Regulations Title 34, Part 99—The Family Educational Rights and Privacy Act (FERPA) – United States Department of Education

Education requirements for principal investigators and co-investigators

All principal investigators and co-investigators are required to complete the seven module course entitled “Protecting Human Research Participants” available via the National Institutes of Health (NIH) Office of Extramural Research (<https://phrp.nihtraining.com/users/login.php>). These modules include:

1. Introduction
2. History
3. Codes and Regulations
4. Respect for Persons
5. Beneficence
6. Justice

This training must be completed by investigators every three years. The IRB secretary maintains a database of investigators who have satisfied the education components noted above. The IRB will not approve any research project involving a principal investigator or a listed co-investigator who does not have a current education certificate on file.

CHAPTER 2: DEFINING RESEARCH

All research projects involving human participants carried out by USBE and UDRC partners and affiliates are subject to review and approval by the IRB.

Research

Federal Regulations define research as “a systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge” [§45CFR46.102(d)]. A systematic investigation is a process that involves the formulation of a hypothesis or research question and the collection and/or analysis of data that will lead to a conclusion that either proves or disproves the hypothesis or that answers the research question.

Research generally does not include operational activities such as defined practice activities in psychology or social work, or studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services. However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge.

Sometimes the issue of whether or not the study will contribute to generalizable knowledge is unclear. For example, some qualitative studies, which may not directly “contribute to generalizable knowledge,” are still research. In addition, course research assignments conducted by students may be research even if they are limited in scope.

For the purpose of determining the need for IRB review (per the above definition of research), generalizable knowledge is knowledge that is “expressed in theories, principles, and statements of relationships” that can be widely applied to our experiences. Generalizable knowledge is usually created to share with other people, such as through presentations and publications. Masters theses and doctoral dissertations are considered to present generalizable knowledge.

“*Generalizable knowledge*” would include one or more of the following concepts:

- The knowledge contributes to a theoretical framework of an established body of knowledge
- The primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study
- Publication, presentation or other distribution of the results is intended to inform the field of study
- The results are expected to be generalized to a larger population beyond the site of data collection
- The results are intended to be replicated in other settings
- Web based publication for professional purposes

If you plan to present or publish the work or otherwise share results of the study, it is probably research. If the research being conducted is only used for instructional purposes, it may be exempt.

As explained in the Belmont Report “...the term ‘research’ designates an activity designed to test a hypothesis and permit conclusions to be drawn... Research is usually described in a formal protocol that sets an objective and a sequence of procedures to reach that objective.”

Criteria used for review of research follow basic principles and guidelines for the protection of its participants, established in The Belmont Report (<http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html#>). These principles outline the acceptable conduct of research involving human participants. The criteria are summarized below.

- *Respect for persons* requires recognizing the personal dignity and autonomy of individuals, and provides special protection for persons with diminished autonomy.
- *Beneficence* creates an obligation to protect people from harm by maximizing anticipated benefits and minimizing possible risks.
- *Justice* requires that the benefits and burdens of research be distributed fairly.

USBE enforces each principle with policies and procedures overseen by the IRB. The principle of “respect for persons” requires researchers to obtain informed consent; “beneficence” requires a risk/benefit analysis of the research to minimize risks and maximize benefits to the research participants; and “justice” requires that participants be fairly selected. All research conducted by or at UDRC that includes human participants is reviewed using these principles, in conjunction with regulatory requirements at 45 CFR 46.

In determining whether a proposed activity is research, the following criteria are applied, as outlined in the “Request for Determination of Non-Research” form:

- Does the activity meet the definition of “research” as defined above?
- If yes, does the research involve “human participants” as defined below?

If both of the above criteria are answered “yes” the protocol must be reviewed and approved by the IRB.

To avoid potential regulatory consequence, researchers should consult the IRB if they are uncertain whether or not a study qualifies as human participant research.

Defining Human Subjects

Human participant is defined by Federal Regulations as: “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.” [§45CFR46.102 (f)(1), (2)].

Living individual: The specimen(s)/data/information must be collected from live participants. Cadavers, autopsy specimens / information from participants now deceased are not human participants; however, IRB review and approval is required for projects involving existing data, including data or specimens from deceased individuals.

About whom: A human participant research project requires the data received from the living individual to be **about** the person.

Intervention: Includes physical procedures, manipulations of the participant or manipulations of the participant's environment for research purposes.

Interaction: Includes communication between the investigator and the participant. This includes face-to-face, mail, and phone interaction as well as other methods of communication.

CHAPTER 3: TYPES OF IRB REVIEW FOR NEW PROTOCOLS

There are three categories of IRB review for new protocols. The categories are shown in the table below and described in more detail in the following sections of this chapter.

Exempt Review	Expedited Review	Full Review
<p>Some research is exempt from federal regulations.</p> <p>Categories of Exemption are listed in 45 CFR 46.101.</p>	<p>The research meets the criteria for review using the expedited procedure.</p> <p>Review by the fully convened IRB is not necessary.</p> <p>Approval is reported at the next IRB convened meeting or by a monthly report to the board.</p>	<p>Research involves issues that do not qualify for exempt or expedited review.</p> <p>A convened meeting of the board is required.</p>

Exempt Review

Under the DHHS regulations, some research is exempt from the requirements in the regulations. Although the regulations allow these exemptions to apply to research involving more than minimal risk to participants, the IRB will not grant an exempt determination to research involving more than minimal risk to participants.

It is important to note that all research – even research that investigators believe falls into one of the exempt categories – must be submitted to the IRB prior to the beginning of research activities. The IRB, not the individual researcher, determines the appropriate review categorization of each study. It is also within the IRB’s purview to establish procedures that are consistent with the protection of the participants, even if the research is found to be exempt.

Consent forms are usually not required for exempt studies, but a Letter of Information and/or verbal consent are typically appropriate and often required, and this information must be submitted with the supporting documentation for the study. The extent of the consent process required for the study will be determined by the IRB.

If the IRB determines a study is exempt, the researcher will receive a Certificate of Exemption which is valid for three years, after which the study will be automatically closed. If the research will extend beyond three years, it is the responsibility of the Principal Investigator (PI) to notify the IRB before the study’s expiration date and submit a new application to continue the research. Research activities that continue beyond the expiration date without new certification of exempt status will be in violation of the federal guidelines.

As part of the IRB’s quality assurance procedures, exempt research may be randomly selected for continuing review during the three-year period of exemption. If so, the PI will receive a

request for completion of a Protocol Status Report during the month of the anniversary date of the certification.

In all cases, it is the PI's responsibility to notify the IRB prior to making any changes to the study by submitting an Amendment/Modification request. This will document whether or not the study still meets the requirements for exempt status under federal regulations.

If the study does not meet the criteria for exemption or if the issue is not clear and/or any of the required supporting documents are missing, the researcher will be notified by e-mail as to what is required before exemption can be granted.

Categories of Exemption

Research that falls into any of the following categories is exempt from regulatory requirements *unless it involves prisoners* as participants.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - Research on regular and special education instructional strategies
 - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subject.
 - Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
 - Children are participating in interactions with the investigator. Such research cannot be exempt unless it is for educational tests and the requirements of FERPA and PPRA are met.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the above, if:
 - The human subjects are elected or appointed public officials or candidates for public office, and
 - Federal statute(s) require(s) without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of DHHS, Federal Agency heads, and which are designed to study, evaluate, or otherwise examine:
 - Public benefit or service programs,
 - Procedures for obtaining benefits or services under those programs,
 - Possible changes in or alternatives to those programs or procedures, or
 - Possible changes in methods or levels of payment for benefits or services under those programs.

In addition:

- The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
 - The research or demonstration project must be conducted pursuant to specific federal statutory authority.
 - There must be no statutory requirement that the project be reviewed by an IRB.
 - The project must not involve significant physical invasions or intrusions upon the privacy of participants.
 - The exemption must have authorization or concurrence by the funding agency.
6. Taste and food quality evaluation and consumer acceptance studies, if:
 - Wholesome foods without additives are consumed, or
 - A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below a level found to be safe, by the Food and Drug Association (FDA) or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Review

Certain types of research do not require review by the convened IRB and may instead undergo an expedited review. These types of studies are reviewed by two board members and reported to the remaining board in a monthly report or at its next convened meeting. All research undergoing initial or continuing review using the expedited procedure must meet the following criteria:

- The research presents no more than minimal risk to participants. (Not applicable for category (8)(b), as explained below).
- The identification of the subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal (not applicable for category (8)(b)).
- The research is not classified.

- The category or categories of research allow review using the expedited procedure (1)-(9). When using category (8), the reviewer document must be able to determine and document whether category (8)(a), (8)(b), or (8)(c) applies.

To be eligible for expedited review, the proposed research must fall into one of the nine categories outlined by the federal regulations (see <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>). These categories apply regardless of the age of participants, except as noted.

1. Clinical studies of drugs and medical devices only when 1 of 2 conditions is met:
 - a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review), or
 - b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

NOTE: USBE does not currently allow research falling in this category to be undertaken at USBE, UDRC.

2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:
 - a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week.
 - b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

NOTE: USBE does not currently allow research falling in this category to be undertaken at USBE, UDRC.

3. Prospective collection of biological specimens for research purposes by noninvasive means, such as:
 - a) Hair and nail clippings in a non-disfiguring manner
 - b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
 - c) Permanent teeth if routine patient care indicates a need for extraction
 - d) Excreta and external secretions (including sweat)
 - e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue
 - f) Placenta removed at delivery
 - g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor

- h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques,
- i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings,
- j) Sputum collected after saline mist nebulization

NOTE: USBE does not currently allow research falling in this category to be undertaken at USBE, UDRC.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. *Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.* Examples:
 - a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
 - b) Weighing or testing sensory acuity
 - c) Magnetic resonance imaging
 - d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity
 - e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where weight and health of the individual are appropriate

NOTE: USBE does not currently allow research falling in this category to be undertaken at USBE, UDRC.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). Some research in this category may be exempt from the federal regulations.

NOTE: USBE does not currently allow research falling in this category to be undertaken at USBE, UDRC.

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

NOTE: USBE does not currently allow research falling in this category to be undertaken at USBE, UDRC.

7. Research on individual or group characteristics or behavior (including, but not limited to: research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral

history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

NOTE: USBE does not currently allow research falling in this category to be undertaken at USBE, UDRC.

8. Continuing review of research previously approved by the convened IRB as follows:
 - a) Where research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions and the research remains active only for the long-term follow-up of subjects, or
 - b) Where no subjects have been enrolled and no additional risks have been identified, or
 - c) Where the remaining research activities are limited to data analysis.

NOTE: USBE does not currently allow research falling in this category to be undertaken at USBE, UDRC.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

NOTE: USBE does not currently allow research falling in this category to be undertaken at USBE, UDRC.

Expedited review may NOT be used when: a) identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, reputation, or be stigmatizing unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal, or b) the information gained from the research is considered "classified", or otherwise protected by the federal government.

The IRB must uphold the standard requirements for informed consent (or its waiver, alteration, or exception) regardless of the type of review (expedited or convened).

Expedited Review Procedures

Two board members, usually the IRB administrator plus a second member with appropriate expertise, conduct expedited reviews. Protocols submitted for expedited review must include all of the materials required in the Protocol Review Packet, as set forth in Chapter 4, "Required Documentation." The IRB may determine that the study is eligible for expedited review if it meets the applicability criteria and falls into one or more categories of research allowing review using the expedited procedure. Reviewers use the IRB Review Checklist to determine whether research meets the applicability criteria and is included in an appropriate category for expedited review. This determination must be made for each review, whether the submission is for initial review, continuing review, or review of modifications. If the reviewers determine that the project requires review by the convened IRB, the researcher will be notified in writing or by e-mail.

The reviewers may exercise all of the authorities of the IRB except they may not disapprove the research. Research may only be disapproved by the convened IRB. A list of the protocols that receive expedited review since the last convened meeting is included in the packet of materials given to IRB members on a monthly basis and in preparation for convened meetings. Members may request additional information on any project which has received approval or those which have been amended through an expedited review process. Such requests are normally made through the IRB office.

The IRB may also approve minor revisions to already approved projects through expedited review. A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in (1) the level of risks to participants; (2) the research design or methodology; (3) the number of participants enrolled in the research; (4) the qualifications of the research team; (5) the facilities available to support safe conduct of the research; or (6) any other factor which would warrant review of the proposed changes by the convened IRB. In addition, added procedures must (7) involve no more than minimal risk, and (8) fall into categories 1-7 of research that would allow review using the expedited procedure. The expedited review procedure can only be used if the reviewers determine the modifications are minor as defined here. See page xxx for additional information and procedures.

Initial Review at Convened Meetings

For all studies that do not qualify as exempt or are not eligible for expedited review, protocol review is conducted by the convened IRB at monthly meetings. In order for a new study to be reviewed, materials must be submitted by the Principal Investigator to the UDRC Office. These materials are called the Protocol Review Packet, and the contents are set forth in Chapter 4, “Required Documentation.”

The Protocol Review Packet is distributed to all members of the IRB and becomes the primary source used by the IRB to determine whether a study will be approved, whether changes will be requested prior to approval, or whether the study will be disapproved.

USBE IRB uses a system of primary reviewers. Under this system, two members of the IRB are appointed to carefully review the Protocol Review Packet. At least one of these primary reviewers will have scientific or scholarly expertise as required to review the study. If the study involves research with vulnerable populations, at least one of the reviewers will be in a position to represent the interests of individuals in that population. If the expertise required to carry out the review is not available on the IRB, the IRB Chair may appoint consultants to work with the IRB.

Continuing Review of Studies at Convened Meetings

For all studies that do not qualify as exempt or are not eligible for expedited review, protocol review is conducted by the convened IRB. In most cases, a study that was initially approved by the convened IRB will also receive continuing review in a meeting of the convened IRB. Studies may be approved by the IRB for up to a year; however, the IRB may choose to review projects

more frequently. In order for a previously approved study to be reviewed, the materials needed to complete the Protocol Review Packet as set forth in Chapter 4 must be submitted by the PI to the IRB Office.

The completed Protocol Review Packet is distributed to the IRB at least one week in advance of the convened IRB meeting. Members of the IRB use the information to determine whether the study may continue, whether changes will be required, or whether the study will be suspended or terminated.

As in the initial review, primary reviewers are assigned to review the materials and present recommendations to the convened IRB.

Review of Amendments by the Convened IRB

The Principal Investigator may apply for changes in ongoing research studies that have been previously approved by the IRB. Preparation for submission shall be as outlined in “Amendments and Revisions,” et seq., in Chapter 6. Minor modifications can be made through the expedited review process. Non-minor modifications will be reviewed in a convened meeting of the IRB. In order to be approved, an Amendment/Modification of a Previously Approved Protocol/IC Form must be submitted by the PI to the IRB Office along with all documents required for the Protocol Review Packet, as set forth in Chapter 4, “Required Documentation.” The Protocol Review Packet is forwarded to IRB members at least one week in advance of the convened IRB meeting.

The outlined materials – along with a copy of the initially approved application, and if appropriate, the approved Informed Consent document – are used to determine whether the amendment will be approved, whether changes will be required, or whether the amendment will not be approved.

Primary reviewers may be assigned by the IRB Chair, and they shall review the materials and present recommendations to the convened IRB. Review of amendments and modifications are further discussed in Chapter 6, below.

CHAPTER 4: PROTOCOL SUBMISSIONS

Submission Deadlines and Meeting Schedule

IRB applications may be submitted at any time. Applications are entered in the queue for review in the order they are received. Most human subject research does not need the full board's review. As soon as a protocol application is received by the IRB office, the IRB staff will determine if the application can be reviewed under the regulations for Expedited Review and, if so, the review process will begin without waiting for a convened board meeting.

Submission deadlines only apply to applications that require Full Board Review and such applications must be received 4 weeks before a scheduled monthly IRB meeting. A list of IRB meeting dates and submission deadlines may be found at UDRC Website. Protocols that require full IRB review but are not received by the deadline will be held over for consideration until the next meeting.

Research that requires Full Board Review includes any protocol in which the risk to participants is more than minimal. Minimal risk is where, "the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." In addition, the Full Board must review any research that does not fit any of the Expedited Review Categories of the federal regulations.

Required Documentation

For any human research that is not exempt from the regulations, the following documentation is required for review. For initial review, the following documents are distributed by IRB staff to all IRB members who will be charged with reviewing the protocol. For review by the convened IRB, the documents are distributed to all members of the IRB:

- The IRB Application
- A copy of the full proposal (e.g., grant proposal, thesis/dissertation proposal)
- The proposed Informed Consent document or Letter of Information
- Any proposed privacy authorization
- Any advertisement to be used for recruitment
- Any brochures to be used during the study
- Any survey instrument to be administered
- Proposed types and amounts of compensation for participation
- The Reviewer's Checklist, to be used by primary reviewers and reviewers assigned to conduct reviews under expedited procedures
- If a multi-site study funded by DHHS, the DHHS-approved sample consent document and the complete DHHS-approved protocol.

In addition to these documents, which make up the Protocol Review Packet for initial review, additional documentation is required to facilitate other types of IRB reviews, as set forth below:

- If the protocol has previously been approved, the minutes from the meeting in which the approval was given, and the initial application which was approved
- If for continuing review, a copy of the IRB Protocol Status Report Form, prepared by the PI
- If for a minor modification, the Amendment/Modification Form, prepared by the PI
- If for review of unanticipated problems that may affect risks to participants or others, the Unanticipated Problem Report form, prepared by the PI
- If for serious or continuing noncompliance, a summary of the allegation and Investigation Report.

The IRB staff checks to verify that all document required for the Protocol Review Packet are delivered to the IRB and IRB reviewers. When the review will be by the convened IRB, the packet is delivered at least 7 days prior to the IRB meeting where the protocol is to be reviewed, whether for initial review, continuing review, review of minor modifications, review of unanticipated problems or review of serious or continuing noncompliance.

Ethical Considerations

- The IRB has jurisdiction over all aspects of the review of research, including:
 - Methods of identifying potential participants
 - Methods proposed for contacting potential participants
 - Recruitment materials and proposed compensation
 - Pilot studies
 - Proposals to use or provide stored blood, tissues, or confidential data
 - Surveys and questionnaires
 - The informed consent document(s) and process (or Letter of Information)
 - The proposal including summary literature review and research design
 - Any risks to participants from the proposed research are reasonable in relationship to anticipated benefits
 - Proposed changes to the research
 - Unanticipated problems involving risk to the participant or others
 - Yearly continuing reviews
 - Determination of a protocol's eligibility for waiver of full review

The submission of any research for initial review must address all of the above issues that are pertinent to the protocol.

Planning an IRB Submission

Principal Investigators (PIs) should understand that human research must be carried out under a research plan or “protocol” that has been submitted and approved by the IRB. All changes in the protocol must be approved by the IRB before they are implemented. PIs must submit a research protocol detailing how all phases of the study are to be conducted. PIs must also submit the

research portion of any grant that will support the proposed research. Note that the grant sections do not replace the detailed description of how all aspects of the study are to be accomplished.

All application forms (exempt, general and oral history) may be found at UDRC Website. Completed forms and supporting documentation are submitted electronically to the IRB office.

- The PI of a research protocol must be a UDRC partner agency or affiliate staff.
- If the researcher is a student, a UDRC partner agency or affiliate staff must be listed as the PI and the student as “Student Researcher” or “Research Assistant.”
- If a study is to be conducted off campus the PI must obtain a letter of approval from the research site and submit a copy of that approval to the IRB.

Preparation for human research should reflect careful and unhurried consideration on the part of the PI. Information such as questions the PI proposes to answer and the precise methodology needed to obtain those answers must be included in the research plan. It is not acceptable to simply give reference to a research grant, or to copy the grant proposal’s narrative into the application.

Approval or clearance from institutions, facilities, school principals, school districts etc. where research will occur is required prior to beginning the study. Ideally, the PI will present appropriate letters of approval with the protocol submission to the IRB for review. However, research involving schools usually requires USBE IRB approval prior to district/school approval. Contact the IRB for more information. A Reviewer’s Checklist is available to assist the investigator in preparing the IRB submission can be found at UDRC website.

When conducting transnational research, the Principal Investigator will have primary responsibility for understanding and complying with the laws and regulations of the country in which the research will be conducted. It may be required, for example, to receive review and approval from an IRB or another review body that has jurisdiction. All research must meet at least the ethical standards required of research performed in the U.S., and research participants must be afforded equivalent protections, whether the research is funded by a U.S. government agency or not. To help researchers identify laws and regulations that might apply in transnational research the following link is available on the OHRP website:

<http://www.hhs.gov/ohrp/sites/default/files/internationalcomp2016%20.pdf>.

The USBE IRB will also provide support to researchers involved in transnational research to the degree possible by, for example, interfacing with foreign IRBs, or helping to locate researchers knowledgeable about the local context in the country where the research is to be conducted.

Dissertation and thesis research must receive approval from the student’s graduate supervisory committee prior to submission to the IRB. A copy of the signed committee approval sheet must be provided to the IRB before the application can be reviewed.

Assigning Study Risk Category and Frequency of Continuing Review Reporting

New protocols are assigned categories of risk and frequency of continuing review. In order to approve research, the IRB must determine the degree of risk. At a minimum, all on-going studies are reviewed on a yearly basis. Studies involving more than minimal risk are reviewed more frequently.

PIs have a responsibility to minimize risks and to maximize the benefits that participants will experience related to the research. In general, benefits, either to the participants themselves or to the participant population, must outweigh the risks participants will experience. In assessing risks and benefits, incentives to participate in research may not be considered benefits to the participants. Risks to vulnerable populations are further discussed in Chapter 7 of this handbook. The IRB Chair and the IRB Administrator are also available to assist in exploring appropriate ways to minimize risk in human research. The risk categories are defined by 45CFR46.102 as follows:

Minimal Risk	Greater Than Minimal Risk
Activity where the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests.	<p>Research involving greater risk of harm than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, but presenting the prospect of direct benefit to the individual subjects; or</p> <p>the research presents no prospect of benefit to the subject, but is likely to yield knowledge about the disorder or condition.</p>

Privacy and Confidentiality Risks

Among the most commonly encountered risks in Social/Behavioral/Education research are those associated with privacy of individuals and confidentiality of data. These issues are sometimes conflated, in large degree because of ambiguity in regulations. For example, the Health Insurance Portability & Accountability Act (HIPAA) includes the Privacy Rule. The Privacy Rule pertains primarily to confidentiality issues, rather than privacy issues; however, a breach in confidentiality can easily impact an individual’s privacy interests. Privacy and confidentiality issues are defined and addressed below.

Privacy is the ability of an individual or group to seclude themselves or information about themselves and thereby reveal themselves selectively. The boundaries and content of what is considered private differ among cultures and individuals, but share basic common themes. When something is private to a person, it usually means there is something within them that is considered personally sensitive. The degree to which private information is exposed therefore depends on how the public will receive this information, which differs between places and over time. Privacy may be sacrificed or knowingly “waived” to some degree when an individual

decides to participate in research. In developing strategies for the protection of subjects' privacy, consideration should be given to:

- The methods used to identify and contact potential participants.
- The settings in which an individual will be interacting with an investigator.
- The observation of the interaction by individuals not related to the research.
- The methods used to obtain information about participants.
- The nature of the requested information.
- The nature of the experiences related to the research.
- Information that is obtained about individuals other than the "target participants," and whether such individuals meet the regulatory definition of "human participant" (e.g., a subject provides information about a family member for a survey).
- Privacy guidelines developed by relevant professional associations and scholarly disciplines (e.g., oral history, anthropology, psychology).
- How to access the minimum amount of information necessary to complete the study.

What is private depends on the individual and can vary according to gender, ethnicity, age, socio-economic class, education, ability level, social or verbal skill, health status, legal status, nationality, intelligence, personality, and the individual's relationship to the investigator. For example, protecting the privacy interests of a young child might mean having a parent present at a session with an investigator. Protecting the privacy interests of a teenager might mean having a parent absent.

Confidentiality refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated. The research proposal should outline strategies to maintain confidentiality of identifiable data, including controls on storage, handling, and sharing of data. When appropriate, certificates of confidentiality could be used to maintain the confidentiality of identifiable data.

When the IRB evaluates research proposals for strategies for maintaining confidentiality, where appropriate, consideration will be given as to whether:

- Methods to shield participants' identity adequately protect participant privacy.
- There is a long-range plan for protecting the confidentiality of research data, including a schedule for destruction of identifiers associated with the data.
- The consent form and other information presented to potential research participants adequately and clearly describe confidentiality risks.
- The informed consent process and the informed consent document, and if applicable the Authorization Form, clearly delineates who will have access to the subject's information and under what circumstances data may be shared (i.e., government agencies, sponsors).

Collaborating with Other Institutions

Collaboration with other institutions may be conducted at various levels. The IRB should be notified of the level of collaboration in order to ensure appropriate procedures are in place.

If IRB review is required at each collaborating institution, there are options available to provide the required review. If the collaborating institution has a FWA, its IRB may accept the review of the second institution through the use of an authorization agreement unless they request that USBE IRB be the IRB of record.

On occasion, the IRB will agree to serve as the institutional review board of record for other institutions if a UDRC partner agency staff is involved as a PI/Co-PI. If a research project at UDRC is to be carried out in conjunction with another institution or entity, USBE IRB will be responsible for review of the project, incurring certain aspects of liability. This requires additional information from the PI. An Authorization Agreement between institution/entity is required and the IRB Office will process the agreement and notify OHRP. A copy of the second institution's FWA may also be necessary.

Internet Research

When doing research on the internet, PI's are still bound by the confidentiality and privacy considerations that govern all research. Since a PI cannot know if participants are legally able to give consent or if participants are who they say they are, the PI must be particularly careful to screen participants to the best of his/her ability. Also, many web communities consider their communications to be private, even when they are publicly available; thus, private information is defined as such by the participant, *not* the PI. Please check with the Chair or IRB Administrator for guidance on internet research.

Existing Data Analysis

Research using previously collected data that received IRB review is generally considered to be exempt. Exceptions occur when the data contain information that could be used to personally identify an individual. Such information could include birth date, addresses, geographical identifiers, or social security numbers. IRB review and approval is required for all existing data research. If uncertain about whether existing data research requires an exempt or general application, contact the IRB Administrator for guidance.

Secondary Research Participants

Often researchers ask participants to describe characteristics of a family member, friend, business associate, or another person who is not the *primary* research participant. These people are called "secondary research participants." If the information gathered from the participant is about a living individual, and the researcher obtains identifiable private information about that person, then that person is considered to be a participant in the research. Much research that asks about secondary participants can be considered to be "minimal risk," and informed consent from the secondary participants may not be required. Under some circumstances, however, informed consent cannot be waived. These instances must be evaluated on a case-by-case basis and follow the same criteria that is followed for waiving consent for primary participants.

International Research

All NIH-supported research that takes place internationally and utilizes human participants must be reviewed by an IRB or the equivalent in the target country. Although unfunded research does not include this requirement, it is the policy of USBE IRB to recommend such review where appropriate. If the research is performed by UDRC then USBE IRB reviews the protocols, keeping in mind the local norms of informed consent, respect for persons, beneficence, and justice in the country where the research will take place.

For a listing of international IRBs that work with NIH and other federal funding agencies, see <http://www.hhs.gov/ohrp/sites/default/files/internationalcomp2016%20.pdf>.

Training in the Protection of Human Participants

USBE and federal regulations require that Principal Investigators, Co-Investigators and any research personnel who will be performing research activities with participants (i.e. obtaining informed consent, collecting data) or performing data analysis must receive training in the ethical protection of human participants. USBE uses NIH online training to fulfill this requirement. The IRB cannot begin review of an application until notification is received the PI and any research staff and students have completed the training with a minimum score of 80%. Renewal is required every three years. Training modules may be accessed at <https://phrp.nihtraining.com/users/login.php>.

PIs are also responsible to adequately train and inform all personnel in their facilities, whether or not they are involved directly in the conduct of human research, concerning participant safety and privacy and preserving the confidentiality of research data associated with participants. The USBE IRB is available to provide appropriate materials to assist the PI in fulfilling this responsibility.

With advanced notice, the IRB can provide various presentations to individual groups or classes; however, certification is not available using this method.

The PI's Responsibility of Assurance

- Participants will not be recruited or entered into a protocol until the PI has received an approval letter/e-mail from the IRB.
- No modifications/revisions of the protocol or informed consent document will be initiated without prior written approval from the IRB. The Amendment Modification form is located on the IRB web page at UDRC Website
- The PI will provide a prompt, written report to the IRB regarding any deviation from the protocol and/or consent form, unanticipated problems that are serious and related to the study, or if a death occurs during the study UDRC Website.
- Annual Continuing Review (CR), Protocol Status Report Form for the protocol will be completed and returned within the time limit stated on the form UDRC Website.
- If the study involves any funding or resources from outside sources, USBE State Superintendent of Public Instruction and the IRB will both be notified of the contract.
- Participants will not be enrolled prior to approval of the contract, unless specified by the institution.

- Informed consent will be obtained from all participants using the method approved by the USBE IRB for the research protocol.
- The USBE IRB will be notified if there is a change in the PI by completing an Amendment Modification form UDRC Website.
- The USBE IRB will be notified if the study is completed by indicating on the Status Report form or notifying the IRB Administrator by email if the completion/closure occurs before a Status Report is due.
- The PI will promptly report the premature completion of a study.
- The PI will sign a statement regarding the protection of human participants. The statement is found at the end of the exempt and general IRB application forms UDRC Website.

Advertisement for Participant Recruitment

Studies may require the use of print or other media (flyers/brochures, television, internet or radio advertisement) in order to recruit the participant population. This information must be submitted to the IRB prior to use. Any type of advertising for research participants that is intended to be seen or heard by possible participants is part of the selection process. The IRB must review both the information contained in the advertisement and the mode of its communications. Information placed on a website for the purposes of study recruitment must be reviewed and approved by the IRB. Further information can be found on the IRB website at: UDRC Website

Advertisements should not be coercive and should not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. No claims should be made, either explicitly or implicitly, that the intervention or assessment will improve a participant's outcome. Such representation would be misleading to potential participants and is in violation of the regulations.

Advertisements should not promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation. The IRB will determine if the promise of treatment without charge is coercive to financially constrained participants. Advertisements may state that participants will be paid, but should not emphasize the payment.

Advertisements must include:

- The name and address of the investigator and/or research facility
- The condition under study and/or the purpose of the research
- A summary of the criteria that will be used to determine eligibility for the study
- A brief list of participation benefits, if any
- The time or other commitment required of the participants
- The location of the research and the person or office to contact for further information

CHAPTER 5: INFORMED CONSENT REQUIREMENTS

A PI may not involve human participants in research unless the PI has obtained the informed consent of that individual or the individual's legally authorized representative, or a waiver of consent has been granted by the IRB. A Letter of Information (which does not require the participant's signature) is an alternative type of informed consent and may be used if a waiver of documentation of informed consent has been granted. Additional information about the conditions required for waiver of documentation and waiver of informed consent is provided later in this chapter.

The PI must seek informed consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence. The informed consent document or Letter of Information must include the following:

- A statement that the study involves research
- An explanation of the purposes of the research
- A clear and concise explanation of the research to be conducted and the procedures to be employed
- If applicable, differentiation between the procedures being performed as part of the research and any being performed for non-research purposes
- Language/vocabulary appropriate for the targeted subject population (e.g.; 6th grade reading level in most situations, English and foreign language versions for a multi-cultural study)
- Explicit language detailing all potential risks or discomforts and procedures to minimize such risks
- Information on direct benefits to participants (if any) and benefits to field of study
- A statement regarding the duration of participation
- A statement defining the right of the participant to withdraw at any time without consequence. If applicable, a statement that participation will not affect the services s/he is now receiving or may receive in the future
- If applicable, a statement describing alternatives to the proposed research activity
- A statement about how the data/information will be kept confidential (e.g., data and personal identifiable information kept separately and locked in a room and file cabinet, explain who has access to the information and when personal identifiable information will be destroyed)
- A statement of whom to contact for answers to pertinent questions about the research and, if applicable, whom to contact in the event of a research-related injury
- Contact information for the research team for questions, concerns or complaints
- Contact information for someone independent of the research team (i.e. IRB) for problems, concerns, questions, information or input
- A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- A statement that the IRB has approved the research and include contact information so that participants may contact the IRB with any concerns or questions about their rights

- A statement that the participant is fully informed and agrees to participate on a purely voluntary basis

Additional elements may also be required in order to comply with federal, state, and institutional regulations. When creating the Informed Consent or Letter of Information, refer to the template located at UDRC Website.

The entire consent process involves:

- providing a participant with adequate information concerning the study,
- providing adequate opportunity for the participant to consider all options,
- responding to the participant’s questions,
- ensuring that the participant has comprehended the information,
- obtaining the participant’s voluntary agreement to participate (minimizing undue influence),
- continuing to provide information as the participant or situation requires,
- providing ample opportunity for the investigator and the participant to exchange information and ask questions, and
- unless a waiver of documentation has been granted (see below), obtaining the signature of the participant or legally authorized representative.

Issues to consider:

1. Where will consent be obtained? Some research topics are sensitive or embarrassing. If this is the case, what location or methods will be used in order to maintain the privacy of the participant? How much time will be given to the process of obtaining the informed consent? When must participants decide?
2. Who will be involved in the consent process, e.g., nurses, social worker, student? Is there any possibility that the participant(s) may feel coerced by the person obtaining the consent?
3. How will the participant’s understanding of the research study be assessed?
4. Has the participant made an informed decision?

Waiver of Documentation of Informed Consent

The IRB may waive the requirement for the investigator to obtain a signed consent for some or all participants (45 CFR 46.117c) if it finds that:

- “The only record linking the [participant] and the research would be the consent document. The principal risk would be potential harm resulting from a breach of confidentiality. Each
- [participant] will be asked if the [participant] wants documentation linking the [participant] with the research and the [participant’s] wishes will govern, or
- the research presents no more than minimal risk of harm to [participants] and involves no procedures for which written consent is normally required outside of the research context.
- In cases where the documentation requirement is waived, the IRB may require the investigator to provide [participants] with a written statement regarding the research.”

Waiver of Informed Consent

In order to grant a waiver of informed consent, the IRB must document that it believes the request meets the following criteria (45 CFR 46.116d):

- “The research involves no more than minimal risk to the subjects;
- The waiver will not adversely affect the rights and welfare of the subjects;
- The research could not be practicably carried out without the waiver; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.”

Payment/Reimbursement of Research Participants

Federal regulations and the various codes of ethics governing human participant research require that no “undue inducements” be offered to potential research participants in order to secure their participation in a study. To comply, the IRB has adopted the following guidelines regarding payments to participants:

- Participants should not be induced to participate in research for financial gain.
- Payment is not a benefit. It is compensation for services. In the consent document, payment cannot be listed in the benefits section but must be in a separate section. There must be equivalence in compensation for completion of research activities.
- PIs who plan to provide any payment/reimbursement to participants for any reason must indicate this clearly in the Informed Consent or Letter of Information, which must be approved by the IRB.

Informed Consent/Permission and Assent Documents

The informed consent document must provide signature and date lines for the PI, CoPI, student researcher, participant or the participant’s legally authorized representative, and in some cases the person obtaining consent (if other than an investigator).

Research studies that involve children should include signature and date lines of the child’s parent or legal guardian who is giving permission. If the individual giving permission for a child’s participation is not the child’s parent, the individual must provide written documentation of authority to consent to the child’s medical care (4CFR 46.402(e)) if the study is supported with funding from DHHS. For all other research, the individual giving permission must provide written documentation of authority to act as the child’s guardian. In some cases, signatures from both parents may be required. In addition, studies involving children old enough to understand the research (generally those over the age of 7), should include a child assent section (or a separate assent document).

Witness Information

In some situations, informed consent documents may require a witness signature. If a witness signature is required, the witness should not be a person who belongs to the study staff. Neither the PI nor the person obtaining consent can act as the witness.

Copies of Informed Consent

The PI must retain the original signed consent form in the respective study file and provide a copy to the participant. This document must be kept for three years after the study is completed or in accordance with the state of Utah's, or the funding agency's record retention requirements.

Deception Research

Deception research is a type of research where the researcher intentionally tells a participant(s) something that is not the truth. This form of research is allowed; however, because informed consent cannot be obtained, the following criteria must be met for deception research to be approved:

- The research provides value to the body of knowledge, and there are measureable benefits.
- The research protocol meets scientific validity requirements.
- The information could not be obtained without the use of deception.
- The deception used would not likely influence the participants' willingness to participate.
- The possibility of harm to the participant is adequately addressed and a plan for debriefing has been established. Debriefing must be conducted as soon as possible after the conclusion of the study. Debriefing language must be provided to the IRB for review. A Deception Research Checklist is available at UDRC Website.
- Participants will be notified that they may withdraw from the study after debriefing by requesting that any data collected from them be deleted and/or destroyed.
- The deception does not cause invasions of privacy to participants or others.

Exculpatory Language

“No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights or releases or appears to release the PI, the sponsor, the institution or its agents from liability for negligence.” (45CFR46.116)

Conflicts of Interest

Conflicts of interest, as defined and based on the “Utah Public Officers and Employees' Ethics Act,” are expected to be disclosed to the IRB and may be managed in conjunction with that policy. If conflicts of interest are present in a research project, such conflicts should be clearly and explicitly described in the informed consent document and must be made clear and apparent to participants in any related research.

CHAPTER 6: CONTINUING REVIEW, REVISIONS, AND REPORTING OF PROBLEMS

Continuing Review

It is the responsibility of the PI to assure that IRB approval of a protocol is continuous. PIs must also maintain continuous approval from each institution where the research is being conducted. The IRB determines how often each protocol must be re-evaluated based on the level of risk. All expedited and full board protocols are reviewed at least annually. For studies determined to be exempt from regulations, a random sample of protocols is selected for review each year as part of the IRB's quality assurance activities. The Status Report form may be found at UDRC Website.

Reminder notices are sent to PIs by e-mail two to three months before the expiration date of each protocol. PIs are requested to submit the completed Protocol Status Report along with a copy of the current Informed Consent or Letter of Information. The report must be reviewed and approved by the IRB prior to the expiration of the previous study approval. If approval is given, an e-mail is sent to the PI, and the continuing review (CR) expiration date is updated for another term's approval.

If the CR is not approved by the date specified, the study approval automatically expires and all research must stop including recruitment, advertisement, screening, enrolment, consent, interventions, interactions, and collection of private identifiable information until approval of the CR. There is no grace period. Interventions and interactions on current participants may continue only when the IRB finds an over-riding safety concern or ethical issue involved such that is in the best interest of individual participants. Under no circumstances can enrolment of new participants occur.

The USBE IRB sends a total of three reminder notices by e-mail to the PI prior to the expiration date. If there is still no response, a letter is then sent to the PI with copies distributed to the Grant Manager, the IRB Committee, and funding agency if applicable. At that point, the study approval expires, the study is closed and any data collected during expiration must be destroyed. A new application will then be required before work can commence again. Patterns of non-compliance by the PI can trigger formal inquiries by the IRB.

In addition to required Protocol Status Reports, the IRB may conduct other types of post-approval reviews including, but not limited to, self-assessment by the PI, document review by IRB staff, interview with the PI, interview with research staff and surveys of past participants.

Amendments/Revision

Federal regulations require that any proposed change or revision to a currently approved study which affects human participants, must be reviewed and approved by the IRB prior to the implementation of that change.

A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in (1) the level of risks to participants; (2) the research design or methodology; (3) the number of participants enrolled in the research; (4) the qualifications of the research team; (5) the facilities available to support safe conduct of the research; or (6) any other factor which would warrant review of the proposed changes by the convened IRB. In addition, revised procedures must (7) involve no more than minimal risk, and (8) fall into categories 1-7 of research that would allow review using the expedited procedure. Minor changes may be reviewed using the expedited procedure. Some examples of minor revisions are: changes in telephone numbers; addition/deletion of associates or staff; the deletion of questions in a survey; changes in funding; addition or deletion of PIs; alteration of the project title; advertisement changes; the number of participants enrolled in the research; the qualifications of the research team; the facilities available to support safe conduct of the research; or similar factors which would not warrant review of the proposed changes by the convened IRB.

Non-minor revisions are those that may involve increased risk to participants or that substantially change the nature of the study. Examples may be: revisions to the recruitment plan, study design, or methodology; replacement of or significant changes to study instruments including surveys and questionnaires; adding/revising eligibility criteria or changes to the study population; adding a research site; and changing the informed consent to include a newly identified risk related to the study (this may require that participants sign a new consent form).

Process for making minor modifications to approved protocols

Requests for minor modifications to protocols may be reviewed on an expedited basis. Minor modifications are reviewed and approved by the IRB Administrator as they are received by the USBE IRB.

When determining what constitutes a non-minor change that will require resubmission of a new application, the following criteria shall be followed:

- Level of risk compared to benefit: Any modification that would result in a change to the Risk Benefit Checklist indicating an increase in risk, or a decrease in benefit shall require submission of a new application.
- Research design or methodology: Research methods shall be considered discreet. Surveys, focus groups, interviews, observations, and other accepted research designs shall not be considered interchangeable. Likewise, methods of delivery shall not be viewed as equivalent. For example, a survey delivered over the internet shall not be considered equivalent to a survey delivered by written instrument. A downward change in the ability to protect privacy or confidentiality shall constitute a non-minor change, requiring submission of a new IRB application.

To apply for approval of a revision, submit an Amendment Modification form by email to the IRB Office. The form is located at UDRC Website. Attach any new and/or revised documents and submit with all documents required in the Protocol Review Packet, as set forth in Chapter 4, "Required Documentation" and described on the Amendment/Modification form. Approval of a revision does not change the approval or expiration date of the protocol. It merely approves the

modification to the study and allows the PI to begin using the modified or new procedures/documents. The PI must receive the approved Amendment/Revision form from the USBE IRB prior to implementing the new changes.

Unanticipated Problems Involving Risks to Participants or Others

An unanticipated problem involving risks to participants or others is any incident, experience, or outcome that meets **both** of the following criteria:

- Is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b), the characteristics of the participant population being studied;
- It suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Reporting requirements are set forth in the table, “Reporting Responsibilities of the Principal Investigator to the IRB,” in Chapter 9, below. The Unanticipated Problems Reporting form located at UDRC Website is available to facilitate such reporting and must be submitted by email or in person to the USBE IRB, along with all documents required in the Protocol Review Packet, as set forth in Chapter 4, “Required Documentation.” Time frames for submission are included in the table.

Data and Safety Monitoring Plans

All research involving greater than minimal risks to participants will require a data and safety monitoring plan. The PI should propose a plan that will provide on-going review of data as it is collected and of participant profiles as they are enrolled to identify unexpected outcomes and to ensure participant safety. In some instances, it may be appropriate to set “stop rules” against which data outcomes would be measured to indicate, statistically, if a study should be stopped based on unexpected outcomes. Alternatively, the PI may describe a plan that meets these objectives and is being implemented by others (in multi-site studies). There are a number of ways to accomplish effective data monitoring. In many cases, monitoring by the PI would be appropriate. The IRB will not fulfil the data monitoring responsibility for any study.

Circumstances that the IRB will consider when evaluating a data and safety monitoring plan may include the level of risk to participants, whether the investigator has a conflict of interest, and whether work is being performed at multiple sites. The convened IRB will consider and approve a plan for data monitoring at the first review of a project where greater than minimal risk has been identified. In each subsequent review the IRB shall take the outcomes of safety monitoring into account in its deliberations.

CHAPTER 7: RESEARCH INVOLVING VULNERABLE POPULATIONS

Certain groups of participants are considered to be particularly vulnerable to coercion or undue influence in a research setting. These groups, as outlined in 45 CFR 46.111(b) are children, wards of the state, prisoners, pregnant women and fetuses, persons who are mentally disabled or otherwise cognitively impaired, and economically or educationally disadvantaged persons.

In reviewing research studies involving all categories of vulnerable participants, the IRB must determine that their use is adequately justified and that additional safeguards are implemented to minimize risks unique to each group. A summary of the additional requirements for review and approval of research involving vulnerable populations is provided below.

Children

Federal regulations (45 CFR 46, Subpart D) require that investigators explicitly address the measures taken to protect the rights and welfare of children participating in research.

Definition of Children (45CFR46.402(a))

Children are defined as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” In the state of Utah, *children* includes any person under the age of 18 unless the child has been emancipated by court order, marriage, or is on active military duty.

Categories of Research Involving Children

Subpart D of 45CFR46 classifies research involving children into one of four categories depending upon the risks and benefits of the proposed study, which can be approved as follows:

Category 1 (Section 46.404) Not greater than minimal risk	
Risk/Benefit Conditions	Consent Requirements
None	Permission of both parents, unless one of the parents has sole legal responsibility for the care and custody of the child, or one of the parents is deceased, unknown, legally incompetent to provide permission, or is not reasonably available. The IRB may determine that permission of one parent is sufficient, even if the other parent shares legal responsibility for the care and custody of the child, and is alive, known, legally competent to provide permission, and is reasonably available.

	Assent of the child is required, unless the IRB determines that assent is not a requirement or waives assent.
Category 2 (Section 46.405) More than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being.	
Risk/Benefit Conditions	Consent Requirements
The risk involved is justified by the anticipated benefit, and the relation of the anticipated benefit to the risk is at least as favorable as that presented by alternative approaches	<p>Permission of both parents, unless one of the parents has sole legal responsibility for the care and custody of the child, or one of the parents is deceased, unknown, legally incompetent to provide permission, or is not reasonably available.</p> <p>The IRB may determine that permission of one parent is sufficient, even if the other parent shares legal responsibility for the care and custody of the child, and is alive, known, legally competent to provide permission, and is reasonably available.</p> <p>Assent of the child is required, unless the IRB determines that assent is not a requirement or waives assent.</p>
Category 3 (Section 46.406) More than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject	
Risk/Benefit Conditions	Consent Requirements
<p>The research is likely to yield generalizable knowledge about the participant's disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition, and</p> <p>the risk represents a minor increase over minimal risk,</p> <p>and the research presents experiences reasonably commensurate with those inherent in the participant's actual or expected medical, dental, psychological, social or educational setting.</p>	<p>Permission of both parents, unless one of the parents has sole legal responsibility for the care and custody of the child, or one of the parents is deceased, unknown, legally incompetent to provide permission, or is not reasonably available.</p> <p>Assent of the child is required, unless the IRB determines that assent is not a requirement or waives assent.</p>

Category 4 (Section 46.407) Otherwise not approvable, but presents an opportunity to understand, alleviate or prevent a serious child health problem.	
Risk/Benefit Conditions	Consent Requirements
The research presents an opportunity to understand, alleviate or prevent a serious child health problem, and will be forwarded to the HHS Secretary for review.	<p>Permission of both parents, unless one of the parents has sole legal responsibility for the care and custody of the child, or one of the parents is deceased, unknown, legally incompetent to provide permission, or is not reasonably available.</p> <p>Assent of the child is required, unless the IRB determines that assent is not a requirement or waives assent.</p> <p>Approval is also required from the Secretary of DHHS before any research is conducted.</p>

Permission of Parents or Guardians and Assent of Children

- **Assent** is a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent
- **Permission** means the agreement of parent(s) or guardian to the participation of their child or ward in research
- **Guardian** is an individual who is authorized under applicable State or local law to act on behalf of a child.

Permission of parents or guardians and assent of children shall be obtained as indicated in the table above.

Waiver of Permission of Parents or Guardians

One set of conditions under which Waiver of Permission may be granted is:

- The research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), and
- The PI has provided an appropriate substitute mechanism for protecting the children, and
- The waiver is not inconsistent with Federal, state or local law.

Another set of conditions under which Waiver of Permission may be granted is:

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

Assent of Children

The IRB can determine that assent is not a requirement of some or all children, when one or more of the following is true:

- The children were not capable of providing assent based on the age, maturity, or psychological state.
- The capability of the children was so limited that they could not reasonably be consulted.
- The intervention or procedure involved in the research holds out a prospect of direct benefit that was important to the health or well-being of the children and was available only in the context of the research.
- The assent can be waived.

Waiver of Assent may be granted only when all of the following criteria are met:

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

Assent shall be obtained either in writing, using an assent form or a signature block on the informed consent form, or may be obtained orally if approved by the IRB.

Exempt Research Involving Children

45 CFR 46.401(b) allows exemptions for research involving children that are listed at 46.101(b)1 and (b)(3) through (b)(6). The exemption at 46.101(b)(2) regarding educational testing is also applicable to this subpart. Research involving children where survey or interview methods are used cannot be exempt.

Child Abuse Reporting

The State of Utah requires the reporting of suspected child abuse or neglect. PIs must abide by this law. If the protocol involves interviewing children about topics that may lead to a suspicion or to knowledge on the part of the investigator of child abuse or neglect, the child (and parent/guardian) must be informed of the reporting requirement as part of the informed consent process. Reports of abuse should be made to the Utah Division of Child and Family Services, or its equivalent in the jurisdiction where the research is conducted.

The following sentence(s) should be integrated into the currently required Informed Consent Document among the statements about confidentiality and its limits:

“Research records will be kept confidential, consistent with federal and state regulations.”

“The researcher is required to report any suspected child abuse or any intention you have to hurt yourself or others. The researcher, if ordered to do so by a court of law, may be required to disclose information you have provided.”

Wards of the State

Where children are wards of the state or another agency or institution, additional restrictions apply. Children may only be included in research that is related to their status as wards or which is conducted in schools or other institutions in which a majority of children are not wards. If the IRB approves research under this provision (45 CFR 46.409), it must appoint an advocate for each child that is a ward.

Emancipated Minors

There are exceptions to the rule of obtaining assent and seeking parental consent for individuals considered emancipated minors by the state of Utah. Emancipated minors **may** include individuals under the age of 18, living on their own and financially independent from their parent or legal guardian, individuals who have borne a child, or individuals who are married. Emancipation may also be sought through legal means, and may be stipulated by the state. **Consent** is sought from an emancipated minor rather than assent. A court document must be included in the supporting documentation application designating the individual as an emancipated minor.

Prisoners

45 CFR 46, Subpart C, provides additional safeguards for prisoners since “Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as participants of research.” The term “prisoner” means someone who is incarcerated or under adjudication, whether an adult or a minor. Research involving prisoners does not qualify for exemptions from IRB review.

Categories of research involving prisoners permitted under 45 CFR 46.306(a)

- Studies regarding 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 subjects.
- Studies of prisons as institutions, or of prisoners as incarcerated persons, if those studies present no more than minimal risk or inconvenience to the subjects.
- Research on conditions affecting prisoners as a class after DHHS publishes a notice in the federal register.
- Research on practices that are intended, and reasonably likely, to enhance the well-being of the subjects; however, if some of the prisoners will be assigned to control groups which will not benefit from the research, then the study must first be approved by DHHS.

In addition to the general requirements for review, in reviewing prisoner research, IRBs are required by 45 CFR 46.305(a) to:

- Ensure that the membership of the IRB reviewing the protocol includes a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, and that the majority of the IRB is not associated with the penal institution involved. If no current member of the IRB meets the prisoner or prisoners' representative criteria, then the State Superintendent for Public Instruction and the IRB Chair will identify and recruit a qualified individual to fulfill this requirement and advise the IRB. In addition, a majority of the IRB members at the meeting must not be associated with the prison.
- Ensure that any advantages prisoners will realize as a result of participating in the research, when compared to the general living conditions within the prison, are not so great as to impair prisoners' ability to weigh the risks and benefits of participation and freely choose whether to participate.
- Ensure that the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
- Review procedures for selecting participants to determine whether they are fair, and free from arbitrary manipulation by prison authorities or prisoners.
- Ensure that control participants will be selected randomly from among the group of eligible volunteers, unless the PI justifies a different procedure.
- Review the information presented during the recruitment and consent procedures to ensure that the language and level of complexity is understandable to the target population.
- Ensure that the parole board will not take participation in the study into account, and that each prisoner will be informed that participation will have no effect on parole.
- Ensure that adequate provision will be made for follow-up care as necessary.

When an IRB reviews research falling within this category, its assurance provides for OHRP to be notified that the above criteria have been met.

A PI may not enroll a prisoner in an ongoing IRB-approved study without the approval of the committee. If a participant becomes a prisoner during the course of a research study, the IRB must be notified.

Pregnant Women and Fetuses

45 CFR 46, Subpart B, provides additional protections for research involving pregnant women. Pregnant women should not be excluded from research as participants if the risk to the fetus is minimal. If pregnant women are included in a research protocol, the informed consent must address the possible impact of the research activity on the fetus.

Researchers who conduct studies targeting conditions specific to pregnant women must obtain informed consent from both the pregnant woman and the father of the fetus, however, consent of the father is not necessary if:

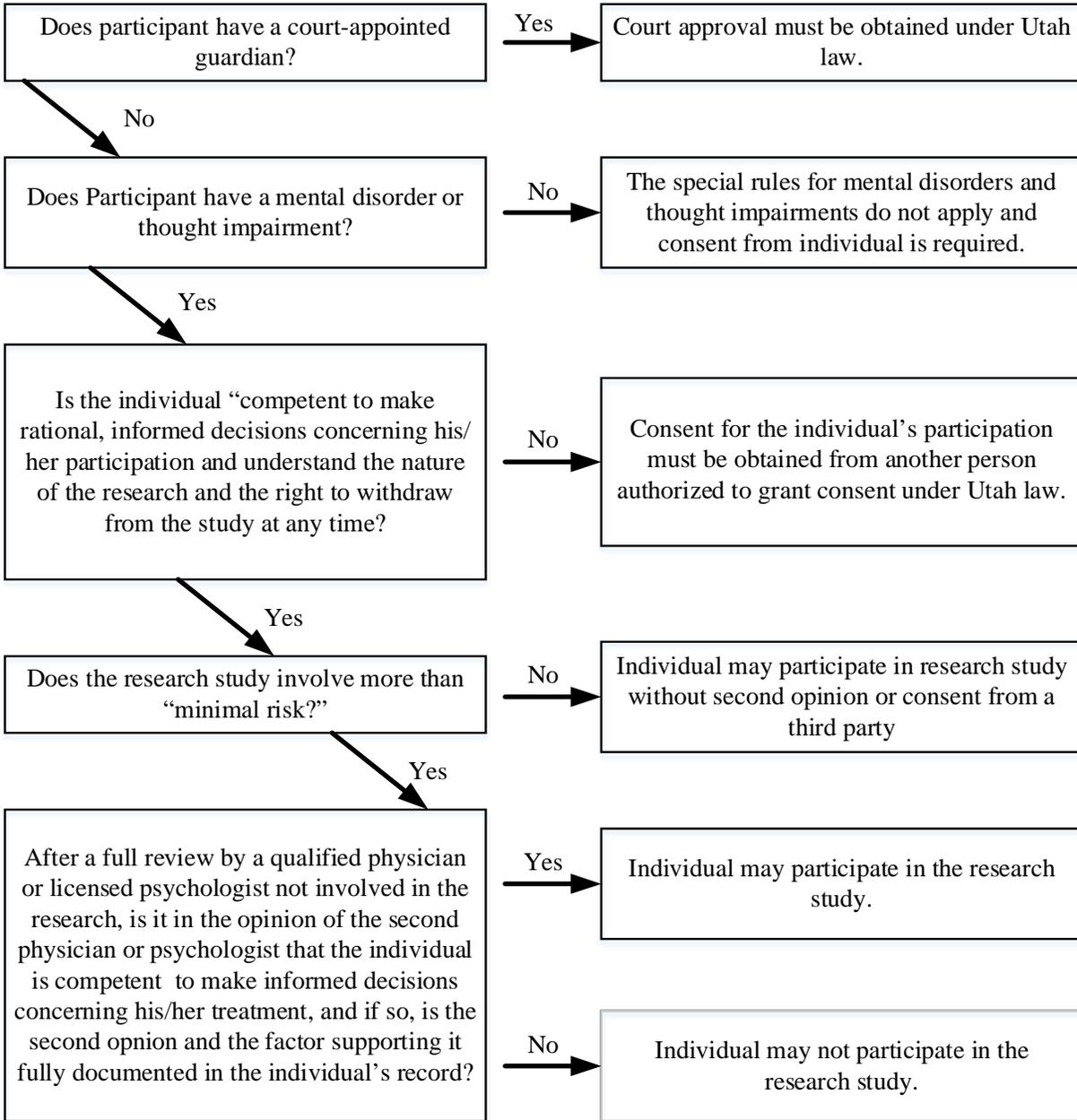
- The purpose of the study is to meet the health needs of the mother.
- The identity or whereabouts of the father cannot be reasonably ascertained.
- The father is not reasonably available.

- The pregnancy is the result of rape.

Participants with Diminished Decision-Making Capacity

Research involving participants with diminished decision-making capacity will not be considered for exemption at UDRC and must be reviewed via a General Application. In addition, such projects must specifically address how an individual's capacity to give informed consent will be determined. *Examples of diminished decision-making capacity include: diagnosed mental retardation, some forms of mental illness, dementia, and coma, whether temporary, progressive or permanent.* The IRB uses the decision tool below to guide the assessment of whether cognitive impairment may prevent a participant or group of participants from giving informed consent. PI's should use the same criteria for making this determination and obtain the appropriate consent. Additional guidance about this process may be found at <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>.

Decision Tree for Informed Consent from Participants with Diminished Decision-Making Capacity



If an individual alternates between periods of mental competence and incompetence:
 The PI should obtain consent from the individual as provided and ask permission from the individual to obtain consent from a relative or other person who could otherwise grant legal consent for treatment in event that the individual becomes incapable of continuing to make informed consent decisions in the future.

If an individual asks to withdraw from a research study at any time:
 His or her participation in the research must be terminated, even if the investigator does not believe the individual to be competent to make informed decisions and even if a second opinion or third party consent has been obtained.

Economically or Educationally Disadvantaged

For research involving economically disadvantaged participants, special care must be taken to assure that any financial incentives offered do not represent the sole grounds for the individual's participation in the research protocol. Financial incentives should also not be used to encourage participants to assume risks that they would not ordinarily incur.

The consent form for research involving educationally disadvantaged participants must be written in language and with terminology appropriate to the participant. The PI must discuss orally every aspect of the study with the participant to insure his/her understanding.

Illiterate English Speaking Subjects

A PI who has received IRB approval for a study may enroll individuals who can speak and understand English, but cannot read or write. The potential participant must be able to place a written mark on the consent form.

The participant must also be able to

- Comprehend the concepts of the study and understand the risks and benefits of the study as it is explained verbally, and
- Be able to indicate approval or disapproval for study enrollment.

If a PI uses the above method to obtain consent, there must be documentation **on the participant's consent form** specifying what method was used to communicate the information and the specific means that the participant communicated agreement to be in the study.

Students as Participants

In many research studies students are recruited as participants. PIs should be aware of possible coercion when using students in their research. For example, if students believe their participation (or lack of participation) will be made known to someone who holds power over his or her academic status (e.g, course instructor), the student may perceive coercion. How the PI plans to handle potential problems of coercion and undue influence must be addressed when the study is submitted to the IRB. In particular, activities that involve students who report directly to the PI or who attend a class for which the PI has responsibility must be described. Additional guidance about students as research participants may be found at: UDRC Website.

Non-English Speaking Participants

Non-English speaking individuals may not be excluded from research studies on the basis of language if there is a possibility that they might benefit by participating in the study.

If a research participant does not understand English, the informed consent document should be in a language readily understood by the participant. If the PI anticipates that consent interviews will be routinely conducted in a language other than English, the IRB requires a certified

translated consent document be submitted after the English version submitted with the protocol has been approved. It is the PI's responsibility to ensure that the translation is accurate.

A copy of the consent document must be given to each participant. While a translator may be helpful in facilitating conversation with a non-English speaking participant, verbal translation of the consent document must not be substituted for a written translation.

If a non-English speaking participant is unexpectedly encountered, enrollment of the participant may not occur until the IRB has prospectively reviewed and approved a written consent document in language understandable to the participant.

At the time of consent for non-English speaking participants, the following is required:

- The short form document should be signed by the participant or the participant's legally authorized representative.
- The English language informed consent document should be signed by the person obtaining consent as authorized under the protocol.
- The short form document and the summary should be signed by the witness.

CHAPTER 8: USING & DISCLOSING HEALTH INFORMATION IN RESEARCH

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 addresses the security and privacy of health data. Research utilizing health-related data is required to be in compliance with the provisions of HIPAA, including The Standards for Privacy of Individually Identifiable Health Information (Privacy Rule). The Privacy Rule covers health plans, health care clearinghouses, and those health care providers who conduct certain financial and administrative transactions electronically. The rule creates national standards to protect individuals' personal health information, and gives patients increased access to their medical records. In the course of conducting research, researchers may create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose such information for research with individual authorization, or without individual authorization, under limited circumstances set forth in the Privacy Rule. Because of certain activities conducted within the partner agencies, USBE/UDRC may be considered a covered entity under HIPAA.

The Privacy Rule also defines the means by which individuals/human research participants are informed of how medical information about themselves will be used or disclosed and their rights with regard to gaining access to information about themselves when such information is held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time, ensuring that researchers continue to have access to medical information necessary to conduct vital research.

Research Use/Disclosure Without Authorization:

To use or disclose health information without authorization by the research participant, a covered entity must obtain one of the following:

- Documentation that an alteration or waiver of research participants' authorization for use/disclosure of information about them for research purposes has been approved by an Institutional Review Board (IRB) or a Privacy Board. This provision of the Privacy Rule might be used, for example, to conduct records research, when researchers are unable to use de-identified information and it is not practicable to obtain research participants' authorization.

Or

- Representations from the researcher, either in writing or orally, that the use or disclosure of the health information is solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove any health information from the covered entity, *and* representation that health information for which access is sought is necessary for the research purpose. This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study.

Or

- Representations from the researcher, either in writing or orally, that the use or disclosure being sought is solely for research on decedents, that the health information being sought is necessary for the research, *and* at the request of the covered entity, documentation of the death of the individuals about whom information is being sought.

A covered entity may use or disclose health information for research purposes pursuant to a waiver of authorization by an IRB or Privacy Board provided it has obtained documentation of *all* of the following:

- a. A statement that the alteration or waiver of authorization was approved by an IRB or Privacy Board that was composed as stipulated by the Privacy Rule.
- b. A statement identifying the IRB or Privacy Board and the date on which the alteration or waiver of authorization was approved.
- c. A statement that the IRB or Privacy Board has determined that the alteration or waiver of authorization, in whole or in part, satisfies the following eight criteria:
 1. The use or disclosure of health information involves no more than minimal risk to the individuals.
 2. The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals.
 3. The research could not practicably be conducted without the alteration or waiver.
 4. The research could not practicably be conducted without access to and use of the health information.
 5. The privacy risks to individuals whose health information is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research.
 6. There is an adequate plan to protect the identifiers from improper use and disclosure.
 7. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
 8. There are adequate written assurances that the health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of the health information would be permitted by this subpart.
- d. A brief description of the health information for which use or access has been determined to be necessary by the IRB or Privacy Board.
- e. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures as stipulated by the Privacy Rule.
- f. The signature of the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable (*from the U.S. Office of Civil Rights, June 6, 2001*).

CHAPTER 9: RESEARCH RECORD-KEEPING & REPORTING

Proper record keeping is integral to the validity and reliability of data collected during research. It is the PI's responsibility to oversee the general organization and design of study records, both paper and electronic, and assure that all records are authentic. A summary of regulatory documents and individual documents, which must be maintained by the PI, appears below.

<i>Regulatory Documents</i>	<i>Individual Participant Files</i>
<ul style="list-style-type: none"> • Participant Log • Copies of all IRB correspondence • Approved Protocol • Approved Consent Form • IRB Approval Letters • Other Institutional approvals • Continuing review reports • Investigator's Brochure (if applicable) • Correspondence with sponsors/agencies • Sample questionnaires • Sample study forms with instructions • Reports of deaths, protocol violations, protocol deviations and serious adverse events. 	<p>Original signed informed consent form</p> <p>Copies of study recording forms (CRFs)</p> <p>Supporting Documentation for:</p> <ul style="list-style-type: none"> • Inclusion/Exclusion criteria • Results of tests or procedures • Adverse events • Deaths • Communications with participants • Protocol deviations

Reporting Protocol Violations and Deviations

Protocol violations are activities clearly occurring outside of the approved research protocol and represent a failure to comply with the protocol. Protocol deviations are study events that are not covered under the approved research protocol, and also represent a failure to comply with the protocol. If an activity occurs that represents a significant alteration in the approved written protocol and/or affects the safety and welfare of the participant, the PI must download and complete the Amendment Modification form found at UDRC Website and return it immediately by email to the USBE IRB.

Reporting Responsibilities of the Principal Investigator to the IRB

A table describing situations and events which require notification of the IRB by the PI is shown on the following page, along the time frame in which the situation must be reported.

Investigator Must Report	Time Frame for Reporting
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Deaths	Within 24 hours, if subject currently in protocol. Otherwise, within 60 days of investigator's notification of the death.
Protocol deviations	Immediately, when it represents a significant alteration in the approved protocol and/or if it affects the safety or welfare of the subject.
Change to the protocol made without prior IRB review to eliminate an apparent immediate hazard to participant	Immediately
Protocol violations	Immediately, when it represents a significant alteration in the approved protocol and/or if it affects the safety or welfare of the subject.
Changes in approved research procedures or protocol (amendments)	Prompt notification within 10 days; must obtain approval prior to implementing.
Allegation or finding of noncompliance with conducting of research protocols.	Immediately upon discovery of noncompliance
Restrictions, suspension, or termination of study by the sponsor or principal investigator.	Within 3 days
Any activity which involves a potential or actual unexpected risk to subjects or others.	Within 7 days of activity
Any harm experienced by a participant which, in the opinion of the investigator, is both unexpected and more likely than not caused by the research procedures.	Within 7 days of report by participant
Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team.	Within 3 days of confirmation the team is unable to resolve the issue.
Information that indicates a change to the risks or potential benefits of the research.	Within 10 days of discovery
Breach of confidentiality	Within 3 days of discovery
Incarceration of a participant in a protocol not approved to enroll prisoners	Within 10 days
Any other problem that the investigator considers to be unanticipated, and indicates that participants or others are at increased risk of harm	Within 7 days of discovery

Notifying IRB of Pending Audits or Inquiries

Investigators conducting research with human participants are required to report *any communication* from a federal or state department, agency, or sponsor that questions the conduct of research or suggests an impending inquiry audit or investigation. The PI *must* inform USBE IRB by phone or e-mail upon notification of inquiry. A formal written notice to the IRB committee that includes a detailed description of the proposed inquiry is required from the PI. This notice should be received in the USBE IRB no less than three (3) days after the notification of the PI by the agency or sponsor.

CHAPTER 10: ADDITIONAL POLICIES AND RESOURCES

Investigators and Study Staff

It is the policy of USBE and UDRC that all PIs desiring to engage in research using human participants must familiarize themselves with related policies, procedures and federal regulations. PIs should maintain an on-going relationship with the IRB to gain assistance in following policies and procedures during the performance of their studies. This will help assure that both PIs and UDRC remain in compliance with all state and federal regulations regarding research involving human participants.

The PI has primary responsibility for the protection of participants involved in studies under their direction, including recruitment practices, equitable and appropriate selection of participants, obtaining informed consent, and conducting and monitoring the research. Delegation of responsibilities and authority to study staff requires careful consideration of staff maturity and training.

IRB Authority in Non-Compliance Issues

Non-compliance is the failure to follow the regulations or the requirements and determinations of the IRB. Incidents of alleged non-compliance are reviewed and disposition made by the IRB unless the nature or duration of non-compliance indicates the need for institutional intervention.

Non-compliant activities may be identified through IRB oversight, self-reporting, reporting from employees, or reporting from research participants or others. The IRB seeks to collect sufficient information to identify who exhibited non-compliant behavior, when it took place, and other pertinent details that would allow for determination of non-compliance, and the nature and duration of the non-compliance. The IRB chair makes the initial determination if the non-compliance involves human research, and if it is serious or continuing. If the non-compliance is not considered to be serious or continuing, the IRB chair will take steps with the investigator to correct the non-compliant behavior and will notify the State Superintendent of Public Instruction or designee of the non-compliance and corrective action.

If the non-compliance is serious or continuing, the incident is referred to the State Superintendent of Public Instruction or designee for investigation. The outcome of the investigation is presented to the convened IRB along with materials required in the Protocol Review Packet (see Chapter 4, “Required Documentation”), and the IRB reviews the non-compliance and takes corrective action.

In resolving incidents of non-compliance, the IRB has the regulatory authority to:

- Increase the frequency of continuing review of the protocol.
- Notify current participants when the incidence of non-compliance may relate to a participant’s willingness to continue to take part in the research.
- Suspend the study approval until compliance is achieved.
- Terminate the PI’s research protocols.

The IRB may also recommend additional sanctions to the State Superintendent of Public Instruction or designee. These sanctions include:

- Research privilege probation
- Suspension of research privileges
- Termination of research privileges
- Embargo of publications

The PI will be notified in writing if non-compliance is considered serious or continuing. The results of any investigation will be communicated in writing to the PI within 30 days following completion of the review. These communications will include notification to the PI that:

- The research may continue OR
- That the research may continue after contingencies are completed OR
- That the research may not continue due to placement of sanctions.

The IRB is required to report to the State Superintendent of Public Instruction or designee, sponsoring agencies, and OHRP of any suspension or termination of research protocols.

Study Closure

At the conclusion of any study, the PI must notify the USBE IRB to request closure of the protocol. Closure is not reported to the State Superintendent of Public Instruction or designee or agency head. Upon closure of a study, all personal identifiable information of the participants must be destroyed. Data analysis related to the original research questions must be completed in order to close a study. When enrollment and data collection are completed and the only remaining activities are data analysis or long-term follow-up, the PI should indicate this information on the Protocol Status Report form and the protocol may remain open.

The USBE IRB must be notified within 90 days of the study completion. Studies that are not closed upon their completion by the PI may be terminated by the IRB. If no participants have been enrolled in the previous year and data analysis related to the original research questions is complete, the investigator should close the study.

A PI may not re-open a study once it has been completed and is considered closed by the IRB. A new application including supporting documentation is required. Applications for analysis of existing data may be considered for exemption if appropriate criteria are met.

Closure of a study may occur in the following situations:

- At the completion of the study (i.e. new enrollment is closed and all data collection and analysis are completed);
- If the PI chooses to close the study (e.g. the study has not met its enrollment goal, but the investigator does not plan to enroll new subjects, collect additional data from enrolled subjects, or perform any additional data analysis);
- The investigator leaves the agency or affiliate and does not intend to transfer responsibility for the study to another investigator within the agency or affiliate.

Suspension

Suspension is a postponement or temporary interruption of research activities. Suspension may occur for the following reasons:

- Unexpected problem or serious adverse events that significantly increase risks relative to benefits
- Evidence that a PI failed to adequately protect participants in a research study
- Willful or repeated failure to comply with federal regulations, state laws, or institutional rules that govern human research activities
- Proven research fraud or scientific misconduct
- At the request of the institutional official who is responsible for oversight of research involving human subjects
- At the request of the study sponsor, OHRP, or other duly authorized regulatory or governmental department or agency head
- Any other reason deemed necessary by a simple majority vote of the convened IRB (a quorum must be present)
- The IRB or the PI decides that new enrollment and risk-bearing activities should be interrupted pending an investigation into any problem, or alleged problem, with a particular study

Any study may be suspended by majority vote of the IRB members. In contrast to a study that has been terminated, a study that is suspended may be reopened without resubmission as a new protocol and with a new consent form.

At the time the study is suspended, the IRB will establish a unique and specific plan that, if completed by the PI, will lead to re-review of the study resulting in a decision as to whether to continue or end the suspension or to terminate the study. An audit of the PI's studies may be required. At a minimum, the unique and specific plan will include a set of questions or conditions that must be addressed in writing by the PI within a specified time period. The IRB may not end the suspension for continuing review delinquency until the requested information is provided by the PI and is reviewed and approved by the committee.

Termination

Termination is a non-voluntary action resulting in discontinuation of all study-related activities. A study that has been terminated may not be reopened without submission and approval of a new protocol. Termination may occur for the following reasons:

- The Protocol Status Report form has not been received and given final approval within 12 months after the last review (or less than 12 months if the study was designated for review at more frequent intervals). This termination occurs automatically if more than 12 months have passed since the last approval was granted. *This is the only situation for which termination is automatic (i.e., without any action on the part of the IRB).* It is the responsibility of the PI to monitor approval dates to ensure that IRB approval for each study is up to date.
- Unexpected and serious adverse events that significantly increase risks relative to benefits

- Evidence that a PI failed to adequately protect participants in a research study
- Willful or repeated failure to comply with federal regulations, state laws, or institutional rules that govern human research activities
- Proven research fraud or scientific misconduct
- At the request of the institutional official who is charged with responsibility for oversight of research involving human subjects
- At the request of the study sponsor, OHRP, or other duly authorized regulatory or governmental department or agency head
- The PI leaves the institution and fails to request closure of the study or fails to reassign the PI's responsibilities and duties to another qualified PI
- Any other reason deemed necessary by a simple majority vote of the convened IRB (a quorum must be present)

A research study that is terminated by the IRB will be reported to the State Superintendent of Public Instruction or designee, study sponsor, and to the appropriate agency head. Disciplinary action or sanctions may be appropriate and decisions will be made on a case-by-case basis. At the IRB level, appropriate sanctions might include a request for further information, an audit of ongoing research activities, or suspension of all ongoing research conducted by the same PI or group of PIs until all research activities are shown to be free of similar problems. The PI will be reminded that if a study is terminated, no further enrollment or data collection is permitted.

Procedures for Appeals of IRB Decisions

The IRB encourages research. The board is aware that some researchers may disagree with suggestions or requirements made by the board. PIs should make an effort to resolve their concerns by involving the IRB chair, State Superintendent of Public Instruction or designee, or IRB administrator in discussing their concerns. Appeals may be made directly to the IRB with a formal letter addressing the following:

1. Identify the project
2. Identify the IRB action in question
3. Describe any steps taken to resolve the concern, and
4. List the reason for appealing the IRB decision.

Upon receipt of the appeal letter, the IRB chair will review the IRB decision in question and obtain additional information from other relevant sources as needed. The final decision about any appeal will rest with the IRB chair.

REFERENCES

Ethical Principles and Codes

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Guidelines for Good Clinical Practice <http://ohsr.od.nih.gov/guidelines/belmont.html>

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) <http://www.veriteq.com/download/ICH-stability-guidelines.pdf>

National Bioethics Advisory Commission <http://www.bioethics.gov/>

Nuremberg Code <http://ohsr.od.nih.gov/guidelines/nuremberg.html>

World Medical Association Declaration of Helsinki

<http://ohsr.od.nih.gov/guidelines/helsinki.html>

Federal Regulatory & Advisory Guidelines

Protection of Human Subjects 45 Code of Federal Regulations 46

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>

Protecting Human Research Subjects: Institutional Review Board Guidebook (DHHS/OHRP)

Office of Human Research Protections <http://www.hhs.gov/ohrp/education/training/>