

WALSH UNIVERSITY

HUMAN SUBJECTS REVIEW POLICY

OCTOBER 1996
REVISED 2005

Approved:	
Academic Assembly	9/20/1996
University Senate	10/06/1996
Revisions Approved:	
Academic Assembly:	2/18/2005
University Senate:	3/31/2005

HUMAN SUBJECTS REVIEW POLICY

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I. ETHICAL AND PROFESSIONAL STANDARDS FOR USE OF HUMAN SUBJECTS IN RESEARCH

The use of human subjects in research can be extremely important to the development of new knowledge in many areas. Ultimately, the only sure means for learning specifically about human beings is by studying them. Responsible investigation involving human beings as subjects, however, demands that careful attention be given to questions of ethics and human dignity.

During the War Crimes Trials following World War II, the Nuremberg Code (1947) was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code has been widely adopted by investigators conducting studies on human beings and has served as the prototype of many later codes intended to ensure that research involving human subjects would be carried out in an ethical manner.

Since 1947, various codes for the proper and responsible conduct of research involving human subjects have been developed by professional associations to guide investigators working in the various disciplines involved. Over the years, experience has shown that while these codes have been helpful, they are frequently difficult to interpret or to apply, particularly in nonmedical research projects that involve human subjects. As part of its work, the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research developed broader ethical principles to provide a basis on which specific rules could be formulated, criticized, and interpreted. These principles are discussed in *The Belmont Report* (1978).

In 1990, *Ex Corde Ecclesiae*, the Apostolic Constitution on Catholic universities, was released by the Vatican. This document provides guidelines for research conducted in Catholic universities. As stated in this document, “By means of a kind of universal humanism, a Catholic university is completely dedicated to the research of all aspects of truth in their essential connection with the supreme Truth, who is God. It does this without fear, but rather with enthusiasm, dedicating itself to every path of knowledge” (p. 267). In today’s world, characterized by rapid growth in science and technology, those who conduct and approve research must keep in mind the authentic good of individuals and society by including the moral, spiritual, and religious dimensions in its research. In addition, members of a Catholic university must “evaluate the attainments of science and technology in the perspective of the totality of the human person”(p. 268).

The Belmont Principles, the Nuremberg Code, and the Apostolic Constitution are stated and/or highlighted below.

A. The Belmont Principles

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

1. Respect for Persons

Respect for persons incorporates at least two basic ethical tenets: first, individuals should be treated as autonomous agents and second, 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 options and choices while refraining from obstructing their actions unless they are dearly 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 wellbeing. Such treatment falls under the principle of beneficence. Two general rules have been formulated as complimentary 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 how 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. Even in the case where 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.

B. 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 so designed and based on the results of animal experimentation and 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 so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur--except perhaps in those experiments where 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 she or he has reached the physical or mental state where continuation of the experiment seems to her or him to be impossible.
10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage if there is probable cause to believe, in the exercise of good faith, superior skill, and careful judgment required, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

C. The Apostolic Constitution on Catholic Universities. *Ex Corde Ecclesiae*.

The basic mission of a university is to search for truth through research as it communicates knowledge for the good of society. A Catholic university participates in this mission with its own specific purposes and characteristics. Through the results of its research, the Catholic university will be able to help the church respond to the problems and needs present in society.

1. The Catholic University is an academic community that assists in the protection and advancement of human dignity and of a cultural heritage through research.
2. Whereas each academic discipline retains its own integrity and has its own methods, a dialogue between faith and reason demonstrates that research within every branch of learning, when carried out in a scientific manner and in accord with moral norms, can never interfere with faith. Freedom in research is recognized and respected so long as the rights of the individual and of the community are preserved.
3. Research in a Catholic university is always carried out with a concern for the ethical and moral implications both of its methods and of its discoveries. The cause of the human person will be served only when knowledge is joined with conscience.
4. A Catholic university community is characterized by a spirit of freedom, an agreement of mutual respect, a quest for sincere dialogue, and a protection of individual rights.
5. Encouraged research activities include the study of serious contemporary problems in areas such as the dignity of human life, the promotion of justice for all, the quality of personal and family life, the protection of nature, the search for peace and political stability, a more just sharing in the world's resources, and a new economic and political order that will better serve the human community at the national and international levels.

II. POLICY FOR USE OF HUMAN SUBJECTS IN RESEARCH

A. Applicability

This policy is applicable to any research activity conducted at or sponsored by Walsh University which involves human subjects, i.e., living individuals about whom an investigator (professional or graduate/undergraduate student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. The policy is therefore applicable to research involving human beings whose physical, emotional, or behavioral conditions, responses, tissues, or fluids are investigated for any purpose other than for the sole purpose of benefiting the subject as an individual. It is applicable to the use of interviews, tests, observations, and inquiries designed to elicit or obtain nonpublic information about individuals or groups.

The policy is applicable whether the research is undertaken on a large or small scale. Pilot projects, student dissertation projects, independent study projects and course projects must follow this policy if they involve human subjects in research (See section C "Definitions").

B. Statement of Policy

Walsh University affirms the need for academic freedom in the conduct of research and the value of well-designed, responsible activities that involve human subjects. At the same time, it recognizes its basic responsibility to ensure the protection of any human subjects so involved. Moreover, as a Catholic institution of higher learning, Walsh University seeks to sponsor research projects that reflect a respect for the dignity of human life and the social justice values proclaimed in the gospel message. To this end, it has adopted the following statement of policy.

1. Investigations conducted at or sponsored by the Walsh University must:
 - a. adhere to the Belmont Principles, and
 - b. comply with the Nuremberg Code or one of the ethical codes developed by the various professional associations, and
 - c. respect the moral principles outlined in *Ex Corde Ecclesiae* and
 - d. adhere to the policies and procedures set forth in this document.
2. Participation of human beings as subjects in research governed by this policy must be voluntary, i.e., it must occur as the result of free choice, without compulsion or obligation.

Both the rights of such individuals to be protected against injury or invasions of their privacy and their interests as members of a free society in preserving their dignity are recognized as major concerns and must be protected. Therefore, research involving human subjects should be undertaken only with the voluntary consent of the subject or, if the subject lacks the capacity to consent, with the consent of her or his authorized representative.

Where minor, cognitively disabled or mentally disabled persons, individuals with limited civil freedom, pregnant women, or children are subjects in research, special care must be taken to ensure that consent for participation is obtained in accordance with applicable statutes and regulations. The consent of authorized representatives is usually required for subjects who have diminished capacity to consent. The assent of the subjects themselves is usually required as well as the consent of their representatives.

3. Adequate standards for informed consent must be satisfied. In addition to **voluntariness** as described above, **disclosure** and **comprehension** are essential elements of the consent process.

Disclosure generally includes: the research procedures; 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. The extent and nature of information should be such that persons, knowing that the procedures are 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, subjects should understand clearly the range of

risk and the voluntary nature of participation.

In some research, fully informing the subject would invalidate the research. In such cases, it may be necessary to withhold information from the subject. However, information should not be withheld if withholding it would affect a reasonable person's decision to participate, or damage her or his subsequent self-esteem. 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.

Incomplete disclosure is only justified if it is clear that:

- a. incomplete disclosure is truly necessary to accomplish the goals of the research,
- b. there are no undisclosed risks to subjects that are more than minimal, and,
- b. where appropriate, there is an adequate plan for debriefing subjects and disseminating research results to them.

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 is the third essential element in informed consent. The manner and context in which information is conveyed is as important as the information itself. Consideration must be given to the subject's ability to understand the language and terminology used as well as the subject's physical and mental state. Investigators are responsible for ascertaining that the subject has comprehended the information.

4. Adequate provision must be made to protect the privacy of subjects and to maintain the confidentiality of identifiable information throughout the research process.

Confidentiality provisions must meet reasonable standards for protection of privacy and comply with applicable laws. Identifiable information must not be disclosed outside the research group unless the subjects expressly agree otherwise.

5. The selection of subjects must be carefully considered.

The principle of **justice** gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects. For example, **individual justice** dictates that subjects should not be selected for potentially beneficial research on the basis of favoritism. Nor should risky research be restricted to subjects who are powerless. **Social justice** requires recognition of differences among groups in the ability to bear burdens; gives an order of preference in the selection of types of subjects (for example, adults before children); and dictates that some types of persons (for example, institutionalized mentally infirm or prisoners) may be involved as research subjects only on

certain conditions.

Certain groups, such as racial minorities, the economically disadvantaged, the very sick, students, employees, and the institutionalized, may continually be valuable as research subjects owing to their ready availability in settings where research is conducted. Given their dependent status and/or 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, socioeconomic condition or subordinate status.

6. The methods used for approaching subjects and securing their participation should be designed carefully to protect the privacy of the subjects and should be reasonable in terms of their condition or circumstances.

No coercion, explicit or implicit, should be used to obtain or maintain cooperation. Where the professional-client, faculty-student or employer-employee relationship is converted into an investigator-subject relationship, special care must be taken to ensure that the subject feels completely free to decline to participate. Where access to subjects is gained through cooperating institutions or individuals, care should be taken not to abridge prior commitments made to the subjects about the confidentiality or other terms of the primary relationship.

7. Any payment made to subjects should not be large enough to constitute excessive inducement for participation of the subjects.
8. Projects involving human subjects should be carefully designed to minimize risks to the subjects.

As far as possible, any risk should be anticipated in advance. Proper precaution should be taken and plans made to deal with emergencies that may develop in the course of even seemingly routine activities.

9. All research involving human subjects conducted at or sponsored by Walsh University must be submitted for **prior preliminary** review to the Chair, Human Subjects Review Committee. After approval, research projects may be required to be submitted for timely periodic review in accordance with the policies and procedures of the Human Subjects Review Committee. Furthermore, changes in approved research may not be initiated without prior review. Projects that meet the "no risk" criteria at the prior preliminary review are, as Level I projects, exempt from further involvement with the Human Subjects Review process.

C. Definition of Terms

1. Research

Human beings may be studied in many ways and under a vast variety of circumstances and conditions. For these reasons, the word *research* is elusive and difficult to define with precision. On the one hand, *research* may be used to describe something as innocuous as a new approach to teaching or the questions in a public opinion survey. On the other hand, *research* may refer to procedures in which the subject may be exposed to the gravest mortal risk, such as the astronaut who prepares to be launched into space to orbit the earth or journey to the moon.

In this document, the word **research** is defined as a trial or special observation, usually made under conditions determined by the investigator, which aims to test a hypothesis, to discover some unknown principle or effect, or to reexamine some known or suggested truth. The term **research** is intended to apply to systematic studies in which any substance or stimulus is administered to a subject by any route. It is intended to apply to studies involving 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 to the use of interviews, tests, observations, and inquiries designed to elicit or obtain nonpublic information about individuals or groups.

Activities that meet this definition constitute **research** whether or not they are supported or funded under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

The term **research** is not intended to apply to routine course development, including evaluation of the effectiveness of such development, of courses sponsored by Walsh University nor is it intended to apply to informal classroom activities which meet Level I (no risk criteria) or demonstrations of research methods that are part of classroom exercises designed to teach research methodology.

2. Human Subject

The term human subject means a living individual about whom an investigator (professional or student) conducting research obtains:

- data through intervention or interaction with the individual, or
- identifiable private information.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subjects' environment performed for research purposes.

Interaction includes communication of 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 that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Information is **individually identifiable** if the identity of the subjects 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 her or his 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 that the investigator is not necessarily fulfilling at that time (IRB, 1992).

D. Walsh University Standards

1. Informed Consent

The ethical and professional codes governing the use of human subjects in research all require that the participation of the subject must be voluntary, i.e., the subject gives her or his informed consent, or her or his authorized representative consents if the subject lacks the capacity to consent.

The principle of voluntary participation of subjects applies whether or not the research is governed by federal regulations.

The methods used to obtain consent may vary. They should be designed to fit the nature of the research, the nature and magnitude of the risks involved, the research setting, the nature of the subjects who will participate, and the requirements of applicable policies, laws, and regulations.

a. Core Elements of Consent

The core requirements for informed consent are:

- disclosure of the nature and general purpose of the research procedures and identification of any procedures which are experimental
- disclosure of any risks and the anticipated benefits of the research, either to the subject or to society

- where therapy is involved, a description of alternative procedures or courses of treatment, if any, that might be advantageous to the subject, and
- provision for ensuring that the subjects understand they may ask questions and/or withdraw at any time from the research.

Please note that additional elements of informed consent are required for work governed by the Department of Health and Human Services (HHS) (i.e., all work supported by HHS and other agencies which have adopted the HHS regulations). The specific elements required by HHS regulations are given in appendix D.

b. Additional Consent Requirements

Five additional requirements regarding consent must be met:

- The consent may not include any exculpatory language through which the subject is made to waive, or appear to waive, any of her or his legal rights, including any release of the institution or its agents from liability or negligence.
- Applicable federal, state, or local laws that require additional information to be disclosed in order for informed consent to be legally effective must be complied with.
- The consent requirements described herein place no limits on 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.
- When children are involved as subjects in research and are capable of assent, normally their assent to participate must be solicited in addition to the permission of their parents.
- Where participation as human subjects of students enrolled in the course of instruction at Walsh University forms an integral part of the conduct of the course, the official University bulletins and timetables shall state that fact in the description of the course. A statement such as the following shall be included in the course description: "Includes limited voluntary participation as a subject in research activities. "

This statement will serve to alert registrants of this characteristic of the course, but would not suffice as the only means of ensuring that the subjects' participation in a specific research activity is voluntary. Care must be exercised to ensure the absence of coercion, either real or perceived, in utilizing students as subjects.

c. Consent Process

An investigator shall seek consent only under circumstances that provide the prospective subject or the subject's representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the

representative shall be in language understandable to the subject or the representative. Investigators are responsible for ascertaining that the subject or subject's representative has comprehended the information.

Occasionally, fully informed consent may itself have an injurious effect on the subject, or it may invalidate the research. Incomplete disclosure is only justified if it is clear that:

- incomplete disclosure is truly necessary to accomplish the goals of research or to protect the subjects; and
- there are no undisclosed risks to subjects than are more than minimal; and
- where appropriate, there is an adequate plan for debriefing subjects and for dissemination of research to them.

Information shall not be withheld if withholding it would influence a reasonable person's decision to participate or damage her or his subsequent self-esteem. Information about risks shall 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 shall be taken to distinguish cases in which disclosure would simply inconvenience the investigator.

The justification for incomplete disclosure must be explicitly stated in the materials submitted for review.

The methods used to obtain consent may vary. They should be designed to fit the nature of research, the nature and magnitude of the risks involved, the research setting, and the nature of the subjects who will participate.

i. Consent Methods for Minimal Risk Research

Written consent or its taped, oral equivalent, should include at least the core requirements for informed consent given above and should also include the telephone number of an individual who will be available to answer inquiries from subjects. When a written consent form is used, a copy shall be given to the subject. If the basic elements of consent are presented orally and only the subject's formal consent is obtained in writing, the subject should be given a copy of a written summary of the oral explanation. The materials submitted for HSR review must include a copy of the written consent form and summary of oral explanation, if any. (Examples of consent forms are provided in the Appendix B).

ii. Consent Methods for Research Involving More Than Minimal Risk

When the **research places the subjects at more than minimal risk**, the investigator is to obtain legally effective informed consent. The informed consent document must be signed by the subject or the subject's legally authorized representative. A copy must be given to the person signing the

form. The subject or the subject's legally authorized representative must be given an opportunity to read the form before it is signed, even if the consent form is read to the subject.

The written informed consent document may either be a long-form document incorporating all the basic elements of informed consent or a short-form document that makes reference to an oral presentation of the basic elements of informed consent. If the short form is used, the HSR Committee must approve a written summary of what is to be said to the subject or the subject's representative. Further, there must be a witness to the oral presentation when the short form is used. Whereas the subject or her or his representative only needs to sign the short form, the witness and the person actually obtaining consent must sign both the short form and a copy of the summary. A copy of the summary must be given to the subject or her or his representative in addition to a copy of the short consent form. (Examples of consent forms are provided in the Appendix B).

The HSR Committee may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds that the only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality.

d. Documentation of Consent

For research which involves only minimal risk, the investigator must keep a description of the consent process used and copies of any written, signed consent documents themselves for three years from the date the consent was obtained.

If the research involves more than minimal risk, the investigator must retain copies of a sample of the written consent form, copies of the signed consent documents, and a copy of the written summary of an oral explanation, if any, signed by the person obtaining consent and the witness to the oral explanation. These consent documents must be retained for a period of three years after the consent was obtained, unless applicable law or supporting agency requirements demand a longer retention of such records.

If the HSR committee permits use of a method other than written informed consent for research involving more than minimal risk, the investigator and the HSR Committee should retain a copy of the description of the method used and the justification for waiving the requirement for written informed consent. Note that work governed by the HHS regulations must comply with the documentation requirements set forth in the Appendix.

2. Confidentiality of Data:

In all research involving human subjects, confidentiality of identifiable information is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise.

The university recognizes the rights of the subjects to be protected against injury or illegal invasions of their privacy, to preserve their dignity, to protect their interests as members of a full society. The more sensitive the material being collected for research, the greater the care that must be exercised in obtaining, handling, and storing data. Ordinarily, the following requirements must be met, subject only to their applicability to the particular activity:

- a. Questionnaires, inventories, interview schedules, and other data gathering instruments and procedures should be carefully designed to limit the personal information to be acquired to that which is absolutely essential to the activity.
- b. Data that include information which would reveal a subject's identity should be transported from and returned to, and stored in files accessible only to the project investigator and his or her authorized project staff.
- c. As early as feasible, the data should be handled in coded form, i.e., the subject's name and information that would reveal her or his identity should be removed. Plans for the ultimate disposition of the data should be made; or if they are to be retained indefinitely, plans must be made for their continued security.
- d. The indemnity of subjects must not be released except with their express permission.
- e. Use of storage data or information, which was originally obtained for different purposes and which involves identifiable subjects, requires examination of the risks involved, a determination of whether the new use is within the scope of the original consent or whether obtaining additional consent is necessary and feasible, and provision for the preservation of anonymity of the subjects.

Data that are part of the public domain are not covered by the foregoing restrictions (IRB, 1992).

3. Classification of Risk and Required Safeguards

a. Types of Risk

There are different risks inherent in different research procedures. Risk is most obvious in medical and behavioral science research projects involving procedures which may induce a potentially harmful altered physical state or condition: surgical procedures; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of strenuous physical exertion; subjection to deceit, public embarrassment, humiliation, or emotional stress.

There is a wide range of medical, social, and behavioral projects and activities which pose no immediate physical risk to the subject, e.g., those involving the use of personality inventories, interviews, questionnaires, observation, photographs, taped records, and stored data. However, some of these procedures may involve varying degrees of discomfort, harassment, or invasion of privacy, or they may constitute a threat to the subject's dignity through the imposition of demeaning conditions.

Some studies depend upon stored data or information that was obtained for different purposes.

If the material to be used in the research involves **identifiable subjects**, the assessment of the risk involved must include a determination of whether the use of these materials is within the scope of the original consent, whether consent is necessary, and whether it can be obtained.

If the material to be used in the research does **not** involve identifiable subjects, there is no risk to the subjects.

b. Classification of Risks and Level of Review

For the purposes of safeguarding human subjects and ensuring that these safeguards are continuously provided, the following classifications of risks are introduced:

Level I. No Risk: If there is no risk to the subjects, the project may qualify for an **exempted review**. The subjects must be 18 years of age or older and the risks of harm anticipated in the proposed research activities are not greater than those ordinarily encountered in daily life and:

- the research does not involve the use of identifiable confidential information;
- the research does not deal with sensitive aspects of subjects' behavior, e.g. illegal conduct, alcohol/drug use, sexual behavior, etc., the disclosure of which outside the research could place subjects at risk for criminal or civil liability, or may be damaging to subjects' financial standing, employability or reputation; and
- the research does not involve a protected group or groups: children, prisoners, pregnant women, and physically or mentally disabled individuals.

Level II. Minimal Risk: If there is minimal risk to the subjects, the project may qualify for an **expedited review**. The subjects must be 18 years of age or older (see exception below) and the risks of harm anticipated in the proposed research activities are not greater than those ordinarily encountered during the performance of routine physical or psychological examinations or tests; or during routine survey or interviews and/or:

- the research is conducted in established or commonly accepted educational settings, involving normal educational practices,

including research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exception: This category may be applied to research involving children.

- the research involves the use of educational testing (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.

Exception: This category relating to standardized educational tests or observation of public behavior may be applied to research involving children.

This level of review is **not** applicable if survey or interview research involves:

- the use of and the recording of confidential information so that the subject can be identified,
- the audiotaping or videotaping of subjects, and
- the research involves a protected group or groups: children (with the exception of the above considerations), prisoners, pregnant women, and physically or mentally disabled individuals.

Level III. More Than Minimal Risk: If the subjects are subjected to more than minimal risk, a full review is required. The anticipated risks in the proposed research activities exceed, either in probability or magnitude, the minimal risks identified above. All research protocols that involve:

- procedures that may induce potentially harmful, altered psychological or physical states, or impose demeaning conditions to individual dignity, or involve the use of deceptions unexplained at the end of the experiment;
- or procedures which involve the use of untried diagnostic or other procedures or devices; biopsy or surgery procedures; the administration of drugs or radiation; the use of indwelling medical devices; or procedures which require strenuous physical exertion fall in this category
- Alternately, or in addition to the above stated risk level, any research project which involves as subjects, children, prisoners, pregnant women, or physically or mentally disabled individuals falls into this category.

c. Specific Safeguards According to Risk Classification

The two categories of risk require different safeguards for the rights and welfare

of the subjects. Investigators, directors, and department heads are responsible for ensuring that these safeguards are provided accordingly.

i. For Activities Involving No Risk or No More Than Minimal Risk

- Participation must be voluntary; ordinarily but not necessarily, voluntary consent is documented through a signed written consent form.
- All subjects should be able to state that they have no disorder or defect contraindicating their participation in the proposed project. (Whether or not subjects are in fact asked to make such a statement will depend upon the nature of the project.)
- The project must be supervised by a qualified faculty or staff member who thereby assumes responsibility for the protection of the human subjects.

ii. For Activities Involving Greater Than Minimal Risk

- Participation must be voluntary and signed written consent forms are mandatory, unless another method for obtaining and documenting consent is specifically approved by the HSR Committee.
- A written record of the research detailing the procedures employed and the results obtained shall be made and kept for reference.
- The project must be supervised by a qualified faculty or staff member who thereby assumes responsibility for the protection of the human subjects.
- When the risk involved is a significant physical or psychological risk, the investigator and those who review her or his plans must determine:
 - whether it will be necessary for the subjects' physical (or psychological) condition to be evaluated by a licensed physician (or licensed mental health professional) who is acquainted with the possible hazards of the proposed investigations; and
 - whether supervision or ready availability of a physician (or licensed mental health professional) is advisable for the project.
- No investigational new drugs (drugs not certified by FDA for clinical use) nor significant risk devices (as defined in 21 CFR 812.3 [m]) may be administered or used without compliance with the FDA requirements.

III. REVIEW PROCESS AND PROCEDURES

Research conducted at or sponsored by Walsh University must adhere to the ethical principles, policies, and procedures set forth in this document.

A. Timing considerations

Review must occur prior to the initiation of research activity and prior to the implementation of changes in procedures involving human subjects (unless changes in the research are necessary to eliminate immediate hazards to human subjects.) If the research is being proposed for external funding, review should take place prior to or shortly after submission of the research proposal to the funding agency. Some funding agencies have imposed deadlines for submission of the certification of the Human Subjects Review Committee. Consideration should be given to provide adequate time for the Human Subjects Review Committee to review the research proposal properly.

Occasionally an investigator undertakes research without the intention of involving human subjects, but she or he later decides to use human subjects in the research. Before work with human subjects can begin, the research must be reviewed in accordance with the policies and procedures of this document. For work funded by agencies governed by the HHS regulations, approval of the proposed change to use human subjects must be given by the agency as well.

B. Application Process and Flow Chart for Research Activities

All investigators must first submit an Application for Approval to Use Human Subjects in Research Form (See Appendix A) to the Human Subjects Review Committee Chair. The Chair then determines if the research should be classified as a Level I (no risk to human subjects), or should be sent to the HSR Committee.

If a preliminary review of the research proposal by the Chair determines that there is a Level I classification, then the proposal is exempt from further Human Subject Review Committee involvement and the research can proceed pending Chair approval and any modifications deemed necessary by the Chair.

If the Chair determines that the research involves a Level 2 or Level 3 classification, then the research proposal is sent to the HSR Committee for review. If Level 2 or Level 3 research proposals are not approved, then the investigator and Human Subjects Review Committee will consult on needed changes.

All research, whether Level 1, 2, or 3, must be approved by the Human Subjects Review Chair or the Human Subjects Review Committee prior to the initiation of any research activity.

C. Continuing Review

For research activities lasting longer than one year, periodic reviews and/or application updates may be stipulated by the Human Subjects Review Committee. The review interval will be specified in the notification to the investigator regarding the results of the initial review. The minimum requirements for a continuing review will include an inquiry regarding the investigator's plans for continuing the research beyond the original period, modifications to the original protocol, occurrence of any problems involving human subjects, and consideration of the applicability of any changes in external or Walsh University review requirements. The HSR Committee may also impose special requirements such as a requirement for a progress report, third party

review of the consent process or third party review of the research. Such specific requirements will normally be stipulated in the original approval letter.

Although the investigator is responsible for initiating the continuing review, the HSR Chair should normally provide a reminder of the necessity for continuing review and any forms to be used for this purpose.

D. Review of Cooperative Research

Cooperative projects may involve distribution of responsibility for aspects of the research or distribution of access to subjects among cooperating investigators. With the approval of the HSR chair, Walsh University may use joint review, reliance upon the review of another qualified HSR Committee, or similar arrangements to avoid duplication of effort. Such special arrangements must be made well in advance through consultation with the HSR chair.

E. Records of Review

The review of all research must be documented. The chair will keep a copy of the Application for Approval to Use Human Subjects in Research Form and will also forward a copy to University Archives. These records must be retained for three years after the completion of the research. The research applications must be accessible for inspection and copying by authorized representatives of the University and/or the sponsoring agencies.

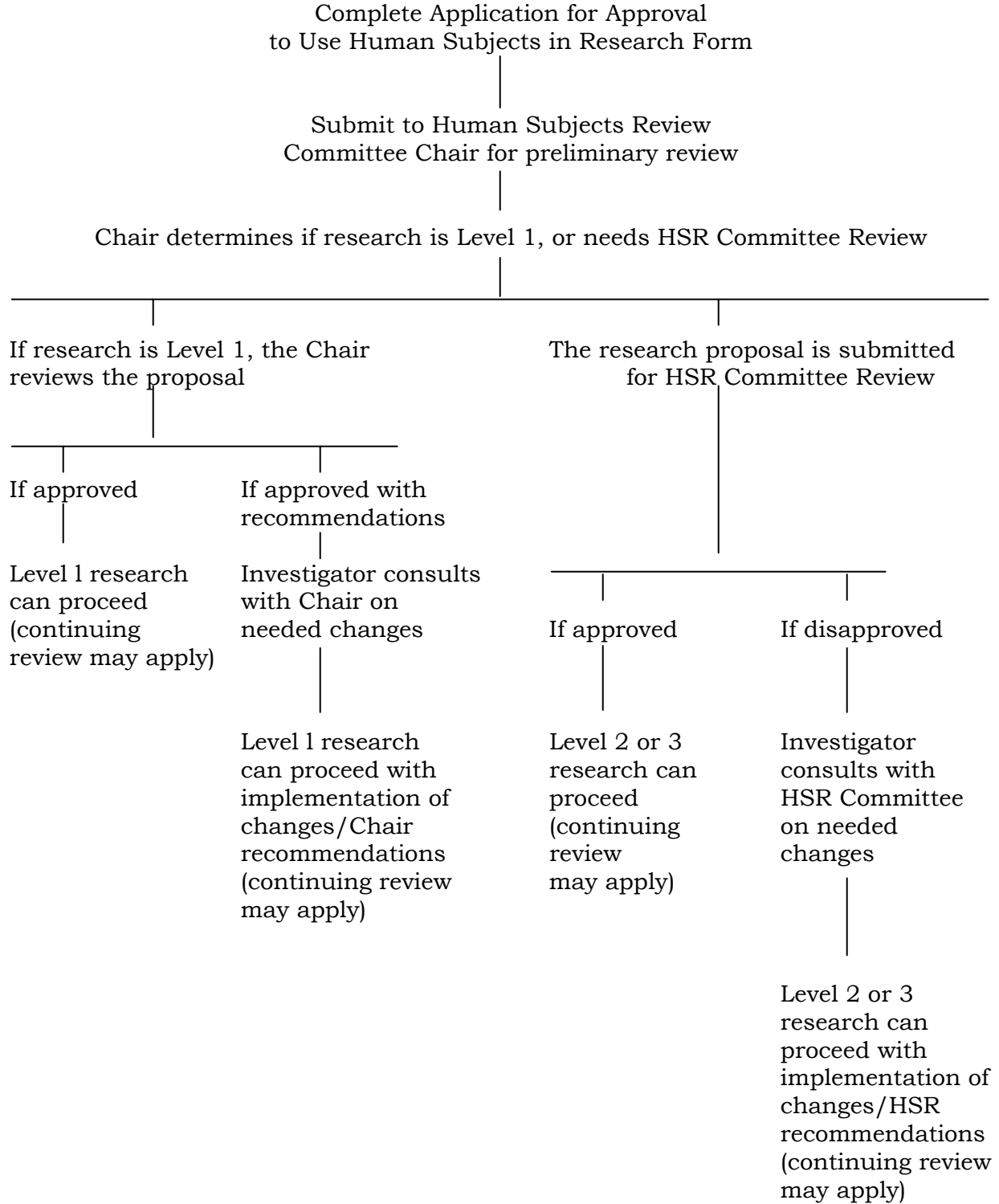
F. Suspension or Termination of HSR. Approval of Research

The HSR Committee has the authority to suspend or terminate approval of any research conducted at or sponsored by Walsh University that is not being conducted in accordance with HSR requirements or that has been associated with unexpected harm to subjects. Any suspension or termination of approval will include a statement of the reasons for the HSR Committee's actions and shall be promptly reported to the investigator and the Walsh University Academic Vice President, Academic Affairs. For any HHS-supported work so terminated, HHS regulations require that the Secretary of HHS be notified as well.

G. Institutional Oversight

Research that has been approved by the HSR Committee may be subject to further appropriate review and approval/disapproval by the officials of the institution. Institutional officials may not approve the research if it has been disapproved of by the HSR Committee.

Flow Chart for Research Activities



IV. STATEMENT OF RESPONSIBILITIES

The responsibility for the protection of subjects is distributed among several parties: faculty/staff and students (principal and/or co-principal) investigators, division/department chairs, the Human Subjects Review Committee, the University administration, sponsoring agencies, the subjects themselves, and those who control access to subjects.

A. Principal Investigator

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 activity, (i.e., the principal investigator) specifically, the investigator is responsible for:

- Careful research design
- Careful adherence to ethical codes and applicable policies and procedures of Walsh University, the sponsoring agency, and cooperating institutions, if any
- Training and supervision of staff and students participating in the research
- Providing information required and taking all steps in initial and continuing review of nonexempt research
- Retaining required records
- Obtaining prior approval of Human Subjects Review Committee for changes in a nonexempt research activity
- Prompt reporting to the Human Subjects Review Committee of unanticipated problems involving risk to subjects or others.

B. Division/Department Chair or University Administrator

The Chair/Administrator has the responsibility to:

- Ensure that faculty, staff, and students are kept informed of the Human Subjects Review Committee policy and procedures and of their responsibilities for protecting the rights and welfare of human subjects involved in research
- Ensure 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 the Walsh University Catalogue
- Report promptly to the Human Subjects Review Committee any unanticipated problems involving risks to subjects or others.

C. Human Subjects Review Committee

The Human Subjects Review Committee is responsible for:

- Initial and continuing review of nonexempt research

- Ascertaining acceptability of proposed research in terms of institutional commitments, applicable laws, and standards of professional conduct and practice
- Documentation of such review in conformity with applicable law, regulations, and policies
- Provision of advice and counsel to investigators engaged in research involving human subjects
- Developing policies, procedures, information, and instructions
- Adjudication of differences and review of problems arising in research involving human subjects
- Ensuring compliance with externally imposed policies and regulations.
- Reporting to the Executive Secretary any unanticipated problems involving risks to subjects and others in work funded by HHS
- Reporting to the appropriate institutional officials and, for research funded by HHS regulations, to the Secretary of HHS, any serious or continuing noncompliance by investigators with the requirements and determinations of the Human Subjects Review Committee

D. Sponsoring Agencies

Sponsoring agencies usually accept responsibility for evaluating research proposed for their support. This evaluation is undertaken in addition to that provided locally. The agency 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. Furthermore, the agency may require that its funding for any project be terminated or suspended if it finds that the institution has materially failed to comply with the terms of its regulations.

E. Subjects

Subjects who participate in research should:

- Consider carefully the decision to participate in research
- Ask questions freely
- Recognize that they are free to withdraw from participation at any time
- Notify the investigator promptly of any adverse effects of participation
- Take unresolved complaints or concerns about their participation in research to the Division/Department Chair or University Administrator and, if the matter remains unresolved, to the Chairperson of the Human Subjects Review Committee.

F. Individual or Institution Providing Access to Subjects

If the individual responsible for conducting research activities is not a Walsh University employee or student but is obtaining access to subjects through Walsh University, the individual providing access to the subjects is responsible for ensuring that Walsh University policies and procedures, including review requirements, are met.

If professional practitioners or service agencies provide access to subjects, the individual providing access should ensure that the professional's commitments to the client are not abridged.

If access is obtained through cooperating institutions, the authorized official of that institution must be informed of the research and should satisfy herself or himself that the subjects' rights and welfare will be protected and that institutional commitments to the subject will not be abridged.

V. ADMINISTRATION OF HSR POLICIES AND PROCEDURES

The Human Subjects Review Committee serves as the primary locus of institutional authority and responsibility for activities involving the use of human subjects in research. Its responsibilities include:

- Development of policy and procedures for such activities
- Development of information and instructions for investigators, reviewers, and subjects involved with such activities
- Initial and continuing review of such activities
- Ascertaining acceptability of proposed research in terms of institutional commitments, applicable law, and standards of professional conduct and practice
- Documentation of review of such activities in conformity with applicable law, regulations, and policies
- Provision of advice and counsel to investigators engaged in such activities
- Adjudication of differences and review of problems arising out of such activities
- Ensuring compliance with externally imposed policies and regulations
- Reporting to the Secretary of Health and Human Services (HHS) unanticipated problems involving risks to subjects and others in work funded by HHS
- Reporting to the appropriate institutional officials and, for research funded by the HHS regulations, to the Secretary of HHS, any serious or continuing noncompliance by investigators with the requirements and determination of the Human Subjects Review Committee.

A. Composition of the HSR Committee and Selection of Its Members

The Walsh University HSR Committee shall have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. Members will be chosen so that the HSR Committee will be sufficiently qualified to ascertain the acceptability of proposed research in terms of institutional commitments in regulations, applicable law, and standards of professional conduct in practice.

The following factors will be considered in selecting members:

- experience and expertise with behavioral or scientific research with human subjects
- diversity of background, including consideration of the racial and

cultural background and sensitivity to such issues as community attitudes

- membership will not consist entirely of men or entirely of women

Specifically, in accordance with federal regulations, the HSR committee will include the following membership categories:

- one member from Philosophy/Theology with representatives alternating from each discipline per term
- one member who is not otherwise affiliated with Walsh University and who is not part of the immediate family of a person who is affiliated with the university
- one member from Nursing, Physical Therapy, or Natural Sciences whose graduate training included education and experience in behavioral and /or scientific research with human subjects
- two members (both of whom may not be from the same departmental unit) from Behavioral Sciences, Counseling and Human Development, Education (graduate and undergraduate) or Business/MAM each of whose graduate training included education and experience in behavioral research with human subjects. At least one of these members must be graduate faculty.

HSR Committee members will serve staggered three-year terms, and may not serve for more than two consecutive terms. Members are responsible for being informed on all HSR policies and procedures and applicable laws and regulations. HSR Committee members are expected to review all materials as well as to attend and to vote at meetings of the HSR Committee as required in this policy.

Procedures for identifying and appointing University members of the HSR Committee are established by the Graduate Council membership; the non-university member is appointed by the Chair, HSR Committee. The Chair of the HSR Committee is elected by HSR Committee members.

B. Operation of the HSR Committee

The HSR Committee meets each semester (3), or more frequently, as needed, to review proposed and continuing research activities involving human subjects and to carry out various responsibilities and activities related to human subjects.

The Committee will determine that the criteria for HSR approval are met and will recommend the frequency on continuing review, if needed, and the nature and extent of any monitoring of the research on consent process to be required. No member shall be involved in either the initial or continuing review of activity in which she or he has a conflicting interest, except to provide information requested by the Committee.

The HSR Committee will adopt a variety of mechanisms to ensure depth and breadth of review. These may include a provision for inviting individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the Committee.

Review and approval of Level I risk research (exempted review) will be done by the Chair of the HSR.

In order for Level II (expedited) or Level III research work to be approved by the Committee, it shall receive the approval of a majority of those members present at the meeting. A level II (expedited) review procedure requires a quorum of at least three members of the committee. If the recommendation is for approval, the decision will be communicated immediately to the investigator. If the decision is for disapproval or a major change, the Chair or a designated Committee member will address the concerns and recommendations in a written memo. The investigator(s) has (have) the opportunity to reapply or to submit additional material or explanations to the Chair of the HSR. If all issues are appropriately addressed (as determined by the Chair), the Chair contacts the investigator about the approval. A written confirmation of approval is also sent to the investigator(s).

The Committee may provide for expedited review of certain categories of research which it will designate with due consideration of applicable regulations of sponsoring agencies. For research work governed by HHS regulations, expedited review will only be available for Level II risk projects and for minor changes in previously approved research during the period of valid approval.

For review of Level III risk and research governed by HHS regulations, the HSR quorum must include at least one member whose primary concerns are in nonscientific areas and at least three of the four committee members.

For all three levels of review, the Committee will provide written notice to principal investigators of the disposition of their proposals. If the proposal is approved, the letter will include any special terms or conditions of approval and/or reporting. If the Committee stipulates changes or if it disapproves the proposal, the written notification will state the basis for this decision. If the decision is for disapproval or a major change, the Chair or a designated Committee member will address the concerns and recommendations in a written memo. The investigator(s) has (have) the opportunity to reapply or to submit additional material or explanations to the Chair of the HSR. If all issues are appropriately addressed (as determined by the Chair), the Chair contacts the investigator about the approval and a written confirmation of approval is sent.

The Committee will maintain adequate documentation of all HSR activities, including minutes of the HSR meetings. These minutes will be kept in sufficient detail to show attendance at the meetings, actions taken by the HSR Committee, the vote on the actions, the basis for requiring changes in or disapproval of research, and a written summary of the discussion of controverted issues and their resolution. Copies of all applications, research projects, and all Committee correspondence and records will be kept with the Chair for seven years.

The HSR Committee functions as a subcommittee of Graduate Council and normally reports on all activities to that body. Additionally, The HSR Committee also reports all decisions and actions directly to the Academic Vice President for administrative review. Copies of all HSR Committee records are forwarded to University Archives.

REFERENCES

Department of Health and Human Services. (Oct. 1995). *Basic HHS policy for protection of human research subjects*. 45 CFR Subtitle A. 46.101-46.409.

Institutional Review Board. (1992). *Handbook for investigators: For the protection of human subjects in research*. Urbana-Champaign, IL: University of Illinois.

John Paul II. (1990). Ex corde ecclesiae. *The Apostolic Constitution on Catholic Universities.*, 20, 265-280.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1978). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research*. (Report No. 78~OOI2): Washington, DC.

Superintendent of Documents. (1947). *Trials of war criminals before the Nuremberg military tribunals*. Washington, DC: U.S. Government Printing Office.

APPENDICES

- A. Application for Approval to use Human Subjects in Research
- B. Examples of Informational Cover Letters and Consent Forms
- C. Criteria for Approval of Research Governed by HHS Regulations
- D. HHS Requirements for Informed Consent
- E. HHS Requirements for Federally Funded Research Involving Certain Subject Populations
 - 1. Research Involving Children as Subjects
 - 2. Research Involving Prisoners as Subjects
 - 3. Research Involving Fetuses, Pregnant Women and Human In Vitro Fertilizations

APPENDIX A

**WALSH UNIVERSITY
APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH**

Principle Investigator	Co-Investigator *
Name:	Name:
Department:	Department:
Address**:	Address**:
Phone:	Phone:
Fax:	Fax:
Email:	Email:
Position: <input type="checkbox"/> Faculty <input type="checkbox"/> Graduate student <input type="checkbox"/> Undergraduate student <input type="checkbox"/> Other	Position: <input type="checkbox"/> Faculty <input type="checkbox"/> Graduate student <input type="checkbox"/> Undergraduate student <input type="checkbox"/> Other
Type of project: <input type="checkbox"/> Faculty Research <input type="checkbox"/> Student Research <input type="checkbox"/> Thesis/Dissertation <input type="checkbox"/> Funding Status <input type="checkbox"/> Pending <input type="checkbox"/> Awarded <input type="checkbox"/> Non-applicable Externally Funded Agency: _____ <input type="checkbox"/> Other Specify: _____	*Submit the names of additional co-investigators on a separate piece of paper, including all the information requested above. **For address, include your preferred contact address.

If the Principle Investigator is a student include the following:

Faculty Advisor: _____ Department: _____

Office Address: _____ Phone/email: _____

Project Title: _____

Date of Application Submission: First: _____ **Revision:** _____

Duration of Project: Start Date: _____ **End Date:** _____

Preliminary Review: (Please type)

Summarize proposed project and procedures to which human subjects will be subjected. Please include any special instruments. **Do not write "See Attached"**

1. Primary Objective(s), purpose(s), hypothesis (es), and significance(s) of the research:

2. Identify the basic research design of the study: (i.e., experimental, quasi experimental, single-case, single-factor, multiple-factor designs or non-experimental, retrospective, prospective designs).

3. Description of Subjects (include age range, selection criteria, recruitment procedures, anticipated and desired sample size)

4. Research Procedures (to which human subjects will be subjected) including each variable, measurement instruments and their reliability and validity:

5. Risks and Benefits: Identify/Describe benefits and risks/or discomforts that will be experienced by the subjects. Include the risks and benefits in the informed consent form.

6. Include a copy of the following:

- ___ Statement of Informed Consent and/or Cover Letter
- ___ Assent forms, if needed
- ___ Copies of material given to the subjects and parents/guardians
- ___ Data collection forms including demographic data, questionnaires, surveys, interview questions, and so on. Copyrighted material that cannot be copied need not be submitted. The Committee may request to review the material.
- ___ Scripts of verbal instructions and project information
- ___ Human Subjects Application or written documentation of approval from other institutions involved in the study.

7. PLEASE ANSWER THE FOLLOWING:

1	Yes	No	N/A	Will subjects be identifiable either through records, responses, pictures, or identifiers (labels, numbers) linked to the subjects?
2	Yes	No	N/A	Will subjects be at risk of criminal or civil liability, changes in conditions of employment, undue damage to financial standing, or undue embarrassment if others than the project director know the responses?
3	Yes	No	N/A	Does research deal with sensitive aspects of subject's behavior such as illegal conduct, drug use, sexual behavior, use of alcohol, beliefs or values, and could present a possible invasion of privacy?
4	Yes	No	N/A	Does research involve the collection or study of existing data (documents, records, pathological specimens or diagnostic specimens) from sources not publicly available?
5	Yes	No	N/A	Will the subject be video/audio taped?
6	Yes	No	N/A	Are subjects free to withdraw at any time without penalty?
7	Yes	No	N/A	Does the research involve deception?
8	Yes	No	N/A	Does the research deal with special populations in addition to minors under 18 years of age? Indicate the special populations included in the research: <small>TM</small> Minors (under 18 years of age) <small>TM</small> Pregnant women √ Prisoners/arrestees <small>TM</small> Economically disadvantaged √ Cognitively/mentally impaired <small>TM</small> Institutionalized √ Patients
9	Yes	No	N/A	Are some or all of the subjects likely to be vulnerable to coercion or undue influence through means other than #8

8. If you answered yes to question number 7, describe the rationale for deception involved in the study, its necessity, and any debriefing procedures that are to be done at the end of the study.

9. If you answered yes to number 8 or 9, include how you will provide special protections to these groups. (They are entitled to special consideration under federal regulations: 45 CFR Subparts B (pregnant women), C (prisoners), and D (children)).

I certify that the research procedures stated and the method of obtaining consent (if any), as approved by the Human Subjects Review Board, will be followed during the period covered by this research project. Any future changes will be submitted for Board review and approval prior to implementation.

Project Director

Faculty Advisor (if student)

Date

FOR HSR USE ONLY

Date received: _____

____ Recommended for exemption from review (Level I No Risk)

____ Recommended for expedited review (Level II Minimal Risk)

____ Recommended for full board review (Level III High Risk)

____ Revisions not required. Approval and comments are addressed in a separate memorandum to the primary investigator.

____ Revisions required. Comments and contingencies are addressed in a separate memorandum to the primary investigator.

Final Approval Date: _____

Denial Date: _____

HSR Approval expires on _____. If the duration of the project takes more than 12 months, continuation of approval will require a renewal application.

Signature HSR Chair _____ **Date** _____

Walsh University
INSTRUCTIONS for Application to Use Humans in Research

To protect the rights, well being and privacy of individuals, all research using humans as subjects conducted by the faculty, staff, and students must be reviewed and approved by the University Human Subject Review Committee in accordance with Federal Regulations (45 CFR 46, as amended). The chair, HSR Committee, serves as Reviewer to conduct preliminary review of the research protocol and to determine the legal aspect of risk and level of review required.

INSTRUCTIONS

- 1) The Application for Approval must be completed in detail. (See the attached application checklist.) Only typed or word processed forms will be accepted. Attach copies of consent forms, questionnaires, surveys, data collection forms, interview questions and so on. **Three copies of the application and required material are to be submitted.**
- 2) Advisor's signatures are required on HSR applications for student research.
- 3) Submit the Application for Approval and required attachments to the Chairperson, Human Subjects Review Committee, 2020 East Maple St., North Canton, OH 44720
- 4) Your project will be reviewed and placed in one of the following categories:

Level I Approved as no risk, you may begin immediately upon receiving approval from the HSR Chair. If you are a student, written approval will be sent to both your advisor and you.
Exempt Review

Level II Approved as minimal risk; you may begin the project after receiving written approval from HSR Committee. If you are student, written approval will be sent to both your advisor and you.
Expedited Review

Level III Your project deals with sensitive issues, special populations or is considered high risk. You may be invited to attend the meeting to answer questions the Committee may have about your project.
Full Review
- 5) Allow adequate time for review and approval. The Human Subjects Review Committee meets on the second Friday of each month. Reviews are to be received by the previous Friday to be considered at the next meeting. **For some academic courses, alternative submission and review dates may need to be arranged with the course coordinator. The course coordinator will inform you of the submission date. Exceptions can also be made for approval needed for grant applications.**

- 6) For all levels of review, a response from the HSR Committee will be sent to the primary investigator within 5-7 workdays of the meeting date. The response will indicate that (1) no revisions are required and the project is approved or (2) revisions are required. If you are a student, written approval will be sent to both your advisor and you.
- 7) If revisions are required, the revised Application for Approval and any additional material requested needs to be resubmitted to the HSR. Responses to revision submissions will be made within 5-7 business days from the date of resubmission.
- 8) Projects involving other facilities. The Human Subjects Review Committees of both Walsh University **and** the involved facilities must approve projects of Walsh University faculty or students to be done at other facilities. If the facility does not have a Human Subjects Review Committee, appropriate approval must be obtained from official of the facility. Copies of the report from other facilities must be submitted to the Human Subjects Committee of Walsh University.

CONSENT FORMS

Consent forms must be typed on departmental letterhead that is available from the department secretary. Contact information including the names and phone numbers of the investigator(s), the HSR contact, and the faculty advisor, if the principal investigator is a student, must be on the consent form. Please follow the sample consent forms included in the Walsh University Human Subjects Review Policy carefully touching on each point. Also consider the attached informed consent checklist. A copy of the consent form must be given to each subject. Signed consent forms must be kept on file with Faculty Advisor/Researcher for a period of three years beyond the end of the project.

Consent Obtained Orally: When consent information is to be presented orally, a transcript must be provided to the HSR Committee and a witness must be present when the transcript is read to the subject. The subject and the witness are to mark or sign the transcript indicating they were present and heard the oral information. The subject must also mark or sign agreeing to be in the project.

PROPOSAL FOR EXTERNAL FUNDING

Proposals for external funds that include humans used as subjects in research should be reviewed prior to submission so that notification of HSR approval can be included with the proposal.

CHANGES TO AN APPROVED NON-EXEMPT PROJECT

Changes to an approved project that affect the subject must be approved before the initiation of the revised research. A copy of the revised portion of the protocol must be submitted for review.

EQUIPMENT

If unusual equipment is to be used, include qualifications of the operator.

CHECKLISTS FOR THE APPLICATION AND INFORMED CONSENT DOCUMENT

Yes	No	N/A	
			Is the cover sheet completed and secured all signatures?

Yes	No	N/A	Does the project application include:
			A description of the research area and the project purposes, objectives, Research questions, or Hypotheses?
			The university/college/department affiliation?
			Descriptions of the subject characteristics and how the subjects will be used?
			Copies of all questionnaires, data collection forms, and a description of all tests?
			A discussion of the risks, benefits, and privacy safeguards?
			A description of data collection methods and maintenance of records considering confidentiality and anonymity?
			A description of the disposition of data and audio/video data records?
			A statement about special subject populations?

Yes	No	N/A	Does the Informed Consent Statement:
			Introduce you and your research?
			Provide the subject with a brief, understandable explanation of the research, including the purposes of the study and the reason for the study?
			Explain the risks/discomforts and benefits of the study?
			Explain the anonymity and/or confidentiality guarantee of the investigator?
			Describe the expected duration of the subjects' involvement in the study?
			Describe the financial costs and/or remuneration for the subjects if applicable?
			Mention that participation is voluntary and that the subject may withdraw at any time without prejudice?
			Include a statement regarding the policy of the University concerning compensation and medical treatment for injuries occurring during or caused by participation in the study.

			Include a statement and information for contacting the investigator and the Walsh University IRB (and the faculty advisor if necessary)?
			Provide a phone number where the subject may contact you for further information?
			Provide a signature and date block for the subject, guardian, and witness (if needed) to complete?
			If a signed consent form is not needed for procedural or substantive reasons, include a statement and your alternative procedure for obtaining consent.

APPENDIX B

SAMPLE CONTENTS

INFORMATIONAL COVER LETTER (LEVEL I)

1. A statement explaining the purpose of the research. If a student, indicate that the research is a course requirement.
2. An explanation of the procedures of the research including explanations of the subject participation.
3. A statement on the expected duration of the subject's participation in the research project.
2. A statement describing the extent, if any, to which confidentiality or anonymity will be maintained and how this will be accomplished.
3. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights. This should include the researchers, the Chair of the Human Subjects Committee, the faculty advisor (if a student project), and a representative of collaborative facilities.
4. A statement that participation is voluntary, and/or that refusal to participate will involve no penalty or loss of benefits, and that the subject may discontinue participation at any time (without penalty or loss of benefits).
5. Researcher's name/telephone
Faculty advisor's name/telephone (if applicable)
Chair of Human Subjects Committee
Representative of collaborative facilities.
6. For research governed by the Regulations of the U.S. Department of Health and Human Services or the Food and Drug Administration additional elements may be required; see Appendix C and D.

APPENDIX B-1

CONSENT FORM (IRB, 1992) EXAMPLE 1 a FOR A PROJECT AT MORE THAN MINIMAL RISK

CONSENT TO PARTICIPATE IN RESEARCH

"The Effects of Sleep Deprivation on Motor Control and Response Time Tasks"

I state that I am over eighteen years of age, in good physical health, and wish to participate in a program of research being conducted by Freda Smith of the Psychology Department.

The purpose of the research is to measure the effects of prolonged sleep loss on motor control and response time tasks.

The experimental procedures involve three sessions four weeks apart during which I will be asked to go without sleep for periods of 24 to 48 hours. I will not know the length of the sleepless period ahead of time. At various times during the sleepless period I will be asked to perform various simple tasks and to respond to sounds or lights by pushing a button.

I understand that there will be a responsible staff member present at all times, after the first twelve hours. I understand that my blood pressure, respiration, and pulse rate will be checked during the experiment.

I understand that as a result of sleep loss I may experience extreme tiredness, feelings of "disorientation, slight depression, irritability, and sleep disturbances over a short period of time. I understand that there is normally no long term effects associated with the periods of sleeplessness involved in this experiment.

I understand that the experiment is not designed to help me personally, but that the investigator hopes to learn about the relationship between sleep loss and the ability to perform tasks like those needed for the safe operation of machinery and cars. I understand that I am free to ask questions or to withdraw my participation at any time.

In the event of injury resulting from participation in this study, I understand that immediate medical treatment is available at the McKinley Health Service. I also understand that the University of Illinois will not provide compensation for any injury sustained as the result of participation in this research except as required by law.

I understand that I will receive a copy of this form.

Principal Investigator:
Research Assistant:
415 Psychology Building, Phone: 333-0110
Chair, Human Subjects Committee:
Signature of Research Subject

APPENDIX B-2

CONSENT FORM (IRB, 1992) EXAMPLE 1 b SHORT FORM OF CONSENT FOR PROJECT AT MORE THAN MINIMAL RISK WRITTEN SUMMARY OF WHAT IS PRESENTED ORALLY TO SUBJECTS (PART 1)

"The Effects of Sleep Deprivation on Motor Control and Response Time Tasks"

Subjects will be over eighteen years of age and in good physical health.

The purpose of the research is to measure the effects of prolonged sleep loss on motor control and response time tasks.

The experimental procedures involve three sessions four weeks apart during which I will be asked to go without sleep for periods of 24 to 48 hours. I will not know the length of the sleepless period ahead of time. At various times during the sleepless period I will be asked to perform various simple tasks and to respond to sounds or lights by pushing a button.

There will be a responsible staff member present at all times after the first twelve hours. Subjects' blood pressure, respiration and pulse rate will be checked during the experiment.

As a result of sleep loss, subjects may experience extreme tiredness, feelings of disorientation, slight depression, irritability, and sleep disturbances over a short period of time. Normally no long-term effects result from the periods of sleeplessness involved in this experiment.

The experiment is not designed to help subjects personally, but the investigator hopes to learn about the relationship between sleep loss and the ability to perform tasks like those needed for the safe operation of machinery and cars. Subjects are free to ask questions and to stop participating at any time.

In the event of injury resulting from participation in this study, immediate medical treatment is available at the McKinley Health Service. The University of Illinois will not provide compensation for any injury sustained as the result of participation in this research except as required by law.

Signature of Staff member _____

Signature of Witness to Explanation _____

Date _____

Freda Smith, Responsible Principal Investigator
Albert Nicholas, Research Assistant
415 Psychology Building
Phone: 333-0110

APPENDIX B-3

CONSENT FORM (IRB, 1992) EXAMPLE 1 b SHORT FORM OF WRITTEN CONSENT
(PART 2)

I state that I am over eighteen years of age, in good physical health, and agree to participate in a program of research being conducted by Professor Freda Smith of the UIUC Psychology Department entitled, "The Effects of Sleep Deprivation on Motor Control and Response Time Tasks." The purpose, procedures, risks, and benefits of this research have been explained to me and I have received a written summary of this explanation. I understand that I may ask questions and I am free to withdraw at any time

In the event of injury resulting from participation in this study, I understand that immediate medical treatment is available at the McKinley Health Service. I also understand that the University of Illinois will not provide compensation for any injury sustained as the result of participation in this research except as required by law.

Signature of Staff Member _____

Signature of Subject or Subject's Representative _____

Signature of Witness to Signature _____

Date_____

APPENDIX B-4

CONSENT FORM (IRB, 1992) EXAMPLE II FOR A PROJECT AT MINIMAL RISK

CONSENT FOR BLOOD TO BE DRAWN FOR USE IN A RESEARCH PROJECT

I, state that I am over eighteen (18) years of age and agree to participate in a program of research being conducted by Professor Stephen Daedalus of the UIUC Entomology Department.

Purpose of the Project

To study the effect of fresh and dried human blood on the digestive system of scarabaeidae and microcentrum.

The experimental procedure for the human subject is to donate a total of 3 samples of 10 ml of blood two weeks apart.

The blood will be drawn by a certified medical technologist, nurse, or other suitably qualified person.

The personal discomforts involved are: slight pain during the drawing of blood and, in rare cases, development of what is commonly known as, "black and blue mark" caused by minor seeping of blood around the puncture.

I acknowledge that I have been told that this procedure is not intended to benefit my personal health but will provide material for certain studies of insects.

I acknowledge that Professor Daedalus has fully explained to me the discomforts involved and the need for the research, has informed me that I may withdraw from participation at any time, and has offered to answer any questions which I may ask about the procedures to be followed. I freely and voluntarily consent to take part in this research project.

Stephen Daedalus, Responsible Project Investigator
Entomology Department, UIUC
20 Morrill Hall
Phone: 333-6714

Signature of Subject _____

Date _____

APPENDIX B-5

CONSENT FORM (IRB, 1992) EXAMPLE III FOR RESEARCH AT MINIMAL RISK INVOLVING CHILDREN AS SUBJECTS

College of Education
Department of Elementary Education
1310 South Sixth Street
Champaign, IL 61820

September 2, 1983

Dear Parent:

We would like to include your child, along with his or her classmates, in a project to see if we can train 10 and 11 years old children in survey and map-making skills.

If your child takes part in this project, she or he will get extra training in the math lab in the school. Your child will also visit the County Court House to look at land plats and surveys and work with maps in the library. The total time needed for all training should not be more than eight hours and will take place over several weeks in April and May. Each child will be asked to give positive agreement to be included in the study; only those students who want to take part will do so. Any student may stop taking part at any time. The information collected from your child during this study will be kept strictly confidential and will not become a part of his or her school record.

Please let us know on the bottom of this letter whether you do or do not want your child to participate in this project. Ask your child to bring the reply to her or his teacher or school principal. If you have any questions about this research, please do not hesitate to ask them either by mail or by telephone at the numbers listed below.

We look forward to working with your child. We think that our research may help improve the map skills of grade school children. We also think that our research will show that some parts of trigonometry can be studied in earlier grades in math than teachers have thought.

Yours truly,

L. Ericksen, Associate Professor
(217) 333-2250

A. Vespucci, Assistant Professor
(217) 333-8187

I do / do not want my child _____ to participate in the study described above. Name of Child

Date

Signature

APPENDIX C

CRITERIA FOR APPROVAL OF RESEARCH GOVERNED BY HHS REGULATIONS

Note: Federal regulations use (Institutional Review Board) for HSR Committee.
In order to approve research covered by these regulations, the HSR shall determine that all of the following requirements are satisfied:

- 1) Risks to subjects are minimized:
 - a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
 - b) 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, HSR 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 HSR 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 HSR 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 Section 46.116, HHS regulations. (See Appendix D). If subjects are children and if they are capable of giving assent, adequate provisions will be made to solicit their assent as well as the permission of their parents or authorized representative (See Item 9 through 13 below).
- 5) Informed consent will be appropriately documented, in accordance with and to the extent required by Section 46.117 of HHS regulations (See Appendix D of this document).
- 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 additional safeguards have been included in the study to protect the rights and welfare of these subjects.
- 9) When children are included in any research:
 - a) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in Appendix D. The HSR will judge whether children are capable of providing assent, taking into account the ages, maturity, and psychological state of the children involved and will determine how assent must be documented.

- b) Where parental permission is required, the HSR will determine when permission of one parent is sufficient, in accordance with HHS requirements described in Appendix E. The HSR will determine when the assent and consent requirement may be waived, in accordance with HHS consent requirements listed in Appendix D.
- 10) When children are included in research in which more than minimal risk is presented by an intervention or procedure that holds out the prospect of direct benefit to the individual subject or by a monitoring procedure that is likely to contribute to the subject's well-being, a) the risk is justified by the anticipated benefit to the subjects, and 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.
- 11) When children are included in research in which more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit to the individual subject or by a monitoring procedure that is not likely to contribute to the well-being of the subject,
 - 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; and c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition.
- 12) When children are included in plans for research not otherwise approvable,
 - a) the HSR must find that the research presents a reasonable opportunity to further understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, and
 - b) the Secretary of HHS after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following an opportunity for public review and comment, must determine either that the research in fact is approvable by the HSR or
 - i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem that affects the health or welfare of children; and
 - ii) the research will be conducted in accordance with sound ethical principles; and
 - iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.
- 13) When children who are wards of the state or any other agency, institution, or entity are included in research.
 - a) involving more than minimal risk and no prospect of direct benefit to individual subject, but likely to yield generalizable knowledge about the subject's disorder or condition, or
 - b) not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, the HSR must determine that the research is
 - i) related to their status as wards or
 - ii) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not

wards and the HSR will require the appointment of an advocate for each child who is a ward. All other determinations required for research must also be made. (See above.)

APPENDIX D

HHS REQUIREMENTS* FOR INFORMED CONSENT

1. Basic Elements of Informed Consent
 - A. Basic elements of informed consent. Except as provided in paragraph (C) of this section, in seeking informed consent the following information shall be provided to each subject.
 - (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
 - (2) A description of any reasonably foreseeable risks or discomforts to the subject;
 - (3) A description of any benefits to the subject or to others 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. In projects regulated by the Food and Drug Administration, subjects must be informed that there is a possibility that their records may be inspected by the FDA.
 - (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 subject's rights, and whom to contact in the event of a research-related injury to the subject; and
 - (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue any time without penalty or loss of benefits to which the subject is otherwise entitled.
 - B. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
 - (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
 - (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 - (3) Any additional costs to the subject that may result from participation in the research;
 - (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

- (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
 - (6) The approximate number of subjects involved in the study.
- C. An HSR may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the HSR finds and documents that:
- (1) The research involves no more than minimal risk to the subjects;
 - (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - (3) The research could not practicably be carried out without the waiver or alteration;
and.
 - (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- D. An HSR may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the HSR finds and documents that:
- (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine;
 - i) program under the Social Security Act, or other public benefit or service " programs,
 - (I) procedures for obtaining benefits or services under those program,
 - (II) possible changes in or alternatives to those program or procedures, or
 - (III) possible changes in methods or levels or payment for benefits or services under those programs; and
 - (2) The research could not practicably be carried out without the waiver or alteration.
- E. The informed consent requirements in those regulations are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.
- F. Nothing in these regulations 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.
2. Consent and Assent Requirements for Research Involving Children
- A. In addition to the consent requirements described in 1. above, the following requirements apply to research involving children:

- (1) When children are subjects in research, solicitation of their assent as well as the consent of their parents or guardians is normally required. (See also Appendix E).
- (2) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, without affirmative agreement, be construed as assent.
- (3) The assent of the children is not required if:
 - (I) the HSR determines that the capability of some or all of the children involved in research under a particular research protocol is so limited that they cannot reasonably be consulted; or
 - (II) the HSR determines that the intervention or procedures 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; or
 - (III) the HSR determines that the circumstances permit consent to be waived in accordance with I.C. D. and F. above.

B. The consent and assent requirements described in I. and 2. above may be waived if:

- (1) The HSR has determined that the 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), and,
- (2) The waiver is not inconsistent with federal, state, and local laws and
- (3) An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. (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 subject; and their age, maturity, status, and condition.) .

3. Requirements for Research Involving Prisoners

In addition to the consent requirements described in 1. above, the following requirements apply to research involving prisoners:

Research on prisoners may be undertaken only if:

- (1) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research when ranking decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on her or his parole; and
- (2) Any possible advantages accruing to the prisoner through her or his 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 her or his ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

4. Requirements for Research Involving Pregnant Women and Fetuses

In addition to the consent requirements described in 1. above, the following requirements apply to research involving pregnant women and fetuses:

- (1) Research directed toward pregnant women may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if:
 - (I) the purpose of the research is to meet the health needs of the mother;
 - (II) his identity or whereabouts cannot reasonably be ascertained;
 - (III) he is not reasonably available; or
 - (IV) the pregnancy resulted from rape.
 - (2) Research directed toward fetuses *in utero* may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if:
 - (I) his identity or whereabouts cannot reasonably be ascertained;
 - (II) he is not reasonably available; or
 - (III) the pregnancy resulted from rape.
5. Documentation of Informed Consent
- §46.117 Documentation of informed consent.
- A. Except as provided in paragraph C of this section, informed consent shall be documented by the use of a written consent form approved by the HSR and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.
 - B. Except as provided in paragraph C of this section, the consent form may be either of the following:
 - (1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read the document before it is signed; or
 - (2) A "short form" written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the HSR shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."
 - C. An HSR may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

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

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. In cases where the documentation requirement is waived, the HSR may require the investigator to provide subjects with a written statement regarding the research.

D. When children are included as subjects in the research, permission by parents or guardians shall be documented in accordance with and to the extent required by (A) through (J) above. When the HSR determines that assent of the children is required, it shall also determine whether and how assent must be documented.

APPENDIX E

REQUIREMENTS FOR FEDERALLY FUNDED RESEARCH INVOLVING CERTAIN SUBJECT POPULATIONS

1. Special Requirements for Federally Funded Research Involving Children

In addition to the requirements specified elsewhere in this handbook, the following requirements are imposed on all research involving children that is supported by or governed by HHS regulations.

A. Consent

1) Assent of Children

(a) The HSR shall determine that adequate provisions are made for soliciting the assent of children who are subjects in research, when, in the judgment of the , the children are capable of providing assent.

In determining whether children are capable of assenting, the HSR 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 HSR deems appropriate.

If the HSR

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 HSR determines that the subjects are capable of assenting, the may still waive the assent requirements under certain circumstances. (See Appendix D)

(b) For research involving children capable of assent, the HSR will require the investigator to propose what the child will be told about the research, how the information will be presented to her or him, and how assent will be obtained. The information presented to the child will vary from a simple description of what the child will experience to the equivalent of the information from a simple description of what the child will experience to the equivalent of the information that would be presented to an adult subject. Younger and less sophisticated children will be given simple information on what they will experience as they participate in the research. For older and more sophisticated children, more detailed information will be given together with a statement about the fact that the project is for the purpose of research. All children must be informed that they are free to withdraw from participation at any time. The HSR will review and approve methods for ensuring assent and base its decisions on the premise that, like maturity, a child's understanding is a gradually expanding

developmental process which cannot be stated in terms of chronological age, as well as on the principle that the autonomy of all persons should be respected.

2) Permission of Parents or Guardians

a) When children are subjects in research, the HSR shall determine, in accordance with and to the extent that consent is required, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the HSR may find that the permission of one parent is sufficient for research to be conducted where:

- the research does not involve greater than minimal risk;
- the research involves greater than minimal risk, but presents the prospect of direct benefit to the individual subjects.

b) When children are included in:

- research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition

or

- research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health of children and permission is to be obtained from parents then 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.

3) Consent May Be Waived

Under several circumstances, the HSR may waive some or all of the consent requirements. In addition, the HSR may waive consent of the parents or guardian if the HSR determines that:

- a) a research protocol is designed for conditions or for a subject requirement to protect the subjects (for example, neglected or abused children), and
 - b) the waiver is not inconsistent with federal, state, or local laws, and
- a) an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. 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, status, and condition.

4) Documentation of Informed Consent and Assent

When children are included as subjects in research, permission by parents or guardians shall be documented in accordance with and to the extent required by 1. through 3. above. When the HSR determines that

assent is required, it shall also determine whether and how assent must be documented.

B. Criteria for Approval by the

- 1) Research involving not greater than minimal risk --When children are included in research involving not greater than minimal risk, the HSR must find that adequate provisions are made for soliciting the assent of children and the permission of their parents.
- 2) Research involving more than minimal risk, but present the prospect of direct benefit to individual subjects--When children are included in research in which the HSR finds that more than minimal risk is presented by an intervention or procedure that holds out the prospect of direct benefit to the individual subject or by a monitoring procedure that is likely to contribute to the subject's well-being, the HSR must find that:
 - a) the risk is justified by the anticipated benefit to the subjects, and
 - 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 children and permission of their parents and guardians.
- 3) Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or conditions. Where children are included in research in which 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 subjects, the HSR must find that:
 - a) the risk represents a minor increase over minimal risk, and.
 - 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, and
 - 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.
- 4) Research not otherwise approvable
Where children are included in plans for research not otherwise approvable,

- a) the must find 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 of Health and Human Services, after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following an opportunity for public review and comment, has determined that the research is, in fact, approvable by the or that:
 - c) 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 the research will be conducted in accordance with sound ethical principles; and adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.
- 5) When children who are wards of the state are involved as subjects in research
- a) The requirements for children who are wards of the state or any other agency, institution, or entity do not differ from those for other children if the research:
 - involves no more than minimal risk or
 - involves greater than minimal risk, but presents the prospect of direct benefit to the individual subjects.
 - b) Children who are wards of the state or any other agency, institution, or entity can be included in research described in Section B., 3. or 4. above only if the research is:
 - Related to their status as wards; or
 - Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
 - c) If the research is approved under Section B.,5.a. (immediately above), the will 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*.

2. Special Requirements for Federally Funded Research Involving Prisoners as Subjects

In addition to the requirements specified elsewhere in this policy, the following requirements are imposed on all research involving prisoners that is supported by or governed by HHS regulations. .

A. General Limitations

The only types of research involving prisoners which may be approved by the are the following:

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

2) 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;

3) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prison 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 of Health and Human Services has consulted with appropriate experts, including experts in penology, medicine, and ethics and published notice in the Federal Register of her or his intent to approve such research;

or

4) 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 HSR to control groups that may not benefit from the research, the study may proceed only after the Secretary of Health and Human Services has consulted with appropriate experts, including experts in penology, medicine, and ethics and published notice in the Federal Register of her or his intent to approve such research.

B. Criteria for Approval by the

In addition to applying other criteria for approval, the HSR shall make the following determinations:

1) Any possible advantages accruing to the prisoner through her or his 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 her or his ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

2) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers.

3) 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 HSR justification in writing for following some other procedures, control subjects be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.

4) The information is presented in language that is understandable to the subject population.

5) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in ranking decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on her or his parole; and

6) Where the 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.

C. Modification or Waiver of Specific Requirements

Upon the request of an applicant (with the approval of the Institutional Review Board), the Secretary of Health and Human Services may modify or waive specific requirements listed above with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the Federal Register.

3. Special Requirements for Federally Funded Research Involving Fetuses, Pregnant Women, or Human In Vitro Fertilization.

In addition to the requirements specified elsewhere in this policy, the following additional requirements are imposed in all research involving fetuses, pregnant women or human in vitro fertilization that is supported or governed by HHS regulations.

A. General limitations.

- 1) No activity to which this subpart is applicable may be undertaken unless:
 - a) Appropriate studies on animals and nonpregnant individuals have been completed;
 - b) Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.
 - c) Individuals engaged in the activity will have no part in (I) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (II) determining the viability of the fetus at the termination of the pregnancy; and
 - d) No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.
- 2). No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

B. Activities directed toward pregnant women as subjects.

- 1) No pregnant woman may be involved as a subject in an activity covered by this subpart unless
 - a) The purpose of the activity is to meet the health needs of the mother and the fetus or will be replaced at risk only to the minimum extent necessary to meet such needs
 - b) the risk to the fetus is minimal.
- 2) An activity permitted under paragraph (I) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding

possible impact on the fetus, except that the father's consent need not be secured if

- a) The purpose of the activity is to meet the health needs of the mother;
- b) his identity or whereabouts cannot reasonably be ascertained;
- c) he is not reasonably available; or
- d) the pregnancy resulted from rape.

C. Activities directed toward fetuses *in utero* as subjects.

- 1) No fetus *in utero* may be involved as a subject in any activity covered by this subpart unless:
 - a) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be replaced at risk only to the minimum extent necessary to meet such needs, or
 - b) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.
- 2) An activity permitted under paragraph (I) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if
 - a) His identity or whereabouts cannot reasonably be ascertained,
 - b) he is not reasonably available, or
 - c) the pregnancy resulted from rape.

D. Activities directed toward fetuses *ex utero*, including nonviable fetuses, as subjects.

- 1) Until it has been ascertained whether or not a fetus *ex utero* is viable, a fetus *ex utero* may not be involved as a subject in an activity covered by this subpart unless:
 - a) There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or
 - b) The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.
- 2) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless
 - a) Vital functions of the fetus will not be artificially maintained.
 - b) Experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and
 - c) The purpose of the activity is the development of important biomedical knowledge that cannot be obtained by other means.

- 3) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.
- 4) An activity permitted under paragraph (1) or of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if:
 - a) identity or whereabouts cannot reasonably be ascertained,
 - b) he is not reasonably available, or
 - d) the pregnancy resulted from rape.

E. Activities involving the dead fetus, fetal material, or the placenta. Activities involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable state or local laws regarding such activities.

F. Modification or waiver of specific requirements.

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the FEDERAL REGISTER.

10. If you answered yes to number 8 or 9, include how you will provide special protections to these groups. (They are entitled to special consideration under federal regulations: 45 CFR Subparts B (pregnant women), C (prisoners), and D (children).