

APPLICATION GUIDELINES

For Research Involving Human Subjects



PORTLAND STATE
UNIVERSITY

Human Subjects Research Review Committee
Office Of Research and Sponsored Projects
P.O. Box 751
Portland, OR 97207
(503) 725-4288 / 1-877-480-4400
FAX: (503) 725-3416
Web site: <http://www.gsr.pdx.edu/compliance/human>

June 2006

► Preface

Dear Applicant,

On behalf of the Human Subjects Research Review Committee (HSRRC), we welcome you to the research approval process. The following application packet is provided as a guideline to investigators who will work with human subjects in the course of their research.

Portland State University is responsible for the protection of the rights and welfare of human and animal subjects used in research. Currently, we have four institutional review boards (IRBs); the Human Subjects Research Review Committee, the Animal Care and Use Committee, the Radiation Safety Committee and the Biosafety Committee, each of which meets on a regular basis.

The Human Subjects Research Review Committee members are appointed by the President of Portland State University and charged with reviewing all research conducted at PSU that involves human subjects. Generally, all research involving human subjects conducted by faculty, staff or graduate students in any program at PSU must have prior approval of the HSRRC.

We will be happy to address your questions and concerns at any point during the formulation, application or review process. Please do not hesitate to contact us at (503) 725-4288, toll-free at 1-877-480-4400, or e-mail us at hsrrc@lists.pdx.edu. Our website is located at: <http://www.gsr.pdx.edu/compliance/human>.

Sincerely,

Chair, HSRRC
Portland State University

Table of Contents

Preface	<i>i</i>
Section I. The Completed Application	<i>1</i>
<i>Investigator’s Assurance</i>	<i>2</i>
<i>Outline for Application Proposal</i>	<i>3-4</i>
Section II. Definitions	<i>5-7</i>
Section III. Types of Review	<i>8</i>
<i>Waived</i>	<i>9</i>
<i>Expedited</i>	<i>10</i>
<i>Full Committee</i>	<i>11</i>
<i>No Review Required</i>	<i>11-11a</i>
Section IV. Informed Consent	<i>12</i>
<i>The Need for Informed Consent</i>	<i>13</i>
<i>Documenting informed Consent</i>	<i>14</i>
<i>Elements of Informed Consent</i>	<i>14</i>
<i>Model Adult Consent</i>	<i>15</i>
<i>Model Child Assent</i>	<i>16</i>
<i>Model Cover Letter</i>	<i>16</i>
<i>Model Consent For Use With Sensitive Populations</i>	<i>17-18</i>
<i>Informed Consent Checklist</i>	<i>19-21</i>
Section V. After The Review	<i>22</i>
<i>Responding to HSRRC Memos</i>	<i>23</i>
<i>Continuing Review</i>	<i>23</i>
<i>Changes to a Previously Approved Protocol</i>	<i>23</i>
<i>Classroom and Administrative Projects</i>	<i>23</i>
<i>Records Retention Requirements</i>	<i>23</i>
<i>Noncompliance</i>	<i>23</i>
Section VI. Special Topics	<i>24</i>
A. <i>Web-based Research</i>	<i>25-26</i>
B. <i>Using the Classroom</i>	<i>26-27</i>
C. <i>Recruiting Women and Minorities</i>	<i>27</i>
D. <i>Recruiting Clients of Social Service, Schools and Other Institutions</i>	<i>27</i>
E. <i>Vulnerable Populations: Children, Mental Health Consumers, Pregnant Women, and Prisoners</i>	<i>28-32</i>
F. <i>Reporting Child & Elder Abuse</i>	<i>32-33</i>
G. <i>HIV Reporting</i>	<i>33-34</i>
Appendices	<i>35</i>
<i>The Nuremberg Code</i>	<i>36</i>
<i>The Belmont Report</i>	<i>37-39</i>

*Note: All federally funded projects – including those receiving federal pass-through money – and projects that do not qualify for a waiver or expedited review must be reviewed in full committee; in order to have a protocol reviewed at the upcoming monthly meeting, Principal Investigator’s must submit their applications according to the submission deadlines (see Appendices).

Section I

◆ The Completed Application ◆

What do I submit?

- Investigator's Assurance Form
 - HSRRC Application (Sections I – IX)
- ❖ If federally funded, **submit original + 10 copies** (see HSRRC committee review schedule for submission deadlines).
- ❖ If non-federally funded, **submit original + 2 copies**.

Mailing address:

HSRRC
Office of Research and Sponsored Projects (ORSP)
Portland State University
PO Box 751
Portland, OR 97207-0751

Delivery Address:

Unitus Building, 6th Floor
2121 SW 4th Avenue
Portland, OR 97201
Campus Mail Code: ORSP

Tel: (503) 725-4288 / 1-877-480-4400

Fax: (503) 725-3416

E-mail: hsrrc@lists.pdx.edu

Web: <http://www.gsr.pdx.edu/compliance/human>

SECTION I
▲ Investigator's Assurance ▲

Principal Investigator _____ E-Mail _____
Co-Principal Investigator _____ E-Mail _____
Other Personnel (GA, Project Mgr., etc.) _____ E-Mail _____
Dept _____ PI ID No. _____ Date of Application _____
Mailing Address _____ Campus Extension _____
_____ Home or Work # _____
Title of Proposed Study _____
Proposed Duration of Project (months/years) _____ Anticipated Start Date _____
Type of Funding (Federal/Federal pass-through/State/Foundation/Other/None) _____
Funding Agency _____

Please note that data collection cannot begin until approval is granted by the HSRRC

INVESTIGATOR'S ASSURANCE

- A. I will promptly report changes in the proposed study and any unanticipated problems involving risk to subjects, including adverse reactions, to the Human Subjects Review Committee. In case of DHHS supported activities, I will also report these problems to the Department of Health and Human Services (through the respective granting office).
- B. I assure that documentary evidence of informed consent will be retained for at least three years after the proposed study has been completed or discontinued.
- C. Since the Committee is obligated to review this activity at least on an annual basis, I will furnish it with a progress report no later than six weeks prior to the expiration of my project's approval.
- D. I, the undersigned, will be responsible for the ethical standards of this project, and for protecting the rights and welfare of the subjects.

Signature of Principal Investigator **Date**

I have read and approved this proposal:

Department Head (PRINT) **Signature** **Date**

If this is part of a thesis/dissertation/project, the proposal must be approved PRIOR to HSRRC Review.

Masters Thesis Masters Project Doctoral Dissertation Special Project

Dissertation/Thesis/Project Advisor (PRINT) **Signature** **Date**

Advisor's E-Mail Address: _____

Revised 6/06

Please complete and return this form, along with your HSRRC application, and copies to the HSRRC, Office of Research & Sponsored Projects (ORSP), 600 Unitus Bldg., Portland State University
Phone: (503) 725-4288 / 1-877-480-4400

SECTION I
▲ HSRRC Application Proposal ▲

Investigator's Assurance Form

This form must be filled out completely and accompanied by the proper signatures.

I. Project Title & Prospectus

In 300 words or less, please provide a summary of the project and its significance, including a brief description of the methods and procedures to be used.

II. Exemption Claim for Waiver of Review

If your research falls into one of the categories of studies exempt from HSRRC review (*see section III, "Types of Review"*), cite the exemption category and the associated rationale. Please note that *anonymity* means that the subject's/respondent's name is unknown to the researcher (in other words, responses cannot be linked to individuals); *confidentiality* implies that, while the researcher can identify each subject and his/her responses, that the identity of the subject will be kept private, and not revealed to others.

III. Subject Recruitment

This section should provide a description of the subject population, including the number of participants which the researcher expects to recruit, the characteristics of that population, which can include age, gender, ethnic background and health status, and the methods to be used for their recruitment. Criteria for inclusion and exclusion should be detailed; justification is required if the subject population is restricted to one gender, age or ethnic group, as the federal government strongly encourages investigators to include women, children and ethnic minorities in their research.

IV. Informed Consent

Both federal and University regulations require researchers to obtain informed consent from their subjects before they may be enrolled in a study. Describe both by whom and in what manner consent will be obtained from each appropriate sample category (*see below*) and include a copy of the informed consent form(s) or cover letter (s) (if requesting a waiver of signed consent) to be used. (*see section IV, "Informed Consent," for help in preparing an appropriate form*).

- Adult subjects (includes persons 18 years of age and over).
- Child subjects (includes all persons under 18 years of age) will require written parent/guardian consent, as well as verbal or written assent from the subjects themselves.
- In some cases, institutional subjects, such as prisoners, mental health or developmentally disabled patients, will require the consent of an appropriate witness in addition to that of the participant.

V. First-Person Scenario

Provide a short paragraph that presents the experience from the subject's point of view (e.g., "I received a letter last week in the mail which described a new research study...Once I decided to participate, I set up an appointment to meet the researcher...I was seated at a table with the investigator and..."). This scenario should begin when the subject is first contacted, whether by letter or in person, and describe each activity in which he or she is required to take part.

VI. Potential Risks and Safeguards

The risk/benefit ratio for subjects is particularly crucial to a human subjects review. Some research cannot be approved unless the possible benefits to participants or to humanity outweigh the possible risks. Please describe any *potential* physical, social, psychological, legal, economic or other risks to subjects, including discomfort or inconvenience (e.g., nature and seriousness of risk, incidence of probability, etc.). Also describe the safeguards which will be adopted to eliminate or reduce these risks, and/or the steps to be taken to detect and treat any injury or distress incurred by subjects. Note: Due to federal regulations, safeguards cannot contain a *guarantee* of confidentiality. Instead, use language such as, “Your confidentiality is protected...” and then describe the measures to be taken to protect confidentiality.

VII. Potential Benefits

Describe briefly the anticipated research benefits of the study. Subjects might benefit directly, as with a cash payment received for participation, or indirectly, as the results of a study of blood donors leads to a better-marketed blood drive and, therefore, increased blood bank stores.

VIII. Records & Distribution

Discuss procedures which will be used to maintain subject confidentiality, including the implementation of any codes or pseudonyms to conceal identities, both during the course of research and in the period thereafter. Also, explain records storage and access methods, the description of which must include information regarding where and for what length of time data provided by subjects will be stored. If subjects will be audio- or videotaped during their participation, this must be addressed, as well, both in this section and on the informed consent or cover letter. Federal regulations *require* all data and records to be kept on file for a minimum of three years after the completion of research.

IX. Appendices

All survey instruments, telephone and introductory scripts, interview questions and informed consent documents must be included in your application.

Section II
◆ Definitions ◆

SECTION II

▲ Definitions ▲

Human Subject is a living individual from whom an investigator conducting research obtains data, either through intervention or interaction with the individual, or through records which contain identifiable, private information.

Research is a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge.

Principal Investigator The researcher, or PI, is accountable for the study. The PI is responsible for seeing that project work is completed and that policies and procedures are followed correctly.

Data Collection is the process of gathering information that will be used in connection with a research study. When dealing with human subjects, this refers to the period of time during which study participants are being surveyed or interviewed, tested or evaluated, etc.

Compliance All research conducted at Portland State must be in compliance with 45 CFR 46, or the Code of Federal Regulations, which governs the protection of human subjects in research (*for the full text go to <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>*).

Institutional Review Board Portland State is responsible for the protection of the rights and welfare of human and animal subjects used in research by, or under the supervision of, faculty and staff members of the University when such research is carried out as part of their duties as teacher, investigator, thesis or dissertation advisor, or other academic activity. This responsibility is delegated to one of several committees, or institutional review boards, to the extent that said Committee will determine for all activity, as planned and conducted, whether the rights and welfare of subjects will be adequately protected. In order to meet this responsibility, the Committee will review all proposed research projects conducted by faculty, staff and graduate students, whether funded or not, when use of the facilities, services or personnel of the University is involved. PSU has four IRBs: the Human Subjects Research Review Committee, the Animal Care and Use Committee, the Radiation Safety Committee and the Biosafety Committee, each of which meets on a regular basis.

Informed Consent This means the knowing, legally effective agreement of any individual, or of said individual's legally authorized representative, to participate as a subject in research. Consent can be obtained only under circumstances that provide the prospective subject—or his/her representative—with complete information regarding both the study and the subject's participation in it. Consent can only be obtained under circumstances which provide the subject sufficient opportunity to consider whether or not to participate, as well as which minimize the possibility of undue influence or coercion.

Assent refers to a child's affirmative agreement to participate in research and must be obtained in addition to the consent of his/her parent or guardian. The failure to object in such a case can not be construed as assent.

Anonymous means "of unknown or unnamed source or origin," according to Webster's Seventh New Collegiate Dictionary. In reference to human subjects, "anonymous" refers to a participant whose identity remains unknown to the researcher. This is often the case when, for example, surveys are mailed out to a group of potential study participants who complete them and mail them back to the researcher *without any identifying information* (names, Social Security numbers, etc.) attached.

Confidentiality, on the other hand, is often guaranteed to a participant by the investigator when that subject's identity is known to the P.I. It is simply an assurance that a participant's identity will not be published or otherwise released before, during or after data collection. A researcher who plans to interview subjects in person, or track information by using Social Security numbers, will often guarantee confidentiality

Minimal Risk means that the probability and the magnitude of harm or discomfort anticipated in the proposed research is not greater in and of itself than those ordinarily encountered in everyday life, or during the performance of routine physical or psychological examinations or tests.

Physical Risk could mean physical discomfort, pain, injury, illness or disease brought about by the methods or procedures of the research.

Psychological Risk may be experienced during the research situation and/or later, as a result of participating. This type of risk includes anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock, loss of self-esteem, and altered behavior.

Social/Economic Risk could involve alterations in relationships to others that are of disadvantage to the subject, including embarrassment, loss of respect of others, labeling with negative consequences, or diminishing the subject's opportunities and status in relation to others. Economic risks include payment by subjects for treatment of a physical injury or psychological distress incurred as a result of participation, loss of wages or income, and damage to employability.

Legal Risk is one of criminal prosecution or civil lawsuit when research data reveal that the subject has or will engage in conduct for which the subject or others may be criminally or civilly liable.

Section III

◆ Types of Review ◆

- Waived
- Expedited
- Full Committee
- No Review Required

SECTION III

▲ Types of Review ▲

A human subjects protocol will fall under one of three categories—waived, expedited or full committee—and will be reviewed accordingly. The time frames listed are approximate; additional time will be needed if a reviewer issues conditions, *which is usually the case*.

WAIVED REVIEW

Under revised federal regulations, many studies now qualify for a waiver of review if one of the following exemptions can be claimed. Many surveys, interviews, and public observation studies will fall in one of these categories, and will, as a result, undergo a process of certification by a member of the HSRRC, rather than review. **PLEASE ALLOW AT LEAST ONE WEEK FOR A WAIVER OF REVIEW.**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests, (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior, unless (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place these subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under exemption 2 above if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. Secondary data that has identifiers falls under waived.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate or otherwise examine (a) public benefit or service programs, (b) procedures for obtaining benefits or services under those programs, (c) possible changes in or alternatives to those programs or procedures or (d) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

EXPEDITED REVIEW

Research activities involving no more than minimal risk, and in which the only involvement of human subjects will be in one or more of the following categories, carried out through standard methods, may be reviewed by the HSRRC through the expedited review process. Proposals which qualify for expedited reviews do not require a convened Committee meeting, but, instead, are mailed to several members of the HSRRC and given a written review. **PLEASE ALLOW 4-6 WEEKS FOR AN EXPEDITED REVIEW.**

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
 - (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - (b) From other adults and children¹ considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in a week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
 - (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant

¹ Children are defined in the DHHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” 45 CFR 46.402 (a). In Oregon, this is 18 years of age.

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

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

FULL COMMITTEE REVIEW

All federally funded proposals (whether funded directly by a government agency or with *pass-through* funding)--regardless of the type of study--must be reviewed in a full committee meeting. Additionally, any protocol which does not fall under the categories for a waiver or expedited review will be scheduled for discussion at the next meeting. To this end, the HSRRC meets twice a month during the academic year and once a month during the summer term. In order to be added to the agenda, proposals must be submitted two weeks prior to the meeting date. For the Committee's meeting schedule and submission deadlines, please stop by the Office of Research & Sponsored Projects, Unitus Building, 6th Floor or visit our website at: www.gsr.pdx.edu/compliance/human. **PLEASE ALLOW 4-6 WEEKS FOR A FULL COMMITTEE REVIEW.**

NO REVIEW REQUIRED

- Data which will not be published or otherwise disseminated that is collected as part of the normal management process of an organization or business
- Secondary data collected by another investigator that meet the four criteria listed on page 11A.
- Research conducted independently by faculty and staff outside of working hours, in which neither PSU facilities, services or University affiliation is used.
- Students applying for graduation and whose project meets the criteria for No Review will need to complete the form titled "Review Not Required" (p.11a).

CAPSTONE course activities, if the following criteria are met:

- Projects are identified as "classroom-directed exercises" and supervised by a faculty member
- Projects will not place subjects at greater than minimal risk
- All data collected by students is recorded anonymously, i.e. without names, Social Security numbers or other identifiers

Faculty and students still have an ethical responsibility to inform community participants of the purpose of the project, the scope and duration of each activity in which they are expected to take part, and the expected outcomes—in essence, to obtain informed consent. In this case, the HSRRC is available for consultation in drawing up informed consents or cover letters.

REVIEW NOT REQUIRED

HUMAN SUBJECTS RESEARCH REVIEW COMMITTEE (HSRRC)
Office of Research and Sponsored Projects, Portland State University
600 Unitus Bldg., (503) 725-4288 / 1-887-480-4400 e-mail: hsrrc@lists.pdx.edu

It is the authority of the HSRRC, not the investigator, to determine whether or not a research project involving human subjects requires review by the HSRRC. The purpose of this form is to provide the investigator with written documentation showing that the HSRRC was consulted and deemed the project "No Review Required."

This form is most commonly used when a project involves SECONDARY DATA analysis and meets all four of the following criteria:

1. All identifying information has been removed and data cannot be linked back to individuals.
2. No contact with subjects is/was involved.
3. Data has been previously collected by another investigator.
4. Data already exists.

Note: If the project involves secondary data but does not meet all four criteria, a complete application must be submitted.

In addition to this form, please submit a one-page summary of the project. It should detail the purpose of the study, a complete description of the data set or sample, recruitment or data collection procedures/circumstances, and an explanation of why you believe the project does not require review by the HSRRC.

Principal Investigator _____ Dept. _____
PSU ID No. _____ Date of Application _____
Mailing Address _____ Campus Extension _____
_____ Home/Work Tel. _____
Email Address _____
Title of Proposed Study _____
Anticipated Length of Project _____ Anticipated Start Date _____

INVESTIGATOR'S ASSURANCE

I do hereby certify that my research as referenced above does not involve any human subjects, and/or it involves only secondary data from which all identifying information has been removed. Therefore, no review is required from the HSRRC.

Signature of Principal Investigator _____ Date _____

Signature of Advisor (Dissertation/Thesis/Project) _____ PRINT Name _____ Date _____

Signature of Department Head _____ PRINT Name _____ Date _____

Check one: Masters Thesis/Project Doctoral Dissertation Special Project

For HSRRC Only:
(Approved _____ Date _____)

Section IV

◆ Informed Consent ◆

- The Need for Informed Consent
- Documenting Informed Consent
- Elements of Informed Consent
- Model Adult Consent(s)
- Model Child Assent
- Model Cover Letter
- Model Consent For Use With Sensitive Populations
- Informed Consent Checklist

SECTION IV

▲ The Need For Informed Consent ▲

The need for a code of ethics to guide researchers in their work with human subjects was made explicit by testimony in the Nuremberg War Crimes Trials, held in Germany in the aftermath of the Second World War. The infamous trial of the “Nazi Doctors,” a group of twenty-two men and one woman accused of participation in war crimes and crimes against humanity in connection with their roles in the conduct of medical experiments that used thousands of Jewish, Russian, Roma and Polish concentration camp prisoners as research subjects without their consent, brought the topic of research ethics to the attention of an international audience. Evidence presented to the Nuremberg Military Tribunals showed that, in many cases, these experiments were performed by persons with little or no medical background and under revolting physical conditions where subjects suffered pain and injury unnecessarily. Few, if any, precautions were taken to safeguard the human subjects from injury, disability, or death and, while most died as a result of their participation in hypothermia, malaria, bone regeneration, vivisection and sterilization experiments (to name a few), those who did survive were often left permanently disabled.

Several of the accused argued in their own defense that no international law or code of ethics existed that differentiated between legal and illegal practice in research involving human subjects. Unfortunately, this was true. Towards that end, Dr. Leo Alexander, an American doctor who worked with the prosecution at the trials, submitted a memorandum to the United States Counsel for War Crimes on April 17, 1947. This letter, which outlined the points by which legitimate research could be defined, would later become known as “The Nuremberg Code,” a document which would inform the drafting of numerous international ethics codes and laws over the course of the 20th century. It remains a landmark document on medical and research ethics.

The Nuremberg Code stresses the fact that “certain basic principles must be observed in order to satisfy moral, ethical and legal concepts,” the first of which is informed consent:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.²

The informed consent requirements set forth in the Code of Federal Regulations (45 CFR 46) are based on legal and ethical standards developed by lawyers, researchers, scientists and ethicists over the course of several decades of work. The procedures have been designed in order to protect the rights, welfare and dignity of those persons who volunteer to participate in research.

² “Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10,” vol. 2, Nuremberg, October 1946-April 1949. (Washington, DC: US Government Printing Office, 1949), p.181.

DOCUMENTING INFORMED CONSENT

Each application submitted to the HSRRC for review must include a thorough description of the process by which consent will be obtained from subjects, as well as a copy of the consent form which the investigator proposes to use. The Committee will review the form to ensure that it meets federal and University requirements (*see “Elements of Informed Consent,” “Model Consents” and “Informed Consent Checklist,” this section*) and, once approved, neither the process or form may be altered without Committee approval. In the case of signed informed consent, the investigator must not only provide each participant with a signed copy, but keep one for his or her records, as well.

Signed informed consent must be obtained from all prospective subjects or their legally authorized representatives, unless this requirement is waived by the HSRRC. The Committee is likely to grant a waiver of signed consent if a) 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 b) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Such a waiver does not eliminate the need for subjects to give their informed consent, however. In cases in which the signature requirement is waived, the IRB will require the investigator to provide subjects with a cover letter, which must contain all the elements of a consent form, but does not have any identifiers or other information which could link the subject to the study, nor does it require a signature.

ELEMENTS OF INFORMED CONSENT

- The consent should be written in the second person (*see “Model Consents” below*), as first person may be considered too suggestive or coercive
- The name of the researcher and his or her affiliation must be clearly stated
- The study and its purpose should be briefly explained
- All procedures and activities to be conducted during the course of the research by participants, including their duration, frequency and locale must be explained
- All potential risks or discomforts, along with their respective safeguards, must be clearly stated
- Benefits to participation, whether direct or indirect, should be outlined
- A statement indicating that participation is voluntary and that the subject may withdraw at any time without penalty should be included
- The extent to which confidentiality can or will be maintained should be clearly defined
- Contact info, including address and telephone number, for both the researcher *and* the HSRRC must be included
- There must be an indication that the subject will receive a copy of the form for his/her own records
- If the researcher is working with children or a vulnerable population, “Special Topics” must be consulted for additional informed consent elements (*see section VI, “Special Topics”*)
- The entire consent must be written in language that is readily understandable to the average subject (for adults, this usually means the 7th grade level)
- Faculty and staff should consider printing informed consents and cover letters on organizational letterhead

MODEL ADULT CONSENT*

(letterhead stationary as appropriate)

Title of Study

You are invited to participate in a research study conducted by *[name of investigator]* from Portland State University, *[departmental affiliation]*. The researcher hopes to learn *[state what the study is designed to discover or establish; if you are a student, please also indicate that the study is being conducted in partial fulfillment of the requirements for a master's or doctoral degree, and indicate that it is under the supervision of a specific faculty member at PSU]*. You were selected as a possible participant in this study because *[state why subject was selected]*.

If you decide to participate, you will be asked to *[describe procedures and activities, their purpose, duration, location and frequency; if these activities are to be audio- or videotaped, please indicate this]*. While participating in this study, it is possible that *[describe all possible risks, discomforts and inconveniences, and explain how you will safeguard against them; describe any alternative procedures or courses of treatment, if applicable]*. You may not receive any direct benefit from taking part in this study, but the study may help to increase knowledge which may help others in the future. *[If this is not the case, then include a statement about likely benefits, including any compensation which will be offered to participants.]*

Any information that is obtained in connection with this study and that can be linked to you or identify you will be kept confidential *[If this is not the case, and subjects will be identified by name or otherwise in a paper, thesis, dissertation, journal or newspaper article, on the web or in a presentation, a statement must be added to that effect. If information will be released to any other party for any reason, please state the nature of such information, identify the person or agency to whom it will be furnished, and the purpose of such a disclosure]*. This information will be kept confidential by *[describe coding methods (if any) and data storage procedures]*.**

Your participation is voluntary. You do not have to take part in this study, and it will not affect your *[course grade or relationship]* with *[name the institution or organization with which the researcher is affiliated]*. You may also withdraw from this study at any time without affecting your *[course grade or relationship]* with *[institution or organization mentioned above]*.

If you have concerns or problems about your participation in this study or your rights as a research subject, please contact the Human Subjects Research Review Committee, Office of Research and Sponsored Projects, 600 Unitus Bldg., Portland State University, (503) 725-4288 / 1-877-480-4400. If you have questions about the study itself, contact *[researcher's name]* at *[address and telephone number]*.

Your signature indicates that you have read and understand the above information and agree to take part in this study. Please understand that you may withdraw your consent at any time without penalty, and that, by signing, you are not waiving any legal claims, rights or remedies. The researcher will provide you with a copy of this form for your own records.

Signature

Date

*Please note that this is a model only and should be tailored to fit your own project specifications. Use this, together with the "Elements of Informed Consent" and "Informed Consent Checklist" to build your own consent form.

**Limits to confidentiality must be stated clearly, as well. The State of Oregon requires that all suspected or confirmed cases of child and elder abuse must be reported to authorities, and subjects must be informed of this limit if the nature of the research makes it likely that such a topic will be discussed.

MODEL CHILD ASSENT

Title of Study _____

Child's name _____

Your parents (or guardian) have said that it is okay for you to take part in a project about *[insert brief description of project here]*. If you choose to do it, you will be asked to *[insert description of the activities which participation will require, as well as an estimate of the amount of time involved]*.

If you want to rest, or stop completely, just tell me—you won't get into any trouble! In fact, if you don't want to do it at all, you don't have to. Just say so. Also, if you have any questions about what you will be doing, just ask me to explain.

If you do want to try it, please sign your name on the line below. Remember—you can stop to rest at any time, and if you decide not to take part anymore, let me know.

Signed _____ Date _____

MODEL COVER LETTER

Title of Study _____

Dear *[prospective subject's name]*:

My name is *[researcher's name]*, and I am a *[student/faculty member]* at *[institutional affiliation]*. I am beginning a study on *[brief description of research project]*, and would like to invite you to participate.

You are being asked to take part because *[explain why subject was selected]*. As part of the study, I am interested in your opinions and attitudes about *[list the theme or focus of research]*, and hope that the information I collect will help us to better understand *[insert subject or theme]*. If you decide to participate, you will be asked to *[provide a complete description of the activities required for participation]*, which involves answering questions about *[provide specifics, such as "substance abuse" or "second language acquirement"]*. It should take approximately *[provide a time estimate]* to complete.

As a result of this study, you may *[describe any risks involved]*. However, I assure you that *[detail safeguards which will be implemented in order to prevent risk]*. You may not receive any direct benefit from taking part in this study, but the study may help to increase knowledge that may help others in the future. *[If this is not the case, then include a statement about likely benefits, including any compensation which will be offered to participants.]*

Any information that is obtained in connection with this study and that can be linked to you or identify you will be kept confidential *[If this is not the case, and subjects will be identified by name or otherwise in a paper, thesis, dissertation, journal or newspaper article, on the web or in a presentation, a statement must be added to that effect. If information will be released to any other party for any reason, please state the nature of such information, identify the person or agency to whom it will be furnished, and the purpose of such a disclosure]*. Subject identities will be kept confidential by *[describe coding methods (if any) and data storage procedures]***

Participation is entirely voluntary. Your decision to participate or not will not affect your relationship with the researcher or with *[name of sponsoring institution]* in any way. If you decide to take part in the study, you may choose to withdraw at any time without penalty. Please keep a copy of this letter for your records.

If you have concerns or problems about your participation in this study or your rights as a research subject, please contact the Human Subjects Research Review Committee, Office of Research and Sponsored Projects, 600 Unitus Bldg., Portland State University, (503) 725-4288 / 1-877-480-4400. If you have questions about the study itself, contact *[researcher's name]* at *[address and telephone number]*.

Sincerely,
[Name of Investigator]
Affiliation

MODEL CONSENT FOR USE WITH SENSITIVE POPULATIONS

BE PART OF AN IMPORTANT PROJECT **The Mental Health and HIV Medication Adherence Study**

The Center for the Study of Mental Health Policy and Services at Portland State University's Regional Research Institute is doing a research study on how people who are living with HIV infection and a mental health condition are managing their healthcare, especially when it comes to medications.

What Will I Have To Do?

If you decide to take part in this project, we will ask you to talk with us for about 90 minutes. The interview will be on these topics:

- ▶ Your experience of living with HIV
- ▶ Your experience of living with a mental health condition
- ▶ Your experience of managing the medications that may have been prescribed for you
- ▶ Your relationship with your medical and mental health providers

Are There Any Risks?

HIV infection and mental health issues are very personal, we know. You do not have to take part in this study. If you do agree to take part, you may feel uncomfortable, angry, sad, guilty, scared or embarrassed because of some of the questions we ask. You don't have to answer any questions you don't want to. And if you don't want to go on, you can stop. If you are upset after the interview and need to talk with someone, you can call (insert name) _____ at the Regional Research Institute; she's the person leading the project in Portland. You will also get a list of organizations that may be able to help you with certain problems.

What Will I Get In Return?

1. \$25 for taking part in this study
You will get \$25 if you decide to be part of this study. You'll get the money as soon as the interview is done. The money is our way of saying Thank You For Your Time.
2. Money for transportation and/or childcare
You will get money, up to \$10, to pay for your transportation to and from the interview. If you have children, you will also get money, up to \$10, to pay for a babysitter.
3. Knowing you are helping others
Many people feel good about helping others. We can learn so much from you, and teach others how to live with HIV and a mental health condition.

What Are You Doing To Protect Me?

Your privacy is very important to us. We have done many things to protect you:

- ▶ We won't tell anyone if you take part in this study or not
- ▶ You will be interviewed alone. What you tell us will be kept private.
- ▶ Your name and what you tell us in the interview will be kept private to the extent allowed by law. (By "kept private" we mean that the names of people who take part in the study will not be given to anyone else. And it means that we will only reveal what you say in a way that no one could ever guess or know it was you who said it.) If, in the course of the interview you disclose that you are, or are intending to, harm yourself or others, we are ethically and legally required to notify the appropriate authorities.

- ▶ Only staff from the research project will know what you say. If you found out about this project at a clinic or through a social service agency, no one from the clinic or the agency will know what you say.
- ▶ Your name and other personal information, which we need in order to keep track of who we talk to, will be kept in a locked file cabinet or in a locked file on the computer so that no one other than the research staff will be able to see it. For example, this form (which has your name on it) will be kept in a locked file cabinet.
- ▶ When we write or talk about what we learned in this study, we will leave things out so no one will be able to tell who we are talking about.

Any Questions?

If you have any questions about this study, this form, or the interview, you can talk to your interviewer or to the person leading the project in Portland. (Insert name of P.I. and telephone #). You can also contact the Chair of the Human Subjects Committee of Portland State University about your rights as a research participant (someone who takes part in a study). Hours are 9:00 a.m. to 5:00 p.m. The office is located at Portland State University, Unitus Building, 6th floor, 2121 SW 4th Avenue, Portland, OR 97201. The telephone number is (503) 725-4288 / 1-877-480-4400, or send e-mail to: hsrrc@lists.pdx.edu.

If I Sign, What Does It Mean?

This is a consent form. Your signature below means that:

- ▶ You have read and understand what this form says.
- ▶ You are willing to take part in the study by talking with us in an interview.
- ▶ You know that you do not have to take part in this study. And even if you agree, you can change your mind and stop at any time. No problem
- ▶ If you found out about this study at a clinic, you know that taking part in this study has nothing to do with the care you get there. If you agree to take part or if you say no, they won't know and it won't matter. They will treat you the same.
- ▶ You will get a copy of this form to keep for yourself.

Participant Signature

Date

Participant name, printed

Interviewer Signature

Date

Interviewer name, printed

▲ Informed Consent Checklist *

I. The Consent Form

Yes	No	
—	—	1. Does the form state who is conducting the experiment?
—	—	2. Does the form state the nature, purpose, and duration of the experiment, including the fact that it is experimental? [46.116(a)(1)]
—	—	3. Does the consent form state the uses to be made of the data?
—	—	4. Does the consent form state the procedures to be employed in the experiment? [46.116(a)(1)]
—	—	5. Does the consent form state the hazards, inconveniences, and risks the subject will undergo, so far as they are known? [46.116(a)(2)]
—	—	6. If appropriate, does the consent form state the availability of compensation and treatment if the subject is injured? [46.116(a)(6)]
—	—	7. Does the consent form state the benefits that might be expected? [46.116(a)(3)]
—	—	8. Does the consent form, if the experiment is therapeutically related, disclose the alternate procedures the subject may choose? [46.116(a)(4)]
—	—	9. Does the consent form state the conditions of participation, if any? [46.116(b)(4)]
—	—	10. Does the consent form contain a statement of the extent to which the confidentiality of the data will be maintained? [46.116(a)(5)]
—	—	11. If appropriate, does the consent form describe the procedures to be employed in maintaining confidentiality?
—	—	12. Does the consent form mention that the subject is at liberty to withdraw his or her prior consent to the experiment or discontinue participation in the experiment at any time without prejudice? [46.116(a)(8)]
—	—	13. Does the consent form contain instruction as to who and how to contact someone if questions or problems should arise later on? [46.116(a)(7)]
—	—	14. Is there a place for the date of signing and for the signature of the subject and witness? [46.117(b)(1)(2)]
—	—	15. Is the consent form likely to be understandable to the intended subject population? [46.116]
—	—	16. Is the HSRRC contact information included on the form?

II. Additional Inclusions

Yes No

- | | | | |
|---|---|----|--|
| — | — | 1. | If appropriate, does the consent form state that the procedure may involve unforeseeable risks? [46.116(b)(1)] |
| — | — | 2. | If appropriate, does the consent form state that any significant new findings affecting risk will be reported to the subject? [46.116(b)(5)] |
| — | — | 3. | If appropriate, does the consent form state the circumstances under which the experimenter may terminate the subject's participation? [46.116(b)(2)] |
| — | — | 4. | If appropriate, does the consent form state any possible additional costs the subject may have to bear? [46.116(b)(3)] |
| — | — | 5. | If appropriate, does the consent form state the consequences of the subject's withdrawal from the study? [46.116(b)(4)] |
| — | — | 6. | If appropriate, does the consent form state the approximate number of subjects in the study? [46.116(b)(6)] |

III. Altering or Waiving the Consent Process

(Note: The answers to questions 1 through 3 must all be "no" and the answer to 4 must be "yes" for alteration or waiver approval to be given.)

Yes No

- | | | | |
|---|---|----|--|
| — | — | 1. | Does the research involve greater than minimal risk? [46.116(d)(1)] |
| — | — | 2. | Will the alteration or waiver adversely affect the rights or welfare of the subjects? [46.116(d)(2)] |
| — | — | 3. | Practically speaking, could the research be carried out without the waiver or alteration? [46.116(d)(3)] |
| — | — | 4. | If possible, will the subjects be provided with additional pertinent information after participation? [46.116(d)(4)] |

IV. Altering or Waiving Consent Documentation

(Note: The answers to questions 1 and 2 must be "yes"; OR, the answers to questions 3 and 4 must be "no" for an alteration or waiver approval to be given.)

Yes No

- | | | | |
|---|---|----|---|
| — | — | 1. | Is the consent form the only record linking the subject to the research and could it potentially be harmful to the subject if the confidentiality of the research were breached? [46.117(c)(1)] |
| — | — | 2. | Will each subject be asked if he or she wants documentation linking him or her to the research? [46.117(c)(1)] |
| — | — | 3. | Does the research involve more than minimal risk? [46.117(c)(2)] |
| — | — | 4. | Does the research involve any procedures for which written consent is normally required outside of the research context? [46.117(c)(2)] |

V. Consent Execution

1. Was a copy of the consent form passed out to the subjects? [46.117]
2. Was the consent form read out loud as the subjects silently read along?
3. Was a brief verbal summary given to the subjects after the reading?
4. Did the experimenter ask for questions?
5. Was a reasonable opportunity given for the subject to consider whether to participate? [46.116]
6. Was there any evidence that the subjects were lied to or in any way forced, coerced, or deceived into signing the consent form? [46.116]
7. Were the subjects asked to sign and date both copies of the consent form? [46.117]
8. Were the subjects instructed to keep one copy of the consent form for their own records? [46.117]
9. Were those who did not sign dismissed in a friendly and courteous manner?

*Numbers in brackets refer to items mandated by 45 CFR 46 (the Code of Federal Regulations), the full text of which can be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm> .

Section V

◆ After The Review ◆

- Responding to HSRRC Memos
- Continuing Review
- Changes to a Previously Approved Protocol
- Classroom and Administrative Projects
- Records Retention Requirements
- Non Compliance

SECTION V

▲ After The Review ▲

Responding to HSRRC Memos

Immediately after a review is completed, the investigator will be notified that a decision on his or her protocol has been made. The Committee will recommend that a) a waiver or approval be granted, or b) a conditional memo be issued. In the former instance, no further correspondence is needed, and the application will be filed. In the latter case, a P.I. has up to six months during which a response may be submitted. If, at the end of that period, there has been no reply from the investigator, a letter will be sent to the P.I. asking for a status report.

Continuing Review

In its initial review of a proposal, the HSRRC will consider the extent of continuing review needed. All active protocols must be reviewed at least annually, but, in certain cases in which subjects are exposed to greater risk, some may be required to undergo review at more frequent intervals. Such an interval would be determined at the point at which the study is approved, and may be changed at the discretion of the Committee.

Changes to a Previously Approved Protocol

If a previously waived or approved research proposal must be altered in any way, the investigator is required to submit a memo to the HSRRC which describes in detail these changes and/or additions to the protocol. All survey instruments, informed consents or cover letters, scripts and other documents which will be altered must be attached, and the P.I. should request a “review of proposed changes.” Such a request qualifies for an expedited review, and **should take approximately two weeks.**

Classroom and Administrative Projects

Class projects and administrative reviews need not be submitted to the HSRRC if the results of research will not be distributed outside the classroom or are used to evaluate or review a campus program in order to make improvements. If, however, the results of the study will be published or otherwise distributed, the project must be reviewed. If in doubt, please call the HSRRC administrator in the Office of Research & Sponsored Projects at (503) 725-4288 / 1-877-480-4400, or send e-mail to hsrrc@lists.pdx.edu.

Records Retention Requirements

Federal regulations state that all research-related data and records must be retained for a minimum of three years after the completion of the study. This may include, but is not limited to, research proposals, informed consent documents, progress reports, reports of injuries to subjects, and all other related correspondence.

Noncompliance

In any instance where federal or University requirements are not being followed, the Committee will inform the Vice Provost for Research, who will be asked to enforce the requirements. In the event that the investigator does not comply, the Vice Provost will terminate the research. Such action will be accompanied by a letter to the PI, stating the reason for the action. If unanticipated problems involving risks to subjects or others occur as a result of noncompliance, these will be reported to the Secretary of the Department of Health and Human Services by the Vice Provost for Research, and can result in fines or sanctions against the PI and/or the University.

Section VI

◆ Special Topics ◆

- Web-based Research
- Using The Classroom
- Recruiting Women and Minorities
- Recruiting Clients of Social Service and Other Institutions
- Vulnerable Populations: Children, Mental Health Consumers, Pregnant Women/Fetuses, and Prisoners
- Reporting Child and Elder Abuse
- HIV Reporting

SECTION VI

▲ Special Topics ▲

A. **WEB-BASED RESEARCH**

Overview

The Internet is being used more and more often in the conduct of research involving human subjects. Investigators and IRBs must find ways to deal with emerging issues and concerns raised by this new forum, including, but not limited to, the traditional matters of consent and confidentiality. The HSRRC expects researchers to be able to provide the Committee with sufficient technical information regarding the manner in which these issues will be handled if subjects will either be recruited or have data collected from them over the web. PIs must remember that the same protections afforded subjects who participate in research not conducted on the WWW must be afforded to those who do. If you plan to use the Internet during the course of your research, please consider the following:

Subject Recruitment

The information required here is similar to that required of other research studies. The investigator must provide the HSRRC with complete information regarding subject recruitment procedures, including the number of participants which the researcher expects to recruit, the characteristics of that population, which can include age, gender and ethnic or educational background, and the methods to be used for their recruitment, including the addresses of websites or discussion groups to which recruitment letters or scripts will be posted. Another issue that must be addressed is the use of methods to determine that subjects are part of the targeted sample group, i.e. that minors are not participating without the consent of a parent or that adolescents and males do not take part in a study whose sample should consist only of older women. For example, if a researcher is attempting to recruit a sample of 100 pregnant females between the ages of 20 and 40, how will those who do not qualify for participation be excluded? Often, researchers choose to outline the criteria for inclusion in the cover letter posted to sites where subjects will be recruited.

Informed Consent

The HSRRC will consider requests for a waiver of *signed* consent, when appropriate (*see section IV, "Informed Consent"*). However, waiver of a written informed consent document does not eliminate the need for subjects to give their informed consent. In cases in which the documentation requirement is waived, the IRB will require the investigator to provide subjects with a written statement or cover letter. Such a document would contain all the elements of a consent form, but would not have any identifiers or other information that could link the subject to the study, nor would it require a signature. In this case, the HSRRC will consider approval of a script or cover letter to be posted on the web. Here are some suggestions for obtaining consent on the Internet:

Signed informed consent required

- Prospective subjects send name & address to researcher over web
- Researcher mails 2 copies of consent to subject to sign
- Once 1 signed copy is received, subject receives password that allows him/her to participate

Signed informed consent *not* required

- Obtain electronic signatures
- Password may be issued to subject once consent form is "electronically signed" and submitted
- Use "portal"; i.e., subject must click on button reading, "I agree to participate," in order to gain access to research page (s)

Consent and Confidentiality Issues on the Internet

• Using Email

Since all forms of email include the sender's email address, the promise of participant anonymity is clearly not possible. Instead, the researcher must describe the methods by which confidentiality will be maintained, including where the collected data will be stored and for what length of time and how it will be protected.

• Using the Web

There are two types of data collection--*active* and *passive*. A researcher engaged in active data collection will distribute surveys, conduct interviews or administer tests, each of which requires the active, informed participation of subjects. Passive data collection might involve the observation of public behavior, analysis of agency records and case histories or the study of information collected by server cookies on users' hard drives. While the issues of obtaining informed consent and maintaining confidentiality for active participants in research are easily resolved, those for passive subjects are not. As the federal government has yet to issue specific regulations for researchers collecting data over the Internet, the HSRRC will review protocols and make recommendations for obtaining consent on a case-by-case basis. It is suggested that researchers consult the Committee while still in the planning stages of any web-based study.

• Participation by minors

The HSRRC may waive the requirement for parental consent only if it determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. For example, in the case of neglected or abused children, it may waive the parental consent requirements provided an appropriate mechanism for protecting the children who will participate is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. If a waiver is granted, however, the assent of the child to participate is still required (*for further detail, see section IV, "Informed Consent" and section VI, "Special Topics"*).

If the Committee requires parental consent, the investigator may choose to issue passwords to those minors whose parents allow them to participate. With this method, a child could only enter the survey site or chatroom once his or her password was entered onto the screen. To screen out minors who have not obtained the requisite permissions, we recommend that researchers use Internet monitoring software, such as SafeSurf, Net Nannies or RSACi ratings, or Adult Check Systems, which puts ratings on Web sites.

Please keep in mind that some research may not be appropriate for the Internet. If in doubt, please contact the Human Subjects Research Review Committee at (503) 725-4288 / 1-877-480-4400.

For further information concerning privacy and the Internet, go to the Center for Democracy & Technology's website at <http://www.cdt.org/privacy/>.

(Information above provided partly by Jeff Cohen, Ph.D., Associate Director for Research Compliance and Information Systems, University of Albany, Albany, New York. Contents delivered at OPRR Conference, New Orleans, LA, 1998)

B. USING THE CLASSROOM

Frequently, investigators at PSU request that University students be allowed to take part in their research studies. In these instances, the PI must first obtain permission from the course instructor to use his or her class time, as well as inform students in advance that the class session will be used to conduct research. In keeping with federal requirements, subjects must be fully informed of the purpose of the project and the activities required for participation. Informed consent must be obtained. See also: Capstone Research Activities (page 11).

The decision to participate in research must be voluntary and, to assure that students feel free to refuse to participate without concern that the evaluation of their classroom performance will be affected, the instructor should not be present during any activities conducted as part of the research. He/she may not be informed of the participants' or non-participants' names. Additionally, an alternate means of receiving credit should be provided if a student chooses not to participate or chooses to withdraw during the course of the study. As students in "research classrooms" comprise a captive audience, care should be taken to respect their rights both as subjects and as students.

C. **RECRUITING WOMEN AND MINORITIES**

U.S. government policy requires that women and members of minority groups must be included in all government-funded biomedical and behavioral research projects involving human subjects. An exception may be made if a compelling rationale or justification establishes that inclusion is inappropriate with respect to the health of the subjects, or to the purpose of the research. The policy requires that investigators must:

- Ensure that women and members of minority groups are included in all human subjects research;
- Initiate programs and support for outreach efforts to recruit these groups into clinical studies;
- In certain clinical trials, ensure that women and minorities and their subpopulations must be included such that valid analyses of differences in intervention effect can be accomplished; and
- Not allow cost as an acceptable reason for excluding these groups.

The inclusion of these groups must be addressed in developing a research design appropriate to the scientific objectives of the study. The human subjects application, under "Subject Recruitment," should describe the composition of the proposed study population in terms of gender and racial/ethnic group, provide a rationale for selection of its subjects and contain a description of the proposed outreach programs for recruiting women and minorities. This policy should result in a variety of new research opportunities to address significant gaps in knowledge about health problems and other issues that affect women and racial/ethnic minorities.

D. **RECRUITING CLIENTS OF SOCIAL SERVICE AGENCIES, SCHOOLS, AND OTHER INSTITUTIONS**

Normally, the HSRRC recommends that the researcher not ask institutions to directly identify potential subjects for a research study. Rather, the investigator shall ask an intermediary (doctor, case worker, school administrator) to first approach potential subjects (or their guardians, as appropriate) and inform them about the research. If a potential subject agrees to participate, the intermediary may provide him or her with the information necessary to contact the researcher. This should be done in such a way that the institution is unaware whether the subject chooses to participate in the research.

Also, we recommend that the researcher not ask institutions to release records or anecdotal information, whether for the purposes of identifying subjects, or for examination by the investigator, unless this information is public. An investigator wishing to examine records must first obtain permission of the subject via an intermediary. If a potential subject agrees to release his or her records, the intermediary should provide the information necessary to contact the researcher. This provision does not apply to records with all identifiers removed (see section III "Types of Review," Waived Review Category #4).

The Committee recognizes, however, that there may be extenuating circumstances in certain projects, and suggests that researchers contact us to discuss alternatives for subject recruitment.

[Note: Approval from participating institutions (e.g., schools, agencies) must be on file with the HSRRC prior to recruitment.]

E.

VULNERABLE POPULATIONS: SPECIAL PROTECTIONS FOR RESEARCH INVOLVING CHILDREN, MENTAL HEALTH CONSUMERS, PREGNANT WOMEN & FETUSES, AND PRISONERS*

CHILDREN

Overview

Federal policy states that children (those individuals under the age of 18) must be included in all human subjects research unless there are scientific and ethical reasons not to include them. Proposals for research must include a description of plans to include children or, if they will be excluded, an acceptable justification for such an exclusion.

Requirements For Consent By Parents Or Guardians And For Assent By Children

Unless permission to forgo obtaining either assent by the child or consent from his or her parents or guardian is explicitly granted by Portland State's Human Subjects Research Review Committee, both are required in research that will involve children.

The HSRRC shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the Committee the children are capable of providing assent. In determining whether children are capable of assenting, the HSRRC shall take into account the ages, maturity, and psychological state of the children involved. If the HSRRC 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 Committee determines that the subjects are capable of assenting, we may still waive the assent requirement under circumstances in which consent may be waived in accordance with general informed consent provisions (*see section IV, "Informed Consent"*). When the HSRRC determines that assent is required, it shall also determine how assent must be documented.

In addition, the Committee shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the HSRRC may find that permission of one parent is sufficient for research involving minimal risk or for research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. For research involving greater risk and no prospect of direct benefit to subjects, permission is to be obtained from both parents, 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.

If the HSRRC determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects--for example, neglected or abused children--it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as subjects is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law.

Research Not Involving Greater Than Minimal Risk

The HSRRC will review projects in which no greater than minimal risk to children is presented, only if adequate provisions are made for soliciting the assent of the children and the consent of their parents or guardians.

Research Involving Greater Than Minimal Risk But Presenting The Prospect Of Direct Benefit To The Individual Subjects

The HSRRC will review projects in which more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if:

- The risk is justified by the anticipated benefit to the subjects;
- 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
- Adequate provisions are made for soliciting the assent of the children and consent of their parents or guardians.

Research Involving Greater Than Minimal Risk And No Prospect Of Direct Benefit To Individual Subjects, But Likely To Yield Generalizable Knowledge About The Subject's Disorder Or Condition

The HSRRC will review projects 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 subject, only if:

- The risk represents a minor increase over minimal risk;
- 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;
- 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
- Adequate provisions are made for soliciting assent of the children and consent of their parents or guardians.

Research Not Otherwise Approvable Which Presents An Opportunity To Understand, Prevent, Or Alleviate A Serious Problem Affecting The Health Or Welfare Of Children

The HSRRC will review projects in this category only if the Committee finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

MENTAL HEALTH CONSUMERS

Requirements For Informed Consent Or Assent Ordinarily, a mentally handicapped person may not be the subject of research unless the person gives assent. The HSRRC may waive the assent requirement if:

- The capability of some or all of the subjects is so limited that they cannot reasonably be consulted; or
- The intervention involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the subjects that is available only in the context of the research.

Requirements For Permission From Competent Adults Acting On Behalf Of The Subjects Under normal circumstances, a mentally handicapped person may not be the subject of research unless permission is also obtained from his or her guardian. For purposes of these rules, a guardian cannot be associated in any way

with the research or the investigator(s). If the mentally handicapped person is a ward of the state or any other agency, institution or entity, a person associated with the entity cannot be a guardian for purposes of these rules.

Information That Must Be Provided In Requests For Assent And Permission & Documentation Of Informed Consent Mentally handicapped subjects and the competent adults acting on their behalf must be given the same information that is generally required when informed consent for participation in research is sought, and their permission and assent must be documented in writing. The assent form for the mentally handicapped subjects should, of course, be written in language appropriate to their level of understanding.

Research That Poses Only Minimal Risk To The Subjects No special limits are placed on this type of research, except that adequate provisions must be made for obtaining assent of the mentally handicapped subjects and consent from their legally appointed representatives.

Research That Poses More Than Minimal Risk But Which Promises To Benefit The Individual Subject Directly will be reviewed if:

- The risk is justified by the expected benefit to the subject;
- The relationship between the risk and benefit is at least as favorable to the subject as that presented by other available approaches; and
- Adequate provisions are made for obtaining assent of the mentally handicapped subjects and consent from their representatives, as described above.

Research Which Involves Mentally Handicapped Subjects Who Are Wards Of The State Or Any Other Agency, Institution, Or Entity And Which Poses No More Than Minimal Risk will be reviewed 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 the subjects involved are not wards. Furthermore, if the research poses more than minimal risk, an advocate must be appointed for each mentally handicapped person who is a ward. The advocate must be a person who has the background and experience to act in, and agrees to act in, the best interests of the mentally disabled person for the duration of the person's participation in the research. The advocate cannot be associated in any way with the research, the investigator(s) or the guardian organization. A person can be the advocate for more than one person. The requirement for an advocate is in addition to any other person acting on behalf of the mentally handicapped person as guardian.

Research That Poses More Than Minimal Risk And Does Not Promise To Benefit The Individual Subject Directly will be reviewed if:

- The risk is only slightly greater than minimal;
- The research will expose the subject to experiences that are reasonably commensurate with those inherent in the subject's actual or expected medical, dental, psychological, social or educational situation;
- The research is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance to understanding or ameliorating the subject's disorder or condition; and
- Adequate provisions are made for obtaining assent of the mentally handicapped subjects and permission from their representatives, as described below.

PREGNANT WOMEN & FETUSES

Activities Directed Toward Pregnant Women

No pregnant woman may be involved in a research activity unless:

- The risk to the fetus is minimal; or
- The purpose of the activity is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs.

Additional Consent Requirements

Research activity permitted above may be conducted only after fully informing the mother and father of any possible impact on the fetus and obtaining informed consent from the legally competent mother and father. Consent by the father need not be secured if:

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

Research Directly Involving Fetuses

Any research directly involving fetuses requires consultation with the HSRRC.

PRISONERS

Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary decision regarding whether or not to participate as subjects in research.

Additional Protections for Prisoners

The HSRRC shall review research only if it finds that:

- The research is in a permissible category (see below);
- Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
- 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 justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- The information is presented in language which is understandable to the subject population;
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- Where the HSRRC 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' sentence, and for informing participants of this fact.

Permitted Research Involving Prisoners

Biomedical and behavioral research may involve prisoners as subjects only if the proposed research involves the following:

- Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk or inconvenience to the subjects;
- Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk or inconvenience to the subjects;
- Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only (when DHHS funding is sought) after the Secretary of DHHS has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register of his intent to approve such research; or
- 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 HSRRC) to control groups which may not benefit from the research, the study may proceed only (when DHHS funding is sought) after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

F. REPORTING CHILD & ELDER ABUSE

Child Abuse

According to ORS 419B.010, “Any public or private official having reasonable cause to believe that any child with whom the official comes into contact has suffered abuse, or that any person with whom the official comes in contact has abused a child, shall immediately report or cause a report to be made to the State Office for Services to Children and Families of the State of Oregon.” Public or private officials include:

- Physicians, interns, residents, chiropractors, dentists, optometrists, licensed practical or registered nurses, naturopathic physicians
- School employees
- Certified providers of day care or foster care, or employees thereof
- Employees of the Department of Human Resources, county health department, community mental health department, county juvenile department, or licensed child-care agencies
- Peace officers, fire fighters, emergency medical technicians
- Attorneys, court appointed special advocates
- Psychologists, clergy members, licensed clinical social workers, licensed professional counselors, licensed marriage and family therapists

If the research either requires subjects to respond to questions about abuse or may lead them to speak about it in relation to the subject at hand, the respondents must be informed about the possible legal ramifications of their answers. The following language is suggested for use in the informed consent:

The questions you will be asked include information regarding child abuse. According to Oregon Revised Statute 419B.010, researchers are required to report any “reasonable cause to

believe that any child...has suffered abuse.” If you share any information with the researcher about abuse you have suffered, then he/she is required to report this to the proper authorities. Likewise, if you inform the researcher that you have abused your own children or children in your care, then he/she is required to report this to the authorities.

Elder Abuse

Those obligated to report suspected or confirmed incidence (s) of elder abuse include employees of:

- Mental health programs, senior centers, nursing facilities, hospitals, the Oregon Human Resources Department and county health departments
- Public officials working with the elderly
- Physical and occupational therapists
- Information and referral workers
- Outreach workers
- Legal counselors for nursing home residents
- Nurses, social workers, physicians and police officers
- Clergy members and relatives of nursing home residents

If an investigator suspects or knows that elder abuse is occurring, he or she must contact the local area agency on aging or law enforcement. If the research either requires subjects to respond to questions about elder abuse or may lead them to speak about it in relation to the subject at hand, the respondents must be informed about the possible legal ramifications of their answers. The following language is suggested for use in the informed consent:

“The questions you will be asked include information regarding elder abuse. According to Oregon statutes 124.060 and 124.065, researchers are required to report any abuse, suspected or otherwise. If you share any information with the researcher about abuse you have suffered, then he/she is required to report this to the proper authorities. Likewise, if you inform the researcher that you have abused elders in your care, then he/she is required to report this to the authorities.”

G. HIV REPORTING

Perhaps the most sensitive aspect of AIDS research from the perspective of the rights and welfare of the subjects is the matter of confidentiality. Federal regulations require a statement in the consent form regarding the extent to which confidentiality of records identifying the subject will be maintained.

Subjects are to be informed if tests confirm the presence of HTLV-III antibodies in their blood. Careful attention is to be given to the methods employed to inform subjects of positive findings. Persons providing this information should be qualified to impart sensitive information, alert to privacy and confidentiality issues, and prepared to provide subjects with references for additional counseling.

Improper disclosure could have the most serious consequences for research participants, by threatening family relationships, job security, employability, or ability to obtain credit or insurance. In light of these risks, special precautions should be taken to preserve confidentiality, and potential subjects should be advised with care of the limits of that confidentiality, so they can make thoughtful, informed decisions, in light of their own circumstances, as to whether to participate in research.

Each study is to be designed with administrative, management and technical safeguards to control authorized use and disclosure of information and to protect against unauthorized disclosure of information. Where identifiers are not required by the design of the study, they are not to be recorded. If identifiers are recorded,

they should be separated, if possible, from data and stored securely, with linkage restored only when necessary to conduct the research. No lists should be retained identifying those who elected not to participate. Participants must be given a fair, clear explanation of how information about them will be handled.

As a general principle, information is not to be disclosed without the subject's consent. The protocol must clearly state who is entitled to see records with identifiers, both within and outside the project. This statement must take account of the possibility of review of records by the funding agency, and by FDA officials if the research is subject to FDA regulations (21 CFR 50).

(taken from OHRP; for the full text, go to: <http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc84dec.htm>)

◆ Appendices ◆

The Nuremberg Code

From “Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10”, Vol. 2, Nuremberg, October 1946 - April 1949. (Washington, DC: US Government Printing Office, 1949). pp 181-182.

The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts.

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the 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 the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe in the exercise of the good faith, superior skill and careful judgement required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

The Belmont Report: Basic Ethical Principles

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

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

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

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

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

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer.

Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to “volunteer” or to “protect” them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

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

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

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

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

Justice, or, who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of fairness in distribution or what is deserved. An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits.

Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

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

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