

**The Institutional Review Board  
Policies and Procedures Manual  
for  
Research with Human Subjects**



**TEXAS TECH UNIVERSITY™**

**Updated 8/2017**

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## Section 1: Introduction

### 1.0 Background

Federal regulation of human subjects research began in 1971. With the background of the Nuremberg Code, shown in Appendix A, in 1974 the National Research Act created the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. This law required every institution applying for federal funds for the conduct of human research to establish an Institutional Review Board (IRB) to protect the rights of the human subjects involved in biomedical and behavioral research.

After meetings at the Smithsonian Institution's Belmont Conference Center in 1976 and extensive deliberations over the next three years, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued a 1979 statement, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," (*The Belmont Report*, Appendix B), laying out basic ethical principles to assist individuals in resolving ethical issues in the conduct of research with human subjects. In 1981, the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) set forth the regulatory standards for the protection of human subjects and for the operation of Institutional Review Boards. In 1983, the U.S. Department of Health and Human Services (DHHS) issued new regulations and mandated special protection for vulnerable populations such as prisoners and children. In 1989, the National Institutes of Health became the coordinator of all the human subjects protection activity of the federal government through what is now known as the Office for Human Research Protections (OHRP). In 1991, OHRP issued regulations to protect human subjects in research (Title 45 of the Code of Federal Regulations, Part 46, Appendix C). It is these regulations, also known as 45 CFR 46 or the Common Rule, that govern human research activity at Texas Tech University.

To certify that Texas Tech complies with these federal regulations, the university has filed a Federalwide Assurance (FWA 00001568; expires 7/19/2020). The assurance commits the university, the Institutional Review Board, and research investigators to the ethical principles of *The Belmont Report* and an institutional policy of compliance with the federal regulations. Importantly, as part of its assurance, Texas Tech is committed to reviewing all research involving human subjects regardless of sponsorship.

### 1.1 Institutional Review Board

#### 1.1.1 Administration of Research Ethics at Texas Tech University

The Vice President for Research is responsible for the application of policies and procedures governing the use of human subjects in research. The HRPP Section Manager (742-2064) is responsible for coordinating IRB activities. The HRPP office maintains all IRB records including meeting agendas and minutes, policies, regulations, forms, reference materials, and protocols (in Cayuse IRB). Active IRB-approved individual protocols are maintained for the life of the project. When notification is received that a project has been completed, the files are archived for three years then removed from Cayuse IRB. Sponsored project guidelines need to be followed on record retention.

### **1.1.2 Composition of the Institutional Review Board**

The Protection of Human Subjects Committee (O.P. 74.09) serves as the IRB for Texas Tech University. It operates under the DHHS regulations for the protection of human research subjects (45 CFR 46), the university's Federalwide Assurance (FWA), and is guided by the ethical principles regarding human subjects research as set forth in *The Belmont Report*. Within the scope of these documents, the IRB is charged with applying both the letter and the spirit of federal regulations designed to protect the rights and welfare of human subjects.

The IRB members represent diverse backgrounds in order to provide the professional competency necessary to review research and to provide an understanding of the ethical, legal, and community contexts in which research takes place. The Vice President for Research is responsible for the appointment of members for the IRB. Members are selected on the basis of their experience and expertise and their sensitivity to issues such as community attitudes. One member is appointed specifically to represent the interests of prisoners. Two members who are not affiliated with the university represent the larger community. An additional member is from the faculty of Texas Tech University Health Science Center. The rest of the IRB consists of Texas Tech University faculty members who represent expertise in a wide variety of areas of human research. The ex-officio members include the Associate Vice President for Research, a representative from Environmental Health and Safety, a representative from the Information Technology Division, a representative from the Office of Research Services, a representative from the Office of the Registrar, a representative from Institutional Compliance, and a representative from Responsible Conduct of Research. There are also alternate members who may replace a regular voting member unable to attend a meeting. Members and alternates are appointed for staggered three-year terms and may be reappointed so that the Board maintains a large number of experienced members. The IRB can and does enlist the help of outside experts whenever review of a proposal requires specialized knowledge concerning research procedures or populations. These outside experts do not have voting privileges.

The Institutional Review Board for the Protection of Human Subjects Committee meets on the last Tuesday of the following months during the academic year: September, October, November, February, March and April. Please check the HRPP website for accurate monthly details.

## Section 2: The IRB and Training

### 2.0 Committee Members

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INSTITUTIONAL REVIEW BOARD  
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September 2016-August 2017

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## 2.1 Education/Training

The IRB helps educate the Texas Tech community generally about issues of human subjects research ethics. Principal Investigators on NIH and NSF projects are required to document the completion of training on human subjects protection for themselves and for key personnel at the time a proposal is submitted. Other investigators are encouraged to complete the same training. In any case, all investigators and members of their research teams are required to be familiar with *The Belmont Report* and the federal regulations at 45 CFR 46.

Here are links to two on-line training programs:

1. NIH Training: Website training for social and behavioral sciences research with human subjects

<http://phrp.nihtraining.com/users>

2. CITI Training: Collaborative Institutional Training Institute

[www.citiprogram.org](http://www.citiprogram.org)

## Section 3: Institutional Review Board Procedures

### 3.0 Does the project involve human subjects research?

The IRB regulates all activity that constitutes *research with human subjects*, as defined below (see 45 CFR 46.102, Definitions) that (a) is conducted by Texas Tech University personnel in the course of their employment by the university and/or (b) uses Texas Tech University facilities or resources. Generally, this means that Texas Tech University personnel conducting research elsewhere need approval by the Texas Tech University IRB even if the work is approved by another IRB. Work that is conducted on the Texas Tech University campus needs approval by the Texas Tech University IRB even if it has approval by another institution. In some cases, Institutional Authorization Agreements can be created that allow one IRB to take the primary role of review and approval, and the other IRB to rely on that IRB. Individuals who are in doubt about whether an activity constitutes research with human subjects or who have questions about the applicability of this policy to a research project should confer with the IRB Chair, HRPP Section Manager or a member of the IRB.

In most cases, multi-site collaborative research requires IRB review and approval. If the research activities at Texas Tech involve *any* interaction or intervention with subjects, then the protocol must be reviewed. In some instances investigators may obtain, receive, or possess private information that is individually identifiable (either directly or indirectly through coding systems) for the purpose of maintaining “statistical centers” for multi-site collaborative research. If the research activities involve no interaction or intervention with subjects, and the principal risk associated is limited to the potential harm resulting from breach of confidentiality, the IRB need not review each collaborative protocol. However, this is still considered research and the IRB must determine and document that the statistical center has sufficient mechanisms in place to ensure that (i) the privacy of the subjects and the confidentiality of data are adequately maintained, given the sensitivity of the data involved; (ii) each collaborating institution holds an applicable Office for Human Research Protections (OHRP) approved Assurance; (iii) each protocol is reviewed and approved by the IRB at the collaborating institution prior to the enrollment of subjects; and (iv) informed consent is obtained from each subject in compliance with Department of Health and Human Services (DHHS) regulations.

Under no circumstances may an investigator undertake research involving human subjects without approval by the full IRB, approval by expedited review, or approval of a claim for exemption. Retrospective approvals and exemptions cannot be granted.

The following definitions from federal regulations apply:

**Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

**Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information

**Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

**Interaction** includes communication or interpersonal contact between investigator and subject.

**Private information** includes "information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects" (45 CFR 46.102).

**Non-research activities** are not subject to review by the IRB and do not have to be certified as exempt from IRB review. Examples of activities that fall outside the jurisdiction of the IRB because they do not have the purpose of contributing to generalized knowledge or are not systematic investigations include, but are not limited to:

- Art
- Classroom projects that are conducted for didactic purposes and do not extend beyond the classroom (i.e., do not contribute to generalizable knowledge)
  - The student and instructor still have the responsibility to respect the rights of the study participants and to treat them in a fair and ethical manner.
  - Instructors should ensure that the projects carried out by their students are being conducted in a manner that is consistent with the ethical principles of their discipline and the federal guidelines for the protection of human subjects.
  - If a student or instructor decides to submit a class project to a conference, journal, etc. an approved IRB is needed prior to recruiting and collecting data.
- Journalism
- Marketing research designed to market the institution as a product
- Oral history is defined by the Oral History Association as "a method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life." In general, oral history interviews are conducted with specific individuals with expertise in certain areas, rather than anonymous individuals selected at random. These individuals most often respond to open-ended questions, rather than a standard survey. In general, oral history interviews are not designed to contribute to "generalizable knowledge" and are therefore outside the jurisdiction of the IRB.
- Program evaluations for internal purposes
- Teacher and student evaluations
- Texas Tech employee performance evaluations

Examples of activities that fall outside the jurisdiction of the IRB because they do not involve interaction or intervention with human subjects and the data do not constitute identifiable private information include, but are not limited to:

- Studies using aggregated archival data that is de-identified
- Studies using people to obtain information that does not involve human subjects (e.g., “how many widgets did you produce last quarter?” or “how many sick days were taken last year by people who work in your school district?”)

**Identifiable Private Information** includes information that can be either directly or indirectly linked to specific individuals. An example of information that could be directly linked to a specific individual would be that person’s social security number. An example of information that could be indirectly linked to a specific individual would be coded information, if a key to decipher the code exists.

However, when the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information pertains, this constitutes non-identifiable information. Examples of non-identifiable information include:

- Identifiable information that is coded (name or social security number could be replaced with a number, letter, symbol, or combination thereof), AND the key to decipher the code is destroyed before the research begins.
- Coded information in a situation in which the investigator(s) and the holder of the key enter into an agreement prohibiting the release of the key to the investigator(s) under any circumstance.

Activities that fall outside the purview of the IRB may still involve some of the same ethical issues that confront researchers (e.g., confidentiality). Such issues ought to be considered from the perspective of ethics for teachers, practitioners, clinicians, or other professions or groups whose ethical guidelines or legal authority are relevant to the activity.

### **3.1 Proposal Processing and Assignments**

When a proposal is received, the HRPP Section Manager or staff may review or prescreen proposals in the Exempt category and may prescreen proposals in the Expedited or Full Board categories. Next, a primary reviewer is assigned from among the IRB members to review the proposal. The IRB reviewer has 10 working days to complete the review. Typically, questions, comments, and notations of concern are communicated to the PI through comments added in the Cayuse IRB system. Reviewers may also email, telephone, or meet with investigators in some situations.

Principal Investigators will be notified by electronic communication of the action of the IRB. These letters will be maintained in the Cayuse IRB system for review by institutional officials.

Pending proposals with no response or communication will be closed after 90 days.

### **3.2 Types of Proposals**

If a project constitutes human subjects research according to the definitions above, there are three types of proposals. Investigators should use the descriptions that follow to determine which category of review is appropriate and check with the HRPP Manager, the IRB Chair, or a member of the IRB if questions remain.

### 3.2.1 Exempt category.

Research in the Exempt category includes research that involves minimal risk and fits certain precisely defined categories such as survey research in which responses are anonymous. The principles of *The Belmont Report* must still be observed in research in the exempt category.

### 3.2.2 Expedited category.

Expedited proposals involve minimal risk and fit within one of nine precisely defined categories such as research with surveys or interviews.

Research projects involving no more than minimal risk are suited for the expedited category. Projects with children or other vulnerable populations must be approved by two expediting reviewers (45 CFR 46, Subparts B-D). Projects that are not suitable for the exempt category or those that raise other than routine ethical issues will, at the discretion of the reviewer, be referred to the Full Board for review. Communication regarding the review will be contained in Cayuse IRB. The PI and primary contact will receive notification by email when a decision has been made by a reviewer in Cayuse IRB. Investigators will be notified of the final outcome of each review by an electronic letter of approval, a copy of which will be contained in the Cayuse IRB system. Expedited proposal review categories are in Appendix D, 63 FR 60364, November 9, 1998.

### 3.2.3 Full Board Proposals

Research projects involving human subjects that do not qualify for either exempt or expedited categories of review must be reviewed and approved by the full IRB at a convened meeting. The IRB meets on the last Tuesday of the following months during the academic year: September, October, November, February, March and April. A Full Board proposal must be submitted at least three weeks before the scheduled meeting. Please check the HRPP website for accurate monthly details. Investigators are urged to submit earlier in order to allow for the possibility of revisions in the proposal before the meeting of the board.

After a full discussion of a full board proposal, the IRB may take one of the following actions by majority vote:

**Approve:** The IRB can approve the project as submitted without any changes for no more than 12 months. Projects that involve significant risks can be approved for less than 12 months at the discretion of the IRB. The decision to require a period of approval of less than 12 months is determined in the course of discussion of the proposal and is part of the motion to approve the project. Any specific findings required by 45 CFR 46 such as those needed for approval of research with prisoners (45 CFR 46.305-306), or for waivers of signed consent (45 CFR 46.117) should be documented in the minutes. Motions to approve a proposal may include a finding that the research involves no more than minimal risk, thus making the project potentially eligible for expedited continuing review.

**Minor Revisions Required:** The IRB may approve a project contingent upon specific, minor modifications by the Principal Investigator. When the revised proposal with the changes incorporated is received in Cayuse IRB, it will be routed to the chair or a member designated in the minutes (usually the primary reviewer) who will compare the modifications received

with the actions requested by the IRB. If the modifications are in compliance with the IRB directives, the chair or the primary reviewer will approve the project for the period of time specified by the IRB. Note: although the approval is not effective and the project may not go forward until the modifications are approved, the period of approval is a maximum of 12 months from the date of the convened meeting.

**Defer Pending Resubmission:** If the IRB deems that the proposal requires substantial revisions, or if unanswered questions remain, the IRB will require the investigator to resubmit the proposal and attachments with all of the changes required and all of the questions resolved. A revised version of the proposal with the incorporated changes will be reconsidered at the next board meeting following resubmission.

**Disapprove:** The IRB may disapprove a research project if it has determined that the human subjects are at a greater risk than the benefits to be accrued. This action is taken only after all negotiations with the investigator have failed to result in a resolution of the pertinent ethical issues. Notification will include the reasons for the disapproval. Upon disapproval, the Principal Investigator can submit a revised proposal to the IRB. Federal regulations specify that the administration of the university cannot approve a project which the IRB has disapproved.

### 3.3 Review Criteria

**Letter and spirit both matter.** The IRB cannot approve a proposal that is not consistent with the criteria set forth in 45 CFR 46 or the interpretations of 45 CFR 46 issued by OHRP (see Guidance Documents at <http://www.hhs.gov/ohrp/policy/>). At the same time, every project is reviewed with consideration of the more general ethical principles of respect for persons, beneficence, and justice described in *The Belmont Report*. The integrity and good will of investigators is assumed, but the IRB is required not only to ensure the protection of human subjects but also to document that their rights and welfare have been protected. In reviewing proposals, the IRB must determine that each one satisfies the following standards:

**Risks to subjects.** Risks to subjects are minimized by the use of procedures that are consistent with sound research and that do not unnecessarily expose the subjects to physical, psychological, social, economic, or other risks. In the case of research involving diagnosis or treatment, risk is minimized by the use of procedures already in use for diagnostic and treatment purposes whenever appropriate.

**Risks vs. benefits.** Risks to the subject are reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge that may reasonably be expected to result. In order to assess the importance of the knowledge resulting from the research, the IRB must be satisfied with the soundness of the rationale and the research design. The board's concern about the scientific validity of research is in direct proportion to the risk involved. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from the risks and benefits of therapies or services that subjects would receive even if they did not participate in the research). The IRB does not consider the long-range effects of applying the knowledge gained in the research as among those research risks or benefits that fall within its responsibility. When students are offered course credit for participation, there must be non-research alternatives for earning the same credit for the similar time and effort.

**Subject selection.** The selection of subjects must be equitable. In making this assessment, the IRB takes into account the purposes of the research, the setting in which the research will be conducted, and the population from which the subjects will be recruited.

**Other considerations.** The IRB may also consider the acceptability of the research project in terms of other applicable standards of professional conduct and special vulnerabilities of the subjects.

### **3.4 Appeals of IRB Decisions**

In virtually all instances, investigators work with the IRB to reach agreement on the best ways to meet human subjects requirements while conducting research. In cases where the investigator and committee reach an impasse, a decision by the IRB to disapprove a project is final. Federal regulations prohibit the university from approving a project which the IRB has disapproved.



## **Section 4. Background for Preparing Proposals**

### **4.0 General**

The Principal Investigator submits the human subjects research proposal in Cayuse IRB and is responsible for the proposal and for the design, conduct, and reporting of the research. Only full-time or tenured Texas Tech University faculty or a full-time employee with the terminal degree in their discipline (Ph.D., Ed.D., J.D., or M.D.) may be the Principal Investigator on proposals. Proposals for research by students, other personnel, or people from outside of Texas Tech University must be submitted with a Texas Tech University eligible Principal Investigator (PI). All other investigators (students, other personnel, or people from outside of TTU) must be listed as Co-Investigators.

Investigators should be aware that consent may be required on legal, ethical, or practical grounds that do not involve the protection of research subjects.

IRB proposals may be considered to be public information in accordance with the Texas open records statute.

Proposals should be submitted to the IRB through the Cayuse IRB system.

### **4.1 IRB Approval from TTUHSC and other Institutions**

Projects that involve human subjects research at both Texas Tech University and another institution need to be reviewed and approved by the other institution's IRB as well as the TTU IRB. For projects where another institution is the primary institution, that institution's complete IRB proposal and approval letter should be submitted in the Cayuse IRB system. It is possible that an Institutional Authorization Agreement can be created that allows TTU IRB to rely on the other institution.

Research being conducted jointly by faculty at Texas Tech University and the Texas Tech University Health Sciences Center (TTUHSC) campuses may be reviewed by a single IRB. The TTU IRB designates the TTUHSC IRB as its IRB of record for projects originating at TTUHSC that use the faculty, facilities, staff, and/or students of TTU. If the most appropriate assignment of an application is in doubt, the administrators and chairs of the two IRBs should reach a consensus on which IRB is most appropriate. The Memorandum of Understanding between TTU and TTUHSC is in Appendix E.

### **4.2 Proposals involving external funding**

When research involving external funding involves work with human subjects, funding from federal and some private sources cannot be expended until an IRB proposal has been approved (see 45 CFR 46.122). The Office for Human Research Protections has noted (May 31, 2000) that some agencies require IRB review before a project can be funded. Regulations require that the IRB review the grant application or proposal to be certain that the grant and IRB proposals are in agreement. The IRB must have a complete copy of the grant proposal for this purpose and for records.

It takes 10 working days before the IRB can complete a proposal review and more than that when changes are necessary or special populations are involved. Some proposals will require a review by the Full Board, which meets once a month. For several years, some federal funding awards have been made with very short time frames required for funds to be awarded. This has led to situations in which the investigator had very little time to document IRB approval. In other words, an investigator had to write an IRB proposal and submit it to the IRB and the proposal had to be reviewed and necessary changes made, sometimes within 24-hours. This is an impossible situation for the TTU IRB and for IRBs across the country. It is in the researchers best interest to submit an IRB proposal along with a grant proposal or soon after.

Occasionally a project already approved by the IRB is submitted for external funding. In such a case, the Office of Research Services will require verification from the IRB that the proposed research protocol is the same as the one previously approved by the IRB. The investigator should submit the grant proposal to the IRB in the form of a modification to the original IRB proposal. The grant proposal and the approved IRB proposal will be forwarded to an expediting reviewer who will verify that the two protocols match.

#### **4.3 Payment to research subjects**

The TTU O.P. 62.25 concerns Payment to Research Participants. This area is complex and goes beyond the work of the IRB.

#### **4.4 Recruitment of Subjects by Subjects**

Referral fees paid to research participants to recruit other research participants introduces possibilities of coercion in recruitment. The TTU IRB will not approve these recruitment procedures.

#### **4.5 Risk**

**Minimal risk** “means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45 CFR 46.102).

The definition of “risk” is determined by assessing the probability of harm and the magnitude of harm. Consideration is given to both aspects of potential harm. In some cases, (perhaps research in physical exercise) one of the possible risks could be death. However, this would be an extremely rare occurrence which is likely to never occur. Thus, the probability of harm would be exceptionally low. Therefore, although the potential magnitude of harm could be high, the probability of that occurring is so low that the research does not necessarily need to be considered high risk.

#### **4.6 Electronic Data Policy**

The Electronic Data Policy Statement is in Appendix F.

## **4.7 Subject Pools**

Departments that have written procedures for organizing pools of research subjects must submit the procedures for IRB approval. The procedures should describe the methods for recruiting and compensating subjects. If credit toward meeting a course requirement is offered to students in the pool, the nature of that credit should be specified. Non-research alternatives for earning the same credit with similar time and effort must be available and should be described. If the subject pool procedures are approved by the IRB, the details of subject recruitment and compensation need not be reported in detail in projects proposing to use the subject pool. It is sufficient to refer to the procedures on file with the IRB. The IRB reviews existing procedures once each year and considers new procedures and modifications as they are submitted.

## Section 5. Preparing and Submitting Proposals

### 5.0 About Proposals

Every proposal should be submitted in the Cayuse IRB system with all applicable and required fields completed. An example proposal can be found in Appendix G. A description of the required elements of consent, discussed below, can be found in Appendix H. A Reviewer Checklist used to assess the inclusion of all required materials is found in Appendix I.

The IRB proposal must include copies of all materials involved in recruiting subjects. Examples of recruiting materials, consent forms, and assent forms are in Appendices M and N. The IRB proposal must also include copies of all questionnaires, tests, interview materials, etc., that subjects will be asked to complete.

### Expedited or Full Board proposals

Particular attention should be directed toward the rationale for, and the details of, research procedures that involve more than minimal risk, including the risk of the disclosure of private information that might be harmful to the subject. If these sections of the proposal do not allow the IRB to judge whether risks have been minimized and are reasonable in proportion to benefits, the investigator will be asked for additional information. Where risks are negligible or minimal, particularly when the project falls into one of the categories suitable for exempt review, a brief description of the rationale and procedures may be all that is necessary. Submission of unnecessary, lengthy material, such as an extended literature review or method sections of a dissertation proposal, *will serve only to slow down* the processing of a proposal. As detailed in the next section, all expedited or full review proposals must include a copy of a consent form or a request to waive the requirement for a consent form.

Investigators should submit their IRB proposals via Cayuse IRB system. The HRPP staff prescreens all proposals for completeness. As part of the initial screening process, the HRPP staff may ask the Principal Investigator to revise the proposal to make it suitable for review. The HRPP Staff will send exempt and expedited reviews to a reviewer. Ten working days should normally be allowed for processing. Proposals involving children or other vulnerable populations must be reviewed by two reviewers, which causes the review process to take longer. Full Board proposals must be received at least three weeks before the Full Board meeting. Full Board meetings occur on the last Tuesday of the following months during the academic year: September, October, November, February, March and April. Please check the HRPP website for accurate monthly details.

Data collection may begin as soon as the human subjects research proposal has received approval from the IRB Reviewer or the Full Board. Any proposed modifications or renewals of the project must be approved prior to their implementation. This action can be completed through Cayuse IRB by submitting a modification and/or renewal.

### 5.1 Recruiting Materials

Recruiting materials must be described and, where relevant, included in the proposal. Examples of recruiting materials are in Appendix J.

## 5.2 Informed Consent

Note: “Consent process” and “consent form” are two terms that are used frequently in this section. Although these terms are similar, they are not interchangeable. The consent process is the overall process by which the participant is made aware of the purpose, risks, benefits, etc. of the research. The consent process often includes the use of a consent form, but is not limited to that alone. The consent process also may include a dialogue between the investigator and the subjects to insure that the subject is able to give informed consent. The consent form is the written document that the participant signs indicating consent. All participants should receive a copy of the consent form.

Human subjects research proposals submitted for research in the exempt category do not require a consent form. However, pertinent information materials such as oral scripts, project summary sheets/an information sheet, etc. are required to provide adequate information to the participant to form a decision to participate.

Documentation of informed consent is the most problematic issue in the review of proposals for human subjects research. The required modification of consent forms is the most frequent reason that proposals submitted for expedited or full review are deferred. However, because federal regulations (45 CFR 46.117) and applicable ethical principles from *The Belmont Report* are reasonably clear about the essential elements required in the consent process, delays in processing many proposals can be avoided by carefully following the guidelines in this section.

**Readability is important.** The content of the consent form is irrelevant if subjects cannot understand it fully. Therefore, the IRB cannot approve a consent form, even if it contains all the required information, if it will not be fully understood by the individuals expected to read it. Technical material and the purpose of the study must be explained in lay terms. Procedures should be explained from the point of view of what will happen to the subject in the course of the study. The consent form should be written in the second person (“You will...”). A general rule of thumb used by federal regulators is that consent forms aimed at the normal adult should be written at a 7<sup>th</sup> grade reading level. Research projects involving children require parental consent and generally require assent from the children. The assent form must be written in language understandable to the age level or comprehension level of the child. The assent form allows the child a choice of whether or not to participate, even though the parent has given permission. Both the consent form (for parents) and the assent form (for minors) are required.

Help with **readability** and language level wording can be found at:

<http://www.plainlanguage.gov/>

### 5.2.1 Written Consent Form

Information about a study that includes the elements of informed consent required by 45 CFR 46.116 may be presented in a written consent form that is signed by the subject or a legally authorized representative. The form may be read to the subject or representative, but in any event, the investigator should give either the subject or representative adequate opportunity to read the form before it is signed. When consent is obtained with a full, written consent form that is understood and signed by a competent subject, no witness is required, and the consent form should not contain a space for the signature of a witness or researcher. A copy of the consent

form should be given to each participant. The signed consent form should be stored by the researcher for three years after the research is complete. Sponsored project guidelines must be followed on record retention.

Appendix K provides examples of consent forms.

### **5.2.2 Elements of Consent**

Appendix H includes the Required Elements of Consent. There are optional elements that must be included in the consent form if they are applicable to the study.

### **5.2.3 Multiple Form Written Consent – Part I, Part II and Part III**

Information about a study may be presented in a short form written consent document that states that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or a legally authorized representative (e.g., Dr. Researcher told me the purpose of the study; Dr. Researcher told me what the risks of this study are). The short form is most useful when a study is complex and the investigator can't be sure that a signed written consent is well enough understood to indicate a valid consent process. The short form allows the individual obtaining the consent to talk with the subject to make sure the subject understands what will be involved.

In this case, the following consent process should be followed:

- (a) The IRB must approve a written summary of the oral presentation
- (b) For the short form consent, there must be a witness to the oral presentation and the witness must sign both the short form consent form and the written summary
- (c) The person making the oral presentation must also sign the written summary
- (d) The subject or a legal representative must sign the short form consent form and be given a copy of both the short form and the summary

### **5.2.4 Internet Research Consent**

Researchers should provide necessary information to potential subjects to assist in the decision-making process to participate. This could be done electronically by having an email recruitment letter which provides all of the required information before the participant begins and/or a short information paragraph or page before the survey

In internet research, the consent process must still be followed if the project is Expedited or Full Board.

### **5.2.5 Waiver or Alteration of the Elements of Consent**

Sometimes an element of consent can be waived. For example, some research involving deception cannot be done with full disclosure in advance. An element of consent might be waived and not disclosed until the subject's participation is complete. Here are two regulations that concern the form.

- (1) The research involves no more than minimal risk to the subjects; the waiver or alteration will not adversely affect the rights and welfare of subjects; the research could not be practicably be carried out without the waiver or alteration; and whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- (2) The research involves the evaluation of public benefit or service programs as specified in 45 CFR 46.116(c).

In section **11.1**, the investigators should select the appropriate boxes that describe the justification of the request for the waiver or alteration.

### **5.2.6 Waiver of Written Consent Form**

Sometimes the IRB can waive the requirement for a signed consent form.

- (1) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- (2) The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

In section **11.1**, the investigators should select the appropriate boxes that describe the justification of the request for the waiver or alteration. In the Risks and Benefits section (**14.2**) of the Cayuse IRB proposal, when a research study involves no risks beyond those of everyday life or routine physical or psychological tests, the investigators should simply say: "Since there are no risks beyond those of everyday life, no liability plan is offered."

### **5.3 Continuing Review, Annual Progress Reports, and Termination of Projects**

Texas Tech University's assurance of compliance with the federal government requires at least annual review by the IRB of all expedited and full review studies involving human subjects research. As part of continuing review, the IRB has regulatory authority to observe, or have observed, the consent process and the research itself and to audit records such as consent forms at any time. When the approval for a project nears expiration, the investigator should complete the Renewal submission in Cayuse IRB. The procedures below apply depending on the level of initial review. Except for Exempt category projects, the investigator will be informed by an emailed letter of the outcome of continuing review.

**Exempt research.** Exempt research is not subject to continuing review. Any modifications that (a) change the research in a substantial way, (b) might change the basis for exemption, or (c) might introduce any additional risk to subjects should be reported to the IRB for review before they are implemented.

**Timing of review.** When a proposal is approved or renewed by either expedited or full review, approval normally extends to the last day of the month preceding the anniversary of the approval. The anniversary is determined by the date of final approval (initial or continuing) by an

expediting reviewer or the date of the convened full IRB meeting at which approval (including contingent approval) occurs, not the date of final approval of required changes. When continuing review is required for a period of less than a year, the expiration date is determined in a similar manner.

Approximately 30 days prior to the expiration of the approval, the HRPP staff will send an email through the Cayuse system to the Principal Investigator noting the date of expiration and the need to complete a Renewal submission. The Renewal requires a report on the status of the project, descriptions of all adverse events affecting the rights or welfare of human subjects, and any changes contemplated in the research protocol and/or informed consent/assent forms. A complete clean proposal may be required every three years if the initial proposal has been amended within the three years.

**Expedited continuing review/Renewal.** Projects initially approved by expedited review will normally undergo expedited continuing review/renewal unless changes to the research are contemplated that might move it out of the expedited category. Because 10 working days should be allowed for processing a proposal and due to the volume of expedited reviews, prompt completion of the Renewal submission is important to ensure that the approval of a project does not lapse. Expediting reviewers will be assigned the renewal, and will have access to the original proposal including the current consent form, any subsequent modifications, and access to the complete file on each project. Criteria are the same as for initial review, but continuing expedited review of research involving children requires review by only one expediting reviewer. At the discretion of the reviewer, independent verification that no material changes have occurred since the previous IRB review may be required.

**Full Board continuing review/renewal.** Projects initially approved by the Full Board will normally not undergo Full Board continuing review unless the progress report identifies additional risks. Prompt completion of the Renewal in Cayuse IRB is important to ensure that the approval of a project does not lapse.

For continuing review/renewal conducted by the Full Board, a primary reviewer will be designated. When deemed appropriate, protocols requesting Full Board review are distributed to all IRB members and include the Renewal, current consent forms, prior modifications and the original proposal. The primary reviewer will be provided with the Renewal, the original proposal, any subsequent modifications, and access to the complete file on each project. Criteria are the same as for initial review. At its discretion, the board may require independent verification that no material changes have occurred since the previous IRB review.

**Termination.** All Principal Investigators must maintain an active IRB-approved protocol until the project is complete. Once data have been rendered non-identifiable, they no longer constitute identifiable private information and further data analysis does not require continuing approval.

If the HRPP does not receive the request for a renewal by the due date noted on the form, IRB approval automatically expires and a letter of termination is sent to the Principal Investigator. By not completing the Renewal or otherwise notifying the IRB that the project has been terminated, the investigator certifies that during the preceding period of approval there were no changes to the protocol or consent form and no adverse events. Projects that continue without IRB approval or projects initiated without IRB approval are out of compliance with federal regulations and with Texas Tech University policy. In such cases a report of non-compliance will be filed with



the Vice President for Research for further action. The university is required to inform OHRP of any serious or continuing non-compliance.

#### **5.4 Reporting Adverse Events or Noncompliance**

If a project is not being conducted in accordance with a protocol approved by the IRB, if there is harm to a subject, or there is any other failure to conform to the requirements of 45 CFR 46 and/or these policies and procedures, the Principal Investigator is required to report the details of these deviations *immediately* to the HRPP office. The HRPP office will create a Post Approval Review report that will be sent to the Chair and Associate Chair for Review. The Chair may ask the IRB to consider the matter. The IRB or IRB Chair has the authority in such cases to suspend or terminate the research and/or to report them to the Vice President for Research. Reports to the Vice President for Research will be made as soon as possible. In the case of serious adverse events or deviations from an approved protocol, Texas Tech University is required by its assurance of compliance with the federal government to report such incidents to the federal Office for Human Research Protections. In addition, the university may need to report the events to research sponsors. Thus, the reporting requirement for investigators is an extremely serious one.

#### **5.5 Modifications to Approved Protocols**

Changes to currently approved projects require approval by the IRB. Such modifications may include, but are not limited to, changes which affect the participation of human subjects, changes to informed consent forms and/or assent forms, additional sites for conducting the research, changes in Principal Investigators or key personnel, and the discovery of unanticipated risks to subjects. Substantive changes to projects must not be implemented until approval has been granted. If a project is not being conducted in accordance with the protocol approved by the IRB, the IRB has the authority to suspend or terminate its approval of the research.

The process and distribution of documents for reviewing changes is the same as for initial review. Modifications must be submitted through the Cayuse IRB system.

## **Section 6: Procedures for Research with Vulnerable Populations**

### **6.0 Protected Populations in Research**

The IRB has a special obligation to protect the rights and welfare of subjects who are particularly vulnerable including all those who cannot give informed and legal consent themselves. Three classes of subjects, (a) fetuses, pregnant women, and human in vitro fertilization; (b) prisoners, and (c) children are singled out in federal regulations for additional protective measures.

#### **6.1 Inclusion of Fetuses, Pregnant Women, and Human In Vitro Fertilization.**

Any research activity that may involve more than minimal risk to a fetus is covered by 45 CFR 46 Subpart B. This includes research that may pose minimal or low risk for subjects themselves, but might present risks if subjects were pregnant or become pregnant during the course of the study. In such cases, screening for pregnancy and exclusion of pregnant subjects is advised. Researchers who are doing research that is directed toward fetuses, pregnant women, or in vitro fertilization should be familiar with the requirements of 45 CFR 46 Subpart B.

#### **6.2 Inclusion of Children in Research**

All research with children receives special scrutiny. Children are defined (45 CFR 46.402) 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 Texas, the legal age for consent is 18. All research for which consent is required must also, where possible, obtain the assent of the child subject. Most often, assent is obtained with the use of a child “assent form” which is a version of the consent form in language appropriate for the child’s ability to understand the elements of consent. Expedited proposals with children as subjects (except those enrolled as regular students at Texas Tech University) will be reviewed by *two* reviewers which may result in a somewhat longer time to process the proposal.

#### **6.3 Inclusion of Prisoners in Research**

Any research activity that involves prisoners as subjects must undergo Full Board review subject to 45 CFR 46 Subpart C.

The regulations require the IRB to provide additional safeguards because incarceration per se could affect the ability of prisoners to make truly voluntary and un-coerced decisions about whether to participate in research. It is required that at least one member of the IRB be a prisoner or prisoner representative in order to approve prisoner research. The Texas Tech University IRB has one member who serves on the board at meetings to represent interest in prisoner research. In order to approve research on prisoners, the board must make specific findings in Appendix L.

Researchers contemplating research in jails and prisons should consult the OHRP guidance at <http://www.hhs.gov/ohrp/policy/index.html#prisoners>.

**6.4 Inclusion of People with Limited Competence.** Under some circumstances it is possible to conduct research with subjects who may not be competent to fully consent to research. In such cases, the consent must be signed by a legally authorized representative, if there is one, and generally an assent must be agreed to by the subject. When no legally authorized representative exists and the competence of the subject might be in doubt, the subject's signature on a consent form should be validated by someone believed to be able to speak on behalf of the subject. That person (a) should be a close relative or family member or a friend of long standing, if possible, and (b) must also sign a declaration stating that s/he knows the subject well enough to be able to express the subject's wishes.

## **Appendices**

Appendix A: Nuremberg Code

Appendix B: The Belmont Report

Appendix C: Code of Federal Regulations

Appendix D: 63 FR 60364-60367, November 9, 1998

Appendix E: Memorandum of Understanding between Texas Tech University and Texas Tech University Health Sciences Center

Appendix F: Electronic Data Policy Statement

Appendix G: Example Cayuse Proposal for Research Using Human Subjects

Appendix H: Required Elements of Consent

Appendix I: Reviewer Checklist for IRB Proposals

Appendix J: Recruiting Materials

Appendix K: Consent Form Instructions, Examples, Assent Form, and Waivers

Appendix L: IRB Approval Criteria for Prisoner Research

## Appendix A

### Nuremberg Code NUREMBERG CODE

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

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Reprinted from *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181-182...* Washington, D.C.: U.S. Government Printing Office, 1949.

## **Appendix B**

### **The Belmont Report**

#### **THE BELMONT REPORT**

#### **OFFICE OF THE SECRETARY**

#### **ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH**

#### **THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH**

**April 18, 1979**

**AGENCY:** Department of Health, Education, and Welfare.

**ACTION:** Notice of Report for Public Comment.

**SUMMARY:** On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: **(i)** the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, **(ii)** the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, **(iii)** appropriate guidelines for the selection of human subjects for participation in such research and **(iv)** the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees. The two-volume Appendix, containing the lengthy reports of experts and specialists who assisted the Commission in fulfilling this part of its charge, is available as DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy. The Department requests public comment on this recommendation.

National Commission for the Protection of Human Subjects  
of Biomedical and Behavioral Research

**Members of the Commission**

*Kenneth John Ryan, M.D., Chairman, Chief of Staff, Boston Hospital for Women.*

*Joseph V. Brady, Ph.D., Professor of Behavioral Biology, Johns Hopkins University.*

*Robert E. Cooke, M.D., President, Medical College of Pennsylvania.*

*Dorothy I. Height, President, National Council of Negro Women, Inc.*

*Albert R. Jonsen, Ph.D., Associate Professor of Bioethics, University of California at San Francisco.*

*Patricia King, J.D., Associate Professor of Law, Georgetown University Law Center.*

*Karen Lebacqz, Ph.D., Associate Professor of Christian Ethics, Pacific School of Religion.*

*\*\*\* David W. Louisell, J.D., Professor of Law, University of California at Berkeley.*

*Donald W. Seldin, M.D., Professor and Chairman, Department of Internal Medicine, University of Texas at Dallas.*

*\*\*\*Eliot Stellar, Ph.D., Provost of the University and Professor of Physiological Psychology, University of Pennsylvania.*

*\*\*\* Robert H. Turtle, LL.B., Attorney, VomBaur, Coburn, Simmons & Turtle, Washington, D.C.*

*\*\*\* Deceased.*



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## **Ethical Principles & Guidelines for Research Involving Human Subjects**

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes (1) intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

### **A. Boundaries Between Practice and Research**

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called “experimental” when the terms “experimental” and “research” are not carefully defined.

For the most part, the term “practice” refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals.(2) By contrast, the term “research” designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is “experimental,” in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal

research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.<sup>(3)</sup>

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

## **B. Basic Ethical Principles**

The expression “basic ethical principles” refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

**1. Respect for Persons.**—Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons’ considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person’s considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual’s life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On

the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to “volunteer” or to “protect” them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

**2. Beneficence.**—Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term “beneficence” is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

The Hippocratic maxim “do no harm” has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients “according to their best judgment.” Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children—even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

**3. Justice.**—Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of “fairness in distribution” or “what is deserved.” An injustice

occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19<sup>th</sup> and early 20<sup>th</sup> centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

### **C. Applications**

Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

**1. Informed Consent.**—Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the

consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

**Information.** Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of “the reasonable volunteer” should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that (1) incomplete disclosure is truly necessary to accomplish the goals of the research, (2) there are no undisclosed risks to subjects that are more than minimal, and (3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

**Comprehension.** The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject’s ability to make an informed choice.

Because the subject’s ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject’s capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provision may need to be made when comprehension is severely limited—for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disabled patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

**Voluntariness.** An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence—especially where possible sanctions are involved—urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

**2. Assessment of Risks and Benefits.**—The assessment of risks and benefits requires a careful array of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

**The Nature and Scope of Risks and Benefits.** The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term “risk” refers to a possibility that harm may occur. However, when expressions such as “small risk” or “high risk” are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term “benefit” is used in the research context to refer to something of positive value related to health or welfare. Unlike, “risk,” “benefit” is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects’ rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

**The Systematic Assessment of Risks and Benefits.** It is commonly said that benefits and risks must be “balanced” and shown to be “in a favorable ratio.” The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator’s estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations: **(i)** Brutal or inhumane treatment of human subjects is never morally justified. **(ii)** Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. **(iii)** When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject—or, in some rare cases, to the manifest voluntariness of the participation). **(iv)** When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and



level of the anticipated benefits. (v) Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

**3. Selection of Subjects.**—Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only “undesirable” persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

(1) Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the

1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

(2) Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (e.g., blood donation, skin grafts, organ transplants) or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (e.g., vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of practice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.

(3) Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be addressed by one of its successor bodies.

Appendix C

Code of Federal Regulations

TITLE 45  
PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46  
PROTECTION OF HUMAN SUBJECTS

[\[PDF 215 KB\]](#)

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Revised January 15, 2009  
Effective July 14, 2009

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**Basic HHS Policy for Protection of Human Research Subjects**

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**Subpart B -- Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research**

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<a href="#">46.203</a>	Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.
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<a href="#">46.205</a>	Research involving neonates.
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**Subpart C -- Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects**

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### **Sec.**

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**Authority:** 5 U.S.C. 301; 42 U.S.C. 289(a).

**Editorial Note:** The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost--sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.

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<b>Subpart A</b>	<b>Basic HHS Policy for Protection of Human Research Subjects</b>
	<b>Authority:</b> 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v-1(b).
	<b>Source:</b> <a href="#">56 FR 28012, 28022</a> , June 18, 1991, unless otherwise noted.

### **§46.101 To what does this policy apply?**

**(a) Except as provided in paragraph [\(b\)](#) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian**

employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in [§46.102\(e\)](#), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in [§46.102\(e\)](#) must be reviewed and approved, in compliance with [§46.101](#), [§46.102](#), and [§46.107](#) through [§46.117](#) of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

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

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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.

(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 paragraph [\(b\)\(2\)](#) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the 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 by the investigator 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 department or agency heads, and which are designed to study, evaluate, or

**otherwise examine:**

**(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.**

**(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.**

**(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.**

**(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.**

**(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.**

**(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.**

**(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.**

**(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.**

**(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes or research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward**

advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.<sup>1</sup>

<sup>1</sup> Institutions with HHS-approved assurances on file will abide by provisions of Title [45 CFR part 46](#) subparts [A-D](#). Some of the other departments and agencies have incorporated all provisions of Title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at [45 CFR 46.101\(b\)](#) do not apply to research involving prisoners, [subpart C](#). The exemption at [45 CFR 46.101\(b\)\(2\)](#), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, [subpart D](#), except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at [70 FR 36328](#), June 23, 2005]

#### §46.102 Definitions.

(a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).



**(f) *Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through intervention or interaction with the individual, or**
- (2) Identifiable private information.**

***Intervention*** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. ***Interaction*** includes communication or interpersonal contact between investigator and subject. ***Private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). **Private information** must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

**(g) *IRB*** means an institutional review board established in accord with and for the purposes expressed in this policy.

**(h) *IRB approval*** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

**(i) *Minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**(j) *Certification*** means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

**§46.103 Assuring compliance with this policy -- research conducted or supported by any Federal Department or Agency.**

**(a)** Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office.

**(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:**

**(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under [§46.101\(b\)](#) or [\(i\)](#).**

**(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.**

**(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with [§46.103\(a\)](#) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.**

**(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.**

**(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.**

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under [§46.101\(b\)](#) or [\(i\)](#). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by [§46.103](#) of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by [§46.103](#) of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

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[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§§46.104--46.106 [Reserved]

§46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote

respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

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

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

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

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

#### **§46.108 IRB functions and operations.**

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in [§46.103\(b\)\(4\)](#) and, to the extent required by, [§46.103\(b\)\(5\)](#).

(b) Except when an expedited review procedure is used (see [§46.110](#)), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting

#### **§46.109 IRB review of research.**

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with [§46.116](#). The IRB may require that information, in addition to that specifically mentioned in [§46.116](#), be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with [§46.117](#).

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

**§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.**

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a [list of categories](#) of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

- (1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
- (2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in [§46.108\(b\)](#).

**(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.**

**(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.**

**[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]**

**§46.111 Criteria for IRB approval of research.**

**(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:**

**(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.**

**(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.**

**(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.**

**(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [§46.116](#).**

**(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by [§46.117](#).**

**(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.**

**(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**

**(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.**

#### **§46.112 Review by institution.**

**Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.**

#### **§46.113 Suspension or termination of IRB approval of research.**

**An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.**

**(Approved by the Office of Management and Budget under Control Number 0990-0260.)**

**[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]**

#### **§46.114 Cooperative research.**

**Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.**

#### **§46.115 IRB records.**

**(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:**

- (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.**
- (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.**
- (3) Records of continuing review activities.**
- (4) Copies of all correspondence between the IRB and the investigators.**
- (5) A list of IRB members in the same detail as described in [§46.103\(b\)\(3\)](#).**

(6) Written procedures for the IRB in the same detail as described in [§46.103\(b\)\(4\)](#) and [§46.103\(b\)\(5\)](#).

(7) Statements of significant new findings provided to subjects, as required by [§46.116\(b\)\(5\)](#).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

#### **§46.116 General requirements for informed consent.**

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if



**injury occurs and, if so, what they consist of, or where further information may be obtained;**

**(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and**

**(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.**

**(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:**

**(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;**

**(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;**

**(3) Any additional costs to the subject that may result from participation in the research;**

**(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;**

**(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and**

**(6) The approximate number of subjects involved in the study.**

**(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:**

**(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and**

**(2) The research could not practicably be carried out without the waiver or alteration.**

**(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:**

**(1) The research involves no more than minimal risk to the subjects;**

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;  
(3) The research could not practicably be carried out without the waiver or alteration; and  
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

#### **§46.117 Documentation of informed consent.**

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by [§46.116](#). This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by [§46.116](#) have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or**
- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.**

**In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.**

**(Approved by the Office of Management and Budget under Control Number 0990-0260.)**

**[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]**

#### **§46.118 Applications and proposals lacking definite plans for involvement of human subjects.**

**Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under [§46.101\(b\)](#) or [\(i\)](#), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.**

#### **§46.119 Research undertaken without the intention of involving human subjects.**

**In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.**

#### **§46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.**

**(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the**

potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

**§46.121 [Reserved]**

**§46.122 Use of Federal funds.**

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

**§46.123 Early termination of research support: Evaluation of applications and proposals.**

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

**§46.124 Conditions.**

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

<b>Subpart B</b>	<b>Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research</b>
	Source: <a href="#">66 FR 56778</a> , Nov. 13, 2001, unless otherwise noted.

**§46.201 To what do these regulations apply?**

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable

neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.

(b) The exemptions at [§46.101\(b\)\(1\)](#) through [\(6\)](#) are applicable to this subpart.

(c) The provisions of [§46.101\(c\)](#) through [\(i\)](#) are applicable to this subpart. Reference to State or local laws in this subpart and in [§46.101\(f\)](#) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of [this part](#).

#### §46.202 Definitions.

The definitions in [§46.102](#) shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(c) Fetus means the product of conception from implantation until delivery.

(d) Neonate means a newborn.

(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.

(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of [subparts A and D](#) of [this part](#).

#### §46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of [this part](#).

**§46.204 Research involving pregnant women or fetuses.**

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

- (a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
- (b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- (c) Any risk is the least possible for achieving the objectives of the research;
- (d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of [subpart A](#) of this part;
- (e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of [subpart A](#) of [this part](#), except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- (f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- (g) For children as defined in [§46.402\(a\)](#) who are pregnant, assent and permission are obtained in accord with the provisions of [subpart D](#) of [this part](#);
- (h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- (i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- (j) Individuals engaged in the research will have no part in determining the viability of a neonate.

**§46.205 Research involving neonates.**

**(a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:**

- (1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.**
- (2) Each individual providing consent under paragraph [\(b\)\(2\)](#) or [\(c\)\(5\)](#) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.**
- (3) Individuals engaged in the research will have no part in determining the viability of a neonate.**
- (4) The requirements of paragraph [\(b\)](#) or [\(c\)](#) of this section have been met as applicable.**

**(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:**

**(1) The IRB determines that:**

- (i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or**
  - (ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and**
- (2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with [subpart A](#) of [this part](#), except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.**

**(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:**

- (1) Vital functions of the neonate will not be artificially maintained;**
- (2) The research will not terminate the heartbeat or respiration of the neonate;**
- (3) There will be no added risk to the neonate resulting from the research;**
- (4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and**
- (5) The legally effective informed consent of both parents of the neonate is obtained in accord with [subpart A](#) of [this part](#), except that the waiver and alteration provisions of [§46.116\(c\)](#) and [\(d\)](#) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent**

of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) **Viable neonates.** A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of [subparts A](#) and [D](#) of [this part](#).

**§46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.**

(a) **Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.**

(b) **If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of [this part](#) are applicable.**

**§46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.**

**The Secretary will conduct or fund research that the IRB does not believe meets the requirements of [§46.204](#) or [§46.205](#) only if:**

(a) **The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and**

(b) **The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has determined either:**

(1) **That the research in fact satisfies the conditions of [§46.204](#), as applicable; or**

(2) **The following:**

(i) **The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;**

(ii) **The research will be conducted in accord with sound ethical principles; and**

(iii) **Informed consent will be obtained in accord with the informed consent provisions of [subpart A](#) and other applicable subparts of [this part](#).**



<b>Subpart C</b>	<b>Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects</b>
	Source: <a href="#">43 FR 53655</a> , Nov. 16, 1978, unless otherwise noted.

**§46.301 Applicability.**

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of [this part](#).

**§46.302 Purpose.**

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

**§46.303 Definitions.**

As used in this subpart:

(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) *DHHS* means the Department of Health and Human Services.

(c) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) *Minimal risk* is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

**§46.304 Composition of Institutional Review Boards where prisoners are involved.**

In addition to satisfying the requirements in [§46.107](#) of [this part](#), an Institutional Review Board, carrying out responsibilities under [this part](#) with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

[43 FR 53655, Nov. 16, 1978, as amended at 46 FR 8366, Jan. 26, 1981]

**§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.**

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under [this part](#), the Board shall review research covered by this subpart and approve such research only if it finds that:

- (1) The research under review represents one of the categories of research permissible under [§46.306\(a\)\(2\)](#);
- (2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- (3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
- (4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- (5) The information is presented in language which is understandable to the subject population;
- (6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- (7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such

examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

#### **§46.306 Permitted research involving prisoners.**

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under [§46.305](#) of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

(b) Except as provided in [paragraph \(a\)](#) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

<b>Subpart D</b>	<b>Additional Protections for Children Involved as Subjects in Research</b>
	Source: <a href="#">48 FR 9818</a> , March 8, 1983, unless otherwise noted.

**§46.401 To what do these regulations apply?**

**(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.**

**(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.**

**(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under [paragraph \(e\)](#) of [§46.101](#) of [subpart A](#), waive the applicability of some or all of the requirements of these regulations for research of this type.**

**(b) Exemptions at [§46.101\(b\)\(1\)](#) and [\(b\)\(3\)](#) through [\(b\)\(6\)](#) are applicable to this subpart. The exemption at [§46.101\(b\)\(2\)](#) regarding educational tests is also applicable to this subpart. However, the exemption at [§46.101\(b\)\(2\)](#) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.**

**(c) The exceptions, additions, and provisions for waiver as they appear in [paragraphs \(c\)](#) through [\(i\)](#) of [§46.101](#) of [subpart A](#) are applicable to this subpart.**

[48 FR 9818, Mar.8, 1983; 56 FR 28032, June 18, 1991; 56 FR 29757, June 28, 1991.]

**§46.402 Definitions.**

The definitions in [§46.102](#) of [subpart A](#) shall be applicable to this subpart as well. In addition, as used in this subpart:

**(a) *Children* are 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.**

**(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.**

**(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.**

**(d) *Parent* means a child's biological or adoptive parent.**

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

**§46.403 IRB duties.**

In addition to other responsibilities assigned to IRBs under [this part](#), each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

**§46.404 Research not involving greater than minimal risk.**

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in [§46.408](#).

**§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.**

HHS will conduct or fund research in which the IRB finds that 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, only if the IRB finds that:

- (a) The risk is justified by the anticipated benefit to the subjects;
- (b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
- (c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in [§46.408](#).

**§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.**

HHS will conduct or fund research in which the IRB finds that 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, only if the IRB finds that:

- (a) The risk represents a minor increase over minimal risk;
- (b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in [§46.408](#).

**§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.**

**HHS will conduct or fund research that the IRB does not believe meets the requirements of [§46.404](#), [§46.405](#), or [§46.406](#) only if:**

(a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) that the research in fact satisfies the conditions of [§46.404](#), [§46.405](#), or [§46.406](#), as applicable, or (2) the following:

- (i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- (ii) the research will be conducted in accordance with sound ethical principles;
- (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in [§46.408](#).

**§46.408 Requirements for permission by parents or guardians and for assent by children.**

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with [§46.116](#) of [Subpart A](#).

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by [§46.116](#) of [Subpart A](#), that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under [§46.404](#) or [§46.405](#). Where research is covered by [§§46.406](#) and [46.407](#) and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in [§46.116](#) of [subpart A](#), if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in [Subpart A](#) of [this part](#) and [paragraph \(b\)](#) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by [§46.117](#) of [subpart A](#).

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

#### **§46.409 Wards.**

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under [§46.406](#) or [§46.407](#) only if such research is:

- (1) Related to their status as wards; or
- (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under [paragraph \(a\)](#) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

<b>Subpart E</b>	<b>Registration of Institutional Review Boards</b>
	<b>Source:</b> 74 FR 2399, January 15, 2009, unless otherwise noted.

#### **§46.501 What IRBs must be registered?**

Each IRB that is designated by an institution under an assurance of compliance approved for federalwide use by the Office for Human Research Protections (OHRP) under [§46.103\(a\)](#) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

#### **§46.502 What information must be provided when registering an IRB?**

The following information must be provided to HHS when registering an IRB:

(a) The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:

(i) All active protocols; and

(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an "active protocol" is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

#### **§46.503 When must an IRB be registered?**

An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under [§46.103\(a\)](#).



**IRB registration becomes effective when reviewed and accepted by OHRP.**

**The registration will be effective for 3 years.**

**§46.504 How must an IRB be registered?**

**Each IRB must be registered electronically through <http://ohrp.cit.nih.gov/efile> unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.**

**§46.505 When must IRB registration information be renewed or updated?**

**(a) Each IRB must renew its registration every 3 years.**

**(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with [§46.504](#).**

**(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.**

**(d) An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.**

## Appendix D

63 FR 60364-60367, November 9, 1998

Dept. of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks

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### Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure\*

63 FR 60364-60367, November 9, 1998

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#### Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability. Nor may it be damaging to the subjects 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 not greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

#### Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) 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.)

(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.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, 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; or
- (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 frequently with which it will be collected. For these subjects, 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.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

***Examples:***

(a) hair and nail clippings in a nondisfiguring 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); (3) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase 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 routing 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.

(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 subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data documents, records, or specimens\_ that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

- (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: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
- (8) Continuing review of research previously approved by the convened IRB as follows:
- (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed research-related interventions; and (iii) the research remains active only for 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.
- (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.

\*An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

\*\* Children are defined in the HHS regulations 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.” 45 CFR 46.402(a).

## Appendix E

# MEMORANDUM OF UNDERSTANDING TEXAS TECH UNIVERSITY INSTITUTIONAL REVIEW BOARD and TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER INSTITUTIONAL REVIEW BOARDS

The mission of both Texas Tech University (TTU) and Texas Tech University Health Sciences Center (TTUHSC) includes conducting research with human subjects in compliance with applicable laws and regulations, such as U.S. Department of Health and Human Services (DHHS) regulations. Both institutions have signed an Assurance with DHHS (TTU Federalwide Assurance # 1568; TTUHSC Federalwide Assurance #6767). Each institution utilizes Institutional Review Boards (IRBs) to assist in protecting the rights and welfare of human subjects participating in research activities conducted at TTU, TTUHSC or their affiliated entities.

Human subjects research must be conducted in accordance with established ethical principles. The research, research staff, the subjects who choose to participate in research, and members of each institution's human research protection programs also share this responsibility.

This Memorandum describes the responsibilities, guidelines and processes which will permit one institution to rely on the other's IRB for initial review and continuing oversight of human subjects research. These can include collaborative efforts between TTU and TTUHSC (a) faculty and/or (b) which use the facilities or (c) study population of one institution by investigators from the other institution. The processes outlined in this Memorandum should serve to eliminate duplicate reviews of the same research project while ensuring that each proposal is reviewed in accordance with federal regulations and applicable institutional policies.

### **Guidelines for Determining the Appropriate IRB:**

#### **1. Collaborating Principal Investigators from TTU and TTUHSC.**

For purposes of this Memorandum of Understanding, collaborative research between TTU and TTUHSC will involve at least one investigator from each institution who meets the employing institution's criteria to serve as a Principal Investigator for research involving human subjects (see TTUHSC OP 73.08 and TTU OP 74.09).

Determination of the appropriate IRB review for research involving collaborating investigators from TTU and TTUHSC will be based primarily on the subject population:

- a) Collaborative research conducted using healthy volunteers or persons who are receiving ongoing treatment only at the TTU Burkhart Center, Counseling Center, Psychology Clinic, Marriage and the Family Clinic, or other places where services are provided at TTU will generally be reviewed by the TTU IRB.
- b) Collaborative research conducted using volunteers with a diagnosed medical condition (requiring the use of medical records of TTUHSC, University Medical Center or another

TTUHSC-affiliated institution to determine eligibility or treatment outcomes) will generally be reviewed by the TTUHSC IRB.

- c) Collaborative research conducted at the Montford Psychiatric Unit will be reviewed by the TTUHSC IRB.
- d) Collaborative research conducted at prison units other than the Montford Unit will be reviewed by the TTUHSC IRB if medical records are necessary for the research. If access to medical records is not required, the project will be reviewed by the TTU IRB.
- e) Collaborative research involving the use of the Texas Tech Neuroimaging Institute (TTNI) equipment or facilities will be reviewed by the TTU IRB.
- f) When necessary research office administrators, with input from the chairs of the TTU and TTUHSC IRBs, will reach a consensus on which IRB is more appropriate for the review of the project and will notify the investigator(s) once the decision has been made.

## **2. Non-collaborating Principal Investigators using population, facilities, or protected private information of the other institution.**

When a Principal Investigator from one institution wishes to conduct research using a subject population, facilities, or private information associated with the other institution (for example, a TTU Psychology faculty member conducting research on diabetic patients seen in a TTUHSC clinic, or a TTUHSC faculty member conducting research on TTU undergraduates' exercise habits) the project will typically be submitted to and reviewed by the IRB of the Principal Investigator's institution.

Exceptions may include the following:

- a) Projects requiring access to medical records belonging to TTUHSC, University Medical Center, or another covered entity affiliated with TTUHSC, will be reviewed by a TTUHSC IRB.
- b) Projects taking place at the Montford Psychiatric Prison Unit will be reviewed by the TTUHSC IRB. Projects taking place at other prison units will be reviewed by the IRB of the Principal Investigator.
- c) Projects taking place at the Texas Tech Neuroimaging Institute and/or utilizing fMRI technology overseen by TTU will be reviewed by the TTU IRB.
- d) The research office administrators, with input from the chairs of the TTU and TTUHSC IRBs, will reach a consensus on which IRB is more appropriate for the review of the project and will notify the investigator(s) once the decision has been made.

### **Review processes:**

1. Once the designated IRB for a particular project has been determined, the investigator and study staff will follow training, submission and review processes of that institution's IRB.

2. If there are significant concerns about a particular project, the designated IRB may request that a non-voting representative from the other institution's IRB serve as a consultant during the review process. The reviewing IRB's written procedures regarding consultants will be followed.
3. The designated IRB's decision to approve, require modifications, or disapprove a research proposal will be honored by the other institution's IRB. Investigators may not submit an identical proposal to the other institution's IRB if the proposal was not approved by the IRB to which it was originally submitted. Exceptions may be considered based upon discussion between research office administrators and the chairs of the TTU and TTUHSC IRBs.
4. The designated IRB will be responsible for continuing reviews, amendments, and any required reporting for the duration of the research project.
5. The designated IRB has primary responsibility for compliance monitoring of ongoing projects. However, compliance personnel from either institution will be permitted access to research records in order to confirm that projects are being conducted in accordance with the protocol using applicable policies and regulations.
6. The designated IRB will inform IRB office staff at the other institution's IRB of decisions regarding the collaborative research project. When possible, the non-designated IRB should be informed prior to final decisions regarding suspension or termination of a collaborative research project.

**Additional Considerations:**

1. Each institution will maintain its Federalwide Assurance during the term of this agreement. If either Assurance is suspended or terminated, the other institution shall be notified within 30 days resulting in immediate termination of this Memorandum of Understanding.
2. This agreement may be modified or amended only if such amendment is made in writing and signed by both parties.

**TEXAS TECH UNIVERSITY  
HEALTH SCIENCES CENTER**

**TEXAS TECH UNIVERSITY**

\_\_\_\_\_  
[On Record]  
Signature  
P. Michael Conn, PhD  
Senior Vice President for Research  
Associate Provost

\_\_\_\_\_  
[On Record]  
Signature  
Robert V. Duncan, PhD  
Senior Vice President for Research

Date: March 2015

Date: March 2015

## Appendix F

### Texas Tech University Institutional Review Board Electronic Data Policy Statement October 2007

Many research projects involve the use of surveys. Over the past few years, the use of online survey software has become increasingly popular. Unlike paper-based surveys, wherein the PI maintains control of collected data, both the survey and the data may be collected and stored elsewhere. Thus, online surveys require the PI to consider several factors regarding the host computer. By this we mean the computer that stores questions and responses to those questions. The following guidelines should assist PIs in their choice of a host server.

There are three possible places the questions can be hosted. (1) a TTU IT-hosted server, that is a server hosted by the TTU IT department; (2) a TTU non-IT hosted server, such as a personal or departmental server, and (3) a private survey hosting provider such as SurveyMonkey, InstantSurvey, or Zoomerang. In all cases, security is important, but in particular, when a PI is collecting data over the Internet from a private provider (SurveyMonkey, Google, Yahoo, etc...), he or she is out-sourcing the dissemination, collection, and storage of participant responses to a non-TTU entity. Therefore, the PI must take steps to ensure participant responses are treated in a professional and ethical manner. Moreover, the PI must demonstrate to the IRB reviewer that the responses to the survey will be handled by all in a responsible and secure manner. People included in this proviso are the administrator of the server, and all the other people who may have access to the server (e.g., other administrators and other users of the server that routes your messages.)

Here are specific steps that the IRB recommends.

- 1) Review the data you are collecting.  
Are participant responses of a sensitive nature? Sensitive information includes, but is not limited to, social security numbers, religious affiliation, sexual preference, information about criminal behavior, political affiliation, and any socially deviant behavior. It may also include information that allows others to gain access to details of participant responses. Some examples of the later include data, such as name, address, mother's maiden name, passwords, telephone numbers, email addresses, which could provide other individuals with the necessary information to contact participants without their prior consent. Note that the IRB will not require strict security measures for non-sensitive data.
- 2) If the data are sensitive, then you need to offer evidence to the IRB that:
  - a. Data are encrypted when transferred across the Internet (e.g. SSL);
  - b. Data are stored on the survey host equipment in an encrypted form;
  - c. People who have access to the decryption algorithm will not use the data to harass (e.g., marketing), steal from, embarrass or contact participants in anyway. In other words, you need to prove that the host has strong security measures and guidelines for all employees that can access data; and Any server hosting sensitive TTU data must comply with the following:



- i. Data storage, transfer, and collection must be in compliance with Texas Tech University (TTU) IT Security Policies (copies available upon request), FERPA standards, and other privacy laws pertaining to higher education;
- ii. Electronic access to all services must be restricted to authorized users, as outlined in the TTU IT Security Policies. Authentication of users must be accomplished through Texas Tech University's official authentication protocol;
- iii. Web based interfaces used in the delivery of services must comply with all applicable federal laws and state statutes, to include, but not limited to:
  1. Texas Administrative Code Title 1, Part 10  
([http://info.sos.state.tx.us/pls/pub/readtac\\$ext.ViewTAC?tac\\_view=3&ti=1&pt=10](http://info.sos.state.tx.us/pls/pub/readtac$ext.ViewTAC?tac_view=3&ti=1&pt=10))
  2. Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d) for accessibility by disable persons  
(<http://www.section508.gov/>)

If you use a TTU IT-hosted server, the systems and policies are already fully compliant with the required criteria. To host a survey or data on a TTU IT-hosted server, you can contact Technology Operations and System Management (TOSM) at 2-2900 or the TTU Office of the CIO at 2-5156. Thus, all that is required is that you name the server being used and certify that it is TTU IT hosted.

For those TTU non-IT hosted servers, college administrators will be aware of these requirements and can provide documentation that satisfies these criteria. If you use a non-TTU server, then the burden of proof and liability is on the investigator.

If you elect to use a TTU-hosted server, you have the following resources to create Internet-based surveys:

- Your college or division technologists;
- You can create your own survey (Technology Support offers training, the Teaching, Learning, and Technology Center offers consulting, the TTU IT Division has a site license for products you can use to create the survey, such as FrontPage and Dreamweaver); and
- For larger scope projects, Institutional Research and Information Management (IRIM) may be of assistance.

Finally, please keep in mind that if you provide an email list of people to send the survey to, you are automatically collecting sensitive information. Moreover, many servers send a unique URL via email to insure that the same person does not fill out the survey twice. This means you can link the records to particular respondents, and hence are not maintaining anonymity.

# Appendix G

## Example Cayuse Proposal for Research Using Human Subjects

The screenshot displays the Cayuse IRB submission interface. The browser address bar shows the URL: <https://ttu-uat.cayuse424.com/rs/irb/#submission/edit/91487/section/0>. The user is logged in as Irene Irbdirector. The main header shows the IRB NUMBER: IRB2016-240 and the STUDY title: TTest - Initial. A navigation menu on the left lists sections from IS1 to IS18, all marked with green checkmarks. The main content area is titled 'IS1 - Review Type' and contains a form for selecting a review type. The form includes radio buttons for 'Exempt', 'Expedited', and 'Full Board'. The 'Exempt' option is selected. Below the form, a comment from Irene Irbdirector is visible, dated 12-09-2016 11:12 AM, with a visibility of 'Restricted'. The comment text reads: 'If you are unsure of which review type to select contact the HRPP office at 806-742-2064 or hrpp@ttu.edu.' Below the comment is a rich text editor with a toolbar and a text input field. A 'SAVE COMMENT' button is located below the editor. The bottom of the page shows the start of section '1.2 External Research'.

Human Research Protect: X Welcome - Evisions Res: X IRB - Submission - TTest: X

Secure | https://ttu-uat.cayuse424.com/rs/irb/#submission/edit/91487/section/0

IRB 371 Irene Irbdirector

STUDY | IRB NUMBER: IRB2016-240 **TTest - Initial** SHOW CHECKLIST CREATE PDF COMPARE SAVE

**Sections**

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9- Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Confi... ✓
- IS14 - Benefits, Risk... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

Exempt  
Project involves no more than minimal risk. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Expedited  
 Full Board

**Collapse Comments**

**Irene Irbdirector** 12-09-2016 11:12 AM Visibility: Restricted  
If you are unsure of which review type to select contact the HRPP office at 806-742-2064 or hrpp@ttu.edu.  
[Edit](#) [Reply](#)

**B I U** [Rich Text Editor]

SAVE COMMENT

**1.2 External Research** ?

Collaboration  
 International research

**Collapse Comments**

**Irene Irbdirector** 12-08-2016 1:28 PM Visibility: Restricted  
Select collaboration if the research team is working with investigators outside of Texas Tech University. Internal investigators are TTU faculty, staff, graduate and undergraduate students.

Human Research Prote... Welcome - Evisions Res... IRB - Submission - TTest

Secure https://ttu-uat.cayuse424.com/rs/irb/#submission/edit/91487/section/1

Irene Irbdirector

IRB NUMBER: IRB2016-240  
TTest - Initial

SHOW CHECKLIST CREATE PDF COMPARE SAVE

Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9 - Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Confi... ✓
- IS14 - Benefits, Risk... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

## IS2 - Research Team

\* 2.1 Principal Investigator: Check the appropriate box below.

Name	Organization	Address	Phone	Email
Casside Street	CASNR, Dean Ofc	2500 Broadway MS2123, Lubbock, TX 79409	806834...	demo.proposals.vpr@ttu.edu

Collapse Comments

**Irene Irbdirector** 12-09-2016 11:40 AM Visibility: Restricted

Cayuse IRB assigns the PI role to the person who creates the initial submission. To change the PI on the study follow these steps.

- Add your name as a Co-Investigator in section 2.3.
- CLICK SAVE
- Then add other co-investigators and complete the rest of section 2.3.
- CLICK SAVE
- Remove your name from the PI list in section 2.1.
- Add PI information to section 2.1.
- CLICK SAVE

(These steps must be done in this order to avoid locking everyone out of your study.)

[Edit](#) [Reply](#)

**B I U** [List] [List] [Link] [Image]

Human Research Prote... Welcome - Evisions Res... IRB - Submission - TTest

Secure | https://ttu-uat.cayuse424.com/rs/irb/#submission/edit/91487/section/1

Irene Irbdirector

IRB NUMBER: IRB2016-240

TTest - Initial

SHOW CHECKLIST CREATE PDF COMPARE SAVE

Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9 - Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Confi... ✓
- IS14 - Benefits, Risk... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

SAVE COMMENT

- TTU full-time or tenured faculty member
  TTU full-time employee with a terminal degree in their discipline
   
 + Add Comment
- College
   

  
 + Add Comment
- Department
   

  
 + Add Comment

\* 2.2 Primary Contact

The primary contact will receive all notifications and letters.

Name	Organization	Address	Phone	Email
Troy Tarpley	Ag Education and Communication	, Lubbock, TX 79409-1035		demo.proposals.vpr@ttu.edu

+ Add Comment

\* 2.3 Co-Investiators: Check all that apply.

Human Research Prote... Welcome - Evisions Res... IRB - Submission - TTest

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IRB NUMBER: IRB2016-240  
**TTest - Initial**

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Irene Irbdirector

Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9 - Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Confi... ✓
- IS14 - Benefits, Risk... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

2.3 Co-Investigators: Check all that apply.

None

List TTU Faculty or Staff Co-Investigator(s): Multiple names are allowed.

Name	Organization	Address	Phone	Email
Rudolph Ritz	Ag Education and Communication	2500 Broadway MS2131, Lubbock, TX 79409	8067422...	demo.proposals.vpr@ttu.edu

+ Add Comment

List TTU Graduate or Undergraduate Co-Investigator(s): Multiple names are allowed.

Graduate Student(s)

Click to enter the name of the Graduate Student(s).

Name	Organization	Address	Phone	Email
Troy Tarpley	Ag Education and Communication	. Lubbock, TX 79409-1035		demo.proposals.vpr@ttu.edu

+ Add Comment

Undergraduate Student(s)

+ Add Comment

The purpose of this study:

- Doctoral Dissertation
- Masters Thesis
- Undergraduate Research
- Classroom Assignment
- Students are members of the research team
- Other

+ Add Comment

External researchers: Co-investigators outside of Texas Tech University.

International Researchers:

+ Add Comment

Human Research Prote... Welcome - Evisions Res... IRB - Submission - TTest

Secure | https://ttu-uat.cayuse424.com/rs/irb/#submission/edit/91487/section/2

IRB NUMBER: IRB2016-240  
TTest - Initial

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Irene Irbdirector

Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9 - Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Conf... ✓
- IS14 - Benefits, Risk, ... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

### IS3 - Funding

3.1 Funding

Yes  
NOTE: TTU researchers who serve as Principal Investigators or Key Personnel on applications to the National Institutes of Health (NIH) must complete human subjects protection training. Completion of the NIH or CITI training courses fulfills the NIH education requirement for research with human subjects.

No  
NOTE: If the research study becomes funded through a sponsored project at a later time, a modification will be required in order to match the study to the sponsored project.

TTU IRB Policy 4.2 - "When research involving external funding involves work with human subjects, funding from federal and some private sources cannot be expended until an IRB proposal has been approved (see 45 CFR 46.122). The Office of Human Research Protections has noted (May 31, 2000) that some agencies require IRB review before a project can be funded. Regulations require that the IRB review the grant application or proposal to be certain that the grant and the IRB proposals are in agreement. The IRB must have a complete copy of the grant proposal for this purpose and for records."

+ Add Comment

3.2 Future Funding

If there is a possibility of future funding, enter the potential sponsor(s) name below.

Collapse Comments

Irene Irbdirector 12-09-2016 1:38 PM Visibility: Restricted  
Identify if this project is funded internally or externally.  
If the research is on file with Office of Research Services provide the sponsored project number and title.  
[Edit](#) [Reply](#)

Irene Irbdirector 12-09-2016 10:15 AM Visibility: Restricted  
If the participants will receive payment select yes to funding and clarify where the money is coming from.  
[Edit](#) [Reply](#)

**B** *I* U

Human Research Protections | Welcome - Evisions Res... | IRB - Submission - TTest

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IRB NUMBER: IRB2016-240  
TTest - Initial

SHOW CHECKLIST | CREATE PDF | COMPARE | SAVE

Irene Irbdirector

Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9- Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Conf... ✓
- IS14 - Benefits, Risk, ... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

## IS4 - Exempt Review

### 4.1 Claim for Exemption

**BASIS OF CLAIM FOR EXEMPTION.** Federal regulations and/or University policy require that in order for research to be exempt from review at least one of the following blocks (1-4) must be checked. See 45 CFR 46.101.

**Note:** Limitations for exemptions for children: Exemptions cannot be granted for:  
 (a) projects with children as subjects that involve interview or survey procedures, or  
 (b) research where public behavior is observed and the investigator participates or interacts.

Project involves no more than minimal risk. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- 1. The research will be conducted only in established or commonly accepted educational settings (like classrooms) AND It involves normal educational practices such as research on regular and special educational instructional strategies, or research on the effectiveness of, or the comparison among, instructional techniques, curricula or classroom management methods.
- 2. The research involves the use of only educational tests, survey or interview procedures, observations of public behavior.
  - Check the applicable technique(s):
    - a. Educational tests (cognitive, diagnostic, aptitude, achievement), or
    - b. Survey or interview procedures, or
    - c. Observation of public behavior of subjects.
  - Add Comment
  - AND
    - aa. The information obtained will be recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects, or
    - bb. If any disclosure of the subjects' responses outside the research could not reasonably place the subject at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation (e.g., information regarding illegal or immoral conduct, drug or alcohol use, sexual behavior, mental illness, or other possibly personally embarrassing subjects), or
    - cc. The subjects are elected officials or candidates for public office.
  - Add Comment
- 3. The research is limited to the collection or study of existing data, documents, records, pathological or diagnostic specimens under specific conditions;
- 4. Taste and food quality evaluation and consumer acceptance studies if,
- 5. Another provision of 45 CFR 46.101(2)

• Add Comment



Human Research Prote... Welcome - Evisions Res... IRB - Submission - TTest

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Irene Irbdirector

IRB NUMBER: IRB2016-240  
**TTest - Initial**

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Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9- Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Confi... ✓
- IS14 - Benefits, Risk... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

### IS7 - Rationale

7.1 State the objective of the research study and summarize relevant background knowledge.

The majority of college students own a cell phone (Smith, 2016). Students use their smartphones during class time to text, check social media, participate in classroom discussion and activities (Davis, 2014). College professors are incorporating smartphone technology as another teaching method. This study will look at the students' smartphone usage and activities during a learning environment.

Collapse Comments

**Irene Irbdirector** 12-09-2016 9:24 AM Visibility: Restricted

Provide a brief overview of the research involved. This allows the reviewers to gain knowledge in your discipline area, an area they may not be familiar with and outside of their discipline.

Edit Reply

B I U

SAVE COMMENT

7.2 What is the research question or questions to be addressed?

Human Research Protect... Welcome - Evisions Res... IRB - Submission - TTest

Secure | https://ttu-uat.cayuse424.com/rs/irb/#submission/edit/91487/section/6

IRB NUMBER: IRB2016-240  
**TTest - Initial**

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Irene Irbdirector

Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9- Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Confi... ✓
- IS14 - Benefits, Risk... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

7.2 What is the research question or questions to be addressed?

The study is designed to survey students daily cell phone habits to better understand their daily usage while in a classroom environment.  
How often do students use their phone in class?  
What apps do they use on their phone during class?  
Do students find their phones as a resource or a distraction in class?

+ Add Comment

7.3 Research design (i.e., quantitative/qualitative, mixed methods, multi-phase, etc.).

This is a quantitative research design focusing on a survey targeted towards the 5,000 Texas Tech University students.

+ Add Comment

7.4 Importance of the knowledge to be obtained as a result of this research.

The research will assist with creating teaching methods that incorporate a college students' smartphone into the learning environment.

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Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9- Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Confi... ✓
- IS14 - Benefits, Risk... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

7.4 Importance of the knowledge to be obtained as a result of this research.

The research will assist with creating teaching methods that incorporate a college students' smartphone into the learning environment.

+ Add Comment

7.5 Enter or attach the citation references from question 7.1.

Smith, J. (2016). Smartphones: A survey on how many students have them!. *Journal of Cellphone Research*, 55, 893-896.

Davis, S. (2014). Smartphone technology in the classroom. *Journal of Cellphone Research*, 43, 548-552.

+ Add Comment

Attach (if applicable)

+ Add Comment

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7.5 Enter or attach the citation references from question 7.1.

Smith, J. (2016). Smartphones: A survey on how many students have them!. *Journal of Cellphone Research*, 55, 893-896.

Davis, S. (2014). Smartphone technology in the classroom. *Journal of Cellphone Research*, 43, 548-552.

+ Add Comment

Attach (if applicable)

+ Add Comment

+ 7.6 Does this study involve approval by the Food & Drug Administration (FDA)?

Yes

No

+ Add Comment

+ 7.7 Is this research study a clinical trial?

Yes

No

+ Add Comment

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### IS8 - Human Subjects

8.1 Is there any relationship between the researcher(s) and the proposed target population?

Yes  
 No  
 + Add Comment

8.2 Define the target population.

Check where applicable.

Gender

- All genders allowed
- Male
- Female
- Other

+ Add Comment

Age Range

- Adult
- Enter the age range

18-30

+ Add Comment

Explain why the research specifically targets this group(s).

College students enrolled at Texas Tech University.

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Children

+ Add Comment

- Nationality, Ethnicity or Religion (if applicable)
- Non-English Speaking Subjects (if applicable)
- Vulnerable Populations (if applicable)  
*Federal regulations require additional protection for research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. (45 CFR 46 Subparts B, C, & D)*
- Other (if applicable)

+ Add Comment

+ 8.3 Describe the population of human subjects to be recruited. (e.g., college administrators, journalists, volunteers from local programs, etc.).

Texas Tech students who are 18-30 years of age.

+ Add Comment

+ 8.4 Number of subjects

5,000

+ Add Comment

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- IS18 - Comments ✓

8.5 Enter or attach any other criteria not mentioned above that would otherwise include or exclude certain subjects from participating in this research.

N/A

+ Add Comment

Inclusion/Exclusion Screening Form (if applicable)

+ Add Comment

8.6 End of Subject Participation

Describe the process as to how a subject may withdraw from the study if they no longer want to participate.

The survey informs all participants that they do not have to take or complete the survey. It also informs them that they may exit the survey at anytime. If a participant decides to withdraw from the study, they will simply close their internet browser.

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8.7 What specific criteria will be used to prematurely end a subject's participation in the study?

The survey will immediately end the survey if the participant does not agree to take the study or self-identifies as being outside the target age range (18-30).

+ Add Comment

8.8 If a subject withdraws from the research, what is the plan to use, disclose, store or destroy the subject's data and/or specimens?

If a subject withdraws their data would likely be removed as it would be incomplete. I would not be able to remove a specific individual's data from the collected data, though, as data collection will happen anonymously.

+ Add Comment



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## IS9- Recruitment Procedures and Documentation

9.1 Recruitment Procedures

How will subjects be recruited (e.g., by email, oral presentation, advertising, etc.)?  
<http://www.depts.ttu.edu/vpr/irb/forms.php>

This study will use Tech Announce to recruit participants.

+ Add Comment

9.2 Recruiting Tools and Documentation

Check all recruitment tools that apply.

- No Recruiting Documents
- Oral Script
- Tech Announce

Enter or attach the TechAnnounce ad.

**Heading:** Current Students Wanted for Cellphone Study!!!

**Body:** We are looking for college students to take a short survey on your daily smartphone usage. Please follow the link below to get to the study. You must be a current Texas Tech student between 18-30 years of age to participate in this study.

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- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

9.2 Recruiting Tools and Documentation

Check all recruitment tools that apply.

- No Recruiting Documents
- Oral Script
- Tech Announcement
 

Enter or attach the TechAnnounce ad.

**Heading:** Current Students Wanted for Cellphone Study!!!

**Body:** We are looking for college students to take a short survey on your daily smartphone usage. Please follow the link below to get to the study. You must be a current Texas Tech student between 18-30 years of age to participate in this study.

**Study Link:** [www.onlineneccellphonestudy.ttu.edu](http://www.onlineneccellphonestudy.ttu.edu)

+ Add Comment

Attach (if applicable).

TechAnnounce Post.pdf | ✕

Information Sheet.pdf | ✕

+ Add Comment

- Recruiting Letters or Email(s)
- Information Sheet
  - Explain when and how the Information Sheet will be provided to subjects.

This information sheet will be on the landing page for the online survey.

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+ Add Comment

Enter or attach the information sheet.

**Attachment B – Information Sheet**

**What is this project studying?**  
 The study is designed to survey students' daily cell phone habits to better understand their daily usage while in a classroom environment.

**What would I do if I participate?**  
 In this study, you will be asked to complete a survey. Some questions will be about you. Some questions will be about your thoughts on campus cell phone policies.

**Can I quit if I become uncomfortable?**  
 Yes, absolutely. Your participation is completely voluntary. Dr. Street and the Institutional Review Board have reviewed the questions and think you can answer them comfortably. You may skip any question you do not feel comfortable answering. You can also stop answering questions at any time. You are free to leave any time you wish. You can keep all the benefits of participating even if you stop. Participating is your choice. However, we do appreciate any help you are able to provide.

**How long will participation take?**  
 We are asking for 30 minutes of your time.

**How are you protecting privacy?**  
 The questionnaires will not request any personal information to protect your privacy.

**How will I benefit from participating?**  
 By researching college students' daily smartphone habits, we will be more informed when making cell phone regulations for class rooms' usage.

**I have some questions about this study. Who can I ask?**

- The study is being conducted by Dr. Street from the Department of Agricultural Education and Communications at Texas Tech University. If you have questions, you can call her at 806-742-2064
- TTU also has a Board that protects the rights of people who participate in research. You can call to ask them questions at 806-742-2064. You can mail your questions to the Human Research Protection Program, Office of the Vice President for Research, Texas Tech University, Lubbock, Texas 79409, or you can email your questions to hrpp@ttu.edu.

+ Add Comment

Attach (if applicable).

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- IS16 - Training ✓
- IS17 - Additional Inf... ✓
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you can email your questions to hrpp@ttu.edu.

+ Add Comment

Attach (if applicable).

IRB2016-240 Information She- x

+ Add Comment

- Fliers
- Newspaper or Magazine Advertisements
- Subject or Participant Pools
- Social Media (i.e., personal Facebook, Twitter, etc.)
- Website
- Other

+ Add Comment

9.3 Third Party Recruitment (other than Social Media or Websites)

Will another party besides the research team be responsible for recruiting (MTurk, SSI, snowballing, etc.)?

Yes

No

+ Add Comment

9.4 Is this research study being conducted in a setting that requires prior permission from an entity to conduct research on their premises (i.e., school system, business, government entity, etc.).

Yes

No

+ Add Comment

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## IS10 - Data Collection Procedures & Documentation

10.1 Provide a brief summary of the data collection procedures.

Participants will complete the survey online..

Recruited participants from TechAnnounce will complete a 30 minute Qualtrics survey over their daily cellphone usage. The survey consists of 26 questions and participants can exit the study at anytime. The first page of the survey will feature the information sheet. After that, participants will answer some questions about demographics and their cell phone usage.

+ Add Comment

+ 10.2 Check all that apply.

- Surveys
  - Online
 

What entity is hosting the survey?

    - TTU REDCap
    - Qualtrics
    - Survey Monkey
    - Other
  - On-Site
  - Mailing
  - Other

+ Add Comment

Enter or attach the survey(s) questions or a list of survey items.

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- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

Other

On-Site  
Mailing  
Other

+ Add Comment

Enter or attach the survey(s) questions or a list of survey items.  
If multiple surveys are used, enter/attach them in the order they will be administered and label them separately.

Survey questionnaire attached.

+ Add Comment

Attach (if applicable).

Study Survey.pdf

+ Add Comment

- Interviews
- Focus Groups
- Observation
- Non-Invasive Procedures (MRI, X-Rays, etc.)
- Invasive Medical Procedures (Blood draws, skin pricks, biopsies, etc.)
- Other

+ Add Comment

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- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

## IS12 - Participant Compensation

12.1 Compensation - Payments to Research Participants

Are subjects being compensated for their participation in this study?

Yes  
 No

Collapse Comments

**Irene Irbdirector** 12-09-2016 10:55 AM Visibility: Restricted  
 If you select yes then you will need to complete section 3.  
[Edit](#) [Reply](#)

**B I U** [Icons]

SAVE COMMENT

12.2 Compensation through TTU funds must comply with TTU OP 62.25  
<http://www.depts.ttu.edu/opmanual/OP62.25.pdf>

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- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

### IS13 - Privacy, Confidentiality & Security

+ 13.1 Personal Identifiers

Check all identifiers that will be collected during the study even if not matched with data.

- Names
- Telephone numbers
- Any elements of dates (other than year) for dates directly related to an individual, birth date, admission date, discharge date, date of death. For ages over 89 all elements of dates (including year) indicative of such age, expect that ages and elements may be aggregated into a single category of age 90 and older
- Any geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code and their equivalent geocodes except for the initial three digits of a zip code.
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers (VIN), including license tag identification
- Device identifiers and serial numbers (e.g., implanted medical device)
- Web universal resource locators (URLs)
- Internet protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images (i.e., videos, etc.)
- Biological specimens
- Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher
- No personal identifiers will be collected.

+ Add Comment

13.2 How is the privacy of the subject protected?

No personal identifiers will be collected at any point during the survey. Also, data collected by the survey system will be downloaded to a password protect computer that is only accessible by the researchers involved with this study.



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13.2 How is the privacy of the subject protected?

No personal identifiers will be collected at any point during the survey. Also, data collected by the survey system will be downloaded to a password protect computer that is only accessible by the researchers involved with this study.

+ Add Comment

13.3 Data Security - Access Control

Who will have access to the research data?

Only researchers within this study.

+ Add Comment

How will the researchers protect the data from unauthorized access?

- Encryption software
- Password Protection
- Physical Barriers (locked doors, file cabinets, etc.)
  - + Explain.

First, the data will stored on a password protected computer located in Administration building within room 357. Only the researchers related to this project have a key to this location and the passwords to access the data.

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+ 13.4 Data Security - Storage

Where will the data be stored?

Electronic Storage

Check all that apply.

- TTU Secured Server
- TTU Computer (PI or Research Team)
- 3rd Party Entity (Qualtrics, Survey Monkey, etc.)

Is this system approved by TTU IT and adheres to TTU IT security policies?  
<http://www.depts.ttu.edu/infotech/security/docs/in...>

Yes  
 No

+ Add Comment

- External Storage (external drive, flash drive, etc.)
- Use of computers or other technology/equipment not associated with Texas Tech University or Texas Tech University IT review (i.e., personally owned computers, 3rd party systems, etc.)
- Other

+ Add Comment

Hard Copy Storage

+ Add Comment

+ 13.5 Data Security - De-Identification

You may state NA if not applicable or explain your plan.

If you plan to de-identify the data or use codes, explain how this will be done.

Data will never have identifiable information, so there is no process needed to de-identify the data.

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+ Add Comment

When and how will the data be destroyed? Note: Anonymous data can be kept indefinitely.

Data are anonymous and will be kept indefinitely.

+ Add Comment

+ 13.7 Data Transcription

If audio or video recordings are made, who will transcribe the data?

- Member of the Research Team
- Professional Transcription Company
- Other
- Not applicable

+ Add Comment

+ 13.8 Transfer of Data

Will paper or electronic data (either internal or external to Texas Tech University) be transferred from one location to another?

Examples may include international traveling, moving data on a laptop from the field back to the office where it is uploaded to a secure server, flash drives, etc.

- Yes
- No

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- IS13 - Privacy, Conf... ✓
- IS14 - Benefits, Risk... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

+ Add Comment

+ 13.7 Data Transcription

If audio or video recordings are made, who will transcribe the data?

- Member of the Research Team
- Professional Transcription Company
- Other
- Not applicable

+ Add Comment

+ 13.8 Transfer of Data

Will paper or electronic data (either internal or external to Texas Tech University) be transferred from one location to another?

Examples may include international traveling, moving data on a laptop from the field back to the office where it is uploaded to a secure server, flash drives, etc.

- Yes
- No

+ Add Comment

13.9 Certificate of Confidentiality

Will a Certificate of Confidentiality be requested for this study?

- Yes
- No

+ Add Comment

Human Research Protect... Welcome - Evisors Res... IRB - Submission - TTest

Secure | https://ttu-uat.cayuse424.com/rs/irb/#submission/edit/91487/section/13

IRB NUMBER: IRB2016-240  
**TTest - Initial**

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Irene Irbdirector

Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9 - Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Confi... ✓
- IS14 - Benefits, Risk, Liability & Reporting ✓**
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

### IS14 - Benefits, Risk, Liability & Reporting

• 14.1 Describe potential benefit(s) to subjects. Payments to subjects should not be included in this section.

We will gain a better understanding of students' cell phone usage, but there is no other direct benefit gained from participating.

+ Add Comment

• 14.2 Describe any potential risk to subjects. What is being done to minimize that risk?

There are no risks in the present study beyond those experienced in everyday life.

+ Add Comment

Human Research Prote... Welcome - Evisions Res... IRB - Submission - TTest

Secure https://ttu-uat.cayuse424.com/rs/irb/#submission/edit/91487/section/13

37% Irene Irbdirector

STUDY IRB NUMBER: IRB2016-240  
**TTest - Initial**

SHOW CHECKLIST CREATE PDF COMPARE SAVE

Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9 - Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Confi... ✓
- IS14 - Benefits, Risk... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

14.3 Does this research involve participants who **could** be coerced or unduly influenced to participate (i.e., students, employees, etc.)?

Coercion - Coercion entails influencing an individual's decision about whether or not to do something by using explicit or implied threats (loss of good standing in a job, poor grades, etc.). This area also includes the perception of students as to any potential backlash for falling to take part in an instructor's research.  
 Undue Influence - This is defined as an offer of an excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance (used in association with recruiting research participants).

Yes  
 No  
 + Add Comment

14.4 Does this research project involve the use of deception?

Yes  
 No  
 + Add Comment

14.5 Is a liability plan offered?

Yes  
 No  
 + Add Comment

14.6 Reporting Adverse Events and Unanticipated Problems

45 CFR 46.103(a) and TTU IRB Policy 5.4 require Adverse Events, Unanticipated Problems and deviations from the research protocol be reported immediately.

<http://www.hhs.gov/ohrp/humansubjects/guidance/45c...>  
<http://www.depts.ttu.edu/vpr/irb/policies.php>

By checking this box, you acknowledge that you understand any unanticipated problems and adverse events (as defined above) or deviations from the approved protocol require immediate notification to the HRPP/IRB. (TTU IRB Policy 5.4)

+ Add Comment

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IRB NUMBER: IRB2016-240  
**TTest - Initial**

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Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9- Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Confi... ✓
- IS14 - Benefits, Risk... ✓
- IS15 - Conflicts of In... ✓**
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

## IS15 - Conflicts of Interest

**15.1 Conflict of Interest**  
 A conflict of interest refers to a situation in which an employee's financial, professional, or other personal considerations may directly or indirectly affect, or have the appearance of affecting, the employee's judgment in exercising any duty or responsibility, including the conduct or reporting of research, owed to the institution (TTU OP 10.20 (2)(d)).

"Significant business or financial interest" means anything of monetary value including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). (TTU OP 74.17).

"...a set of conditions in which an investigator's judgment concerning a primary interest (e.g., subject welfare, integrity of research) could be biased by a secondary interest (e.g., personal or financial gain)." *Institutional Review Board Management and Function*, Bankert and Amdur, 2006, p. 167.

Does anyone on the research team have a potential conflict of interest with the research project?

Yes  
 No

**Collapse Comments**

**Irene Irbdirector** 12-09-2016 9:37 AM Visibility: Restricted

Indicate whether you have a financial or non-financial conflict of interest and describe the management plan, if any. For assistance with identifying or managing conflicts of interest, please contact the HRPP Office at hrpp@ttu.edu or call (806) 834-2285.

[Edit](#) [Reply](#)

**B I U** [List Icons] [Link Icon] [Image Icon]

SAVE COMMENT

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IRB NUMBER: IRB2016-240  
**TTest - Initial**

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Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9- Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Confi... ✓
- IS14 - Benefits, Risk... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓**
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

### IS16 - Training

16.1 Has the research staff completed human subjects research CITI or NIH training? (Check the appropriate box.)  
<http://www.depts.ttu.edu/vpr/irb/training.php>

Yes

CITI (Collaborative Institutional Training Institute)

Attach certificates.

+ Add Comment

NIH (National Institute of Health)

Attach certificates.

+ Add Comment

No

+ Add Comment



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Secure | https://ttu-uat.cayuse424.com/rs/irb/#submission/edit/91487/section/16

IRB NUMBER: IRB2016-240  
**TTest - Initial**

SHOW CHECKLIST CREATE PDF COMPARE SAVE

Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9 - Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Conf... ✓
- IS14 - Benefits, Risk, ... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

### IS17 - Additional Information

17.1 Include any additional points to help clarify the research, if applicable.

+ Add Comment

17.2 Enter or attach any additional documentation

+ Add Comment

Attach (if applicable).

+ Add Comment

Human Research Prote... Welcome - Evisions Res... IRB - Submission - TTest

Secure | https://ttu-uat.cayuse424.com/rs/irb/#submission/edit/91487/section/17

IRB NUMBER: IRB2016-240  
**TTest - Initial**

SHOW CHECKLIST CREATE PDF COMPARE SAVE

Sections

- IS1 - Review Type ✓
- IS2 - Research Team ✓
- IS3 - Funding ✓
- IS4 - Exempt Review ✓
- IS7 - Rationale ✓
- IS8 - Human Subjects ✓
- IS9 - Recruitment Pr... ✓
- IS10 - Data Collectio... ✓
- IS12 - Participant Co... ✓
- IS13 - Privacy, Conf... ✓
- IS14 - Benefits, Risk, ... ✓
- IS15 - Conflicts of In... ✓
- IS16 - Training ✓
- IS17 - Additional Inf... ✓
- IS18 - Comments ✓

### IS18 - Comments





Comments.

Collapse Comments

**Irene Irbdirector** 12-09-2016 11:13 AM Visibility: Restricted

If you have additional questions or comments contact the HRPP office at 806-742-2064 or [hrpp@ttu.edu](mailto:hrpp@ttu.edu).

[Edit Reply](#)

**B I U**    

[SAVE COMMENT](#)

## Appendix H

### Required Elements of Consent

The consent process, whether written or oral, must cover all of these basic elements unless a waiver is formally requested. Use this checklist to construct your Consent Form document.

√	Element
<b>1</b>	A statement that the study involves research
<b>2</b>	A statement of who is responsible for the research including the name and phone number of the Principal Investigator
<b>3</b>	An explanation of the purpose of the research
<b>4</b>	A description of the procedures to be followed
<b>5</b>	The expected duration of the subject's participation
<b>6</b>	A description of any reasonably foreseeable risks or discomforts to the subject. If there are no such risks or discomforts, the consent form should so state
<b>7</b>	A description of any benefits to the subject or to others which may be reasonably expected from the research. If there are no such benefits, the consent form should so state
<b>8</b>	A statement describing the extent to which confidentiality of records identifying the subject will be maintained
<b>9</b>	A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits
<b>10</b>	The following statement about subjects' rights: "Dr. (Principal Investigator) will answer any questions you have about the study. You can call (phone number) or email (email address). Questions can also be directed to the Human Research Protection Program (HRPP), Office of the Vice President for Research, Texas Tech University, Lubbock, Texas 79409, 806-742-2064."
<b>11</b>	A statement about the expiration date of the project's approval: "This consent form is not valid after (expiration date)." The expiration date is the anniversary of last day of the month preceding the approval. The letter informing the investigator of the approval of a proposal specifies the date of expiration.

Additional elements of consent as appropriate.

*Additional elements of informed consent that must be included to meet the standard of fully informed consent on the part of research subjects may involve items such as the following:*

√	Element
A	For research involving more than minimal risk: An explanation concerning compensation for research-related injury as follows: "If this research project causes injury (physical, psychological, social, economic, legal, etc.), Texas Tech University or the Student Health Services, may not be able to treat your injury. You will have to pay for treatment from your own insurance. The University does not have insurance to cover such injuries. More information about these matters may be obtained from Dr. Alice Young, Associate Vice President, Research Integrity, Office of the Vice President for Research, (806) 742-3905, 355 Administration Building, Texas Tech University, Lubbock, Texas, 79409." If there is a specific plan for liability, it should be described in place of this statement.
B	For research that involves any procedures or treatments that a subject might reasonably construe to be therapeutic: A description of any procedures that are experimental and a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
C	A statement that the particular treatment or procedure may involve risks to the subject (or to an embryo or fetus if the subject is pregnant) which are currently unforeseeable.
D	Anticipated circumstances under which the participation may be terminated by the investigator without regard to the subject's consent
E	Any additional costs to the subject that may result from participation in the research.
F	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
G	A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.
H	The approximate number of subjects involved in the study.

## Appendix I

### Reviewer Checklist for IRB Proposals

#### General:

1.  Proposal does not need to be routed to TTUHSC.
2.  The PI is faculty member/administrator/professional staff.

#### I. Rationale:

3.  Includes clear statement of problem, present knowledge relevant to it, and the aims of the proposed study.
4.  Includes statement of potential benefits to subjects and/or importance of the knowledge to be obtained.

#### II. Subjects:

5.  Describes specific population of human subjects involved and how they will be recruited. Selection of participants is equitable.
6.  Describes recruitment procedure. If necessary, includes appropriate attachments (copies of newspaper ads, fliers, etc. used in recruiting subjects).

#### III. Procedures:

7.  Describes all procedures involving the subjects.
8.  Identifies and assesses all potential risks. Risks are minimized and are reasonable in relation to benefits. If there are no risks, this fact is clearly stated.
9.  Includes any precautions that will be taken to avoid risks. Privacy and confidentiality are assured.
10.  Describes any benefits to the subjects (including payment).
11.  Provides protection for vulnerable populations.

IV. Adverse Event and Liability:

12.  If risk to subjects is more than minimal, specifies steps to deal with unexpected, adverse events.
13.  If risk to subjects is more than minimal, specifies arrangements for handling liability for unexpected injuries.
14.  If no liability plan is offered, this fact is stated in this section.

V. Consent Process:

15.  Does the project need a waiver of written consent or any elements of consent?  
 If so, a section of the proposal requests a waiver of consent.  
 Each element to be waived is listed and justification is provided.  
 Each item on the waiver form is addressed.
16.  Consent form is attached that covers all the relevant elements of informed consent. (Consent forms normally are not required for exempt research.)
17.  The consent form is written in language that participants can understand.
18.  The consent form is written in the 2nd person.

Attachments:

19.  All appropriate attachments are included, e.g., recruiting materials, questionnaires, interview schedules, consent forms, requests for waivers of consent, a copy of the related grant proposal, if any, and other relevant information.
- The word “research” is used
  - The purpose of the research is clear
  - What the research involves (i.e. online survey) is stated
  - Time involved included
  - Subjects informed that participation is voluntary, questions can be skipped, quit at any time
  - Confidentiality/Anonymity is addressed
  - Researcher(s) contact information is included
  - States that the research is approved by the IRB and include HRPP office information

## Appendix J

### Recruiting Materials

#### Recruiting Materials – Example 1

Date

Dear (salutation):

Influenza (“the flu”) is a common disease affecting millions of Americans each year. Some people choose to take a vaccination (\*flu shot) each year to decrease their risk of getting the flu. The New Research Center together with the West Texas Research on Disease Control Center, is trying to learn more about why some people choose to get a flu shot and others do not.

Enclosed is a short survey asking questions that many help us to understand this issue. No information will be gathered that could personally identify you, and we would ask that you not put your name on the survey. By filling out and returning the survey, you may help us better understand how we can protect the people of West Texas from influenza. A return-addressed stamped envelope is provided for your convenience. Thank you for your time and consideration in helping us answer this important question.

If you have any questions, please do not hesitate to call Dr. Researcher at XXX-XXX-XXXX.

Sincerely,

Dr. Researcher  
Title/University  
Address  
Phone Number

#### Recruiting Materials – Example 2 Introduction to Survey

Dr. Researcher would like to find out more about what people know about the flu vaccination and why they choose to get it or choose not to be vaccinated. There are no right or wrong answers to the questions, just what you think. This survey will take about 5 minutes of your time, and we will use the results for a research study. We will not be able to identify you individually – *please do not put your name on this survey*. If you would prefer not to answer a question, please leave it blank. Your participation is voluntary and you can stop at any time. Please put the survey in the envelope provided and mail it back to me. If you have any questions about this study, please call Dr. Researcher at XXX-XXX-XXXX. Please keep the Information Sheet provided.

Thank you for helping us with this research.

### **Recruiting Materials – Example 3**

#### **Oral Script**

Hello, my name is Dr. Researcher and I would like to ask you some questions about hair colors and hair styles. I am working on a research study and hope that you would volunteer 5 minutes of your time to answer a few questions. This is voluntary and you do not have to answer all the questions if you do not want to and you can quit at any time. Here is the survey. I do not need your name so I will never know what your answers are. Please place your survey in the box on the table. You can keep the information sheet on the top of the survey. The information includes contact information of the researchers.

Thank you.

### **Recruiting Materials – Example 4**

#### **TechAnnounce**

Moms & 6-Year-Olds Needed for Child Development Study

We are looking for moms and their 6-year-old children to participate in a research study on parent-child interaction and children's development. Families will be visited in their homes by two Texas Tech research assistants. Home visits will last approximately 90 minutes to 2 hours and will include a mother-child session and a researcher-child session. Home visits can be scheduled at a convenient time for families, including evenings and weekends. Research participation is completely confidential.

Participating families receive \$40 and children receive a small gift.

For more information or if you are interested in participating, please contact Dr. Researcher at [doctor.researcher@ttu.edu](mailto:doctor.researcher@ttu.edu) or by phone at XXX-XXX-XXXX.

### **Recruiting Materials – Example 5**

Dear (Name):

We are currently conducting a research study and would like to invite you to participate.

The study is looking at how you and your child relate during games and conversations. Two research assistants will visit you and your child in your home for a visit lasting approximately 90 minutes to 2 hours. We will record some conversations between you and your child, then we will ask you to complete some surveys while your child engages in additional tasks with one of our research assistants. Home visits can be scheduled at a day and time that is convenient for you. We are available evenings and Saturdays. We know that many families have more than one child, and one of our research assistants can watch over your other children while you are participating with (subject).

To thank you for your time, you will receive \$40 and your child will receive a small gift.

Please call XXX-XXX-XXXX next week if you are interested in participating in this study. You can also email us at [doctor.researcher@ttu.edu](mailto:doctor.researcher@ttu.edu).



We hope that you can help us understand more about the development of children. We look forward to working with you and your child.

Sincerely,

Dr. Researcher  
Contact Information

# Moms & 6-Year-Olds Wanted

Young Generation University  
Department of Learning

{Graphic}

**We are currently looking for moms and their 6-year-old children to participate in our new project!**

Research Assistants will visit you at your home. We will videotape conversations between you and your child and then we will engage children in a number of game-like activities. Home visits usually last about 90 minutes - 2 hours.

**Families receive \$40.**

Participation is confidential & visits can be scheduled at a time that works best for families, including evenings and weekends.

Siblings or other children may be looked after by one of our research assistants while mothers participate in the project.

Interested?

Contact the research team at  
XXX-XXXX or [doctor.researcher@ttu.edu](mailto:doctor.researcher@ttu.edu)

## **Recruiting Materials – Example 7 Information Sheet**

We would like to invite you to participate in our research project.

### **What is this project studying?**

The study is called “Thinking about things in college.” This study will help us learn how students’ thinking relates to their lives. What we learn may help people, and we hope to publish this study widely to make it as beneficial as possible.

### **What would I do if I participate?**

In this study, you will be asked to complete surveys. Some questions will be about you. Some questions will be about your thoughts. Some will be about how you feel and what you do.

### **Can I quit if I become uncomfortable?**

Yes, absolutely. Dr. Researcher and the Protection Board have reviewed the questions and think you can answer them comfortably. However, you can skip questions or stop answering the questions at any time. You can leave any time you wish. You will keep all the benefits of participating even if you stop. Participating is your choice.

### **How long will participation take?**

We are asking for 45 minutes of your time.

### **How are you protecting privacy?**

The questionnaires will not request any personal information to protect your privacy.

### **I have some questions about this study. Who can I ask?**

- The study is being run by Dr. Researcher from the Department of Phrenology at Texas Tech University. If you have questions, you can call her at 806-742-XXX #XXX.
- TTU also has a Board that protects the rights of people who participate in research. You can ask them questions at 806-742-2064. You can also mail your questions to the Human Research Protection Program, Office of the Vice President for Research, Texas Tech University, Lubbock, Texas 79409.

### **How will I benefit from participating?**

You will get credit for a class requirement. You will receive half a credit for each 30 minutes you spend with us.

## Appendix K

### Consent Form Instructions, Examples, Assent Form, and Waivers

#### CONSENT FORM - Adults INSTRUCTIONS

The purpose of a consent form is to help the investigator protect *subjects* by *informing* them about the research and their rights as human subjects. Thus, it takes two components in achieving this goal: the consent process and the consent form.

A written consent form must contain all the required information (see Elements of Consent checklist in Appendix K) and it must be capable of being fully understood by the individuals expected to read it. All the relevant information should be included. It is not sufficient to say, “Dr. Jones has explained” such things as the procedure or risks and discomforts. You should put these explanations in the written consent form or else use the short form consent that requires a script of the accompanying oral presentation about the procedure, risks, etc. One way or the other, the IRB needs to know *what* the subjects will be informed of, not merely that they *will* be informed. Technical material and the purpose of the study must be explained in lay terms. Procedures should be explained from the point of view of what will happen to the subject in the course of the study.

A general rule of thumb used by federal regulators is that consent forms aimed at the general public should be written at a 7<sup>th</sup> grade reading level. Adjustments up or down from that standard can be made depending on the target population of subjects. Short sentences and the use of smaller words help to achieve lower reading levels. The Flesch-Kincaid grade level estimate is available by clicking on Tools, Options, Spelling & Grammar in Microsoft Word. It may be helpful but is only an aid for writing at the appropriate level. Common sense is sometimes a better guide. The example below is a consent form written for college students. The Flesch-Kincaid grade level is 6.7. The link below may be useful in writing consent forms:

<http://www.plainlanguage.gov>

The document is not supposed to be a legal document that somehow protects the *researcher*. In fact, courts have ruled that a signed consent form that is too difficult for the subject to understand neither constitutes consent nor protects the investigator and the institution from liability. Therefore, pseudo-legal language such as “hereby”, “aforementioned”, etc should be avoided on the grounds that it detracts from communication.

Federal regulators also suggest that, in order to facilitate communication, consent forms need to be written in the second person and avoid phrases such as “I understand that...” because they add nothing meaningful beyond the subject’s signature.

Texas Tech University does not have a model consent form and the consent forms below are just examples. The IRB believes that subjects’ rights will be better protected if investigators have to think about the best way to inform subjects rather than simply filling out a form.

Any format is acceptable as long as it serves its intended purpose and includes the elements of consent. Investigators should craft consent forms that clearly include the elements of consent but

which are specific to their own research program and to particular projects. It may be a good idea for each researcher to create a model consent form or template that can be modified for specific projects.

The consent process is a critical component in achieving understanding of the research and the participant's involvement throughout the study. There are different methods of conducting the consent process and the researcher can determine the best method based upon the project's procedures. The end result of the consent process should also be two-fold: (1) the participant's understanding of their involvement in the research project and (2) the researcher's assurance that the participant has been properly informed and comprehended the research requirements involved.

One copy of the consent form must be given to the subject and one copy must be retained by the investigator. The investigator must keep consent forms for a period of three years after the termination of the IRB approval. Expiration dates on consent forms change when annual reviews are conducted and approved. Investigators should be cognizant of consent form expiration dates.

## CONSENT FORM - EXAMPLE

Please share your thoughts in our research project.

### **What is this project studying?**

The study is called “Thinking about things in college.” This study will help us learn how students’ thinking relates to their lives. What we learn may help people, and we hope to publish this study widely to make it as beneficial as possible.

### **What would I do if I participate?**

In this study, you will be asked to complete surveys. Some questions will be about you. Some questions will be about your thoughts. Some will be about how you feel and what you do.

### **Can I quit if I become uncomfortable?**

Yes, absolutely. Dr. Researcher and the Protection Board have reviewed the questions and think you can answer them comfortably. However, you can stop answering the questions at any time. You can leave any time you wish. You will keep all the benefits of participating even if you stop. Participating is your choice.

### **How long will participation take?**

We are asking for 45 minutes of your time.

### **How are you protecting privacy?**

The questionnaires will not request any personal information to protect your privacy.

### **I have some questions about this study. Who can I ask?**

- The study is being run by Dr. Researcher from the Department of Phrenology at Texas Tech University. If you have questions, you can call her at 806-742-XXX #XXX.
- TTU also has a Board that protects the rights of people who participate in research. You can ask them questions at 806-742-2064. You can also mail them at Institutional Review Board for the Protection of Human Subjects, Office of the Vice President for Research, Texas Tech University, Lubbock, Texas 79409.

### **How will I benefit from participating?**

You will get credit for a class requirement. You will receive half a credit for each 30 minutes of your time.

---

Signature

---

Date

---

Printed Name

This consent form is not valid after Month/Date/Year.

## MULTIPLE FORM CONSENT

### Part I: INSTRUCTIONS

The consent process, whether written or oral, must cover all basic elements unless a waiver is formally requested.

The short form is most useful when a study is complex and the investigator can't be sure that a signed written consent is understood well enough to indicate a valid consent process. The short form allows the individual obtaining the consent to engage in a continuous dialog with the subject to ensure fully informed consent.

For IRB approval, two documents must be submitted for short form consent.

- (1) One is a summary of the oral presentation of the elements of consent required by 45 CFR 46.116. After the consent process that includes an oral description of the research to the subject, a written copy of the summary should be signed by a witness to the oral presentation certifying that all the points in the summary were covered during the consent process. The subject does not sign the summary but must receive a copy of it.
- (2) The second document is the short form itself that states that the elements of informed consent have been presented orally to the subject or a legally authorized representative (e.g., Dr. Researcher told me the purpose of the study; Dr. Researcher told me what the risks of this study are). The short form must be signed by the subject or a legally authorized representative and by a witness to the oral presentation.

#### Witness:

Observe the Oral Presentation of Informed Consent Information to the Subject

Sign and date the Short-form Written Consent

Sign a copy of the Summary of the Oral Presentation

#### Subject:

Sign Short-form Consent

#### Investigator Conducting Consent Process:

Sign the Summary of the Oral Presentation

## MULTIPLE FORM CONSENT

### Part II: ORAL PRESENTATION/SCRIPT - EXAMPLE

For the project “Exercise, Heat Stress, Lung Function, Cognitive Problem Solving and Their Relationship to Academic Achievement” (Dr. Researcher of the Department of Phrenology at Texas Tech, 742-XXXX), the following summary explains how the elements of consent are explained to subjects.

#### Purpose

Understanding the relationship between exercise and the ability to solve problems.

Understanding the possible role of lung functioning and stress on the body due to heat in this process. Compare the test performance with academic records, including GPA and entrance test scores.

Understand some of the effects of stress from heat on both physical (e.g., lung functioning) and cognitive functions (e.g., solving complex problems).

#### Procedures

- Interview: In the first step in this research, you will fill out a questionnaire about your health and be interviewed about your health by trained professionals before any tests. In the course of the interview they will determine if there are any reasons that would make it unsafe for you to take the test. Consequently, it is important that you provide complete and accurate answers to the interviewer. Any failure to answer completely and honestly could lead to possible unnecessary injury during the test. Also, if you think there is any reason you should not participate in a study that involves physical stress in hot conditions, you must inform the interviewer.
- Pulmonary and graded exercise tests: The second step, which will take place today, is a set of tests of your lung functioning. To start, standard pulmonary function testing will be performed to demonstrate normal lung function. To do these tests you will have to inhale and exhale into a tube several times as hard as you can. Second, a graded exercise test on a stationary bicycle will be performed. You will continue to exercise until you tell the operator that you feel fatigue, shortness of breath, or chest discomfort. During the test, expired respiratory gases will be collected in order to determine your maximal oxygen consumption. Your blood pressure will be taken prior to and during the test with a standard blood pressure cuff. Your heart rate and rhythm will be monitored during the test with a standard electrocardiograph. This requires attaching electrodes to your chest with tape.
- Monitoring: During the test itself, a trained observer will monitor your responses continuously and take frequent readings of blood pressure, the electrocardiogram, and your statements about your effort. A true determination of your exercise capacity depends on continuing the test to the point of fatigue (when you tell the operator to stop) or reaching a pre-determined exercise stopping point (when the operator tells you to stop) It is important to remember to tell the operator to stop the test at any point if you feel unusual discomfort or fatigue. Following the test, you will be monitored for



approximately 10 minutes to insure the heart rate and blood pressure have returned to pre-test levels. The questionnaire and interview should take about 30 minutes and the exercise test about 45 minutes for a total of about an hour and 15 minutes.

- Second exercise test and heat manipulation: The third step in the research will take place in another session two days from today. You will be asked to ride the exercise bike for endurance at about 55-60% of the exercise intensity that you reached on the first test. This level of exertion should produce respiratory muscle fatigue (labored breathing) but will fall short of the level of exertion you got to in the first test. You will perform this second test in either hot (100 degrees Fahrenheit, 45% humidity) or normal (70 degrees Fahrenheit, 45% humidity) conditions. Otherwise this second test will be exactly like the first test. It will end when you are no longer able to breathe at 85% of your maximum oxygen consumption.
- Cognitive tests: The last step in the research will be a test of your performance on a test of thinking ability. Immediately after you finish the exercise, you will sit at a computer and do a series of tasks that require you to do such things as respond quickly to identify characteristics of words, or find associations between words, or determine whether briefly presented strings of letters are words or not. During this test your breathing, heart rate, and blood pressure will continue to be measured just as they were during the exercise test. The second session should take about an hour and a half altogether, 45 minutes for the exercise task and 45 minutes for the cognitive tests.

Academic Records: Finally, because we want to compare your performance on the cognitive tests with your academic record, we are asking you to give us permission to obtain information on your grade point average and your entrance test scores.

## **Risks**

Due to the extensive exercise, you will feel tired and may experience muscle soreness.

The blood pressure cuff and attaching or removing the electrodes from your skin may make you uncomfortable.

During the actual exercise tests there is a very small possibility for healthy individuals of more serious effects. These could include:

- abnormal blood pressure
- fainting
- disorders of heart rhythm
- stroke
- heart attack or even death in very rare instances

Precautions: Every effort will be made to minimize these occurrences by precautions and observations taken during the test. Oxygen and trained CPR personnel will be available on site during all exercise tests. You should consider these risks when you decide whether or not be a subject in this research.

## Benefits

1. Learning something about exercise testing
2. Course credit: If you are enrolled in (class), you will receive 5 extra points on the third examination. The instructor will offer you a chance to earn the same credit in an activity that involves about the same time and effort but that does not involve research.

## Confidentiality

Access: Data and your academic records seen only by Dr. Researcher and her assistants. All the records will be kept in Dr. Researcher's laboratory in a locked file cabinet. Only those working on this project will have access to that cabinet.

Recording and storage: Once all the data are recorded and entered into a computer, you will be identified only by a code and anything with your name on it, except a copy of this consent form, will be destroyed.

Publication: If any of the findings from this study are published, your name will not be used.

## Rights and Information About Consent

Voluntary participation: You will not lose anything to which you are entitled by refusing to participate.

Withdraw from the study any time you want, even in the middle of a test. If you do withdraw, and you are in a (class) you will receive proportionate credit toward your grade on the third examination.

Staff may discontinue participation: If they believe that there is a risk to you based on their observations or measurements. You will be referred for medical examination and treatment if this occurs.

If you decide to withdraw: You may be required to keep the monitoring equipment in place for enough time for the staff to ensure that you have not been harmed by the tests.

New information and unforeseeable risks: If we obtain information during this study that changes our assessment of the risks involved or if we find any other information that might affect your willingness to continue with the study, we will inform you.

## Contact and Insurance Information

Dr. Researcher will answer any questions you have about the study. For questions about your rights as a subject or about injuries caused by this research, contact the Texas Tech University Institutional Review Board for the Protection of Human Subjects. Refer to contact information on short form consent document.

If this research project causes physical injury, Texas Tech University or the Student Health Services, may not be able to treat your injury. You will have to pay for treatment from your own insurance. The University does not have insurance to cover such injuries. Refer to contact information on short form consent document.

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Signature of Witness to Oral Presentation

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Date

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Signature of Investigator Conducting Consent Process

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Date

This consent form is not valid after September 1, 2017.

## CONSENT FORM

### Part III: MULTIPLE FORM - EXAMPLE

The research project you are being asked to participate in is entitled “Exercise, Heat Stress, Lung Function, Cognitive Problem Solving and Their Relationship to Academic Achievement”.

Contact Information:

- For questions about the study or the procedures, contact Dr. Researcher of the Department of Phrenology at Texas Tech is in charge of the study. Her phone number is 742-XXXX. You can also contact Mr. Research Assistant, who is responsible for carrying out the procedures for the study at 742-YYYY.
- For information related to injuries or insurance, contact Dr. Alice Young, Associate Vice President, Research Integrity, Office of the Vice President for Research, (806) 742-3905, 355 Administration Building, Texas Tech University, Lubbock, Texas, 79409.
- For information about your rights as a subject, contact the Texas Tech University Human Research Protection Program (HRPP), Office President for Research, Texas Tech University, Lubbock, Texas 79409. Or you can call (806) 742-2064.

Dr. Researcher or Mr. Research Assistant has explained the purpose of the study and described the procedures to you. They have also informed you about how much time you will put into this study and how much payment you will receive. They have informed you of the risks you are taking and the discomforts you may experience in this study.

Dr. Researcher or Mr. Research Assistant has explained when your data will be kept confidential and when other people may be able to look at it. They described your rights as a subject and told you who to contact with questions you may have. They explained what to do in case you are injured by this research and the arrangements for insurance. They explained that your participation is totally voluntary and how your participation might be ended either by you or by them.

Dr. Researcher or Mr. Research Assistant described how they would let you know if they obtained new information during the study that might make me reconsider participating.

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Signature of Subject

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Date

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Signature of Witness to Oral Presentation

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Date

This consent form is not valid after September 1, 2013.

## ASSENT FORM – Minors

### INSTRUCTIONS

The purpose of a consent form for minors, called an Assent Form, is to help the investigator protect *subjects* by *informing* them about the research and their rights as human subjects, even as a minor. There are four components in achieving this goal when research involves minors: the consent process and the consent form for parents; and the consent process and assent form for minors. A minor in the State of Texas is an individual under the age of 18.

Most proposals will need to include a cover letter to the parents explaining the research study and directions on how the consent process will be conducted and the consent forms collected.

## **PARENT CONSENT FORM.**

### **EXAMPLE**

Thank you for your interest in participating in our research project. This form describes the project and what will be asked of you today. Please read over it carefully and let us know if you have any questions.

#### **What is the purpose of this research?**

We are interested in knowing how mother-child conversations relate to children's development.

#### **What will be asked of me today?**

First, we are going to ask you and your child to play a game together for 10 minutes. After this, we are going to ask you to have four conversations with your child. We will give you some specific instructions on what you should talk about. After this, we will have some questionnaires for you to fill out. These questionnaires will ask you about your child's behavior and your interactions with your child. While you are filling out the questionnaires, we will be engaging your child in a number of tasks that tap your child's cognitive, social, and emotional development. Our session today will be videotaped to allow us to analyze the results later. We expect our visit today to last about 90 minutes to 2 hours.

#### **Are there any risks to participating?**

We don't expect you to encounter any risks other than those experienced in everyday life. Our experience with tasks such as these is that parents find them interesting and children find them to be fun.

#### **Will my privacy be protected?**

Yes! Your privacy is very important to us. Your information will be kept in a locked office and only Dr. Researcher or her trained research assistants will have access to this information. We will give you and your child a unique ID number and we will use this number in our files, not your name. Your name will never be publically shared. We will never publically share the videos we take today. In any report we may publish, we won't report individual responses, only overall responses for the group. All videos will be destroyed five years after the study is complete.

#### **Is this research voluntary?**

Yes! Your participation today is completely voluntary. You can decide right now that you don't want to participate and that is okay. You can stop at anytime once we begin. You can skip any questions on the survey that you don't feel comfortable answering. If your child seems uncomfortable with a task we will stop. If you sense your child feels uncomfortable with a task you can ask us to stop. Whether or not you participate will not affect you or your child's relationship with Texas Tech University

#### **Will I receive any compensation for participating?**

To thank you for your time today, you will receive \$40. Your child will receive stickers throughout the session and will receive a small gift at the end of the session.

#### **Can I find out the results of this study?**

Once we complete the data collection and analysis for the study we will send you an update with our finds. Please note that this may take up to two to three years. We cannot provide you with individual results for your child. We want to emphasize that our tasks are not diagnostic, meaning they don't say whether your child has any problems. Children just respond differently to these tasks, and we are interested in understanding these differences.

**Who should I contact if I have more questions?**

The researcher conducting this study is Dr. Researcher. Dr. Researcher may be reached by email at [doctor.research@ttu.edu](mailto:doctor.research@ttu.edu) or by phone at XXX-XXX-XXXX. For additional questions about your child's rights as a subject, contact the Texas Tech University Human Research Protection Program, Office of the Vice President for Research, Texas Tech University, Lubbock, Texas 79409. Or, you can call (806) 742-2064.

Print Name: \_\_\_\_\_

Signature of Parent or Guardian: \_\_\_\_\_

Name of Child: \_\_\_\_\_

Date: \_\_\_\_\_

This consent form is not valid after August 31, 2013.

(Remember, even if you do say, "Yes," now, you can change your mind later.)

## CHILD ASSENT FORM

### EXAMPLE

I am here today because I am interested in learning more about kids. I hope that you and your mom can help me today. I'm going to ask you and your mom to play a game and then I'm going to ask your mom to talk to you. After that, you and I are going to play a bunch of different games together. I'm going to videotape all of this with my camera over there so I can remember everything that happened today. I'm going to give you some stickers for playing games with me and at the end you can pick a prize to keep.

Helping me today is up to you. If you decide you don't want to play these games with your mom and me, that's okay, nobody will be mad at you.

If you want to help me today, I'm going to ask you to write your name on this line. Let me know if you need some help writing your name.

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Child Name

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Date

This consent form is not valid after August 31, 2013.



## Appendix L

### IRB Approval Criteria for Prisoner Research

- (1) The research under review represents one of the categories of research permissible under (a)(2);
  - a) Study of the possible causes, effects, and processes of incarceration, and criminal behavior
  - b) Study of prisons as institutional structures or of prisoners as incarcerated persons
  - c) Research on conditions particularly affecting prisoners as a class; . . . and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults
  - d) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well being of the subject.
- (2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- (3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
- (4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- (5) The information is presented in language which is understandable to the subject population;
- (6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole;
- (7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.