Manual of Policies Procedures for Conducting Research with Human Subjects
(Revised July 1, 2024)

Introduction

The University of Hartford established an Institutional Review Board in response to Public Law 93-348, The National Research Act (1974), which amended the Public Health Service Act (PHSA). Grounded in significant concerns regarding medical investigations using humans during World War II, this law sets forth an ethics guidance program with respect to conducting research using human subjects and, further, established a National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. The Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991. The HHS regulations, 45 CFR part 46, include four subparts: subpart A, also known as the Federal Policy or the "Common Rule"; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and subpart D, additional protections for children. The Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance. Human subject research conducted or supported by each federal department/agency is governed by the regulations of that department/agency. The head of that department/agency retains final judgment as to whether a particular activity it conducts or supports is covered by the Common Rule. (Source: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html)

1.0 History and Background

1.1 The Nuremberg Code and the Belmont Principles

During the post-World War II era, a number of ethical codes dealing with treatment of human subjects were established, and among them, the Nuremberg Code (1947) was perhaps the most well-known code developed to deal with standards for medical experimentation with human subjects. This was the first set of standards for judging conduct with human subjects and served as a prototype of a variety of later codes. Furthermore, the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research used the Nuremberg Code as the basis to expand consideration beyond medical human subject experimentation to include broader ethical principles of research with human subjects. The Commission's work resulted in the *Belmont Report* (1978) that established an ethical framework and basis by which specific rules guiding research with human participants may be formulated and interpreted. These principles involve respect for persons, beneficence/ non-maleficence, and distributive justice (Lederer & Grodin, 1994, p. 19). Both the Nuremberg Code and the Belmont Principles[1] are stated below, and a bibliography of various ethical codes is provided in Appendix A.

The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be designed and based on the results of animal experimentation and a knowledge of the natural history of disease or other problems under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur---except perhaps in those experiments where experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made, and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end if they have reached the physical or mental state where continuation of the experimentation seems to them to be impossible.

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

The Belmont Principles

Three basic principles, in addition to those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: respect for persons, beneficence, and justice.

1. **Respect for Persons**

   Respect for persons incorporates at least two basic ethical tenets: (1) that individuals should be treated as autonomous agents and (2) 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.

   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. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

   In most cases of research involving human subjects, respect for persons demands that subjects enter the research voluntarily and on the basis of adequate information about the research situation and possible consequences.

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. 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. 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 possible 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 risks 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.

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. The selection of research subjects needs to be scrutinized in order to determine whether some groups (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. Especially when research supported by public funds leads to the development of therapeutic devices and procedures, justice demands that such research should not unduly involve persons from groups unlikely

to be among the beneficiaries of subsequent applications of the research.

1.2 Charge to the Institutional Review Board

The Institutional Review Board at the University of Hartford is charged with the ethical review and oversight of research that involves the participation of human subjects. The complementary concerns of the Institutional Review Board are to protect the individual from harm and to support the advancement of science, while also protecting principal investigators and the institution through Federal wide (FWA): an assurance of compliance with the U.S. federal regulations for the protection of human subjects in research. In an effort to address these concerns, the Institutional Review Board seeks to apprise the University community of its responsibilities toward human participants in research. It notifies faculty, staff, and students of the purpose of the committee, the federal regulations and institutional policies that support the protection of human subjects, and the procedures to follow in developing research protocols and conducting research over time to ensure that human subjects are properly protected. The members of the Institutional Review Board have prepared this Manual for distribution to the University community. It provides detailed information to support institutional initiatives for compliance with federal regulations regarding the protection of human subjects and to guide investigators in procedures relevant to research protocols that include human subjects.

Criteria for Approval of Research

The Institutional Review Board approves research conducted with human subjects according to the regulation set forth in 45 CFR 46.111. Research must satisfy all of the following criteria in order to be approved.

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

diagnostic or treatment purposes.

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

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

(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 45 CFR 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

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

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

(8) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons

who are economically or educationally disadvantaged, appropriate safeguards have been included in the study to protect the rights and welfare of these subjects (Office for Protection from Research Risks, 1983, p. 8).

2.0 Distribution of Responsibility for the Protection of Human Subjects

The responsibility for protection of human subjects is shared among several essential parties, including the principal and co-principal investigators, department heads, Institutional Review Board, University administration, sponsoring agencies, and participants themselves.

2.1 Principal and Co-principal Investigators

The primary responsibility for the day-to-day assurance for protection of the rights and welfare of human subjects lies with the individual responsible for the conduct of the research activity, (i.e., the principal investigator and/or co-principal investigator). Specifically, the investigator(s) is responsible for:

(1) careful research design;

(2) careful adherence to ethical codes and applicable policies and procedures of the University of Hartford, the sponsoring agency, and cooperating institutions, if any;

(3) training and supervision of staff and students participating in the research;

(4) providing proof of human subjects training of principal investigator(s) and research personnel,

(5) providing information required and taking all steps in initial and continuing review of research with human subjects;

(6) retaining required records;

(7) obtaining prior approval of Institutional Review Board for changes in research activity; such as addendums and modifications, and

(8) prompt reporting to the Institutional Review Board of unanticipated problems and adverse events involving risks to subjects or others.

2.2 Departmental/Executive Officer

The executive officer of each University of Hartford department (department chair or supervisor) has the responsibility to:

(1) assure that faculty, staff, and students are kept informed of the University of Hartford policy and procedures and of their responsibilities for protecting the rights and welfare of human subjects involved in research;

(2) assure that for any course offered by the department in which participation of the registrants as human subjects is expected, notification to this effect is given in the course description in official University bulletins and course registration materials;

(3) report promptly to the Institutional Review Board any unanticipated problems involving risks to subjects or others.

2.3 Institutional Review Board

The Institutional Review Board is responsible for:

(1) initial and continuing review of research with human subjects;

(2) ascertaining acceptability of proposed research in terms of institutional commitments, applicable law, and standards of professional conduct and practice.

(3) documentation of such review in compliance with applicable law, regulations, and policies; and

(4) provision of advice and counsel to investigators engaged in research involving human subjects.

(5) providing assistance to University officials in developing policy, procedures,

information, and instructions concerning human subject research;

(6) adjudication of differences and review of problems arising in research involving human subjects;

(7) reporting to the appropriate institutional officials unanticipated problems involving risks to subjects and others in work funded by external agencies, including but not limited to federal agencies such as HHS and PHS; and

(8) reporting to the appropriate institutional officials any serious or continuing noncompliance by investigators with the requirements and determinations of the Institutional Review Board.

2.3 Sponsoring Agencies

Sponsoring agencies usually accept responsibility for evaluating research proposed for their support. This evaluation is undertaken in addition to that provided locally. Investigators should be aware that sponsoring agencies may impose additional conditions prior to or at the time of funding if additional conditions are judged to be necessary for the protection of human subjects.

S ponsoring agencies may require that their funding for any project be terminated or suspended if they find that the institution has materially failed to comply with the terms of its regulations.

2.4 Subjects

Subjects who participate in research should:

(1) consider carefully the decision to participate in research;

(2) ask questions freely;

(3) recognize that they are free to withdraw from participation at any time;

(4) notify the investigator promptly of adverse effects of participation;

(5) take unresolved complaints or concerns about their participation in research to the department chair and, if the matter remains unresolved, to the Associate Provost.

3.0 Institutional Review Board

The Human Subjects Research of the University of Hartford was established in response to Public Law 93-348, The National Research Act, and continues to function in response to the 1983 revisions and the Health Research Extension Act (1985). The Institutional Review Board (i.e., the Committee) is responsible for *monitoring and maintaining accurate records on all proposed and ongoing research* undertaken by faculty, staff, and students at the University of Hartford, which involves human subjects, and for *reviewing institutional training, research, or demonstration grant applications* which include human subject research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has set forth specific guidelines (the Belmont Report and Title 45, Part 46 of the Code of Federal Regulations) to guide research with human subjects and ensure their protection in the design and conduct of the research. As an institution where federal funds are applied for and received, federal regulations require that any proposal that involves the use of human beings as subjects be reviewed and approved by the University's Institutional Review Board.

3.1 Areas and Activities Covered by the Institutional Review Board

Any research undertaken at or under the auspices of the University of Hartford that involves human subjects shall be under the jurisdiction of the Institutional Review Board, and principal investigators who propose human subject research must submit all proposed research studies to Chair of the Institutional Review Board for review. Moreover, principal investigators who intend to conduct a proposed research project for more than one year, must supply to the Chair of the Institutional Review Board an annual summary of the research for the life of the project and request a project extension when needed.

3.2 Institutional Review Board Membership

The Institutional Review Board shall consist of at least seven persons (always an uneven number), including the Chair, with varying professional, racial, ethnic, cultural, and gender differences who are sensitive to community attitudes and knowledgeable about professional conduct and regulations.

The Chair of the Institutional Review Board will serve at the request and be appointed by the Provost for a period of three years and may be reappointed. The Chair shall be a full-time faculty member or University staff member with parallel experience and responsibilities at the University of Hartford.

Institutional Review Board members will also serve at the request of and be appointed by the Provost for a period of overlapping four-year terms, so that when terms expire at least one-half of the members shall have experience in Institutional Review Board issues. At least one member of the IRB shall have no affiliation with the University. If a particular class or type of subject becomes the object of frequent study, a person from this class or type whose primary concern on the IRB shall be protecting the welfare of these subjects shall be added to the committee. In the case where people who are under the age of majority, i.e., children or adolescents, are a class or type of subjects frequently studied, an advocate of one or both of these classes will be selected to serve on the Committee on their behalf.

3.3 Meetings

Meetings of the IRB shall be convened by the Chair or by, at least, any two members. For regular meetings, members shall have at least seven (7) days' notice. Emergency meetings may be convened if the conditions underlying the request warrant such meetings; emergency meetings require at least 48 hours' notice. One half of the members of the full Institutional

Review Board must be present in order to constitute a quorum and for the meeting to be an official one. The Chair will not vote, except in the case of a tie.

The operating rules and regulations of the Institutional Review Board may be changed at a Committee meeting by a vote of the majority of the Committee members present, based on a quorum of two-thirds of the members present. Operating rules and regulations shall be made to facilitate the effective and efficient work of the Committee while maintaining compliance with the rules and regulations set forth by federal statutes and regulations relating to the protection of human subjects.

4.0 Proposals Submitted to the Institutional Review Board

4.1 Definition of Terms

The terms below are defined in the context of PL93-348 and 45 CFR 46 and serve as a basis for reviewing and determining the status of proposals submitted to the Institutional Review Board.

(1) **Research:** is a systematic investigation designed to develop or contribute to generalizable knowledge. Research includes the concepts and processes of "trial" or "special observation," usually made under conditions determined by the investigator. Research aims to test a hypothesis, to discover some unknown principle or effect, or to re-examine some known or suggested truth. The term research applies to systematic studies in which any substance or stimulus is administered to a subject by any route. It is intended to apply to studies which involve changes in physical or psychological state or environment or major changes in diet and to the pertinent methods for studying alterations in body functions and behavior under such conditions. It is intended to apply the use of interviews, tests, observations, and inquiries designed to elicit or obtain

nonpublic information about individuals or groups.

Activities which meet this definition constitute "research" for purposes of 45 CFR 46, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities. However, the term research is not intended to apply to routine course development, including evaluation of the effectiveness of such development, at the University of Hartford.

(2) **Human subject:** a living individual about whom a researcher (whether a student or University faculty or staff member, or someone outside the University using University of Hartford students or facilities), obtains data through interaction or intervention, or the gathering of identifiable private information.

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

The definition of subject excludes all accepted and established service relationships, such as the normal relationship of patients to physicians, students to

professors, and other clients to professionals in which the patient, student, or client is receiving aid or services consistent with accepted and established practice, and intended only to meet his or her own personal needs. The professional-client relationship has the welfare of the client as the primary objective, whereas the investigator-subject relationship has the discovery of new knowledge as its primary objective. This difference may not be fully understood by the subject who is also a client, and can result in the investigator's gaining consent without free decision---in part due to a trust based on a presumed role which the investigator is not necessarily fulfilling at that time.

The normal employer-employee relationship, in which legitimate services are rendered for salary, wages, or remuneration in keeping with customary written or verbal contracts, is also excluded from the definition of subject. Payment of subjects does not alter their status as subjects.

If doubt exists as to whether the procedures to be employed are within accepted and established practice or whether the purpose is only for the personal needs of the client, the activity should be considered to involve subjects whose rights and welfare are to be protected in accord with this policy statement. Similarly, if doubt exists as to whether the procedures are within the normal limits of the employee's work scope, employees should be considered to be participating as human subjects, and their rights and welfare must be protected.

Of particular concern are the following types of subjects:

(a) children, including the newborn, and adolescents (i. e., minors), because of their vulnerability, diminished autonomy, and incomplete understanding;

(b) subjects with limited civil freedom, such as prisoners, residents or clients of

institutions for the mentally ill and mentally retarded, and persons subject to military discipline; and

(c) pregnant women and the viable fetus, both *in utero* and *ex utero*. (The unborn should be considered subjects to the extent that they have rights that can be exercised by their next of kin or legally authorized representative.)

(3) **Human subject at risk:** any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or daily life, including the recognized risks inherent in a chosen occupation or field of service.

(4) **Minimal risk:** means that the risks of harm anticipated in the proposed research are not greater than those risks normally encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Certain risks are inherent in life itself, at the time and in the places where life runs its course. Risks of daily life include the ordinary risks of public or private living; those risks associated with admission to a school or hospital; and the risk inherent in professional practice, as long as these do not exceed the bounds of established and accepted procedures, including innovative practices applied in the interest of the individual patient, student, or client.

The fact that some types of research do not involve risks beyond those experienced in daily life situations does not mean that the investigator is any less responsible for his or her subjects.

(5) **Responsible project investigator:** is a qualified faculty member at or above the level of instructor or a qualified staff member who will monitor the conduct of research involving human subjects.

(6) **Children and adolescents:** refer to persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted.

(7) **Legally authorized representative, parent, guardian:** 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. Parent means a child's biological or adoptive parent. Guardian means an individual who is authorized under applicable state or local laws to consent on behalf of a child to general medical care.

(8) **Assent:** is a child's affirmative agreement to participate in research. Assent should not be construed in cases where a child simply fails to object and also does not affirmatively agree to participate in a research study.

(9) **Advocate:** means 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 Institutional Review Board) with the research, the investigator(s), or the guardian organization.

(10) **Permission:** means the agreement of parents(s) or guardian to the participation of their child or ward in research.

(11) **University activity:** means those projects sponsored by the University itself, as well as projects carried out by University faculty, staff, or students, using the facilities, personnel, or records of the University.

4.2 Categories of Review Procedures:

All proposals that concern research conducted with human subjects must be submitted to the Institutional Review Board for review. It is the responsibility of the Committee, not the investigator or any other formal or informal group of University faculty or staff otherwise constituted, to determine the categorical status of proposed human subject research.

4.2a Expedited Review of Proposals.

In accordance with the code of federal regulations, it is the policy of the Institutional Review Board to expedite review procedures for proposals that satisfy certain conditions. These conditions are that (1) there may be no more than minimal risk to the human subjects and the proposed activities in the proposal must be among those on the list in Appendix B or (2) if changes are made in previously approved research during the period of one year or less for which approval is authorized by the Institutional Review Board, the changes must be forwarded to the Chair of the Committee and determined to be minor. If neither condition is satisfied in the proposal, then the full membership of the Institutional Review Board will review the proposal.

In sum, the Chair and/or members of the Institutional Review Board designated by the Chair will review each research proposal and either approve it (i.e., determine that the proposal qualifies for expedited review and complies in every way with federal regulations for the adequate protection of human subjects) or refer it to the Institutional Review Board sitting-as-a-whole. If it is determined that the proposal meets the qualifications for expedited review but is not in full compliance with federal regulations and guidelines, it will be returned to the principal investigator with an accompanying critique of the proposal relative to the protocol and, specifically, treatment of human subjects and specified modifications to be made to ensure the proposal's compliance with federal regulations. In this case, the proposal's approval will remain to be determined by the Committee pending resubmission of the modified proposal to the Chair of the Committee. If it is determined that the proposal does not satisfy either of the conditions for an expedited review, it will be referred to the full Committee for review and discussion.

4.2b Exempt Status Review.

The Institutional Review Board may find that some proposals are exempt from federal regulations for full Committee review. As indicated in 45 CFR 46.101(b), research activities that involve the use of human subjects in one or more of several categories are exempt from certain regulations; ***however, they are not exempt from submission to the Institutional Review Board***. Appendix D describes the categories exempt from the federal regulations developed to implement the amendments to the Public Health Service Act, which is PL93-348, the National Research Act.

4.2c Full Committee Review.

Sitting as a committee of the whole, the Institutional Review Board will review proposals to determine approval in the case where a proposal qualifies for neither expedited nor exempt.

4.3 Guidelines for Preparing and Submitting a Proposal

Principal investigators should submit their proposal using the eProtocol System. At minimum, all proposals submitted to the Institutional Review Board for review should follow the guidelines listed below:

(1) The proposal should detail the purpose and design of the proposed research and explicitly address how human subjects' welfare and rights will be protected.

(2) All parts of the Proposal Transmittal form must be completed and submitted.

(3) Research proposals must be submitted to the Committee for review and approval prior to beginning any collection of data and/or submitting a proposal for grant support.

(4) In the case of a master's or doctoral research study, the student should submit to the Institutional Review Board, after the proposal is approved by their departmental committee.

(5) If a faculty member's or student's proposed research is initially approved by the Institutional Review Board or Institutional Review Board of another institution that governs the subjects or data, a copy of the approval form should be submitted along with the full proposal to the Institutional Review Board at the University of Hartford.

(6) Prior to the collection of data, investigators must inform subjects of their rights, voluntary nature of their participation, any anticipated positive and negative consequences of participating in a research project, and solicit their signed consent to participate (see section 4.5 in this Manual). None of the subjects' legal rights may be waived. Neither the project, the University, the college, nor the researcher(s) may be waived from the responsibility of providing informed consent.

(6) Allow approximately 3 to 4 weeks from the date of receipt and when classes are in session for proposals to be processed and response letters concerning the results of the

review to be issued to the principal investigator. Investigators should take note that when the University is on an official break and during the summer months, proposals will not be reviewed.

4.4 How to Submit Proposals to the Institutional Review Board:

4.4a Procedures for Initiating Contact with the Institutional Review Board.

Contact with the Committee should be made through the Chair, or any designated member, if the Chair is away from campus for a lengthy period of time. A researcher who is in the process of developing a proposal may contact the Institutional Review Board Chair for assistance in understanding the role of the committee or in setting up human subjects procedures. If any problems arise in the consultation process, either the committee member or the researcher may bring the problem to the full Committee.

Those who propose research projects involving human subjects shall submit to the Committee, prior to (1) beginning any data collection and/or (2) submitting a proposal for grant support, a completed submission in eProtocol that details all of the issues related to the welfare and rights of the subjects who would be involved. If a master's or doctoral research study is proposed involving human subjects, the same process will be followed along with the research advisor's signature, which designates that they have read and approved the Institutional Review Board research proposal.

The Chair of the Committee and/or designated member of the Committee shall review each proposal to determine whether it meets the conditions for an expedited review and, in effect, is or is not exempt from review and full discussion by the Institutional Review Board sitting-as-a-whole. When the University is officially in session, allow 3 to 4 weeks from the date of receipt of the proposal for review and written communication of results of the review.

Investigators should note that proposal will not be reviewed when the University is not in official session or during summer months.

When the Institutional Review Board sitting as-a-whole reviews a proposal, the IRB Chair will assign a review through the eProtocol system. In addition, the Committee may request the principal investigator to meet with it for a discussion of the proposal before a decision is made. Such a request will be made at least 48 hours in advance of the meeting. In order to be approved, a project must receive a favorable vote of a majority of the Committee members present at the meeting, with a necessary one half quorum in attendance (which must include at least one "scientist" and at least one "non-scientist" member of the committee). If the proposal is not approved, the Chair will communicate in writing to the principal investigator the full Committee's concerns.

4.4b Proposal Transmittal Form

The Institutional Review Board seeks to improve its monitoring and record keeping role with regard to treatment of human subjects in research studies at the University of Hartford via the eProtocol system. It is the responsibility of the principal investigator to ensure that proposal is accurately completed and submitted. The results of the review will be provided via email 3 to 4 weeks from the day the Chair receives the proposal. ***Incomplete proposals will be returned.***

4.5 Informed Consent

In obtaining informed, voluntary consent from human beings to participate as subjects in a research study, no implied or explicit coercion shall be involved in their selection and request to participate. For example, an instructor in authority over potential subjects (students) should not

place himself or herself in the position of suggesting that participation is required to fulfill the requirements of the course. In such a situation, a description of alternatives for those who choose not to participate should be made available. The language of the consent form shall be clear and understandable to the subject, including those who may not use English as their first language. None of the subjects' legal rights may be waived, and neither the project, the University, the college, nor the researcher(s) may be waived from responsibility.

An acceptable consent form should contain explicit information that states and/or describes:

the project is research;

participation is voluntary and will result in no loss of benefits to which the subject is entitled;

the purpose of the research; the procedures to be followed;

the risks to the participant that may occur if they choose to participate;

the benefits that may follow should the individual decide to participate; how the participant may withdraw from the study without penalty;

how the results will be used;

the level at which the results will be aggregated; to whom the results will be reported; and what the participant may do and who they or they may contact if there is a problem, e.g., names, addresses, and phone numbers of the researcher(s) and, in the case of a master's or doctoral project, that of the thesis advisor.

4.5a Guidelines for Writing Informed Consent Forms[3].

The purpose of an Informed Consent to Participate in a Research Study Form is to tell participants exactly what they will have to do in a study and to obtain their agreement to participate (see Appendix C). Although it is not required that consent forms be standardized, the following guidelines are helpful in writing one for any study involving human subjects.

(1) Description of the Study and the Participant's Role:

Describe the study in non-technical language specifying what the participants will do and how long they will do it. Participants cannot really give their informed consent unless they know exactly what they are consenting to do.

Example:

This is a study of visual attention. You will watch a computer screen and press a key when you see certain shapes and letters. You will do this for about an hour.

(2) Permission to Withdraw from the Study:

An important protection for participants is the right to withdraw from a study without penalty. The consent form should tell participants that they can withdraw from the study and describe the procedure for doing so.

Example: You may withdraw from the experiment at any time you feel uncomfortable and do not want to continue. There will be no penalty for stopping. You will still receive your experimental credit and your pay for the time you have participated. If you want to stop at any time, tell the experimenter and leave the room.

(3) Use of Data:

In the Informed Consent Form, explain clearly how the data you collect about the participants will be handled. The most secure procedure is to collect no identifying information (e.g., no names or social security numbers).

Example:

You will not put your name or any identifying information on any of the surveys and tests. Therefore, the information you give will be completely anonymous.

Although this procedure is possible for some surveys and observational studies, it is not practical for most studies. Therefore, a coding procedure should be used in which the person's name is linked to a code number. The code number is used on all data. A list linking the code number with the person's name is kept secure and destroyed as soon as possible.

Example:

The information gathered in this study will be handled in a secure manner to protect you. Your data will be identified by a code number that can be linked to your name only by a code list which will be kept in a secure place and destroyed after the study is completed. Reports written about the study will not identify you in any way; only data about groups will be reported.

It is probably impossible to remove identifying information from videotapes. Therefore, it is

necessary to describe to participants who will view their tapes and when the tapes will be erased.

Example:

Your actions in the study will be videotaped. Later, your videotape will be shown to six (6) University of Hartford students who will watch you on the tape and decide if you are describing a real or fictitious event. Some of the videotapes will be used to illustrate the study's findings in reports at professional meetings, in publications and in courses.

Do not promise that your data are completely secure since it is possible that any data could be obtained by court order---even over the objection of the experimenter.

(4) Contact

Tell the participants how they can contact you or the faculty member supervising your research if they have questions or concerns about the study.

Example:

If you have any questions or concerns about the study, you may contact [the Experimenter's Name] at [Phone Number] or at [Mailing Address], University of Hartford, 200 Bloomfield Ave., West Hartford, CT 06117. You may also contact the faculty member who is supervising this research study, [Faculty Research Advisor's Name] at [Campus Phone Number] or at [Campus Mailing Address], University of Hartford, 200 Bloomfield Ave., West Hartford, CT 06117.

(5) Signature:

End the consent form with a consent statement and a line for the participant's signature and date. If the participant is a minor, see section 5.0 in this Manual.

Example:

I agree to participate in the study described above.

_____*Signature of Participant*

4.6 Research in Progress

Once a project has been approved, the Institutional Review Board must review it on an annual basis until the project has been completed. It is the principal investigator's responsibility to present the Committee with progress reports on dates determined by the Committee. Failure to do so will be taken as a breach of the Human Subjects regulations, and the study will come to a halt until the Committee has reviewed the situation.

If it is discovered that a project has commenced that has not been cleared by the Institutional Review Board, the Chair of the Committee shall notify the principal investigator to halt the investigation and notify the Provost of the University of the action taken. The full Institutional Review Board shall review the situation, recommend action, and forward the review and recommended actions to the Provost. The Provost will pursue appropriate actions which may include referring the case back to the Committee for implementation of recommended actions.

4.7 Inter-Institutional Research.

There may be some cases in which research proposed by a researcher in one institution will actually be conducted with human participants in another institution. For example, a medical

researcher in orthopedics in a university teaching hospital proposes research that involves students enrolled in physical therapy programs in two nearby but separate universities. This research will be conducted out of the physician's home institution. In another case, a faculty member in education proposes research out of his home institution with adolescents in four middle schools.

Instances of inter-institutional research involve procedures different than procedures followed when the proposed research involves participants in the researcher's home institution. In the case of a University of Hartford investigator who proposes research with participants at another institution, they or they should:

1. Submit the proposal to the University's Institutional Review Board for review and approval; if the proposal meets the criteria for approval, the Committee will provide conditional approval.
2. The researcher then submits the conditionally approved proposal and copy of the letter from the Institutional Review Board to the appropriate review body (e.g., Institutional Review Board or Institutional Review Board) at the institution where the proposed research will take place.
3. Upon the other institution's review and approval of the proposal, the researcher then informs the Institutional Review Board of the approval by submitting the approval letter and copy of the final, approved proposal to the Chair who will keep the letter and proposal on file.
4. The Institutional Review Board will then inform the researcher in writing of full unconditional approval of the proposal.

5.0 Conducting Research with Special Populations: Children and Adolescents

Research with vulnerable populations such as children and adolescents has been regulated in earnest since 1974 with the passage of the National Research Act (PL93-348) and the work of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. In addition to the *Belmont Report*, the Commission also issued an extensive appendix concerning its "Report and Recommendations: Research Involving Children" (National Commission, 1978). In this report, the Commission exerted the first explicit attempt to distinguish the unique problems associated with the use of children as research subjects. Concurrently, the American Academy of Pediatrics issued its first set of professional guidelines on "Ethics of Drug Research" that defined and described the ethical standards for conducting biomedical research with children (Lederer & Grodin, 1994). Specific federal regulations have been issued since those milestone publications, including "Additional Protections Pertaining to Research Development and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization" (45 CFR 46, Subpart 9, 1981); "Additional Protections for Children Involved as Subjects in Research" (45 CFR 46, Subpart D, 1983); and "Federal Policy for the Protection of Human Subjects" (Federal Policy, 1991), which kept intact the 1983 protections for children involved as research subjects.

The history of research using children has, unfortunately, been dominated by patterns of exploitation and abuse throughout the centuries (Lederer & Grodin, 1994). With the advent of concern for and actions in behalf of humane treatment of children and adolescents as research subjects in the latter half of the twentieth century, new issues have emerged. Chief among

them is promoting the health and well-being of children and adolescents through advances undertaken in research versus protecting child and adolescent research subjects from exploitation and harm. Children and adolescents are exceptionally vulnerable to potential exploitation and harm "...because of their more limited cognitive competencies and experiential backgrounds, which constrain their capacities to understand and defend their rights as research participants and to make reasoned decisions concerning research participation...[and also] because of their limited social power..." (Thompson, 1990, p. 1).

Issues relating to research with children and adolescent subjects are both sensitive and complex and extend across multiple fields and disciplines. Two essential issues with unique implications in child and adolescent research in any field or discipline are further examined in this Manual. It is important that investigators who propose research with children and/or adolescents be thoroughly aware of these issues and sensitive to them in the development of their research designs.

5.1 Risk Assessment with Children and Adolescents

Federal regulations specify degrees of risk and benefit to minors as subjects in research studies. Such distinctions in degree lead to different requirements for the Institutional Review Board's review of the proposed research with particular focus placed on the nature of the procedures being used with the subjects. Research study categories are described below and includes examples of the types of projects included in each category and the requirements for approval.

5.1a Research not involving greater than minimal risk. This category is determined by the degree of intervention that a research design imposes on children or adolescents. It refers to two types of research: one that involves no direct intervention with children or

adolescents and a second that involves direct intervention with children or adolescents. The case where research is designed with *no direct intervention* is included in the research design is illustrated by the following:

1. anonymous, non-interactive, non-participating observation of public behavior;
2. secondary analysis of existing data;
3. education research that does not modify or disrupt regular classroom activity, for example, testing of curriculum or teaching methods, or observation of classroom activity; and
4. research involving the use of educational tests if information taken from these sources is recorded in such a manner that subjects cannot be identified.

Proposed research illustrated by these examples is eligible for expedited review and no parental or guardian permission or child's assent is required. However, a formal research proposal must be directed to the Institutional Review Board in order for an expedited review to be made. For research on school children, permission from the school district is required (section 5.2c) and compliance with the provisions of the Buckley Amendment (section 5.2d) is required.

The case where research is designed with *direct intervention* with children or adolescents is illustrated by the following examples:

1. research on individual or group behavior of children;
2. interviews and surveys;
3. education research that modifies or disrupts regular classroom activity, such as the researcher introduces unusual activities or tests or takes children individually or in groups out of the classroom; and

4. the use of identifiable test information.

Research that directly intervenes with children or adolescents requires review by the full Institutional Review Board, written parental or guardian consent, and where appropriate assent from the children or adolescents. In the case of education research, expedited or full Committee review of the proposal is determined by the degree to which the research disrupts regular classroom activity. Thus, proposed research that includes activities considered as normal curricular activities for the students involved in the research would be eligible for expedited review. For research on school children, investigators must gain written permission from the school district and comply with the Buckley Amendment.

5.1 b Research involving greater than minimal risk.

It is clear in the federal regulations that this category of research which increases risk to children and adolescents should be undertaken only when absolutely critical to carrying out the investigation. Ethical concerns are heightened when considering this level of research and must be given serious deliberation by researchers as well as by the Institutional Review Board. Two types of research are distinguished in this category: research that presents the *potential of direct benefit* to the individual subjects and that which presents *little to no direct benefit* to individual subjects but is *likely to yield generalizable knowledge* about the subject's disorder or condition. In the case where the potential for direct benefit resides in undertaking the research, federal regulations indicate that the Institutional Review Board can approve such research only if it finds that:

1. the risk is justified by the anticipated benefit to the subjects;
2. 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
3. adequate provisions are made for seeking and acquiring the assent of the children or adolescents and permission of their parents or guardian.

On the other hand, where little to no direct benefit to individual subjects exists but such research is likely to result in generalizable knowledge about the subject's conditions or disorder, federal regulations state that the Institutional Review Board may approve this type of research only if:

1. the risk presents a minor increase of minimal risk;
2. 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;
3. the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding of the subject's disorder or condition; and
4. adequate provisions are made for soliciting the assent of the children or adolescents and permission of their parents or guardians.

Research involving these extremely sensitive ethical issues directs the Institutional Review Board to take extra measures to adequately protect children and adolescents. Thus, when reviewing this type of research the Committee will have as a member an individual who will serve as a child advocate, whose professional responsibility will be primarily concerned with the welfare of the child or adolescent and who, if appropriate,

may be requested to monitor the consent process. In addition, the Committee may solicit recommendations from individuals with sufficient professional expertise to evaluate the potential benefits of research and who are not associated with the proposed research. Finally, to ensure that all aspects of the research project are given serious consideration, including the interests of the researcher, the Institutional Review Board may invite the researcher or a representative of his or her choosing to the meeting where the project is being considered.

As in previously described situations, research on school children must include permission from the school district and compliance with the Buckley Amendment.

5.2 Informed Consent for Children and Adolescents

5.2 a Parental or Guardian Consent.

In the design of research involving children and adolescents, researchers should make provisions to request the permission of each child's parents or guardian. For situations where risk to the child is assessed as minimal or greater than minimal but having direct benefit to the individual subjects, the Institutional Review Board may find that the permission of one parent is sufficient for research to be conducted. In other situations (1) where risk to children and/or adolescent subjects exceeds minimal risk and there is no prospect of direct benefit to individual subjects, yet the research is likely to yield generalizable knowledge about the subject's disorder or condition or (2) where research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, 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.

In all cases where parental or guardian permission is requested and/or required, such permission will be documented in accordance with the guidelines for consent presented in section 4.5 of this Manual and following the sample written parental consent form provided in Appendix E. More specifically, investigators must present parents or guardians with the following information (Institutional Review Board, The University at Albany, 1993):

1. a statement that the study is a research project;
2. identification of the investigator and his or her research advisor, if necessary;
3. a statement of the purpose of the study;
4. an explanation of how and why their child was selected;
5. an explanation of the procedures, including setting, time involved, and with whom the child will be interacting;
6. a description of any discomforts or risks;
7. a description of any benefits to the child;
8. a clear indication that participation is voluntary and confidential; and
9. an offer to answer questions along with information for contacting the investigator.

Moreover, for subjects whose parents have not given permission for them to participate, investigators must inform them of the procedures that will be followed for their children during the time that data collection occurs. All information must be in language that is understandable to the parent, and for research conducted in schools, information must be clear that the research is separate from and has no positive or negative effect on regular school activity. It must be made clear that the research is not being conducted

under the auspices of the school.

Some research may be judged by the Institutional Review Board as innocuous and, therefore, may require a less rigorous consent process where the requirement for a signed informed consent form is waived. If judged appropriate, the Institutional Review Board may suggest in some cases that the investigator obtain oral parental or guardian consent or inform parents or guardian in writing that the research is taking place without requiring signed consent (known as passive consent). However, regardless of one or the other of these specific cases, investigators must provide parents with the same information required in signed consent forms.

There may be some circumstances where research is designed for particular conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. Such populations are illustrated, for example, by neglected or abused children. In these cases, the Institutional Review Board may waive the consent requirements for children and/or adolescents if the investigator provides in the design an appropriate mechanism for protecting the children and/or adolescents who will participate as subjects and if the waiver is consistent with federal, state, or local law. The determination of an appropriate mechanism is based upon the nature and purpose of the activities described in the proposal, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

5.2b Children's or Adolescents' Assent.

Not only must investigators gain parental or guardian consent for research with their children or adolescents, but they must acquire the assent of child and adolescent subjects when and if appropriate. Assent is not to be inferred from lack of a child's or adolescent's affirmative agreement and his or her failure to object to participating in

research. Rather, assent is clearly stated affirmative agreement to participate in research (see Appendix F).

The child's or adolescent's age, maturity level, and psychological state determine the procedures for soliciting assent. Combined, these factors determine how and in what form information is provided to children or adolescents. Regardless of these particular factors, however, investigators must clearly and understandably inform all children or adolescents of the procedures of the study, their participation is voluntary, and they may stop at any time without harm to themselves or anyone else. Children and adolescents must also know that, if the research is conducted in school, it is not part of their regular school program, is not conducted under the auspices of the school, and their grade will not be affected by their decision to participate or not to participate.

All information that is provided to children or adolescents must be stated in language that is understandable to them. The implication of language-appropriate information is that the investigator must be knowledgeable of and able to apply theories and models of child and adolescent development to the design of their research where the purpose is to gain better understanding of how children and adolescents function and/or the usefulness of a particular technique or intervention relevant to them. Theories concerning child and adolescent development that investigators should know include cognitive, psychosocial, and physical development. If an investigator is not familiar with theories in these developmental areas and therefore is not aware of aspects of development necessary to effectively design research that protects children and adolescents and minimizes risk to them, it is recommended that they consult with experts. The Institutional Review Board can assist an investigator in locating an expert(s) to provide relevant information that will assist in the research design.

There may be some instances where parental consent and a child's or adolescent's assent are discrepant with one another (Institutional Review Board, The University at Albany, 1993, p. 7). In these instances, a particular rule should be followed: A "no" from the child or adolescent overrides a "yes" from the parent. Alternatively, a "yes" from the child or adolescent does not override a "no" from the parent. In cases where parents or guardians do not give permission for their child or adolescent to participate, investigators must also inform these children or adolescents as to what to do while those children or adolescents who are permitted to participate engage in the research activity.

The design of procedures to gain children's or adolescents' assent must be sensitive to the unique relationship of dependency that children have with adults. Indeed, it is a relationship based upon adults having *power over* children or adolescents, and this type of inequality places a greater responsibility upon researchers to ensure that they present information clearly and plainly to the potential subjects and that children's and adolescents' decisions to participate are unequivocally voluntary. Investigators must take the following factors into account when they are designing research and developing procedures to carry it out (Institutional Review Board, The University at Albany, 1993, p. 7):

1. Take special care to minimize social pressure on children or adolescents to participate, particularly peer pressure and fear of ridicule for not participating.
2. Concrete rewards for participating may be used but should not be so valuable within the value system of the child or adolescent as to outweigh the individual's legitimate reluctance to participate.

In addition, investigators should not have teachers or parents request children or

adolescents to participate in research and should avoid using phrases such as "will you help me" or "we would like your help with this." Children in particular typically want to help others and are not likely to refuse an adult's request for help. Both populations of subjects should simply be asked if they want to participate. A sample assent form may be found in Appendix F to assist in the development of an appropriate assent form.

5.2c School Permission. Schools do not have the authority to provide consent for children or adolescents to participate in research. Only parents or guardians have that authority. Investigators, however, must obtain permission from the school district before conducting research in schools within the district. Neither principals nor teachers have the authority to give permission for research to be conducted in the school. Such permission must come from district-level administrators. In most school districts, such authority resides in the superintendent while in other districts another individual or committee has been given the authority to grant permission. Researchers should check with the respective district office to ascertain the appropriate procedures for acquiring permission. Granted permission must be submitted to the Institutional Review Board in writing on school district letterhead stationery. Although the Institutional Review Board may grant provisional approval of the research pending receipt of school district permission, the research cannot begin until written permission is received by the Committee.

5.2d Buckley Amendment. There are issues and questions regarding the conduct of research with human subjects that are clearly human subjects issues, and there are issues and questions that are not human subjects issues but affect directly the conduct of

research with human subjects. These non-human subject issues concern federal, state, and local laws and regulations which influence the interpretation of the Institutional Review Board responsibilities and tasks. One such federal law is the Family and Educational Rights and Privacy Act of 1979, known as the Buckley Amendment. This law states, "An educational agency or institution shall obtain the written consent of the parent or a student, or the eligible student before disclosing personally identifiable information from educational records of a student, other than directory information...".

Investigators who wish to obtain identifiable information from student records must, therefore, gain written permission from the parents or guardian and, under law, parental permission must specify the exact information to be released from the student's records. Seeking and receiving blanket permission giving access to any information in the records is not acceptable. The Institutional Review Board cannot approve a research study unless the investigator clearly describes acceptable procedures that comply with the Buckley Amendment. It may be the case, though unlikely, that a school district is willing to release the information without written parental or guardian permission. Although the school district is assuming responsibility for violation of the Buckley Amendment, the University and the investigator would also be liable for such violation.

References

US Department of Health and Human Services, Code of Federal Regulations 45 CFR 46. Department of Health and Human Services. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111

Institutional Review Board, The University at Albany State University of New York. (1993). *Guide to research involving minors as subjects*. Albany, NY: Author.

Institutional Review Board, University of Illinois at Urbana-Champaign. (1983). *Handbook for investigators: For the protection of human subjects in research*. Champaign, IL: Author.

Lederer, S., & Grodin, M. (1994). Historical overview: Pediatric experimentation. In S. Lederer and M. Grodin (Eds.), *Children as research subjects: Science, ethics, and law* (pp. 3-25). New York: Oxford UP.

National Commission for the Protection of Human Subjects of Research. (1978). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of biomedical and behavioral research* [Publication No. (OS) 78-0012]. Washington, DC: Department of Health, Education, and Welfare.

Office for Protection from Research Risks. (1983, March). *Protection of human subjects*. Washington, DC: National Institutes of Health, Department of Health and Human Services.

Thompson, R. A. (1990). Behavioral research involving children: A developmental perspective on risk. *IRB---A Review of Human Subjects Research, 12*(2), 1-6.

University Committee for the Protection of Human Subjects. (1990). *Informed consent to participate in a research study*. Charlottesville, VA: University of Virginia.

APPENDIX A

Bibliography of Ethical Codes

The Declaration of Helsinki: Recommendations Guiding Doctors in Clinical Research, adopted by World Medical Association in 1964

American Medical Association
535 North Dearborn Street
Chicago, IL 60610

Professional Ethics: Statements and Procedures of the American Anthropological Association (September, 1973)

American Anthropological Association
1703 New Hampshire Avenue, NW
Washington, DC 20009

Patients' Bill of Rights (November, 1972)

American Hospital Association, Inc.
840 North Lake Shore Drive
Chicago, IL 60611

AMA: Principles of Medical Ethics including "Ethical Guidelines for Clinical Investigation" in *Current Opinions of the Judicial Council of the American Medical Association* (1981)

American Medical Association
535 North Dearborn Street
Chicago, IL 60610

Human Rights Guidelines for Nurses in Clinical and Other Research (1975)

American Nurses' Association
2420 Pershing Road
Kansas City, MO 64108

Ethical Standards (1981

American Personnel and Guidance Association
5203 Leesburg Pike
Falls Church, VA 22041

Ethical Principles in the Conduct of Research with Human Participants (1973)

American Psychological Association, Inc.
1200 Seventeenth Street, NW
Washington, DC 20036

Ethical Principles of Psychologists (1981 Revision)

American Psychological Association, Inc.
1200 Seventeenth Street, NW
Washington, DC 20036

Code of Ethics of American Sociological Association (September, 1971)

American Sociological Association
1722 N Street, NW
Washington, DC 20036

Code of Ethics of the National Association of Social Workers (1979)

National Association of Social Workers, Inc.
1425 H Street, NW, Suite 600
Washington, DC 20005

Ethical Standards for Research with Children

Society for Research in Child Development
University of Chicago Press
5801 Ellis Avenue
Chicago, IL 60637

APPENDIX B

Research Activities Which May Be Reviewed Through Expedited Review Procedures

[45 CFR 46.110]

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the Institutional Review Board (or, Institutional Review Board; *clarification added*) through the expedited review procedure.

(1) Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

(2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at the time of rupture of the membrane prior to or during labor.

(3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

(5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recordings made for research purposes such as investigations of speech defects.

(7) Moderate exercise by healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

(10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

APPENDIX C

Informed Consent to Participate in a Research Study (SAMPLE)

Study of Jury Decisions*

This is a study of how juries make decisions. You will read descriptions of crimes and then complete a questionnaire that asks you to make decisions about the verdict, sentence, parole, etc. The study will take you about 1 hour.

You may withdraw from the study at any time you feel uncomfortable about continuing. You will still receive your experimental credit for participating. If you want to stop at any time, simply do so by tearing up your questionnaire, placing it in the trash can, and leaving the room. There will be no penalty for withdrawing from this study.

Your data will be handled in a secure way using a code number that can be linked to your name only by a code list that is kept in a secure place. The code list will be destroyed after the data is analyzed. Reports of the study will not identify any individual; only group data will be reported.

If you have any questions about the study, please contact the principal investigator, Dr. Mary Smith, at 768-5555 or at 123 Hartford Hall, University of Hartford, 200 Bloomfield Ave., West Hartford, CT 06117.

I agree to participate in the study described above.

_____ _____

Signature Date

Please sign both copies and return one to the experimenter. Keep the other signed form for your records.

*Excerpted from University of Virginia. (1990). *Committee for the Protection of Human Subjects*.

APPENDIX D

Research Activities Exempt from Regulations

Implementing Amendments to PL93-348 [45 CFR 46.1.1(b)]

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from these regulations *(emphasis added)* unless the research is covered by other subparts of this part:

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

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(3) Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview

procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

(4) Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(5) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

APPENDIX E

Sample Written Parental or Guardian Consent Form

Student's Name_____Grade_____

Dear Parent:

Researchers at the University of Hartford are asking permission for your child to be in a research study on reading.

The study compares children reading below grade level with those reading at or above grade level on various measures of learning and memory.

We selected your child based on the testing you agreed to when your child started school.

With your permission, they will work with a person from the University on six occasions for approximately 20-30 minutes each time.

During each session, they will work on a variety of tasks designed to measure learning, memory and other things related to reading. The tasks are not difficult and in most instances the children find them quite enjoyable.

We will see each child on a one-to-one basis and arrange scheduling with his/her teacher to make sure that they do not miss important classroom activities.

This study has the approval and support of your child's school.

Your child's responses will remain confidential.

No reports about the study will contain your child's name. We will not release any information about your child without your permission.

Taking part is voluntary.

If you choose not to have your child take part, neither you nor your child will be penalized. We will also ask your child to participate and only children who want to will take part in the the study. Your child may choose to stop at any time.

If you have questions about the study, please contact Martin Smith, University of Hartford, College of Education, West Hartford, CT 06117 at (860)768-0000. If you have questions about your rights as a parent or your child's rights as a volunteer, please contact Charlotte Chairperson, University of Hartford Institutional Review Board at (860) 768-1111 or visit her at Hartford Hall, Room 000 at the University.

Attached is a form for you to sign. Please indicate whether or not you agree to have your child be in the study and have him/her return the form to school tomorrow. We would greatly appreciate your cooperation in this research.

READING STUDY CONSENT FORM

I have read and understood the information provided to me about the research study on reading being conducted in my child's classroom by researchers from the University of Hartford.

_____

(Date)

I ____give my permission to have my child_____

____do not give (child's name)

included in the study.

_____

(Parent's or Guardian's Signature

*Adapted from Institutional Review Board, The University at Albany. (1993). *Guide to research involving minors as subjects* (pp. 9-10). Albany, NY: Author.

APPENDIX F

Sample Student Assent Form

Student Assent Form* Student's Name _____

School_____

RESEARCH STUDY ON READING

Do you remember the permission slip you took home for your parents to sign a few days ago?

[The investigator should explain the relationship between parental permission slip and testing whether S remembers or not.]

The people I work with and I are interested in learning about reading in children. We are asking you and a lot of other students to work with us to find out about it.

If you agree to do this, I will ask you to take a reading test and solve some puzzles. Most students think this is fun to do.

This is not a test like you usually have in school. You won't be graded on anything you do and the results will not affect your school grade. All you have to do is try as hard as you can to do the things I ask, and you will do fine.

Your teachers and parents and the other children will not know how you do. It will be just between you and me and the people I work with.

Of course, you don't have to do this if you don't want to, even if your parents gave their permission. If you do not want to do this or your parents asked you not to do this, just tell me and you can go back to your classroom. It is okay with me if you don't want to be in the study and no one else, not even your teacher, will know.

Do you have any questions?

[The investigator should answer any question the child might have.]

Again, this will not affect your grades even if you choose not to be in the study. If you agree to do this, I would like you to sign this paper.

[If necessary, the investigator reads the assent statement to the child.]

_____Date_____

The study on reading has been explained to me and any questions I had have been answered. I would like to take part in the study.

_____

(Student's Signature)

*Adapted from Institutional Review Board, The University at Albany. (1993). *Guide to research involving minors as subjects* (p. 12). Albany, NY: Author.