Policies and Procedures Manual
Human Subjects
Institutional Review Board
(IRB)

Northwestern State University
Natchitoches, Louisiana 71497
an Institution in the
University of Louisiana System
Revision Approved: February, 2019

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I. STATEMENT OF PURPOSE

"Whether testing a new medical treatment, interviewing people about their personal habits, studying how people think and feel, or observing how they live within groups, research seeks to learn something new about the human condition."

(National Bioethics Advisory Commission (NBAC), 2001)

The IRB's purpose is to ensure the ethical treatment of subjects by protecting the rights and welfare of every person who may be involved in human subject research. To do this, the IRB has the scientific expertise to judge the merits and weaknesses of whatever research projects they review and to determine whether it conforms to the rules, (Belmont Report and HHS Regulation 45 CFR 46) and draw conclusions on that basis.

The Institutional Review Board at Northwestern State University bases its requirements and actions regarding human subject research on the principles underlying the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (National commission 1979) and the Department of Health and Human Services (HHS) regulations for the Protection of Human Subjects (45 CFR 46, as amended). These guidelines emphasize that research must respect the autonomy of participants, must be fair in both conception and implementation, and must maximize potential benefits while minimizing possible harms (NBAC, 2001).

II. DEFINITION OF TERMS

Research: Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, even if they are not considered research for other purposes.

NOTE: Internal program evaluations that are intended to improve the quality of programs or services, do not put participants at risk or harm, and are NOT intended for publication or presentation do NOT meet this university's definition of research. Activities that are associated with accreditation requirements and utilized strictly for institutional assessment or to inform internal policy-makers also do not meet the definition of research. These projects are part of quality control for the university. Therefore, they are not subject to IRB review. Supervisors or personnel who engage in these activities, however, assume all liability for the activities they approve or conduct and therefore should complete the on-line training course (https://about.citiprogram.org/en/homepage/). If these activities are adapted for publication, then they do meet the university's definition of research and MUST be submitted to the IRB for review before the research can be submitted for publication.

Other activities that do not meet this university's definition of research involve information produced by student media and the NSU News Bureau. Therefore, they are not subject to IRB review.

Human Subject: A human subject is defined as 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 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 an individual's behavior when the individual can reasonably expect that no observation or recording is taking place. It may also include information that has been provided by an individual that 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 retrieval of the information to constitute research involving human subjects.

Legally Authorized Representative: A legally authorized representative is an individual 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.

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.

Informed Consent: Informed consent is a process, not just a document. Informed consent is usually obtained by using a written consent form, signed by the subject or the subject's legally authorized representative, that provides the prospective subject or the representative sufficient opportunity to consider whether to participate. No informed consent may include any exculpatory language through which the subject or the representative is made to waive any of the subject's legal rights, or releases or appears release the investigator, the sponsor, the institution or its agents from liability for negligence. A copy shall be given to the person signing the form.

Conflict of Interest: Conflict of interest occurs when the researcher or any member of the research team has a financial or personal interest in companies or company materials involved in the research. If a conflict of interest is present, the study's scientific integrity is at risk. However, researchers may minimize this conflict by disclosing the nature of the conflict to the potential subjects. This explanation and/or statement of conflict must be on the informed consent form. The researcher must also complete and sign the section on the review application identifying the occurrence or nonoccurrence of a conflict of interest. The IRB will review the conflict of interest and its explanation before approving the research.

Definitions are taken in part from the Code of Federal Regulations 45 CFR 46.

III. INSTITUTIONAL REVIEW BOARD MEMBERSHIP AND RESPONSIBILITIES

A. Membership

1. The IRB members must represent a variety of backgrounds, including experience, gender, race and age. The IRB shall be sufficiently qualified through the experience and expertise of its members to promote complete and adequate review of research activities commonly conducted at Northwestern State University.
2. The IRB may, in its discretion, invite consultants with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. **These individuals may not serve as voting IRB members.**
3. The IRB membership shall be as follows (one member per unit unless indicated otherwise):
   a. College of Education and Human Development: 2 members
   b. College of Arts and Sciences: 3 members (to include one member from the Louisiana Scholars' College)
   c. College of Nursing and School of Allied Health
   d. College of Business and Technology
   e. Student Affairs
   f. Graduate Student
   g. A member who is not affiliated with the University.
   h. Chair (votes only in case of a tie)
   i. Dean of the Graduate School (non-voting)
   j. Office of Sponsored programs (non-voting)
4. The IRB must have 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.
5. The IRB reserves the right to add voting members in various areas of expertise.
6. The IRB must have at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. Members who fulfill these requirements may also fill other required areas on the IRB. The review of applications at convened meetings requires at least one member whose primary concerns are in nonscientific areas.
7. Membership in the IRB is for three years. Once a member's term is complete, the IRB chairperson will contact the appropriate department head to request a replacement or to renew a current member's IRB term. Membership in the IRB, including the appointment of the chairperson, is subject to approval by the Dean of the Graduate School.
8. The IRB chair should be a tenured faculty member; however, the Dean of the Graduate School may appoint any faculty member to the position.
9. The IRB shall report directly to the Dean of the Graduate School. The Office of Sponsored Programs (OSP) will facilitate the IRB by providing clerical support as stated in the Grants and Contracts section of the Business Affairs Policy and Procedures Manual.
10. All members of the IRB must have active e-mail accounts, have operating phone numbers, and have continual access to and ability to operate the course management system (CMS) on the university server.
11. All members of the IRB must provide proof of completion of the CITI Program's Research Ethics and Compliance Training online course.

B. Responsibilities

All research involving human subjects must be approved by the IRB before any research activities may begin. Failure to submit research proposals/applications to the IRB for approval may result in discontinuation or removal of university support for the project.

1. The IRB applications will be electronically submitted via email to irb@nsula.edu and processed and maintained digitally by the IRB Chairperson and the Office of Sponsored Programs.

2. The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities.

3. The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove any 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.

4. The IRB shall require all persons involved in the administration of the research, including investigators, sponsors, and approving agents, to provide proof of completion of the CITI Program's Research Ethics and Compliance Training online course before a research proposal can be approved (https://about.citiprogram.org/en/homepage/).

5. The IRB shall have authority to suspend or to 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 reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

6. The IRB shall require that information given to subjects as part of informed consent is in accordance with Sec. 46.116. The IRB may require that information, in addition to that specifically mentioned in Sec. 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.

7. The IRB shall require documentation of informed consent when appropriate.

8. Expedited applications may be reviewed and voted on through the university CMS. A simple quorum is required for voting purposes with the majority of the vote constituting the IRB's decision.

9. Full Review applications must be reviewed at a convened IRB meeting.

10. The IRB shall conduct continuing reviews of research covered by this policy at intervals appropriate to the degree of risk, but those reviews must be conducted at least once a year.

11. The IRB shall have authority to observe or have a third party observe the consent process and the research.

12. The IRB may officially meet and review applications only when a quorum is present and at least one member is from a non-scientific area.

13. The IRB chairperson will review all applications resubmitted with conditional approval. If all conditions are met, the chairperson may grant approval. If all conditions are not met, the chairperson may elect to have the entire committee or a selected sub-committee re-review the application for recommended action.

14. The IRB will view all resubmitted applications as a new application and will act on them accordingly.

15. The IRB will determine when a continuation review will be conducted for each application. This action will be recorded in the IRB minutes. The minutes will also reflect recommended action for continuing review.

16. The IRB meeting minutes will include all conditions recommended by the committee on each research application and a recording of the action vote. Minutes will have attached the recommended actions taken by the chair and/or appropriate sub-committee that occur between scheduled meetings.

17. The IRB chairperson may not vote unless there is a tie. No member of the IRB may participate in reviews of applications where there may be a conflict of interest.

18. The IRB will keep applications and associated records for at least 5 years.

19. The IRB may have graduate assistants or office personnel to help organize records and/or to take minutes at the IRB meetings.

20. The IRB will have an active roster of all research, including but not limited to initial review dates, other review dates, actions of the committee on each submission, and dates of final report submissions. It is the responsibility of the researchers or supervisors to ensure that the final report is submitted. If this report is not submitted, future applications to the IRB may not be considered.

21. The IRB will assign each application with a number for tracking purposes. This number will represent the month, year, and the order in which the proposal was submitted to the IRB for review. (e.g., 02.19.006 for February 2019, Application #6)

IV. IRB PROCEDURES

A. Initial Reviews

1. All research applications will be submitted to the IRB directly. The IRB will disseminate copies to the appropriate members. This includes resubmissions and conditional applications.

2. Each application will be assigned a number for tracking purposes.

3. For full review, a copy of each application will be delivered to every IRB member. The chairperson may initiate a threaded discussion on the university CMS (course management system) for each application. However, for full review applications, the IRB must convene in a face-to-face meeting to recommend action on the application. The minutes of the meeting will record the action and/or conditions set by the IRB for each application. The chairperson will provide written notification of the IRB action to the researcher as well as, when appropriate, a faculty sponsor/advisor.

4. For expedited review, a copy of each application will be delivered to every IRB member for review in accordance with the submission guidelines. The chairperson will initiate a threaded discussion on the university CMS for each application. The chairperson will also assign each Expedited Review application to a subcommittee composed of three members of the IRB, along with a chair of the subcommittee, which will be responsible for reviewing the application. Members of this subcommittee will communicate, through the university CMS or other means, and reach a decision on the application, which will be communicated to the IRB chairperson along with conditions that must be fulfilled before the application is approved. Assignment of applications will be rotated through different subcommittees. Records will be maintained of all CMS activities regarding actions on proposals. The chairperson will provide notification of the IRB action to the researcher, as well as, when appropriate, the faculty advisor/sponsor.

   The Expedited Review procedure cannot result in disapproval of a research project by the IRB subcommittee. Rather, Approval or Conditional Approval are the only decisions available. If Expedited Review of an application yields a majority vote for Resubmission, action on the application will be deferred to a convened meeting of the IRB.

5. For Exempt applications, a copy of each proposal will be delivered to the chairperson. The chairperson will review the application to verify exempt status. If accepted as an exempt application, the chairperson may approve the application, set forth conditions of approval, or may elect to have the entire IRB committee or an IRB sub-committee review the application. Records will be maintained of all activities regarding actions on applications. The chairperson will provide written notification of the IRB action to the researcher, as well as, when appropriate, the faculty advisor/sponsor.

6. Conditionally approved applications must be resubmitted to the IRB along with the conditional action letter from the IRB. If all conditions are met, the chairperson may grant approval. If all conditions are not met, the chairperson may elect to have the entire IRB committee or an IRB sub-committee re-review the application for recommended action. In this case, the application will be reviewed at the next IRB meeting.

7. Resubmitted applications will be reviewed in accordance with the guidelines outlined for the specific type of review (i.e., full, expedited, or exempt). A copy of the IRB resubmit action letter must be attached.

8. For projects that are longitudinal for more than five (5) years, a Continuation Form must be submitted. If the project was initially approved under the pre-2018 requirements, then the researchers must re-apply under the 2018 requirements as a way of transitioning to the new requirements.

9. Researchers whose projects have a change in procedures from the originally submitted application must complete a Continuation/Change in Protocol application. If the project was initially approved under the pre-2018 requirements, then the researchers must re-apply under the 2018 requirements as a way of transitioning to the new requirements.

B. Continuing Review

If the research time frame is less than one year, no continuing review is required unless changes in protocol are requested, changes occur, or unless adverse effects occur. If the research time frame is more than one year, a continuing review is required in accordance with the outlines already specified under the Continuing Review section of this document. Research that was submitted as full, or expedited and deemed not minimal risk, must follow this policy.

If the research was initially approved under the pre-2018 requirements, then it is not eligible for continuing review. The researchers must re-apply under the 2018 requirements as a way of transitioning requirements.

If the research was approved under the 2018 requirements, then it is eligible for continuing review and must follow this policy.

The IRB shall conduct continuing reviews of research covered by this policy at intervals appropriate to the degree of risk, but those reviews must be conducted at least once a year. The IRB shall have authority to observe or have a third party observe the consent process and the research.

A current IRB member will be designated by the chairperson to conduct a review of the research. This representative will review the activities associated with the proposed research and will conclude whether the research follows the original proposal. The findings of this representative will be brought before the IRB at its next convened meeting. If further action is required because of this representative's findings, the chairperson will contact appropriate personnel and inform them in writing of the findings and IRB recommended actions. The researcher must complete and submit to the IRB either a Continuation/Change in Protocol application or an Adverse Effect Form and wait for written approval before the project may continue.

In conducting continuing review of research, all IRB members should receive a copy of the original proposal and a summary report of the representative's findings. This report should include: a) number of subjects accrued; b) a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research; c) a summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review; d) any relevant multicenter trial reports; e) any other relevant information, especially information about risks associated with the research; and f) a copy of the current informed consent document and any newly proposed consent document(s).

If the IRB representative who conducts the continuing review determines the need for verification from sources other than the investigators that no material changes have occurred since the previous IRB review, the chairperson will appoint a person knowledgeable in that area to assist the IRB representative in the continuing review.

The principal investigator and a faculty sponsor (if applicable) must certify by signature that the study will be monitored to assure compliance with the submitted design. These people, along with the Approving Agent/Budget or Unit Head, are required to report immediately (not longer than one week) to the IRB chairperson any changes or unanticipated problems involving risks to subjects or others. The continuing review will also address these issues.

The IRB may set a shorter continuing review period for high-risk research proposals. The IRB reserves the right to randomly select projects for continuing review. The IRB also reserves the right to conduct continuing reviews in the following cases: a) complex projects involving unusual levels or types or risk to subjects; b) projects conducted by investigators who previously have failed to comply with regulations or with the requirements or determinations of the IRB; and c) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in other continuing review reports or from other sources.

C. Continuation/Change in Protocol Application

If the research was approved under the 2018 requirements as exempt or expedited and deemed no more than minimal risk, then it does not need to apply for continuation. Any other research project that extends beyond the original project date, must be resubmitted to the IRB for approval of a new time frame. For example, a project may originally be submitted as a one-time project; however, the researcher may propose to convert the project into a longitudinal study. The researcher must complete the Continuation/Change in Protocol Application and wait for project continuation until written approval from the IRB is received. Likewise, if a researcher proposes to change any part of the project, including methodology, administration procedures, etc., he/she must complete and submit the Continuation/Change in Protocol Application to the IRB and wait for written approval before the new procedures may be implemented.

D. Adverse Effects Report

If adverse effects are detected at any time by the investigator, other involved research personnel, participants, or an IRB member, research will terminate. The researcher must complete and submit the Adverse Effects Report explaining the problem to the IRB. The IRB may recommend to the researcher alternatives and/or actions to assist in dealing with these adverse effects. Any changes to the original proposal must be submitted to the IRB on the Continuation/Change in Protocol Application. Research cannot recommence until the IRB approves an amended proposal.

E. Reporting of IRB Actions and Findings

All IRB actions on all research proposals will be documented in the IRB minutes. Those actions voted on through university CMS or those actions approved by the chairperson will be documented and voted on for acceptance as attachments to the minutes at the next convened IRB meeting.

The chairperson will provide notification of the IRB action to the researcher as well as, when appropriate, the faculty sponsor.

The chairperson also will report in writing to the university administration any adverse effects or non-compliance activities associated with IRB-reviewed research.

F. Other review procedures

No other institutional office or official may approve research that has not been approved by the IRB. The 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 reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head. The university reserves the right to discontinue the projects of those in noncompliance.

All researchers and all signature personnel must complete the on-line Research Ethics and Compliance Training course (https://about.citiprogram.org/en/homepage/). By completing this course, research personnel have demonstrated knowledge of regulations regarding human subjects research and have acknowledged that no changes in research protocol may be implemented without prior IRB review and approval.

G. IRB Meeting Procedures

The IRB will schedule its meetings once per month (except December) during the academic year (September-May). At least one meeting should be scheduled during June or July. If all submitted proposals meet expedited or exempt criteria, the IRB may discuss the proposals through the university CMS in lieu of a meeting. The meeting will convene when a quorum is present. This includes CMS discussions.

The minutes of the previous meeting will be voted on as the first action of the board. These minutes will be amended or approved and included in the IRB records stored in the OSP office. The minutes must include:

1. Separate deliberations, actions, and votes for each protocol undergoing review by the convened IRB.
2. The vote on all IRB actions including the number of members voting for, against, and abstaining. In order to document the continued existence of a quorum, the votes will be recorded in the minutes using the following format: Total: 11; Vote: For - 9, Opposed-0, Abstained-2.
3. The IRB will make and document four findings (see V.B., item 12, Researcher Handbook) when approving a consent procedure which does not include, or which alters, some or all the required elements of informed consent, or when waiving the requirement to obtain informed consent. This also applies when approving procedures that waive the requirement for obtaining a signed consent form for research involving: a) pregnant women, human fetuses, or neonates; b) prisoners; or c) children. These findings will be documented in the IRB minutes.

The next action of the committee will be to review all proposals individually and offer a motion for an IRB action for each. The committee will follow accepted parliamentary procedure.

In addition to a recommended action on each proposal, the IRB must determine continuing review time frames, as appropriate to the degree of risk. This recommendation will be included in the IRB minutes.

Any other business that the IRB needs to discuss will be brought forth after all proposals are reviewed.

The IRB records must be retained for at least five years, and records relating to research that is conducted must be retained for at least five years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of regulating agencies at reasonable times and in a reasonable manner.

V.

Researcher Handbook

Human Subjects
Institutional Review Board

Northwestern State University
Natchitoches, LA 71497

A. Submission Guidelines

All research involving human subjects must be approved by the IRB before any research activities may begin. This includes all surveys, interviews, and/or data collection involving human subjects, whether it is administered online or face-to-face. Failure to submit a research proposal to the IRB for approval may result in discontinuation and/or removal of university support for the project.

The following is a step-by-step guide for human subject researchers to follow when preparing a proposal for IRB review.

1. Complete the ethics certification course. All persons involved in the administration of the research, including investigators, sponsors, and approving agents, must complete the Research Ethics and Compliance Training online course before a research proposal can be reviewed. This online course is located at https://about.citiprogram.org/en/homepage/. The course requires approximately one hour to complete.

2. Save a digital copy of the certificate at the end of the course. Sponsors and approving agents may wish to save a copy to be kept on file. This certificate must accompany the application packet.

3. Consider the IRB application process for research proposals and target completion of the application with these timelines in mind.

    a. All applications will be processed on a rolling basis.
        1. An application/proposal for a Full Review will be addressed at the next convened IRB meeting, assuming there is at least 3 weeks for members to review the proposal. Although the IRB attempts to meet once a month, this is not guaranteed and therefore the decision of a Full Review may not be made for several weeks.
        2. An application/proposal for an Expedited Review will be disseminated to the subcommittee and a vote will be conducted within 3 weeks.
        NOTE: if the subcommittee does not vote to approve or conditionally approve the study, it will then be brought to the entire board at the next convened meeting, similar to the Full Review process described in 1.
        3. Applications submitted in the Exempt from Review category may be submitted at any time and will be processed on a rolling basis as quickly as possible, however, in some instances the process may still require 1-2 weeks.
    b. No exceptions will be made.

4. Determine whether the research may be approved using exempt, expedited, or full-review criteria.

    a. Only the IRB chair can make the final determination as to whether the research is exempt, expedited, or needs full review.
    b. If an application submitted as "exempt" does not meet the "exempt" criteria, it will automatically be considered for "expedited" review.
    c. If an application submitted as "expedited" review does not meet the "expedited" criteria, it will automatically be considered for "full review."

5. Complete the appropriate application. All application files and checklists are available on the IRB website www.nsula.edu/irb and are in fillable PDF format.

    a. "Expedited" and "full review" applications are identical with the exception of the second and third page of the "expedited" review. These pages list "expedited" criteria. At least one of the criteria must be met to qualify for review under that status.
    b. When completing the application forms, do not complete any item with "Not Applicable." All statements and questions must be addressed.
    c. Do not leave any sections blank.

6. Obtain the appropriate signatures. In order to complete this task electronically, the principal investigator (PI) should electronically sign and date the application before emailing it to the faculty advisor (FA), if applicable. The FA should electronically sign and date the document before emailing it to the appropriate department/budget/unit head to obtain their electronic signature and date. An official electronic signature is not necessary, instead all parties can type their names and dates directly into the designated boxes to serve as signatures.

7. View the checklist for proposal submissions to ensure all materials are completed and included.

8. Submit the application packet directly to the IRB via email irb@nsula.edu.

    a. When submitting an IRB application, save each file separately (i.e. Informed Consent form, ethics training certificate, survey instrument, etc.) as a Word or PDF format.
    b. On the first page of the application, the PI should specify which attachments are included in the submission packet.
    c. The PI should carbon copy (CC) every person who electronically signed and dated the application in the submission email.
    d. If a faculty advisor was required in the process, a copy of their separate checklist must be included in the PI's completed application packet. The FA's checklist must contain their electronic signature and date to be acceptable.

9. A letter with IRB recommendations or approval will be sent to investigators, sponsors/advisors and approving agents. No research may begin until an approval letter from the IRB is received. Actions the IRB may recommend are:

    a. Approval: Research may begin.
    b. Conditional Approval: Investigator must revise application to meet the conditions recommended by the IRB. Conditional approval may be resubmitted at any time and does not have to meet the regular IRB deadlines. However, if all conditions are not met, the IRB chairperson may elect to have the entire committee or a subcommittee re-review the application for recommended action. In this case, the application will be reviewed at the next IRB meeting. Procedures for re-submission of conditional reviews are:

1. Resubmit the entire application with changes specified, appropriate signatures, and all necessary attachments to irb@nsula.edu NOTE: All appropriate signatures must be obtained again to reflect that all persons involved are aware of the changes.
2. Include a copy of the conditional approval letter/email as an attachment in your application email.

c. Resubmit: Investigator must revise the application and resubmit under appropriate guidelines for either "full," "expedited," or "exempt" review.
1. Resubmit the entire application with changes specified, appropriate signatures, and all necessary attachments to irb@nsula.edu NOTE: All appropriate signatures must be obtained again to reflect that all persons involved are aware of the changes.
2. Include a copy of the resubmission letter/email as an attachment in your application email.
3. Resubmitted proposals will be treated as new proposals regarding deadlines for submission.

10. At the completion of the research (within six weeks of completion at the latest), submit an electronic final report to the IRB. An abstract or a copy of the final report or article is acceptable. NOTE: It is not necessary to include a copy of the proposal. However, the final report must have the identical title as stated in the proposal and the same identifier (i.e. 02.19.006). The IRB will consider the research open for continuing review until this is completed.

11. If proposed research is a continuation of previously IRB approved research, a Continuation/Change in Protocol Application must be submitted before research may continue past the original project completion date. Please refer to the submission guidelines for the appropriate category of research (i.e., full, expedited, or exempt). A copy of the original proposal must be attached.

12. If adverse effects are detected at any time by the investigator, other research personnel, participants, or IRB member, research will terminate. The investigator will complete an adverse effects report with recommended action and submit it to the IRB. Research cannot recommence until the IRB approves the amended proposal.

13. If, during the continuing review, an IRB representative finds problems or areas of concern, research must terminate. The IRB chairperson will contact appropriate personnel and inform them in writing of the findings and IRB recommended actions. The researcher must complete and submit to the IRB a Continuation/Change in Protocol Application or an Adverse Effect Form and wait for written approval before the project may continue.

B. Informed Consent

Informed consent is a process, not just a form. Information must be represented to enable persons to voluntarily decide whether to participate as research subjects. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures,

alternatives, risks, and benefits) must be written in "lay language," (i.e., understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

The following are mandatory components of all informed consent documents:

1. **Describe the overall experience that will be encountered.** Explain the research activity. Inform human subjects of the reasonably foreseeable harms, discomforts, inconveniences and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are re-contacted or newly contacted.

2. **Describe the benefits that subjects may reasonably expect to encounter.** There may be none other than a sense of helping the public at large. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution.

3. **Describe any alternatives to participating in the research project.** For example, in drug studies the medication(s) may be available through subjects' family doctor or clinic without the need to volunteer for the research activity.

4. **The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence.** For example, some studies require disclosure of information to other parties. Some studies inherently are in need of a Certificate of Confidentiality that protects the investigator from involuntary release (e.g., subpoena) of the names or other identifying characteristics of research subjects. The IRB will determine the level of adequate requirements for confidentiality in light of its mandate to ensure minimization of risk and determination that the residual risks warrant involvement of subjects.

5. **If research-related injury (i.e., physical, psychological, social, financial, or otherwise) is a possible risk in research, an explanation must be given of whatever voluntary compensation and treatment will be provided.** Note that the regulations do not limit injury to "physical injury."

6. **The regulations prohibit waiving or appearing to waive any legal rights of subjects.** Therefore, for example, consent language must be carefully selected that deals with what the institution is voluntarily willing to do under circumstances, such as providing for compensation beyond the provision of immediate or therapeutic intervention in response to a research-related injury. In short, subjects should not be given the impression that they have agreed to and are without recourse to seek satisfaction beyond the institution's voluntarily chosen limits.

7. **The regulations provide for the identification of contact persons who would be knowledgeable to answer questions of subjects about the research, rights as research subjects, and the risk of research-related injuries.** These three areas must be explicitly stated and addressed in the consent process and documentation. Furthermore, a single person is not likely to be appropriate to answer questions in all areas. This is because of

potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects or the risk of research-related injuries may best be referred to those not on the research team. These questions could be addressed to the IRB, an ombudsman, an ethics committee, or other informed administrative body. Therefore, the consent document may have multiple names with local telephone numbers for contacts to answer questions in these specified areas.

8. **The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations 45 CFR 46.** It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of either not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences to them should they unilaterally withdraw while dependent on some intervention to maintain normal function.

9. **If extra-credit points or other compensation is offered to participants in the research study, the researcher must provide equitable opportunities for nonparticipants.** This must be included in the consent form.

10. **Include a statement concerning conflict of interest.** If a conflict of interest is present, an explanation of the conflict must be presented to the potential subjects in the informed consent. Conflict of interest occurs when the researcher or any member of the research team has a financial or personal interest in companies or company materials involved in the research. If there is no conflict of interest a statement saying this must be included.

11. **Include an offer of the study's results to participants.** Provide a space for participants to write a mailing or e-mail address where a summary of the study's results can be sent, if they desire this information. Alternatively, a statement should encourage participants to make a request to the study contact person for a summary of the results.

12. **Some research may not need consent from subjects.** If the validity and/or reliability of the data could be biased if the subjects were aware they were participants in a research project, informed consent may be waived. The IRB makes the final determination of this waiver. Following these guidelines will help make this determination:

    A. Will the research in its entirety involve greater than "minimal risk"?
       1. Yes. No waiver of informed consent.
       2. No. Go to next question.

    B. Is it practical to conduct the research without the waiver?
       1. Yes. No waiver of informed consent.
       2. No. Go to next question.

    C. Will waiving informed consent adversely affect subjects' rights and welfare?
       1. Yes. No waiver of informed consent.
       2. No. Go to next question.

    D. Will pertinent information be provided to subjects later, if appropriate?

1. Yes. Waiver, if IRB documents these four questions (A-D) and approves the waiver.
2. No. No waiver of informed consent.

The IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent if the IRB finds and documents:

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.
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Parts of the above information were taken from the Office for Protection from Research Risks – TIPS ON INFORMED CONSENT. This document can be found at: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ictips.htm

Below are instructions for preparing the written consent form. Please follow the instructions carefully.

1. Use the sample standardized consent format found in Appendix I as a guide.

2. The consent form should be written at a SIXTH GRADE READING LEVEL. Whenever possible, simple sentences should be used instead of complex ones. Ordinary language should replace technical terms. In general, the document should be written in language the participant can reasonably understand.

3. AVOID using EXCULPATORY LANGUAGE through which the subject or the representative is made to waive or appear to waive any of his or her legal rights or release the investigator, the sponsor, the institution, or its agents from liability for negligence.

4. If the RESEARCH INVOLVES THE PARTICIPATION OF MINORS (under 18 years of age), please refer to the section of this document labeled ASSENT (V.C.). Additional requirements concerning the parental consent forms and children assent forms are discussed.

5. IF the RESEARCH ACTIVITIES ARE DIRECTED TOWARD PREGNANT WOMEN, both the woman and child's father must give consent after having been fully informed regarding the impact on the fetus. (NOTE: Contact the IRB chairperson for more information about this type of research.)

6. For research involving HIV SCREENING and/or AIDS RESEARCH, there are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Contact the IRB chairperson for more information about this type of research.

7. For research involving GENETIC RESEARCH, additional issues must be addressed when obtaining informed consent. Contact the IRB chairperson for more information about this type of research.

C. Assent Form

Children are considered a vulnerable research population because their intellectual and emotional capacities are limited and they are legally incompetent to give valid consent. Special procedures and considerations are, therefore, required by the federal regulations for the review of research involving children. For Assent purposes, children are generally identified as those individuals 6 to 17 years of age. Children under the age of 6 years may be incapable of giving informed assent.

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. 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. Refer to 45 CFR 46 46.116 of Subpart A.

The IRB may find that the permission of one parent is sufficient for research to be conducted unless the research falls into categories identified in 45 CFR 46 46.406 and 46.407. Where research is covered by these two categories, 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.

The IRB is required to consider the degree of risk inherent in the proposed research and the methods for obtaining the assent of the children as well as the permission of parents or legal guardians. The IRB's policy with respect to obtaining consent from the parents or legal guardians and assent from minors is specified below:

1. In most cases, parental consent must be obtained if the research involves minors under the age of 18. A written consent form must be used to document informed consent. Both parents must sign the consent form unless this requirement is waived by the IRB. (The requirement for parental consent may be inappropriate in some cases such as research on child abuse.)

2. Minor subjects 6 years of age to 17 should be involved in the decision to participate in a research project unless:
   a. The subject is incapable, mentally or emotionally, of being reasonably consulted;
   b. The IRB specifically waives this requirement.

3. Unless the requirement is waived by the IRB, documentation of assent is required for subjects aged 6-17. In most cases, a written assent form should be used to document assent. A copy of the assent form must be submitted to the IRB for review. The form should include a simplified version of the elements of informed consent. Note that the child should be given an explanation, at a level appropriate to the child's age, maturity, and condition, of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research.

4. For clinical research, individuals under the age of 18 may possibly be considered emancipated minors for whom parental consent is not required. This occurs when individuals under the age of 18 are living on their own, have borne a child, or are

married. If pregnant individuals under the age of 18 are neither married nor living on their own (i.e., living at home under the care of their parents or some other adult), both parental consent and subject assent are needed. For social/behavioral research, however, parental consent is required for individuals under the age of 18, unless the requirement is waived by the IRB or the individuals are living on their own, are married, or have borne a child.

D. Debriefing Form

The purpose of the Debriefing Form is to provide the participant with information about the study in which he/she was a participant. The debriefing form is a document that remains in the possession of the participant(s) at the conclusion of their participation in the research activity. The Debriefing Form should contain all information that is in the Informed Consent, but should be written in past tense.

E. Use of Surveys: Copyright Issues

Investigators must provide written assurance in the application that all instruments (surveys, interviews, stimulus items presented to participants, etc.) used in a study may be used without risk of legal or other considerations. Thus, instruments must be either:

1. Developed by the investigator.
2. Considered public domain. The investigator must provide evidence.
3. Used with permission of the developer. In cases of copyrighted material, permission may be needed from the person who developed the instrument and/or a publisher.

Appendix A

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.
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Patricia King, J.D., Associate Professor of Law, Georgetown University Law Center.
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***Eliot Stellar, Ph.D., Provost of the University and Professor of Physiological Psychology, University of Pennsylvania.
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*** 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.

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Part A: Boundaries Between Practice & Research

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 an 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.

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.

Part B: Basic Ethical Principles

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 selfdetermination 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 th ethics of research involving human subjects. For example, during the 19th and early 20 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.

Part C: Applications

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 disable 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 entitle.

2. Assessment of Risks and Benefits. -- The assessment of risks and benefits requires a careful arrayal 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.

National Institutes of Health Bethesda, Maryland 20892

Appendix B

45 CFR 46

TITLE 45 CODE OF FEDERAL REGULATIONS PART 46

PROTECTION OF HUMAN SUBJECTS

*** * ***

Revised July 19, 2017 Effective July 19, 2018 - January 21, 2019

*** * ***

Subpart A

Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)

Source: 82 FR 7259, 7273, Jan. 19, 2017, unless otherwise noted.

§46.101 To what does this policy apply?

(a) Except as detailed in §46.104, this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that 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. Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy.

(b) [Reserved]

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy and this judgment shall be exercised consistent with the ethical principles of the Belmont Report.[62]

[62]The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.- Belmont Report. Washington, DC: U.S. Department of Health and Human Services. 1979.

(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 Federal 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 that provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations that may otherwise be applicable and that 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. 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 of research activities otherwise covered by this policy, provided the alternative procedures to be followed are consistent with the principles of the Belmont Report.[63] 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, or to the equivalent office within the appropriate Federal department or agency, and shall also publish them in the Federal Register or in such other manner as provided in department or agency procedures. The waiver notice must include a statement that identifies the conditions under which the waiver will be applied and a justification as to why the waiver is appropriate for the research, including how the decision is consistent with the principles of the Belmont Report.

[63] *Id.*

(j) Federal guidance on the requirements of this policy shall be issued only after consultation, for the purpose of harmonization (to the extent appropriate), with other Federal departments and agencies that have adopted this policy, unless such consultation is not feasible.

(k) [Reserved]

(l) Compliance dates and transition provisions:

(1) *Pre-2018 Requirements.* For purposes of this section, the *pre-2018 Requirements* means this subpart as published in the 2016 edition of the Code of Federal Regulations.

(2) *2018 Requirements.* For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this subpart. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for §46.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to §46.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under §46.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation through January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 46.102(l) of the 2018 Requirements (definition of research) (instead of §46.102(d) of the pre-2018 Requirements);

(*2*) Section 46.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of §46.103(f) of the pre-2018 Requirements); and

(*3*) Section 46.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of §46.103(b), as related to the requirement for continuing review, and in addition to §46.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019;

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019; and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

(m) Severability: Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

[82 FR 7259, 7273, Jan. 19, 2017, as amended at 83 FR 28518, June 19, 2018]

§46.102 Definitions.

(a) *Certification* means the official notification by the institution to the supporting Federal department or agency component, 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.

(b) *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

(c) *Department or agency head* means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

(d) *Federal department or agency* refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (*e.g.*, the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

(e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

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

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

(4) *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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.*,a medical record).

(5) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(6) *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

(7) Federal departments or agencies implementing this policy shall:

(i) Upon consultation with appropriate experts (including experts in data matching and re-identification), reexamine the meaning of "identifiable private information," as defined in paragraph (e)(5) of this section, and "identifiable biospecimen," as defined in paragraph (e)(6) of this section. This reexamination shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance.

(ii) Upon consultation with appropriate experts, assess whether there are analytic technologies or techniques that should be considered by investigators to generate "identifiable private information," as defined in paragraph (e)(5) of this section, or an "identifiable biospecimen," as defined in paragraph (e)(6) of this section. This assessment shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. Any such technologies or techniques will be included on a list of technologies or techniques that produce identifiable private information or identifiable biospecimens. This list will be published in the Federal Register after notice and an opportunity for public comment. The Secretary, HHS, shall maintain the list on a publicly accessible Web site.

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

(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) *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. If there is no applicable law addressing this issue, *legally authorized representative*means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

(j) *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.

(k) *Public health authority* means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

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

(1) Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

(m) *Written,* or *in writing,* for purposes of this part, refers to writing on a tangible medium (*e.g.,* paper) or in an electronic format.

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

(a) Each institution engaged in research that is covered by this policy, with the exception of research eligible for exemption under §46.104, and that 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 of 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 Federal-wide 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. Federal departments and agencies will conduct or support research covered by this policy only if the institution has provided an assurance that it will comply with the requirements of this policy, 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 (if such certification is required by §46.103(d)).

(b) 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.

(c) The department or agency head may limit the period during which any assurance shall remain effective or otherwise condition or restrict the assurance.

(d) Certification is required when the research is supported by a Federal department or agency and not otherwise waived under §46.101(i) or exempted under §46.104. For such research, institutions shall certify that each proposed research study covered by the assurance and this section has been reviewed and approved by the IRB. Such certification must be submitted as prescribed by the Federal department or agency component supporting the research. Under no condition shall research covered by this section be initiated prior to receipt of the certification that the research has been reviewed and approved by the IRB.

(e) For nonexempt research involving human subjects covered by this policy (or exempt research for which limited IRB review takes place pursuant to §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8)) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (*e.g.,* in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol).

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

§46.104 Exempt Research

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

(b) Use of the exemption categories for research subject to the requirements of subparts B, C, and D: Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

(1) *Subpart B.* Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

(2) *Subpart C.* The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

(3) *Subpart D.* The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(c) [Reserved]

(d) Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be

maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(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.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

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

§§46.105-46.106 [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 (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) 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 category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

(b) 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.

(c) 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.

(d) 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.

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

§46.108 IRB functions and operations.

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

(1) Have access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties;

(2) Prepare and maintain a current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses 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;

(3) Establish and follow written procedures for:
(i) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;
(ii) 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) Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

(4) Establish and follow written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency 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.

(b) Except when an expedited review procedure is used (as described in §46.110), an IRB must 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.

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

§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, including exempt research activities under §46.104 for which limited IRB review is a condition of exemption (under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

(b) An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) 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 requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in §46.109(f).

(f)(1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

(i) Research eligible for expedited review in accordance with §46.110;

(ii) Research reviewed by the IRB in accordance with the limited IRB review described in §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);

(iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

(2) [Reserved]

(g) An IRB 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)

§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 of 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 Secretary will evaluate the list at least every 8 years and amend it, as appropriate, after consultation with other federal departments and agencies and after publication in the Federal Register for public comment. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b)(1) An IRB may use the expedited review procedure to review the following:

(i) Some or all of the research appearing on the list described in paragraph (a) of this section, unless the reviewer determines that the study involves more than minimal risk;

(ii) Minor changes in previously approved research during the period for which approval is authorized; or

(iii) Research for which limited IRB review is a condition of exemption under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8).

(2) 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 nonexpedited procedure set forth in §46.108(b).

(c) Each IRB that uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals that 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.

§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 that are consistent with sound research design and that 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 (*e.g.,* 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. The IRB should be particularly cognizant of the special problems of research that involves a category

of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, 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 or appropriately waived in accordance with §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.

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

(ii) [Reserved]

(8) For purposes of conducting the limited IRB review required by §46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §46.116(a)(1)-(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §46.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, 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, individuals with impaired decision-making capacity, 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 or 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 9999-0020.)

§46.114 Cooperative research.

(a) Cooperative research projects are those projects covered by this policy that 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.

(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

(2) The following research is not subject to this provision:

(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another 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 forms, 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, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in §46.109(f)(1).

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in §46.108(a)(2).

(6) Written procedures for the IRB in the same detail as described in §46.108(a)(3) and (4).

(7) Statements of significant new findings provided to subjects, as required by §46.116(c)(5).

(8) The rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.
(9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in §46.103(e).

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

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

§46.116 General requirements for informed consent.

(a) *General.* General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:
(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
(5) Except for broad consent obtained in accordance with paragraph (d) of this section:
(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of

isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized 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.

(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

(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 that are experimental;

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

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

(4) 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;

(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; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(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) that are currently unforeseeable;
(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative'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 that may relate to the subject's willingness to continue participation will be provided to the subject;
(6) The approximate number of subjects involved in the study;
(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(d) *Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.* Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:
(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section;
(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information

or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

(e) *Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials—*

(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (e)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) 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:

(A) Public benefit or service programs;

(B) Procedures for obtaining benefits or services under those programs;

(C) Possible changes in or alternatives to those programs or procedures; or

(D) Possible changes in methods or levels of payment for benefits or services under those programs; and

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

(f) *General waiver or alteration of consent*

(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

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

(ii) The research could not practicably be carried out without the requested waiver or alteration;

(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

(g) *Screening, recruiting, or determining eligibility.* An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

(h) *Posting of clinical trial consent form.*

(1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

(i) *Preemption.* The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

(j) *Emergency medical care.* 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 (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

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

§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 informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

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

(1) A written informed consent form that meets the requirements of §46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

(2) A short form written informed consent form 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, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized 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 subject's legally authorized representative, in addition to a copy of the short form.

(c)(1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) 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; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research

presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

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

§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 Federal 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. Except for research waived under §46.101(i) or exempted under §46.104, 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 Federal department or agency component supporting the research.

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

Except for research waived under §46.101(i) or exempted under §46.104, 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 Federal department or agency component supporting the research, and final approval given to the proposed change by the Federal department or agency component.

§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 Federal department or agency through such officers and employees of the Federal 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 Federal 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 of either the conducting or the supporting Federal department or agency 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.

Subpart B

Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

Source: 66 FR 56778, 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 are 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.

Subpart C
Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Source: 43 FR 53655, 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 8386, 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:

(A) 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;

(B) 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;

(C) 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

(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. 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.

Subpart D

Additional HHS Protections for Children Involved as Subjects in Research

Source: 48 FR 9818, Mar. 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.

https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML

Appendix C

Full Review Application

Full Application for Approval of Investigations Involving the Use of Human Subjects Northwestern State University

The Principal Investigator must complete this application and electronically sign and date it before forwarding the document to others who also need to electronically sign and date it. Then the Investigator should email the application along with all supporting documents to irb@nsula.edu

All supporting documents must be saved as separate digital files (i.e. Word or PDF documents) and emailed together as one complete packet in one email to irb@nsula.edu

Please check below all the documents that are being submitted in your application.

Office PI

_____ _____ Informed consent form

_____ _____ Assent form

_____ _____ Debriefing form

_____ _____ Ethics Training Certificate (if your certificate is on file with the IRB and was earned in the last 5 years, then it does not need to be included in this packet.)

_____ _____ Site permission letter

_____ _____ Appendices of surveys/questionnaires/other materials that will be used in the study

_____ _____ Permission to use above mentioned surveys/questionnaires/other materials that will be used in the Study

_____ _____ Statement about maintaining and storing data for at least 5 years.

_____ _____ Statement about submitting a final report to the IRB within 6 weeks of project completion.

_____ _____ Faculty Advisor checklist (only if the PI is a student)

_____ _____ Other: _____

For Office Use Only

IRB Proposal ID#: _____

Date of Submission: _____

Ethics Training Certificate PI: _____

Ethics Training Certificate FA: _____

Risk Designation: _____

Approval Date: _____

Full Application for Approval of Investigations
Involving the Use of Human Subjects
Northwestern State University

This application must be completed by the Investigator and sent to the Office of Sponsored Programs by email to irb@nsula.edu All correspondence will be sent to the principal investigator and sponsor unless otherwise specified.

1. Investigator(s) Names(s): _____

2. Local Address of Principal Investigator: _____

   Campus and Local Phone Number:_____

   Email address:_____

3. If you are a student, complete the following:

   Faculty sponsor & rank: _____ College/Department: _____

   Phone: _____ Email address: _____

4. Research Project Title:_____

5. Expected Starting Date: _____ Expected Completion Date: _____

6. Where is the study taking place? (Please indicate the location from which the participants will be recruited, and where data collection will be conducted. Note that site permission letters will be required if the location is anywhere other than an NSU campus.)

   _____

7. Number and age level of human subjects: Number: _____ Age:_____

8. Indicate the categories of subjects and controls to be included in the study. Check ALL that apply:
   ___Students ___Normal Volunteer ___Minors (17 yrs or less) ___ Prisoners ___Abortuses/Fetuses

   ___Decisionally Impaired ___ Decisionally Impaired (Institutionalized) ___Pregnant Women ___ Patients

9. Is this project: (Check all that apply) A graduate thesis? ___ A field study? _____
   A Case study? ___ A Class project ? ___ Publishable research? ___

   Being conducted in a foreign country? ___ Undergraduate Thesis? ___

10. Has this project previously been considered by the IRB and a formal decision was made?

    ____ Yes _____ No If yes, give approximate date of review _____

11. Is this proposal being submitted to a sponsor for financial support? _____ Yes _____ No

    Is notification of human subject approval required to a granting agency? _____ Yes _____ No

    What agency? _____

****** If submitted externally, a complete copy of the proposal must be submitted to the IRB.******

12. Indicate which of the categories listed below accurately describes this protocol (This does not constitute expedited or exempt):

___ Not greater than minimal risk

___ Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects

___ Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

___ Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects

13. Identify other KEY personnel assisting in research project (attach additional sheets if necessary): (Indicate all personnel authorized by the principal investigator to obtain informed consent.)

Name, Rank/Degree_____

Responsibility in Project _____ Authorized to Obtain Consent: ___ Yes ___ No

Name, Rank/Degree_____

Responsibility in Project _____ Authorized to Obtain Consent: ___ Yes ___ No

I. Purpose and Objectives of the Project

What is (are) the purpose(s) and objectives of the study?

II. Design of the Project:

Describe the project design (e.g., control and experimental groups, etc.). Indicate whether or not the subjects will be randomized for this project. Address whether deception will be involved.

III. Description of the Subject Population(s)

A. Describe the characteristics of the subject populations, such as anticipated number, age range, gender, ethnic background and health status. **If advertising for subjects, include a copy of the proposed advertisement.**

B. Who are the subject groups and how are they being recruited? Explain how sign-up will occur.

C. Approximately how many subjects are in each group? _____

D. What are the criteria for selection and/or exclusion of subjects?

E. If a special or vulnerable population is being used, please explain why they must be in the study and how their special rights and welfare will be protected. (Vulnerable populations include such groups as children under 18, minority groups, pregnant women or fetuses, prisoners, and those with mental impairment. Other populations may qualify, depending on the project.)

IV. Recruitment Methods

A. Describe plans for the recruitment of subjects and the consent procedures to be followed, including how the population will be accessed, the circumstances under which consent will be sought and obtained, who will seek it and the method of documenting consent.

B. Describe alternative procedures (treatment, care) that might be available to subjects who choose not to participate in the study which offer the subject equal or greater advantages. For example, if extra credit is awarded to students recruited from classes for participation, indicate that alternate and equivalent options are available; if experimental treatment is provided in study and a control group is employed, the control group must have the eventual option of receiving the experimental treatment.

V. Activities Involving Human Subjects

A. Describe in detail the activities and procedures involving each subject group. Include the expected amount of time subjects will be involved in each activity and when and where the activities will be conducted. (Attach additional sheets as needed.)

B. How will the data be collected?

_____ questionnaires (Submit a copy. If the questionnaire was developed by the investigator, state it. Otherwise, provide evidence that the questionnaire is in the public domain or provide copyright holder and author permission statements if the questionnaire is copyrighted.)

_____ interviews (Submit sample of questions.)

_____ observations (Briefly describe below.)

_____ standardized tests (If yes, list names.)

_____ other (Describe below.)

VI. Treatment of Data

A. How will the data be recorded (notes, video or audio tapes, computer files, completed questionnaires, tests, etc.)?

B. Who will have access to the gathered data during the study and after the study?

C. How will confidentiality be maintained during the study, after the study and in reporting the results?

D. What are the plans for the data after completion of the study, and how and when will data be maintained or destroyed? Include special measures used to secure data (e.g. locked file cabinet, limited access, location of archival data, stored for at least five years)

VII. Benefits, Risks, Costs

A. What are the potential benefits to the subjects, to the field or discipline, and to the university? Discuss why the risks to subjects are reasonable in relation to the anticipated benefit to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

B. What compensation (money, extra credit, etc.) will be offered to the subjects, and how will it be dispersed? If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms of payment.

C. What risks to the subjects are most likely to be encountered?

_____ social (employability, financial/personal reputation, etc.)

_____ psychological (emotional, behavioral, etc.)

_____ physical

_____ loss of confidentiality

_____ criminal or civil liability

_____ deception (benevolent misdirection)

_____ financial (any expense including travel)

_____ other (explain below)

D. Explain any of the risks identified above.

What safeguards will you use to eliminate or minimize these risks, including risks to confidentiality? If subjects experience adverse reactions, how will these reactions be managed or where can they seek help and at whose cost? Also, where appropriate, describe the provisions for maintaining the data collected to ensure the safety of subjects' anonymity.

VIII. Off-Site Research

A. If the research project receives federal funds from an agency, each study site will need to negotiate a Federal Wide Assurance with the Office for Human Research Protections (OHRP). Guidance may be found at OHRP's web site, **http://ohrp.osophs.dhhs.gov/irbasur.htm**.

B. If the research project will receive no federal funds, a letter from the appropriate administrator of each facility should be submitted on the facility's letterhead stationary and should contain the following information: agreement for the study to be conducted; identification of someone at the site who will provide information about appropriateness for its population; assurance of adequate capabilities to perform the research as approved by the IRB; and, if applicable, assurance that facility personnel involved in data collection have appropriate expertise and will follow IRB approved procedures.

IX. Follow-up Procedures

All approved projects will submit a final report (e.g., abstract of thesis or article) to the IRB within six weeks of the conclusion of the project. If the project will continue past the reported completion date, the investigator will provide to the IRB chairperson a written continuance request with an explanation of why more time is needed for the project. The IRB chairperson must approve the request before the project will be allowed to continue.

X. Informed Consent

Attach all the informed consent form(s), permission letters, sample documents and if applicable) release forms you will use in this study.

A. How will the study be explained to the subjects and by whom?

B. Does the consent form include the following information? Answer "yes" or "no" in each blank.

_____ The title, the principal investigator's name, and purpose of the project.

_____ A statement that explains what the participant will have to do.

_____ A statement that participation in this project is voluntary.

_____ A statement that explains the cost, if any, to the subject to participate.

_____ A statement that the subject's name will not be revealed or linked in any way to the data that is collected **OR** request to waive this requirement is explained below. Conditions for waiver usually include written consent of the subject and justification that the need to use the subject's name is integral to the study.

_____ A statement that explains who will have access to the requested information.

_____ A statement that the participant may withdraw from the study at any time without penalty.

_____ The name and phone number of a specific person to contact if the participant has questions or concerns about the project.

_____ The name and phone number of counseling or treatment center should subjects experience any adverse effects as a result of the project. Include who will pay for treatment if treatment is sought.

_____ A statement that neither participation nor non-participation will effect a student's grade in any institution

_____ If participants receive extra credit points, non-participants must have an opportunity to earn equivalent points.

_____ A statement that explains benefits to subjects and/or department.

_____ A statement or space for participants to receive the summary of results (if applicable).

_____ A conflict of interest statement.

C. Explain "no" answers or request for waiver (above), or other special conditions relating to informed consent.

D. If subjects are less than the age of legal consent, or are mentally incapacitated, indicate how consent of parents, guardians, or other qualified representatives will be obtained.

E. If the project involves minors, the informed consent form must also include the following information:

_____ The consent form must be clearly identified as a consent form of a minor.

_____ At least one parent or guardian must sign the consent form

_____ Minors six (6) years of age or older should be involved in the decision to participate.

XI. Debriefing Form

A. The debriefing form should be a past-tense form of the informed consent form.
B. The subject must be allowed to keep the debriefing form.

Certification and Approval Certification by Investigator: I agree to accept responsibility for the scientific and ethical conduct of this research study; to obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form; to immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study; to submit a written continuance request to the IRB, if needed; and to submit a final report to the IRB within six weeks of the conclusion of the project.

_____

Signature of Investigator Date

Faculty Sponsor: If the Investigator is a student, his/her Faculty Sponsor must approve this form. I certify that this project is under my direct supervision and that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project.

_____

Signature of Faculty Sponsor Date

Approving Agent/Budget or Unit Head: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. I also attest to the scientific merit of this study and the competency of the investigator(s) and give my permission to conduct the project.

_____

Signature of Approving Agent/Budget or Unit Head Date

Chairperson of IRB: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. The principal investigator and a faculty sponsor (if applicable) also certify that the study will be monitored to assure compliance with the design.

_____

Signature of Chairperson of IRB Date

Appendix D

Expedited Review

Expedited Application for Approval of Investigations
Involving the Use of Human Subjects
Northwestern State University

The Principal Investigator must complete this application and electronically sign and date it before forwarding the document to others who also need to electronically sign and date it. Then the Investigator should email the application along with all supporting documents to irb@nsula.edu

All supporting documents must be saved as separate digital files (i.e. Word or PDF documents) and emailed together as one complete packet in one email to irb@nsula.edu

Please check below all the documents that are being submitted in your application.

Office PI

_____ _____ Informed consent form

_____ _____ Assent form

_____ _____ Debriefing form

_____ _____ Ethics Training Certificate (if your certificate is on file with the IRB and was earned in the last 5 years, then it does not need to be included in this packet.)

_____ _____ Site permission letter

_____ _____ Appendices of surveys/questionnaires/other materials that will be used in the study

_____ _____ Permission to use above mentioned surveys/questionnaires/other materials that will be used in the Study

_____ _____ Statement about maintaining and storing data for at least 5 years.

_____ _____ Statement about submitting a final report to the IRB within 6 weeks of project completion.

_____ _____ Faculty Advisor checklist (only if the PI is a student)

_____ _____ Other: _____

For Office Use Only

IRB Proposal ID#: _____

Date of Submission: _____

Ethics Training Certificate PI: _____

Ethics Training Certificate FA: _____

Risk Designation: _____

Approval Date: _____

Expedited Application for Approval of Investigations
Involving the Use of Human Subjects
Northwestern State University

This application must be completed by the Investigator and sent to the Office of Sponsored Programs by email to irb@nsula.edu All correspondence will be sent to the principal investigator and sponsor unless otherwise specified.

1. Investigator(s) Names(s): _____

2. Local Address of Principal Investigator: _____

   Campus and Local Phone Number:_____

   Email address:_____

3. If you are a student, complete the following:

   Faculty sponsor & rank: _____ College/Department: _____

   Phone: _____ Email address: _____

4. Research Project Title:_____

5. Expected Starting Date: _____ Expected Completion Date: _____

6. Where is the study taking place? (Please indicate the location from which the participants will be recruited, and where data collection will be conducted. Note that site permission letters will be required if the location is anywhere other than an NSU campus.)

   _____

7. Number and age level of human subjects: Number: _____ Age:_____

8. Indicate the categories of subjects and controls to be included in the study. Check ALL that apply:

   ___Students ___Normal Volunteer ___Minors (17 yrs or less) ___ Prisoners ___Abortuses/Fetuses

   ___Decisionally Impaired ___ Decisionally Impaired (Institutionalized) ___Pregnant Women ___ Patients

9. Is this project: (Check all that apply) A graduate thesis? ___ A field study? _____

   A Case study? ___ A Class project ? ___ Publishable research? ___

   Being conducted in a foreign country? ___ Undergraduate Thesis? ___

10. Has this project previously been considered by the IRB and a formal decision was made?

    ____ Yes _____ No If yes, give approximate date of review _____

11. Is this proposal being submitted to a sponsor for financial support? _____ Yes _____ No

    Is notification of human subject approval required to a granting agency? _____ Yes _____ No

    What agency? _____

****** If submitted externally, a complete copy of the proposal must be submitted to the IRB.******

12. Indicate which of the categories listed below accurately describes this protocol (This does not constitute expedited or exempt):

    ___ Not greater than minimal risk

    ___ Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects

    ___ Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

    ___ Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects

13. Identify other KEY personnel assisting in research project (attach additional sheets if necessary): (Indicate all personnel authorized by the principal investigator to obtain informed consent.)

    Name, Rank/Degree_____

    Responsibility in Project _____ Authorized to Obtain Consent: ___ Yes ___ No

    Name, Rank/Degree_____

    Responsibility in Project _____ Authorized to Obtain Consent: ___ Yes ___ No

14. Will data be collected from individuals through intervention or interaction with the individuals?

    ___ Yes ___ No

15. Will identifiable private information be collected from other sources (e.g. medical records)?

    ___ Yes ___ No

16. 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. 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.
    a. The categories in this list apply regardless of the age of subjects, except as noted.
    b. 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 or 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 no greater than minimal.
    c. The expedited review procedure may not be used for classified research involving human subjects.
    d. 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.

17. Check the one that best applies to your project.

___ 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 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 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.

___ 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 frequency 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.

___ 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 rountine patient care indicates a need for extraction;
(c) permanent teeth if routine patient care indicates a need for extraction;
(d) excreta and external secretions (including sweat);
(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing 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 or rupture of the membrane prior to or during labor;
(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
(j) sputum collected after saline mist nebulization.

___ Collect 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 cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
(b) weighing or testing sensory acuity;
(c) magnetic resonance imaging;
(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, 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.

___ 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. This listing refers only to research that is not exempt.)

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

___ 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. This listing refers only to research that is not exempt.)

18. Explain why you believe this project should be expedited.

19. Complete the rest of the application to explain your project. The chairperson of the IRB retains final judgment as to whether this project meets the expedited criteria.

I. Purpose and Objectives of the Project

What is (are) the purpose(s) and objectives of the study?

II. Design of the Project:

Describe the project design (e.g., control and experimental groups, etc.). Indicate whether or not the subjects will be randomized for this project. Address whether deception will be involved.

III. Description of the Subject Population(s)

Describe the characteristics of the subject populations, such as anticipated number, age range, gender, ethnic background and health status. **If advertising for subjects, include a copy of the proposed advertisement.**

A. Who are the subject groups and how are they being recruited? Explain how sign-up will occur.

B. Approximately how many subjects are in each group? _____

C. What are the criteria for selection and/or exclusion of subjects?

D. If a special or vulnerable population is being used, please explain why they must be in the study and how their special rights and welfare will be protected. (Vulnerable populations include such groups as children under 18, minority groups, pregnant women or fetuses, prisoners, and those with mental impairment. Other populations may qualify, depending on the project.)

IV. Recruitment Methods

A. Describe plans for the recruitment of subjects and the consent procedures to be followed, including how the population will be accessed, the circumstances under which consent will be sought and obtained, who will seek it and the method of documenting consent.

B. Describe alternative procedures (treatment, care) that might be available to subjects who choose not to participate in the study which offer the subject equal or greater advantages. For example, if extra credit is awarded to students recruited from classes for participation, indicate that alternate and equivalent options are available; if experimental treatment is provided in study and a control group is employed, the control group must have the eventual option of receiving the experimental treatment.

V. Activities Involving Human Subjects

A. Describe in detail the activities and procedures involving each subject group. Include the expected amount of time subjects will be involved in each activity and when and where the activities will be conducted. (Attach additional sheets as needed.)

B. How will the data be collected?

_____ questionnaires (Submit a copy. If the questionnaire was developed by the investigator, state it. Otherwise, provide evidence that the questionnaire is in the public domain or provide copyright holder and author permission statements if the questionnaire is copyrighted.)

_____ interviews (Submit sample of questions.)

_____ observations (Briefly describe below.)

_____ standardized tests (If yes, list names.)

_____ other (Describe below.)

VI. Treatment of Data

A. How will the data be recorded (notes, video or audio tapes, computer files, completed questionnaires, tests, etc.)?

B. Who will have access to the gathered data during the study and after the study?

C. How will confidentiality be maintained during the study, after the study and in reporting the results?

D. What are the plans for the data after completion of the study, and how and when will data be maintained or destroyed? Include special measures used to secure data (e.g. locked file cabinet, limited access, location of archival data, stored for at least five years)

VII. Benefits, Risks, Costs

A. What are the potential benefits to the subjects, to the field or discipline, and to the university? Discuss why the risks to subjects are reasonable in relation to the anticipated benefit to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

B. What compensation (money, extra credit, etc.) will be offered to the subjects, and how will it be dispersed? If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms of payment.

C. What risks to the subjects are most likely to be encountered?

_____ social (employability, financial/personal reputation, etc.)

_____ psychological (emotional, behavioral, etc.)

_____ physical

_____ loss of confidentiality

_____ criminal or civil liability

_____ deception (benevolent misdirection)

_____ financial (any expense including travel)

_____ other (explain below)

D. Explain any of the risks identified above.

What safeguards will you use to eliminate or minimize these risks, including risks to confidentiality? If subjects experience adverse reactions, how will these reactions be managed or where can they seek help and at whose cost? Also, where appropriate, describe the provisions for maintaining the data collected to ensure the safety of subjects' anonymity.

VIII. Off-Site Research

A. If the research project receives federal funds from an agency, each study site will need to negotiate a Federal Wide Assurance with the Office for Human Research Protections (OHRP). Guidance may be found at OHRP's web site, http://ohrp.osophs.dhhs.gov/irbasur.htm.

B. If the research project will receive no federal funds, a letter from the appropriate administrator of each facility should be submitted on the facility's letterhead stationary and should contain the following information: agreement for the study to be conducted; identification of someone at the site who will provide information about appropriateness for its population; assurance of adequate capabilities to perform the research as approved by the IRB; and, if applicable, assurance that facility personnel involved in data collection have appropriate expertise and will follow IRB approved procedures.

IX. Follow-up Procedures

All approved projects will submit a final report (e.g., abstract of thesis or article) to the IRB within six weeks of the conclusion of the project. If the project will continue past the reported completion date, the investigator will provide to the IRB chairperson a written continuance request with an explanation of why more time is needed for the project. The IRB chairperson must approve the request before the project will be allowed to continue.

X. Informed Consent

Attach all the informed consent form(s), permission letters, sample documents and (if applicable) release forms you will use in this study.

A. How will the study be explained to the subjects and by whom?

B. Does the consent form include the following information? Answer "yes" or "no" in each blank.

_____ The title, the principal investigator's name, and purpose of the project.

_____ A statement that explains what the participant will have to do.

_____ A statement that participation in this project is voluntary.

_____ A statement that explains the cost, if any, to the subject to participate.

_____ A statement that the subject's name will not be revealed or linked in any way to the data that is collected **OR** request to waive this requirement is explained below. Conditions for waiver usually include written consent of the subject and justification that the need to use the subject's name is integral to the study.

_____ A statement that explains who will have access to the requested information.

_____ A statement that the participant may withdraw from the study at any time without penalty.

_____ The name and phone number of a specific person to contact if the participant has questions or

concerns about the project.

_____ The name and phone number of counseling or treatment center should subjects experience any adverse effects as a result of the project. Include who will pay for treatment if treatment is sought.

_____ A statement that neither participation nor non-participation will effect a student's grade in any institution

_____ If participants receive extra credit points, non-participants must have an opportunity to earn equivalent points.

_____ A statement that explains benefits to subjects and/or department.

_____ A statement or space for participants to receive the summary of results (if applicable).

_____ A conflict of interest statement.

C. Explain "no" answers or request for waiver (above), or other special conditions relating to informed consent.

D. If subjects are less than the age of legal consent, or are mentally incapacitated, indicate how consent of parents, guardians, or other qualified representatives will be obtained.

E. If the project involves minors, the informed consent form must also include the following information:

_____ The consent form must be clearly identified as a consent form of a minor.

_____ At least one parent or guardian must sign the consent form

_____ Minors six (6) years of age or older should be involved in the decision to participate.

XI. Debriefing Form

A. The debriefing form should be a past-tense form of the informed consent form.
B. The subject must be allowed to keep the debriefing form.

Certification and Approval Certification by Investigator: I agree to accept responsibility for the scientific and ethical conduct of this research study; to obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form; to immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study; to submit a written continuance request to the IRB, if needed; and to submit a final report to the IRB within six weeks of the conclusion of the project.

_____

Signature of Investigator Date

Faculty Sponsor: If the Investigator is a student, his/her Faculty Sponsor must approve this form. I certify that this project is under my direct supervision and that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project.

_____ Signature of Faculty Sponsor Date

Approving Agent/Budget or Unit Head: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. I also attest to the scientific merit of this study and the competency of the investigator(s) and give my permission to conduct the project.

_____

Signature of Approving Agent/Budget or Unit Head Date

Chairperson of IRB: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. The principal investigator and a faculty sponsor (if applicable) also certify that the study will be monitored to assure compliance with the design.

_____

Signature of Chairperson of IRB Date

Appendix E

Exempt Application

Exemption - Application for Approval of Investigations
Involving the Use of Human Subjects
Northwestern State University

The Principal Investigator must complete this application and electronically sign and date it before forwarding the document to others who also need to electronically sign and date it. Then the Investigator should email the application along with all supporting documents to irb@nsula.edu

All supporting documents must be saved as separate digital files (i.e. Word or PDF documents) and emailed together as one complete packet in one email to irb@nsula.edu

Please check below all the documents that are being submitted in your application.

Office PI

_____ _____ Informed consent form

_____ _____ Assent form

_____ _____ Debriefing form

_____ _____ Ethics Training Certificate (if your certificate is on file with the IRB and was earned in the last 5 years, then it does not need to be included in this packet.)

_____ _____ Site permission letter

_____ _____ Appendices of surveys/questionnaires/other materials that will be used in the study

_____ _____ Permission to use above mentioned surveys/questionnaires/other materials that will be used in the Study

_____ _____ Statement about maintaining and storing data for at least 5 years.

_____ _____ Statement about submitting a final report to the IRB within 6 weeks of project completion.

_____ _____ Faculty Advisor checklist (only if the PI is a student)

_____ _____ Other: _____

For Office Use Only

IRB Proposal ID#: _____

Date of Submission: _____

Ethics Training Certificate PI: _____

Ethics Training Certificate FA: _____

Exempt Category: _____

Approval Date: _____

Exemption - Application for Approval of Investigations
Involving the Use of Human Subjects
Northwestern State University

This application must be completed by the Investigator and sent to the Office of Sponsored Programs by email to irb@nsula.edu All correspondence will be sent to the principal investigator and sponsor unless otherwise specified.

1. Investigator(s) Names(s):_____

2. Local Address of Principal Investigator:
   _____

   Campus and Local Phone Number:_____

   Email address:_____

3. If you are a student, complete the following:

   Faculty sponsor & rank: _____ College/Department: _____

   Phone: _____ Email address: _____

4. Project Title:_____

5. Expected Starting Date: _____ Expected Completion Date: _____

6. Where is the study taking place? (Please indicate the location from which the participants will be recruited, and where data collection will be conducted. Note that site permission letters will be required if the location is anywhere other than an NSU campus.)
   _____

7. Number and age level of human subjects: Number: _____ Age:_____

8. Indicate the categories of subjects and controls to be included in the study. Check ALL that apply:

   ___Students ___Normal Volunteers ___Minors (17 yrs or less) ___ Prisoners ___Abortuses/Fetuses

   ___Decisionally Impaired ___ Decisionally Impaired (Institutionalized) ___Pregnant Women ___ Patients

9. Is this project: (Check all that apply) A graduate thesis?___ A Case study?___ A Class project ?___
   Publishable research? ___ Being conducted in a foreign country?___ Undergraduate Thesis?___

10. Has this project previously been considered by the IRB and a formal decision was made?
    ____ Yes _____ No If yes, give approximate date of review _____

11. Is this proposal being submitted to a sponsor for financial support? _____ Yes _____ No
    Is notification of human subject approval required to a granting agency? ____Yes ____No

    What agency? _____

****** If submitted externally, a complete copy of the proposal must be submitted to the IRB.******

12. Identify other KEY personnel assisting in research project (attach additional sheets if necessary):

(Indicate all personnel authorized by the principal investigator to obtain informed consent.)

Name, Rank/Degree_____

Responsibility in Project _____ Authorized to Obtain Consent: ___ Yes ___ No

Name, Rank/Degree_____

Responsibility in Project _____ Authorized to Obtain Consent: ___ Yes ___ No

Complete the following information about your study.

13. What is (are) the purpose(s) or objectives of the research project?

14. What are the benefits to (1) study subjects and (2) institution?

15. Who are the study subjects?

16. Briefly describe the methodology of the study. Be sure to specify the procedure and what data be collected, and how it will be collected?

17. How will confidentiality of subject information and data be maintained?

18. Will subject anonymity be assured? ___ Yes ___ No If yes, how will anonymity be assured?

19. How will results be disseminated?

20. Include an explanation of a conflict of interest. If no conflict of interest is present, please provide a statement that says, "No conflict of interest."

IMPORTANT NOTE: Please attach copies of and permission to use all instruments, copies of Informed Consent. Also include statements that records will be maintained for five years and that a final summary report will be submitted to the IRB within 6 weeks of the project's completion.

Check all of the following exempt categories where you believe your proposal fits.

21. Research activities are exempt from the federal policy for the Protection of Human Subjects when the ONLY involvement of human subjects falls within one or more of the categories below. Check the appropriate categories that apply to your research project:

_____ 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.

_____ Research only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, public observation if at least ONE of the following criteria is met:

(i) recorded information cannot readily identify the subject (directly or indirectly/linked); OR
(ii) any disclosure of responses outside of the research would reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); OR

(iii) information is recorded with identifiers or code linked to identifiers & IRB conducts Limited Review

_____ Research involving benign behavioral interventions (BBI) through verbal, written responses, (Including data entry or audiovisual recording) from adult subject who prospectively agrees and ONE of the following met: :

(A) recorded information cannot readily identify the subject (directly or indirectly/linked); OR
(B) any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); OR
(C) information is recorded with identifiers & IRB conducts Limited Review.

_____ Secondary research for which consent is not required: use of identifiable information or identifiable biospecimen that have been or will be collected for some other "primary" or "initial" activity, if ONE of the following criteria met:

(i) biospecimens or information is publicly available; OR
(ii) information is recorded so subject cannot be readily identified (directly or indirectly/linked); investigator does not contact subjects and will not re-identify the subjects; OR
(iii) Collection and analysis involving investigators use of identifiable health information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"; OR
(iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities

_____ 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:

(v) public benefit or service programs;
(vi) procedures for obtaining benefits or services under those programs;
(vii) possible changes in or alternatives to those programs or procedures; or
(viii) possible changes in methods or levels of payment for benefits or services under those programs.

_____ 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 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.

Certification and Approval Certification by Investigator: I agree to accept responsibility for the scientific and ethical conduct of this research study; to obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form; to immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study; to submit a written continuance request to the IRB, if needed; and to submit a final report to the IRB within six weeks of the conclusion of the project.

_____

Signature of Investigator Date

Faculty Sponsor: If the Investigator is a student, his/her Faculty Sponsor must approve this form. I certify that this project is under my direct supervision and that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project.

_____ Signature of Faculty Sponsor Date

Approving Agent/Budget or Unit Head: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. I also attest to the scientific merit of this study and the competency of the investigator(s) and give my permission to conduct the project.

_____

Signature of Approving Agent/Budget or Unit Head Date

Chairperson of IRB: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. The principal investigator and a faculty sponsor (if applicable) also certify that the study will be monitored to assure compliance with the design.

_____

Signature of Chairperson of IRB Date

Appendix F

Continuation/ Change in Protocol Application

Continuation/Change in Protocol Application

1. Title of previously approved research project. _____

2. Principal investigator'(s) name for previously approved research. _____

3. Date of previous IRB approval letter. (Please provide a copy of the approval letter.)

4. Is the previous research project completed? __ Yes __ No

5. Was a final report filed? __ Yes ___ No

6. Were there any adverse effects reported during the previous research project? ___ Yes ___ No

Proposal Revisions

(Check all that apply and provide appropriate information.)

___ New Title ___ New Population ___ New Informed Consent

___ New Time Frame ___ New Sample Design ___ New Debriefing

___ New Investigators ___ New Protocol/Procedures ___ Other Changes (define)

Certification and Approval

Certification by Investigator: I agree to accept responsibility for the scientific and ethical conduct of this research study; to obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form; to immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study; to submit a written continuance request to the IRB, if needed; and to submit a final report to the IRB within six weeks of the conclusion of the project.

Signature of Investigator Date

Faculty Sponsor: If the Investigator is a student, his/her Faculty Sponsor must approve this form. I certify that this project is under my direct supervision and that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project.

Signature of Faculty Sponsor Date

Approving Agent/Budget or Unit Head: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. I also attest to the scientific merit of this study and the competency of the investigator(s) and give my permission to conduct the project.

Signature of Approving Agent/Budget or Unit Head Date

Chairperson of IRB: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. The principal investigator and a faculty sponsor (if applicable) also certify that the study will be monitored to assure compliance with the design.

Signature of Chairperson of IRB Date

Appendix G

Continuing Review Form

Continuing Review Form

IRB # _____

Type of Original Review_____

Date of Review _____

Reviewer: _____

Title of Project: _____

Principal Investigator: _____

Address and phone number: _____

Faculty Sponsor (if applicable): _____

1. Have there been any changes in the study subjects (numbers, age range, gender, ethnic identity, etc.) or method of recruitment of subjects since the last review?
_____ Yes _____ No (If yes, provide full details on separate sheet).

2. Have the procedures/protocols changed in any manner since the last IRB approval?
_____ Yes _____ No (If yes, provide full details on separate sheet).

3. Were any complications, adverse reactions, or unexpected results (positive or negative) encountered as a result of human subjects being involved in this study?
_____ Yes _____ No (If yes, provide full details on separate sheet).

Certification and Approval

Certification by Investigator: I agree to accept responsibility for the scientific and ethical conduct of this research study; to obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form; to immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study; to submit a written continuance request to the IRB, if needed; and to submit a final report to the IRB within six weeks of the conclusion of the project.

Signature of Investigator Date

Faculty Sponsor: If the Investigator is a student, his/her Faculty Sponsor must approve this form. I certify that this project is under my direct supervision and that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project.

Signature of Faculty Sponsor Date

Approving Agent/Budget or Unit Head: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. I also attest to the scientific merit of this study and the competency of the investigator(s) and give my permission to conduct the project.

Signature of Approving Agent/Budget or Unit Head Date

Chairperson of IRB: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. The principal investigator and a faculty sponsor (if applicable) also certify that the study will be monitored to assure compliance with the design.

Signature of Chairperson of IRB Date

Appendix H

Adverse Effects Form

Adverse Effects Form

IRB # _____
Type of Original Review_____

Title of Project:
_____

Principal Investigator: _____

Address and phone number: _____

Faculty Sponsor (if applicable): _____

1. How many adverse effects occurred? _____
2. What are these adverse effects? Please list on separate sheet of paper.
3. When did the adverse effects occur? _____
4. What actions were taken to reverse, alleviate or deal with these adverse effects? Please list these separately on an additional sheet of paper.

Certification and Approval

Certification by Investigator: I agree to accept responsibility for the scientific and ethical conduct of this research study; to obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form; to immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study; to submit a written continuance request to the IRB, if needed; and to submit a final report to the IRB within six weeks of the conclusion of the project.

Signature of Investigator Date

Faculty Sponsor: If the Investigator is a student, his/her Faculty Sponsor must approve this form. I certify that this project is under my direct supervision and that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project.

Signature of Faculty Sponsor Date

Approving Agent/Budget or Unit Head: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. I also attest to the scientific merit of this study and the competency of the investigator(s) and give my permission to conduct the project.

Signature of Approving Agent/Budget or Unit Head Date

Chairperson of IRB: I have reviewed the design of the proposed study and certify that the safeguards utilized do adequately protect the rights and welfare of the human subjects involved. The principal investigator and a faculty sponsor (if applicable) also certify that the study will be monitored to assure compliance with the design.

Signature of Chairperson of IRB Date

Appendix I

Informed Consent

Informed Consent Form

Summary of key points:

- **This study will take about _____** *(specify length of study)* **to complete.**
- **In this study, you will _____** *(brief, one statement description of what the participant will do)*
- *(briefly describe any potential risks)*
- *(briefly describe any potential benefits)*

You are being invited to take part in a research study about _____.
You are being invited to participate in this research study because _____.
(*If a condition or circumstance exists that makes participants eligible for the study, specify this information; however, this may not be applicable for some social science studies.)*
If you take part in this study, you will be one of about _____ *(specify total number of participants expected in study)* **people to do so.**

The person in charge of this study is _____ *(PI)* of_____*(Affiliation). (If the PI is a student, add the following statement:)* He/She is being guided in this research by _____*(Advisor)*. **Other people on the research team may assist at different times during the study.** *(Include the preceding sentence only if other people are involved in the study, and then identify the other investigators.)*

(Describe the purpose of the study).

(Describe where the study will be conducted. Include how many times the participants will be asked to attend and how long the administration will take. If this is a longitudinal study, include the length of time involved..

(Tell the subject what to expect. Describe all procedures in simple language. Provide a timeline for longitudinal studies. Also, explain random selection procedures.)

(If the research involves minimal risk to the subject, include the following statement:) **To the best of my knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.** *(If the research involves procedures that could cause possible physical harm, describe the risks and any consequences that could result should an adverse/negative event occur.)*

(If the research involves any procedures that could cause possible emotional or mental harm, include the following statement:)

Although we have made every effort to minimize harm, you may find some questions we ask you (or some procedures we ask you to do) to be upsetting or stressful. If so, we can tell you about some people who may be able to help you with these feelings. *(Provide information about contacts. Free services are available through the Counseling Center at NSU.)*

(If a conflict of interest exists in the project, please explain; otherwise, use the following or a similar statement to indicate that no conflict of interest exists.)

Neither the person in charge of the study nor any personnel involved in this study have any financial or personal interest in any company or instrument being used.

There is no guarantee that you will get any benefit from taking part in this study. However, some people have experienced _____ when _____. We cannot and do not guarantee that you will receive any benefits from this study.

OR

You will not get any personal or financial benefit from taking part in this study.

(If no rewards or payments are granted for participants, use the following statement:)

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering.

(If subjects are students, include the following:)

Your decision to participate or not participate in this study will not affect your grade in any course. *(See statement below about extra credit for exceptions.)*

(If participants will receive payment, extra credit, etc., you must include one of the following:)

You will receive _____ for taking part in this study. If you should have to quit before the study is through, the payment you receive will be based on the amount of time you were in the study.

OR **You will not receive any payment or reward for taking part in this study.**

OR **You will receive _____ extra credit points for participating in this study. Equivalent alternative extra credit will be available for those who elect not to participate.**

(You must address the costs to participants. If there are costs involved to subjects, state how much the costs are and when the money is due. If there are no costs to subjects, include the following:)

There are no costs associated with taking part in this study.

(Include the following paragraph to explain who will see the information from the study:)

Your information will be combined with information from other people taking part in the study. When the report of the study is written to share with other researchers, it will include combined information for all participants. You will not be identified in these written materials.

(If the study is anonymous, include the following:)

This study is anonymous. That means that no one, not even members of the research team, will know that the information you give came from you.

(If the study is not anonymous, include the following:)

The researchers will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. For example,

your name will be kept separate from the information you give, and these two things will be stored in different places under lock and key.

(Include the following about right to withdraw:)

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

The researchers conducting the study may need to take you off of the study. They may do this if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of reasons.

(Include the following statement to provide contact information for questions that may arise:)

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact the investigator, _____ at _____.

(Include a statement offering participants a summary of the study's results:)

Provide a mailing or e-mail address if you would like a copy of a summary of the study's results:

_____.

OR

A copy of the summarized results of the study will be available by request made to the primary investigator, _____.

(Include the following statement:)

You will be told if any new information is learned that may affect your condition or influence your willingness to continue taking part in this study.

_____

Signature of Participant Date

_____

Printed name of Participant

Appendix J

Assent Form

ASSENT FORM

Summary of key points:

- **This study will take about _____** *(specify length of study)* **to complete.**
- **In this study, you will _____** *(brief, one statement description of what the participant will do)*
- *(briefly describe any potential risks)*
- *(briefly describe any potential benefits)*

You are being invited to take part in a study about _____. You are being invited to participate in this research study because _____.

The person in charge of this study is _____ *(PI)* **of**_____*(Affiliation). (If the PI is a student, add the following statement:)* **He/She is being guided in this study by _____ .***(Advisor).* **There may be other people helping at different times during the study.** *(Include the preceding sentence only if other people are involved in the study, and then identify the other investigators.)*

(Describe the purpose of the study in lay terms.)

(In lay terms, describe where the study will be conducted. Include how many times the participants will be asked to attend and how long the administration will take. If this is a longitudinal study, include the length of time involved).

(Tell the subject what to expect. Describe all procedures in simple language. Provide a timeline for longitudinal studies. Also, explain random selection procedures.)

(If the research involves minimal risk to the subject, include the following statement:)
To the best of my knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.

(If the research involves procedures that could cause possible physical harm, describe the risks and any consequences that could result should an adverse or negative event occur.)

(If the research involves any procedures that could cause possible emotional or mental harm, include the following statement:)

Although the researcher(s) have/has made every effort to reduce harm, you may find some questions we ask you (or some things we ask you to do) to be upsetting. If so, we can tell you about some people who may be able to help you with these feelings.
(Provide information about contacts. Free services are available through the Counseling Center at NSU.)

(If a conflict of interest exists in the project, please explain; otherwise, use the following or a similar statement to indicate that no conflict of interest exists.)

No one in this study has any financial or personal interest in any company or materials being used.

(If no rewards or payments are granted for participants, use the following statement:) **You will not get any personal/financial benefit from taking part in this study.**

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any rights you would normally have if you choose not to volunteer. You can stop at any time during the study and keep the rights you had before volunteering. *(If subjects are students, include the following:)*

Your decision to participate or not participate in this study will not affect your grade in any course.

There are no costs associated with taking part in this study.

(Include the following paragraph to explain who will see the information from the study:)

Your information will be combined with information from other children taking part in the study. When we write about the study to share it with other people, we will write about this combined information. You will not be identified in these written materials.

(If the study is anonymous, include the following:)

This study is anonymous. That means that no one, not even members of the study team, will know that the information you give came from you.

(If the study is <u>not</u> anonymous, include the following:)

The researchers will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. For example, your name will be kept separate from the information you give, and these two things will be stored in different places under lock and key.

(Include the following about right to withdraw:)

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

The researchers conducting the study may need to take you off of the study. They may do this if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of reasons.

(Include the following statement to provide contact information for questions that may arise:)

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact the investigator, _____ at _____.

(Include a statement offering participants a summary of the study's results:)

Provide a mailing or e-mail address if you would like a copy of a summary of the study's results:

_____.

OR

A copy of the summarized results of the study will be available by request made to the primary investigator, _____.

(Include the following statement:)

You will be told if any new information is learned that may affect your condition or influence your willingness to continue taking part in this study.

I have read and/or have had this Assent Form explained to me and agree to be a participant in the study. My signature on this form gives you my permission to use me as a subject in your research.

Because I am under 18 and considered a minor, my parents/guardian(s) must also read and/or have read this Assent Form. Their signature on this Assent Form gives you their permission to use me as a subject in your research.

I understand that both my signature on the informed consent and my parent/guardian(s) signature must be obtained before I may become a participant in the study.

_____

Signature of Child Date

_____

Printed name of Child Date

_____

Signature of Parent/Guardian Date

_____

Printed name of Parent/Guardian Date

Appendix K

Guidance for Computer and Internet-Based Research Involving Human Participants, Sample Informed Consent for Online Surveys

Guidance for Computer and Internet-Based Research Involving Human Participants

Computer- and internet-based methods of collecting, storing, utilizing, and transmitting data in research involving human participants are developing at a rapid rate. As these new methods become more widespread in research in the social, psychological, and social sciences, they present new challenges to the protection of research participants. The NSU Institutional Review Board (IRB) believes that computer- and internet-based research protocols must address fundamentally the same risks (e.g., violation of privacy, legal risks, psychosocial stress) and provide the same level of protection as any other types of research involving human participants. All studies including those using computer and internet technologies must (a) ensure that the procedures fulfill the principles of voluntary participation and informed consent, (b) maintain the confidentiality of information obtained from or about human participants, and (c) adequately address possible risks to participants including psychosocial stress and related risks.

At the same time, the NSU IRB recognizes that computer- and internet-based research presents unique problems and issues involving the protection of human participants. The IRB further recognizes that computer and internet technologies are evolving rapidly, that these advances may pose new challenges to the protection of human participants in research, and that both the NSU IRB and researchers employing new technologies must maintain diligence in addressing new problems, issues, and risks as they arise in the coming years.

The purpose of these guidelines is to help researchers plan, propose, and implement computer- and internet-based research protocols that provide the same level of protection of human participants as more traditional research methodologies. The guidelines are comprised of requirements and recommendations that are consistent with the basic IRB principles applied to all research involving human participants.

Internet-based research may not be suitable for greater than minimal risk studies where the research involves data that:

1. places participants at risk of criminal or civil liability, or
2. could damage their financial standing, employability, insurability, reputation, or
3. could be stigmatizing, or
4. could result in stolen identity.

Data Collection:

- Any data collected from human participants over computer networks must be transmitted in encrypted format. This helps insure that any data intercepted during transmission cannot be decoded and that individual responses cannot be traced back to an individual respondent.
- The level of security should be appropriate to the risk. For most research, standard security measures like encryption and secure socket layer (SSL) will suffice. However, with sensitive topics additional protections include certified digital signatures for informed consent, encryption of data transmission, technical separation of identifiers.

- Researchers are cautioned that encryption standards vary from country to country and that there are legal restrictions regarding the export of certain encryption software outside US boundaries.

- Internet-based survey instruments must be formatted in a way that will allow participants to skip questions if they wish or provide a response such as "**I choose not to answer**." Also, at the end of the survey, there should be two buttons: one to allow participants to discard the data and the other to submit it for inclusion in the study. Finally, if applicable, online surveys must include mechanisms for withdrawal. For example, if a participant decides to withdraw, there should be a mechanism for identifying the responses of a participant for the purposes of discarding those responses.

- Researchers working with children online are subject to Children's Online Privacy Protection Act (COPPA – http://www.coppa.org/) in addition to human subjects' regulations. Researchers are prohibited from collecting personal information from a child without posting notices about how the information will be used and without getting verifiable (likely written) parental permission. For minimal risk research written permission may be obtained via paper mail, fax, or email. If the research is more than minimal risk, parental permission should be obtained in a face-to-face meeting.

Server Administration:

Use of SurveyMonkey.com, Psychsurveys.com and other online survey tools are permitted for minimal risk studies that do not involve the collection of sensitive data. As noted above, the IRB recommends that data be transmitted in a secure format.

For more than minimal risk studies that involve the collection of sensitive data, the IRB recommends it be housed on an NSU server. (At the time this version of the IRB Policies and Procedures Manual was developed, the LIME survey tool is available on the NSU server. Contact the NSU Information Systems office for more information on using this survey tool.) Regardless of the specific survey tool that is used, it should be administered by a professionally trained person with expertise in computer and internet security. Access to the server should be limited to key project personnel. The server should receive frequent, regularly scheduled security audits.

Data Storage/Disposal:

- If a server is used for data storage, personal identifying information should be kept separate from the data, and data should be stored in encrypted format. Use of Social Security Numbers is not permitted.

- It is recommended that data backups be stored in a safe location, such as a secure data room that is environmentally controlled and has limited access.

- It is recommended that competent data destruction services be used to ensure that no data can be recovered from obsolete electronic media.

Informed Consent Process For Internet-Based Research:

- For anonymous internet-based surveys, include "**I agree**" or "**I do not agree**" buttons or checkboxes on the website for participants to click to indicate their active choice of

whether or not they consent to participate. For anonymous surveys sent to and returned by participants through email, include an information sheet with consent information and inform participants that submitting the completed survey implies their consent.

- If the IRB determines that written consent is required, the consent form can be mailed or emailed to the participant who can then sign the form and return it via fax, postal mail, or email.
- Researchers conducting computer and internet-based research should be careful not to make guarantees of confidentiality or anonymity, as the security of online transmissions is not guaranteed. A statement in the informed consent form indicating the limits to confidentiality is typically required. The following statement may be used: "**Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties**."

Source material for this document guidance was provided by the Office for Research Protections at Pennsylvania State University and is used with permission. The NSU IRB gratefully acknowledges this support.

Sample Informed Consent Form for Online Surveys

Primary Investigator(s):
Address: ***(campus address or appropriate business address*****)**
Phone and Email:

(If the project involves Co-Investigators, Research Advisors, etc., provide same information for them as above.)

Summary of key points:

- **This study will take about _____** *(specify length of study)* **to complete.**
- **In this study, you will _____** *(brief, one statement description of what the participant will do)*
- *(briefly describe any potential risks)*
- *(briefly describe any potential benefits)*

You are being invited to take part in this study about _____. You are being invited to participate in this study because _____. *(If a condition or circumstance exists that makes subjects eligible for the study, specify this information; however, this may not be applicable for some social science studies.)*

If you choose to participate in this study, you will indicate your willingness by clicking below on the link to the online survey. The survey that you will complete… *(Describe what the participants will be asked to do and to estimate the amount of time required to complete the survey. If appropriate, describe the number and type of questions and even provide an example of the questions to be asked.)*

[Note: Research conducted online must be classified as "minimal risk," and as such requires the following paragraph:]

To the best of my knowledge, this investigational procedure does not pose any more risk of harm than you would experience in everyday life.

If you participate in this study, you may experience *(…any potential benefits to the participant…)* **and the satisfaction that comes with research and discovery. We appreciate your assistance in our research effort and hope you will find the experience rewarding. We do not promise, however, that you will receive any of these benefits**.

(Be certain to state if conflicts of interest exist or do not exist.)

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and keep the benefits and rights you had before volunteering.

(If participants will receive payment, extra credit, etc., you must include the following:)

You will receive _____ for taking part in this study. If you should have to quit before the study is through, the payment you receive will be based on the amount of time you were in the study.

OR

You will not receive any payment or reward for taking part in this study.

OR

You will receive _____ extra credit points for participating in this study. Equivalent alternative extra credit will be available for those who elect not to participate.

(You must address the costs to participants. If the study involves costs to subjects, please state how much they are and when the money is due. If there are no costs to subjects, please include the following:)

There are no costs associated with taking part in this study.

(Include the following paragraph to explain who will see the information from the study:)

Your information will be combined with information from other people taking part in the study. When the report of the study is written to share with other researchers, it will include combined information for all participants. You will not be identified in these written materials.

(If the survey is anonymous, include the following:)

This study is anonymous. That means that no one, not even members of the research team, will know that the information you give came from you.

(If the study is not anonymous, include the following:)

The researchers will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

By clicking on the survey link below and by submitting a completed survey, you are giving permission to use your data record in this study. The results of this study may be published in the journal article or it may be presented at a professional conference, but no publication or presentation will contain information that will identify you.

If you decide to take part in the study, you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

Appendix L

Checklists for IRB Applications: Exempt, Expedited and Full Review

CHECKLIST for Exempt from Review IRB Applications

This checklist is designed to assist the researcher in determining if the Human Subjects Application is complete. These are items that committee members expect to be included in an application so that a determination can be made that the rights and welfare of human subjects have been protected.

_____ Title page of application complete with names of all key personnel involved in the project.

_____ Signature page complete with appropriate signatures.

_____ Samples of surveys/questionnaires/instruments.

_____ Written permission to use surveys/questionnaires/instruments from developer OR written evidence that the surveys/questionnaires/instruments are in the public domain OR a statement that the investigator developed the instrument.

_____ Written permission from appropriate persons to use designated subject group or data (e.g., Department chair, dean, university representative in charge of data or subjects). If data are collected at only one school, then permission from the school principal is sufficient unless the school system also requires the superintendent's approval. If data are collected from more than one school in a system, the system superintendent's approval is required.

_____ Informed Consent form (if applicable). The Informed consent form should include names of all people involved in the project in addition to the investigators, and names of additional personnel should be included under item 13 (Key Personnel). The Informed Consent should also include a statement regarding conflicts of interest or state no conflicts of interest exist.

_____ Assent form (if applicable).

_____ Debriefing form (if applicable).

_____ Statement about maintaining and storing data for at least 5 years.

_____ Statement about submitting a final report to the IRB within 6 weeks of project completion.

_____ All statements/questions of the application are complete.

_____ Certificates of completion for the online training course for all involved personnel.

Important Note: The application itself, including appendices that are clearly noted within the application, should contain all information and materials required for review of the application. Investigators should not submit a draft or methods section of a thesis, paper in-lieu of a thesis, or other proposal materials with the application to the IRB.

CHECKLIST for Expedited and Full Review IRB Applications

This checklist is designed to assist the researcher in determining if the Human Subjects Application is complete. These are items that committee members expect to be included in an application so that a determination can be made that the rights and welfare of human subjects have been protected.

_____ Title page of application complete with names of all key personnel involved in the project.

_____ Signature page complete with appropriate signatures.

_____ All parts of application completed.

_____ A statement regarding conflicts of interest or no conflicts of interest.

_____ Samples of surveys/questionnaires/instruments.

_____ Written permission to use surveys/questionnaires/instruments from developer OR written evidence that the surveys/questionnaires/instruments are in the public domain OR a statement that the investigator developed the instrument.

_____ Written permission from appropriate persons to use designated subject group or data (e.g., Department chair, dean, university representative in charge of data or subjects). If data are collected at only one school, then permission from the school principal is sufficient unless the school system also requires the superintendent's approval. If data are collected from more than one school in a system, the system superintendent's approval is required.

_____ Informed Consent form. The Informed Consent form should include names of all people involved in the project in addition to the investigators, and names of additional personnel should be included under item 14 (Key Personnel). The Informed Consent should also include a statement regarding conflicts of interest or state no conflicts of interest exist.

_____ Assent form (if applicable).

_____ Debriefing form (if applicable).

_____ Statement about maintaining and storing data for at least 5 years (item VI.D.).

_____ Statement about submitting a final report to the IRB within 6 weeks of project completion (item IX.A.)

_____ All statements/questions of the application are complete.

_____ Certificates of completion for the online training course for all involved personnel.

Important Note: The application itself, including appendices that are clearly noted within the application, should contain all information and materials required for review of the application. Investigators should not submit a draft or methods section of a thesis, paper in-lieu of a thesis, or other proposal materials with the application to the IRB.

CHECKLIST for Exempt from Review IRB Applications – Faculty Advisor

If the principle investigator is a student, then the Faculty Advisor needs to complete this checklist and it must be included in the IRB application.

_____ Title page of application complete with names of all key personnel involved in the project.

_____ Signature page complete with appropriate signatures.

_____ Samples of surveys/questionnaires/instruments.

_____ Written permission to use surveys/questionnaires/instruments from developer OR written evidence that the surveys/questionnaires/instruments are in the public domain OR a statement that the investigator developed the instrument.

_____ Written permission from appropriate persons to use designated subject group or data (e.g., Department chair, dean, university representative in charge of data or subjects). If data are collected at only one school, then permission from the school principal is sufficient unless the school system also requires the superintendent's approval. If data are collected from more than one school in a system, the system superintendent's approval is required.

_____ Informed Consent form (if applicable). The Informed consent form should include names of all people involved in the project in addition to the investigators, and names of additional personnel should be included under item 13 (Key Personnel). The Informed Consent should also include a statement regarding conflicts of interest or state no conflicts of interest exist.

_____ Assent form (if applicable).

_____ Debriefing form (if applicable).

_____ Statement about maintaining and storing data for at least 5 years.

_____ Statement about submitting a final report to the IRB within 6 weeks of project completion.

_____ All statements/questions of the application are complete.

_____ Certificates of completion for the online training course for all involved personnel.

_____ _____

Signature of Faculty Advisor Date

CHECKLIST for Expedited and Full Review IRB Applications – Faculty Advisor

If the principle investigator is a student, then the Faculty Advisor needs to complete this checklist and it must be included in the IRB application.

_____ Title page of application complete with names of all key personnel involved in the project.

_____ Signature page complete with appropriate signatures.

_____ All parts of application completed.

_____ A statement regarding conflicts of interest or no conflicts of interest.

_____ Samples of surveys/questionnaires/instruments.

_____ Written permission to use surveys/questionnaires/instruments from developer OR written evidence that the surveys/questionnaires/instruments are in the public domain OR a statement that the investigator developed the instrument.

_____ Written permission from appropriate persons to use designated subject group or data (e.g., Department chair, dean, university representative in charge of data or subjects). If data are collected at only one school, then permission from the school principal is sufficient unless the school system also requires the superintendent's approval. If data are collected from more than one school in a system, the system superintendent's approval is required.

_____ Informed Consent form. The Informed Consent form should include names of all people involved in the project in addition to the investigators, and names of additional personnel should be included under item 14 (Key Personnel). The Informed Consent should also include a statement regarding conflicts of interest or state no conflicts of interest exist.

_____ Assent form (if applicable).

_____ Debriefing form (if applicable).

_____ Statement about maintaining and storing data for at least 5 years (item VI.D.).

_____ Statement about submitting a final report to the IRB within 6 weeks of project completion (item IX.A.)

_____ All statements/questions of the application are complete.

_____ Certificates of completion for the online training course for all involved personnel.

_____ _____

Signature of Faculty Advisor Date