

**Furman University
Institutional Review Board
(FUIRB)
Guidebook**

May 14 , 2002

FUIRB Submission Protocol Description

Furman University is dedicated to the protection of both the rights and welfare of volunteer human subjects engaged in research endeavors under the auspices of the University. The University has entered into an agreement with the Office for Human Research Protections (**OHRP**) termed the IRB Registration and Federal Wide Assurance (FWA) program, pledging compliance with the “Common Rule” for federally supported research. Furman University will apply this Assurance to all research using human subjects, irrespective of the funds or guidance of the research. To this end, the University has established an Institutional Review Board for Proposed Research Involving Human Subjects, referred to as the **FUIRB** throughout the remainder of this document. Guidelines are adopted from those guidelines detailed in the IRB guidebook by the US Department of Health and Human Services (DHHS) Office for Human Research Protections (<http://ohrp.osophs.dhhs.gov/>).

This brief overview of the Furman University Institutional Review Board policy is written to aid researchers in negotiating the IRB procedures. It is not intended as a replacement for the FUIRB Guidebook, which is available to all Furman Faculty. Researchers may use this brief guide to ensure that they are following the IRB submission protocol but should consult the full guidebook for specific concerns related to their submission. Below are listed steps in submitting an IRB proposal:

1. In order for any researchers to submit research proposals to the FUIRB, that researcher must demonstrate completion of the educational criteria of the IRB Guidelines (See section VII). IRB proposals will not be reviewed until and unless the researcher has obtained educational certification. Criteria for certification include: completion of NIH computer-based tutorial, reading of the *Belmont Report* (FUIRB Appendix 2) and *Responsibilities of the Investigator Prior To and After Project Approval* (FUIRB Section XII)
2. The FUIRB maintains the right and responsibility to oversee all activities, research and otherwise, in which teachers and researchers submit human participants to activities that are of minimal or greater risk. Minimal risk is defined as *risk(s) of harm anticipated by the research protocol that are no greater, considering the probability and magnitude, than those encountered in daily life or during the performance of routine physical or psychological examination or tests* (OHRP: 45 CFR 46.102i). Classroom activities in which students and other known or anonymous participants are subjected to deception or incomplete disclosure constitutes minimal or greater risk.
3. The FUIRB maintains three levels of evaluation for IRB submissions. These include 1) Exempt status, 2) Expedited review and 3) Full-board review. Researchers and teachers should consider the definition of each level of submission prior to completing the IRB Forms. See sections VIII-1, VIII-2 and VIII-3 for respective description of each of these categories.
4. All submissions to the FUIRB should include FUIRB Form A, plus Form B (Exempt status), C (Expedited review) or D (Full-board Review).
5. Use of human participants, which does not constitute research (see section V of FUIRB Guidebook) and does not place participants at greater than minimal risk (section V) should submit Form A plus an exempt status notice (Form B). Submissions for Exempt Status will be acted upon by the FUIRB within one week of receipt.
6. Expedited Review requires the evaluation of the FUIRB Chair and two FUIRB members. Proposals will be acted on within two weeks of submission to the FUIRB Chair.
7. Researchers must await approval and notification by the FUIRB prior to commencement of any activities being reviewed by the FUIRB.
8. Full-Review proposals require evaluation by the full FUIRB. The full FUIRB meets monthly and considers Full-Review proposals at the monthly meeting. The FUIRB Chair must receive proposals two weeks prior to the committee meeting. Researchers should consult with the FUIRB Chair (Professor Ray Moss) for specific deadlines.

9. Researchers are encouraged to refer to the Decision Tree Diagram to aid in the process of determining the appropriate FUIRB submission (See FUIRB Appendix 4).

FUIRB Members

Ray Moss, Chair	Health and Exercise Science
James Edwards	Philosophy
Kailash Khandke	Economics and Business administration
Timothy Patrick	Health and Exercise Science
Paul Rasmussen	Psychology
David Redburn	Sociology
David Rutledge	Religion
Victoria Turgeon	Biology
Mr. Scott Pfeiffer	Attorney at Law

Table of Contents

	FUIRB Submission Protocol Description	2
	FUIRB Members	3
I.	Introduction	6
II.	Purpose of FUIRB	6
III.	Jurisdiction of the Institutional Review Board	6
IV.	Background for the Guidebook	6
V.	Definitions	6
VI.	Responsibilities of the FUIRB Prior to Approval	8
VII.	Implementation of the FUIRB Responsibilities	8
VIII.	Categories of Review	10
	• Exempt Status	10
	Guidelines for Exemption	10
	Studies That Cannot Be Exempt from Review	11
	• Expedited Reviews	11
	Guidelines for Expedited Reviews	12
	Research Categories	12
	• Full Reviews	14
	Guidelines for Full Committee Review	14
IX.	Continuation Review	14
X.	Protocol Modifications	15
XI.	Additional Responsibilities of the FUIRB for Vulnerable Populations	15
	a. Women	15
	b. Pregnant Women as Human Research Participants	16
	c. Women of Childbearing Potential as Human Research Participants	16
	d. Risk to Fertility	17
	e. Risk to Fetus or Infant	17
	f. Minorities	18
	g. Children	19
	Parental Permission and Research of Minimal Risk	19
	Parental Permission and Research of More Than Minimal Risk	19
	h. Terminally Ill Patients	21
	i. Students	21
	j. Student Assistants	22
	k. Employees	22
	l. Prisoners	22
	Categories of Research in Which Prisoners may Participate	22
	m. Additional Responsibilities/Duties of the FUIRB	23
XII.	Responsibilities of the Investigator Prior to and After Project Approval	24
XIII.	Components of Protocol	25
	a. Full Review Requirements	25
	Deception and Incomplete Disclosure (Failure to Disclose)	27
XIV.	Responsibilities of the FUIRB Following Project Approval	28
	a. Reporting Adverse Experiences	28

b.	Proposed Changes in Research Proposal	29
XV.	Record Retention	29
a.	Investigator Records	29
b.	FUIRB Record	30
Appendix 1	Adverse Effects Report (Form)	31
Appendix 2	Sample Consent Form	32
Appendix 3	The Belmont Report	33
Appendix 4	Decision Flowchart	43
Form A	Project Description	44
Form B	Exempt Research	46
Form C	Expedited Review	47
Form D	Full Review	49

I. INTRODUCTION

Furman University is dedicated to the protection of both the rights and welfare of volunteer human subjects engaged in research endeavors under the auspices of the University. The University has entered into an agreement with the Office for Human Research Protections (OHRP) termed the IRB Registration and Federal Wide Assurance (FWA) program, pledging compliance with the “Common Rule” for federally supported research. Furman University will apply this Assurance to all research using human subjects, irrespective of the funds or guidance of the research. To this end, the University has established an Institutional Review Board For Proposed Research Involving Human Subjects, referred to as the **FUIRB** throughout the remainder of this document. Guidelines are adopted from those guidelines detailed in the IRB Guidebook by the US Department of Health and Human Services (DHHS) Office for Human Research Protections (<http://ohrp.osophs.dhhs.gov/>). (These guidelines are referred to throughout this document and denoted by OHRP:).

II. PURPOSE OF FUIRB

The Purpose of the FUIRB is to review all research that proposes the inclusion of human subjects as a part of the research design. The review is undertaken to ensure the safety and confidentiality of human subjects, determine that protocols meet a level of scientific merit which is commensurate with the risk/benefit ratio as defined by the study’s protocol and assesses the appropriateness of data analysis. Any investigator under the auspices of Furman University (faculty, staff, and students) will be required to submit their research proposal to the FUIRB before it may be submitted for grant monies and prior to recruiting subjects for the investigation.

III. JURISDICTION OF THE INSTITUTIONAL REVIEW BOARD

The Furman University IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities. The Furman University IRB has the authority to approve, require modification in or disapprove all research activities that fall within the jurisdiction of the FUIRB as specified by both the federal regulations and local institutional policy. Research that has been approved by the FUIRB may be subject to further review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the FUIRB, according to Federal Policy 46.112 of OHRP. Furthermore, any approved research is subject to continuing FUIRB review and must be reevaluated at least annually; and more frequently, as specified by the FUIRB (OHRP: 46.109(e)).

IV. BACKGROUND FOR THE GUIDEBOOK

The *Nuremberg Code*, developed for the Nuremberg Military Tribunal and adopted in 1949, was the first official document directly addressing the responsibility of investigators to ensure the welfare of human subjects participating in research trials. Another major advancement came in 1964, with the adoption of *The Declaration of Helsinki: Recommendation Guiding Medical Doctors in Biomedical Research Involving Human Subjects*. In 1974, the United States Congress passed the National Research Act, from which arose the National Commission for the Protection of Human Subjects of Biomedical and Behavior Research. The commission generated the *Belmont Report* that was published in 1978. All of these reports are included in the Appendices of this Guidebook.

V. DEFINITIONS:

Adverse Experience is defined as any experience, whether or not it is anticipated or expected, that causes a serious adverse effect upon the health, safety or welfare of the participant.

Assent is defined as an affirmative agreement to participate in research by a subject not able to give personal consent for reasons of age, mental state, legal or other such status. Mere failure to object should not be construed as assent. (OHRP: 45 CFR 46.102)

Benefit is defined as a valued outcome; an advantage.

Children are defined as minors in the jurisdiction in which they reside. South Carolina defines anyone less than 18 years of age as a minor. Participation of children in a study requires parental/guardian consent, which is their permission, and the children's assent.

Confidentiality is defined as the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Deception is defined as any information provided or not provided, which deviates from the true purpose or intent of the investigation. Failure to provide pertinent information concerning the intent of the investigation (referred to as "Failure to Disclose"), which reveals potential risk or that may lead a participant to withdraw from the study, constitutes deception.

Emancipated Minor as defined by OHRP (OHRP: 45 CFR 46) is a legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law, but who are entitled to treatment as if they were of legal age by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage or procreation.

Human Subject is defined as a living individual about whom a research investigator obtains data through intervention or interaction with the individual or identifiable private information (OHRP: 45 CFR 46.102f).

Identifiers are defined as any material that would allow an individual to identify a subject in a research study either directly or through identifiers linked to the subject. This could include, signed consent forms, test protocols, instruments, demographic data, and computer or medical files with identifiers. Voice and video recordings have the potential to be classified as identifiers.

Informed Consent is defined as a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their rights. See section XIII, 5 for further discussion of Informed Consent Guidelines,

Intervention is defined as physical procedures by which data are gathered such as computer trials or where manipulation of the subject or the subject's immediate environment for the purpose of research.

Interaction is defined as personal contact or communication between the investigator and the subject.

Minimal Risk is defined as risk(s) of harm anticipated by the research protocol that are no greater, considering the probability and magnitude, than those encountered in daily life or during the performance of routine physical or psychological examination or tests (OHRP: 45 CFR 46.102i).

Permission is defined as the agreement of the parent(s) or guardian(s) to the participation of their child or ward in research. (OHRP: 45 CFR 46.402)

Private Information is defined as information about behavior that is in an environment or context in which an individual can reasonably expect no observation or recording is being undertaken, and information, which has been provided for specific purposes by an individual, and which the individual can reasonably expect will not be made public.

Protocol is defined as the formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s) and the proposed methods of analysis that will be performed on the collected data.

Research is defined as a systematic investigation, inclusive of measurement and evaluation, designed to develop or contribute to generalizable knowledge (OHRP: 45 CRF 46.102d).

Implicit in this definition is that the data obtained from the investigation will be published or disseminated to the population at large. If you have a question concerning whether your activity is research, contact the FUIRB Chair by e-mail: ray.moss@furman.edu.

Risk is defined as the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

Voluntary is defined as free of coercion, duress or undue inducement. Used in the research context to refer to a subject's decision to participate, or to continue to participate, in a research project.

VI. RESPONSIBILITIES OF THE FUIRB PRIOR TO APPROVAL

To ensure that a review process for the use of human subjects is responsive to all parties involved, federal regulations require the composition of the IRB to reflect expertise in the areas of academic research with regard to clinical and behavioral investigations. The board should also reflect research expertise with concern for racial, cultural and gender balance; along with a sensitivity to the attitudes represented by the community. The IRB committee must also avail itself of outside expertise if protocols require subjects from vulnerable populations such as prisoners or persons with cognitive deficits. The FUIRB needs to 1) ensure integrity of the individual, 2) ensure beneficence, 3) ensure justice in all research involving human subjects, 4) determine that all protocols requiring the use of human subjects are in compliance with both the letter and **SPIRIT** of the guidelines mandated by the Federal Agencies, along with the principles defined by the Belmont report, respect for the individual person, beneficence, and justice, and 5) evaluate all components of the research protocol involving human subjects including but not limited to:

- a. Scientific merit of research protocols
- b. Evaluating the risk and direct benefits to the volunteer if any, or to future knowledge
- c. Recruitment procedures for volunteers
- d. Incentives for volunteering for study participation
- e. Process of informed consent
- f. Determine if data analysis is adequate as relates to the risk of the protocol.

VII. IMPLEMENTATION OF FUIRB RESPONSIBILITIES

Education of Investigators. One of the responsibilities of the FUIRB is to assure informed competency of all researchers who make use of human participants in their research activities. Informed competency implies that the researcher has been exposed in a formal and focused manner to the critical

issues of concern related to the use of human participants. Such exposure is assumed to assist the researcher in making critical decisions related to the appropriate and ethical use of human participants. With this responsibility, the *FUIRB requires that all researchers demonstrate informed competency via certified completion of the Computer-Based Training Program for Researchers*, which has been produced and made available by the U. S. Department of Health and Human Services, National Institutes of Health. This tutorial can be accessed at the following website address: <http://ohsr.od.nih.gov/cbt/nonNIHpeople.html>. Researchers at Furman University who intend to use human participants in their research can certify their informed competency via completion of this NIH tutorial and by submitting to the FUIRB a copy of the personalized certificate that can be printed following completion of the tutorial. Upon receiving the researcher's certification, the FUIRB Chair will assign the researcher a certification number that the researcher will use when submitting Form A of the FUIRB protocol to the Furman IRB. Consideration of any proposal by the FUIRB requires that the researcher has demonstrated informed competency via this tutorial. While the primary investigator is responsible for demonstrating informed competency, researchers are encouraged to have all members of their research team complete the NIH tutorial.

Further, upon submission of any IRB proposal, the researcher, through his or her signature documents that he or she has 1) completed the NIH tutorial, 2) read and understood the *Belmont Report* [appendix 2], and 3) read and understood the **Responsibilities of the Investigator Prior To and After Project Approval**, which is described in section XII of this Guidebook.

Researchers are also required to keep their understanding of IRB policy current by attending scheduled workshops sponsored by the FUIRB, or other recognized local or national IRB organization (e.g., ARENA), at least once every two years. Researchers who do not attend scheduled workshops with lose FUIRB certification.

Scientific merit of research protocols will be evaluated in relationship to risk of human subjects who will be selected for participation in the study.

Evaluating risks and benefits will be a major component of all IRB reviews. Benefits and future knowledge must be fully commensurate with any risk that is greater than minimal to subjects participating in the proposed research. All aspects of the protocol and defined outcomes will be studied very closely in relation to these components.

Recruitment procedures will be studied to determine if subjects are recruited in an equitable manner, and that there is no coercion explicit or implicit in the recruiting process. Consideration will be given to the type of study, the environment of the study, the intended population that the study addresses and the availability of subjects.

Incentives will be reviewed in relation to the background of the subject as well as to the level of risks imposed by the protocol of the study. This will be taken into consideration with the benefits to be received by the subject, if any, or the importance of the knowledge that is reasonably expected from the protocol.

Informed consent is a critical feature of all studies using human subjects. The FUIRB is to ensure that the subject is aware of 1) the purpose of the study, 2) the risk(s) involved with participation in the study, 3) how confidentiality will be protected, 4) incentives to be received from their participation, 5) benefits to be derived by participation, 6) the right to terminate their participation at anytime during the study without fear of reprisals or loss of any benefits accrued during their participation in the study, and 7) the right to have his or her data withheld from analysis following completion of the investigation.

To ensure their awareness of these issues, each subject will be presented a consent form, which includes but is not limited to, the topics discussed in the previous paragraph. They may keep the consent form as a copy to study. If they decide to participate in the study, they may sign the consent form and return it to the investigator, or they may request a second consent form to sign and turn in, allowing them to keep a consent form for personal records. To the extent possible, the experimenter should obtain a witness signature.

Informed consent must be obtained and documented prior to the collection of any data.

Refer to section XIII, 5 for further elaboration on Informed Consent procedures and Appendix 2 for a sample Consent Form.

VIII. CATEGORIES OF REVIEW

1. Exempt Research

Research protocols that meet the specific guidelines listed below are exempt from FUIRB approval. This does not mean that the protocol is exempt from submission to the FUIRB. The protocol must be submitted for review (FUIRB Forms A and B) and approval of exemption. Only the Chair of the IRB can approve a research protocol to be exempt from review. Protocols submitted for exempt review cannot be disapproved by the Chair but can be referred for Exempt or Full-Board Review. PI's must reapply for exempt status 1 year after the FUIRB allowed for the exempt status. The resubmission will include any changes to protocol, informed consent and most recent findings.

Guideline for Exemption

- a. Research conducted in established or commonly accepted education settings, involving normal education practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.
- b. Research involving the use of educational test (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, UNLESS: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.
- c. Research involving the used of educational test (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph b. above, IF: (i) the human subjects are elected or appointed public officials or candidates for public office; OR (ii) Federal statute(s) require(s) without exception that the confidentiality or other personally identifiable information will be maintained throughout the research and thereafter.
- d. Research involving the collection or study of existing data, documents, records, pathological 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.
- e. Research and demonstration projects which are conducted by, or subject to the approval of, a federal agency sponsoring the research, and which are designed to study, evaluate or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or

- alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- f. Taste and food quality evaluation and consumer acceptance studies, IF (i) wholesome foods without additives are consumed, OR IF (ii) a food is consumed that contains a food ingredient at or below the level and for a use 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.

STUDIES THAT CANNOT BE EXEMPT FROM REVIEW

- a. Research that involves prisoners, fetuses, pregnant women, the seriously ill or mentally or cognitively impaired.
- b. Research that involves collection or recording of behavior which, if known outside the research, could reasonably place subjects at risk of criminal or civil liability, be stigmatizing or be damaging to the subject's financial standing, employability, insurability or reputation
- c. Research that involves the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
- d. Research that involves subjects less than 18 years of age except as listed above (a,c,d,e,f).
- e. Research that involves deception and/or failure to disclose.
- f. Research that may involve foreseeable risks to the subject.
- g. Research that requires informed consent or a waiver of informed consent from the FUIRB.

2. EXPEDITED REVIEWS

Expedited reviews do not require the approval of the full FUIRB. The FUIRB Chair, or his or her designee, and two members of the FUIRB may grant approval, after reviewing the IRB submission (FUIRB Forms A and B).

Research protocols may be considered for expedited review if they meet the following criteria:

- a. There is no more than minimal risk to human subjects participating in the study.
- b. Does not involve any of the vulnerable subject populations with the exception of children as discussed below
- c. Involves only procedures listed in one or more of the categories listed below
- d. The appropriate form is filed with the FUIRB Chair.

The FUIRB Chair, or the Chair's designated member of the FUIRB, is empowered to approve expedited review for a submitted proposal.

Guidelines for Expedited Reviews

- a. Only research protocols that present minimal risk to a subject and involve only those procedures listed under Research Categories below, may be reviewed by the FUIRB through the expedited review procedures as authorized by 45 CFR 46.110 and 21 CFR 56.110 (FUIRB Forms A and B). The activities listed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- b. The categories in this list apply regardless of the age of the subjects, except as noted (see FUIRB Guidebook, section XI).
- c. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation or be stigmatizing unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- d. The expedited review procedure may not be used for classified research (research being conducted, which is regarded as "classified" by the US Government or other valid agency) involving human subjects.
- e. Standard requirements for informed consent (or its waiver, alteration or exception) apply regardless of the type of review (i.e., expedited or full-review) utilized by the IRB.
- f. The following Research Categories pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when conditions a and b are met:
 - a. Research on drugs for which an investigational new drug application (21 CFR par 312) is 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 par 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, non-pregnant adults who weigh at least 110 lbs. For these subjects, the amounts drawn may not exceed 500 ml in an eight (8) week period, and collection may not occur more frequently than two (2) times per week; or
 - b. from adults and children considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected and the frequency with which it will be collected. For these subjects, the amount of blood drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight (8) week period, and collection may not occur more frequently than two (2) times per week. (See OHRP: 45 CFR 46, 1991; Appendix 4, A-49)

3. Prospective collection of biological specimens for research purposes by non-invasive means. Examples:
 - a. Hair and nail clippings in a non-disfiguring manner;
 - b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
 - c. Permanent teeth if routine 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 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 or 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 amounts of energy into the subject or an invasion of the subjects' privacy;
 - b. weighing or testing of sensory acuity;
 - c. magnetic resonance imaging
 - d. electrocardiography, thermography, electro-encephalography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow and echocardiography;
 - e. moderate exercise, muscular strength testing, body composition 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 non-research purposes (such as medical treatment or diagnosis). Note: Some research in this category may be exempt from the DHHS (OHRP and FDA) regulations for the protection of human subjects. (See 45 CFR 46.101(b)(OHRP: 4)).

6. Collection of data from voice, video, digital or image recording 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 factor evaluation or quality assurance methodologies. Note: Some research in this category maybe exempt from the DS regulations for the protection of human subjects. (See OHRP: 45 CFR 46.1010(b)(2) and (b)(3)).

8. Continuing review of research previously approved by the convened IRB as follows:
 - a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. where no subjects have been enrolled and no additional risks have been identified; or
 - c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but that the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk, and no additional risks have been identified.

3. FULL REVIEWS

When protocols do not meet the criteria for either exempt or expedited review, they will be reviewed by the full membership of the FUIRB committee. A quorum (greater than 51%) of the voting members is necessary for the committee to take action on a protocol (FUIRB Forms A and D).

GUIDELINES FOR FULL COMMITTEE REVIEW

All research characterized by any of the following require full IRB review:

- a. Research involving prisoners, fetuses, pregnant women, the seriously ill or mentally or cognitively compromised adults as subjects.
- b. Research that involves deception or failure to disclose in which the procedure introduces any risk of harmful effects.
- c. Research that involves the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability, be stigmatizing or be damaging to the subjects' financial standing, employability, insurability or reputation.
- d. Research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior.)
- e. The procedures of the research involve more than minimal risk to the subject (where "more than minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological tests).

IX. CONTINUATION REVIEW

All research protocols, once approved by the FUIRB, must be evaluated a minimum of once annually from the day of approval. Research protocols may be evaluated more often as dictated by the degree of risk associated with a specific protocol and with the populations being used as subjects in the study. The investigator should receive a reminder for continuing review approximately 2-months prior to the review date, for annual reviews, reminding the investigator that the protocol approval will lapse soon. If the project is ongoing, the investigator must submit a continuing progress report for review and approval prior to the anniversary of the prior approval (FUIRB Form A). Studies that do not have continued approval certified within 12-months of initial approval must be suspended immediately. The responsibility of the continuing review is that of the investigator, and is not reduced in any way by failure of receiving a reminder prior to the date for review.

The progress report serves to inform the FUIRB of the status of the project. FUIRB review and approval of the progress report extends the approval of the project for another period of time, up to 12 months (to be determined by the FUIRB). As part of the progress report, the investigator is required to incorporate the original protocol and modifications to the study during the previous 12 months (or less as determined by the FUIRB).

Should the IRB approval lapse and the study is still going on, the study would no longer be eligible for the continuing review process and a new protocol must be submitted. Recruitment of participants and all other study procedures must cease until IRB approval is once again in place.

Renewal: Researchers who intend to resume an unaltered and previously approved investigation, in which IRB approval has expired, may submit a renewal request, if the research is being resumed within three-months of date of IRB expiration. A renewal request requires completion of FUIRB Form A and submission of a copy of the original FUIRB approval notification.

X. PROTOCOL MODIFICATIONS

When any revisions to an approved research protocol, written consent form and/or advertisement for participant recruitment is desired, the investigator must submit in writing to the FUIRB a modification request (FUIRB Form A). The modification request must include a description of the original study in enough detail to allow FUIRB to evaluate the requested change(s) and should explain the changes and the rationale for the change(s). A revised copy of the pertinent documents (e.g., consent form and/or advertisement) must also be submitted with the change(s) italicized or underlined. A cover letter or additional information may be attached as necessary.

Modifications to approved protocols may not be initiated until FUIRB approval has been obtained, except where necessary to eliminate apparent immediate hazards to the subjects.

An expedited process may review minor revisions, which reflect administrative changes or do not increase the risk of the participants. An example of a minor modification would be a change in the title of the research project. Those modifications, which are not deemed as minor, will require full-board review.

A letter sent to the investigator and recorded in the FUIRB files may acknowledge non-substantive (administrative) changes to approved protocols.

XI. ADDITIONAL RESPONSIBILITIES OF THE FUIRB FOR VULNERABLE POPULATIONS

Women

Historically, in order to avert harm to a developing fetus in an unsuspected pregnancy, physicians and lay community have expressed concerns regarding the participation of women of childbearing age in research. As a result, federal agencies developed special guidelines ostensibly for the protection of the developing fetus that excluded women of childbearing potential from participation in some research. In 1977, for example, the FDA published a guideline that excluded women of childbearing potential from early phases of drug trials. An exception was made for studies involving women with serious and life-threatening diseases.

Over the past decade, questions raised by grassroots, professional, consumer and governmental groups regarding the adequacy and fairness in the distribution of the benefits and risks of research resulted in changes to the regulations for the involvement of women in research. At the same time improved

pregnancy tests and methods of contraception became widely available. In 1988, the FDA issued guidelines that called for safety and efficacy profiles for women, elderly and diverse racial groups as part of new drug applications (NDAs). Then in 1993, following broad public discussion about participation of women in clinical trials, the FDA issued a new guideline that eliminated restrictions on women of child-bearing potential participating in all phases of drug trials. The guideline detailed procedures for minimizing risks of pregnancy in women participants, such as contraceptive counseling, pregnancy testing, timing of short-term studies in relation to the menstrual cycle and the process of informed consent. Though the FDA emphasized the importance of risk/benefit determinations for participants entering various phases of clinical trials, they underscored that initial determinations regarding whether risks to a fetus were adequately addressed were best left to patients, physicians, local IRB's and study sponsors. The new guidelines also called for gender analysis with special attention to factors affecting the role of the menstrual cycle and exogenous hormone therapy in relation to the drug, as well as the influence of the drug on oral contraceptives.

The DHHS has also carefully examined the issue of participation of women in research. It is imperative to determine if an intervention or therapy being studied affects men and women differently. As stated in its new guideline, NIH Outreach Notebook of the Inclusion of Women and Minorities in Biomedical and Behavioral Research (1994), the NIH has concluded that the inclusion of women in research is sufficiently important that the only justifiable reason to exclude non-pregnant women of child-bearing potential from research is compelling evidence that the proposed project would be inappropriate with respect to the health of the participant or the purpose of the research.

The policy statement referenced above pertains to the inclusion of women as research participants in clinical trials, i.e., medical research testing new treatments. However, the inclusion of women in behavioral research is also important and should be accomplished unless there is compelling rationale that establishes that inclusion is inappropriate with respect to the health of the subject or the purpose of the research.

Significant portions of the text below are presented verbatim as published in the Code of Federal Regulations and the Federal Register.

Pregnant Women as Human Research Participants

Drug research using pregnant women as research participants is governed by the federal regulations (CRF 46, Subpart B).

In accordance with the code of federal regulations (OHRP: 45 CFR 46.207 (a): "No pregnant woman may be involved as a subject in a human clinical research project unless: (i) 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, or (ii) the risk to the fetus is minimal."

Research involving pregnant women is permitted only if the mother and father are legally competent and both have given their consent after having been fully informed regarding the possible impact on the fetus, except that the father's consent need not be secured if (i) the purpose of the activity is to meet the health needs of the mother; (ii) his identity or whereabouts cannot reasonably be ascertained; (iii) he is not reasonably available; (iv) the pregnancy resulted from rape. (OHRP: 45 CFR 46.207 (b)).

Women of Childbearing Potential as Human Research Participants

Non-pregnant women should not be excluded from any phase of research unless the science of the project or the health of the subject will be compromised. Regarding clinical drug research, Phase I, II and III trials should have the proportion of women in the study which at least reflects the proportion of

women in the population which will receive the drug when it is marketed, and should enroll numbers adequate to detect clinically significant sex differences in drug metabolism and response.

Risk to Fertility

It is expected that both male and female research participants will be informed about potential risks to their fertility, including the development of any abnormalities or abnormalities in the function of reproductive organs as a consequence of the proposed study intervention.

“Where abnormalities of reproductive organs or their function (spermatogenesis or ovulation) have been observed in experimental animals as a consequence of the proposed study intervention, the decision to include patients of reproductive age in a clinical study should be based on a careful risk/benefit evaluation, taking into account the nature of the abnormalities, the dosage needed to induce them, the consistency of findings in different species, the severity of the illness being treated, the potential importance of the drug, the availability of alternative treatments and the duration of therapy.”

“Where (subjects) of reproductive potential are included in studies of drugs showing reproductive toxicity in animals, the clinical studies should include appropriate monitoring and/or laboratory studies to allow detection of these effects. Long-term follow-up will usually be needed to evaluate the effects of such drugs in humans.) (Federal Register, Vol. 58, No. 139, p 39411, G, Thursday, July 22, 1993)

Risk to Fetus or Infant

1. General guidelines: “Appropriate precautions should be taken in research studies to guard against inadvertent exposure of fetuses to potentially toxic agents and to inform subjects and patients of potential risk and the need for precautions. In all cases, the informed consent document and investigator’s (drug information) brochure should include all available information regarding the potential risk of fetal toxicity. If animal reproductive toxicity studies are complete, the results should be presented, with some explanation of their significance in humans. If these studies have not been completed, other pertinent information should be provided, such as general assessment of fetal toxicity in drugs with related structures of pharmacological effects. If no relevant information is available, the informed consent should explicitly note the potential for fetal risk.”
2. “In general, it is expected that reproductive toxicity studies will be completed before there is large-scale exposure of women of child-bearing potential, i.e., usually by the end of Phase II and before any expanded access program is implemented.” (Federal Register, Vol. 58, No. 139, p 39411, G, Thursday, July 22, 1993).
3. Minimizing the Possibility of Fetal Exposure: “Pregnancy testing may be used to detect unsuspected pregnancy prior to initiation of study treatment. Timing of the start of the study to coincide with or immediately follow the onset of menses is also an adequate indication that the subject is not pregnant. The investigator should ascertain that the subjects will responsibly employ a reliable method of contraception or abstinence for the duration of the drug or treatment exposure, which may exceed the length of the study. If requested, the investigator should be able to refer the subject to a knowledgeable counselor or physician for contraceptive advice.”
4. Inclusion of Women in Early Clinical Trials (Phase I and Early Phase II): “In some cases, there may be a basis for requiring (inclusion) of women in early studies. When the disease under study is serious and affects women, and especially when a promising drug for the disease is being developed and made available rapidly under FDA’s accelerated approval or real access procedures, a case can be made for requiring that women (be allowed to) participate in clinical studies at an early stage. When such a drug becomes available under expanded access mechanism (for example, treatment IND or parallel track or is marketed rapidly under Subpart E procedures because an affect of survival or irreversible morbidity has been shown in the earliest controlled trials), it is medically important that a representative sample of the entire population likely to receive the drug has been studied, including representatives of both genders. Under these circumstances, clinical protocols

should not place unwarranted restrictions of participation of women.” (Federal Register, Vol. 58, No. 139, p 39409, G, Thursday, July 22, 1993)

5. Risk to Infant or Nursing Mother: The potential for harm from exposure to a drug with unknown risks exists for nursing infants as well as fetuses. Therefore, this policy applies to breastfeeding female subjects who are potential research participants in a drug trial in the same manner in which it applies to gestating women.

Minorities

In addition to requiring the equitable selection of women as research participants, federal regulations require the equitable selection of minorities as research subjects (OHRP: 45 CFR 46.111.(a)(3)). The inclusion of minorities in research is important both to ensure that they receive an equal share of the benefits of research and to ensure that they do not bear a disproportionate burden.

Most diseases affect all population groups. In order to contribute to the pool of generalizable knowledge, investigators are required to include the widest possible range of population groups in their research. However, sometimes minorities are subject to a different risk. For example, some research pertains to conditions such as sickle cell anemia or Tay Sachs disease that specifically affect only a few minority groups. Other research focuses on characteristics of diseases or effectiveness of therapies in particular populations (e.g., HIV transmission, treatment for hypertension), and may also concern conditions or disorders that disproportionately affect a certain racial or ethnic group. Exclusion or inappropriate representation of these groups, by design or inadvertence, would be unjust. Further, to the extent that participation in research offers direct benefits to the subjects (in HIV research, for example, the receipt of a promising new drug), under-representation of minorities denies them, in a systematic fashion, the opportunity for direct benefit. A glaring example of this type of research abuse of minority populations bearing the burden of research can be found in the Tuskegee Syphilis study, in which a group of African-American men suffering from syphilis were left untreated, despite the availability of penicillin, in order to study the natural course of the disease.

Due to these concerns, the federal regulations require that research designs include diverse populations. Investigators submitting protocols for FUIRB review that do not call for heterogeneous populations are required to justify in their submission, why a homogenous study population has not been chosen.

After a heterogeneous population has been chosen, investigators should pay careful attention to the following two issues:

1. Special vulnerabilities: The DHHS recognizes that certain subject populations might require additional protections because they are economically or educationally disadvantaged. The FUIRB will attempt to safeguard every participant's rights and welfare by making sure that any possible coercion or undue influence is eliminated (e.g., compensation that is not commensurate with the risk, discomfort or inconvenience involved or recruiting in institutional settings where voluntary participation might be compromised). Investigators should address these issues specifically when submitting protocol information to the FUIRB for review.
2. Consent Form Presentation: Effort should always be made to ensure that the consent process and the relationship between the investigator and prospective research participant are safeguarded. The federal regulations require the translation of consent documents into the language that is most easily understood by research subjects; the possibility of illiteracy should be accounted for, as should the need for communicating in non-English languages. The FDA indicated in October 1995, that non-English speaking subjects must have informed consent form information presented in a written language that they understand. (21 CFR 50.20-27 and FDA Information Sheets, October 1, 1995, p49)

A potential participant's inability to speak or read English is not an appropriate basis for exclusion from most research.

The FUIRB approved informed consent documents should be available in English and other languages as appropriate to the subject population(s). For investigators proposing to use non-English languages consent documents, quality assurance procedures should be developed such as the translation of the consent document from English to the second language and then the review all non-English consent forms and recruitment tools. The role of cultural norms of subjects should also be addressed. This information should be provided in a clearly identifiable form to the FUIRB for review.

Children

The legal mandate of the FUIRB is to protect the rights and welfare of human research participants. This task becomes more difficult when considering children and minors as study participants. The federal regulations provide for "Additional Protections for Children Involved as Subjects of Research" (OHRP: 45 CRF 46 Subpart D).

Parental Permission and Research of Minimal Risk

Parental permission is required in most circumstances for the participation of children in research. Investigators are required to gain parental permission from at least one of the child's parents or guardians if the research involves only minimal risk.

Parental Permission and Research of More Than Minimal Risk

1. If the research poses more than minimal risk and no direct benefit to the child, the investigator is required to gain permission from both parents, or the child's guardian, in order for the child to participate in the research.

2. If the research poses more than minimal risk but may directly benefit the child, only one of the child's parents or guardian need give permission.

3. The investigator is not required to gain permission from both parents if one of the parents is not reasonably available, deceased, unknown, legally incompetent or from a parent who does not have legal responsibility for the care and custody of the child. This caveat does not exempt the investigator from obtaining the permission from at least one parent who has legal responsibility for the child.

4. The FUIRB is required to make additional considerations for the inclusion of children in research who are wards of the state or any other agency or institution. For research that involves more than minimal risk with no prospect of direct benefit to the individual participant or for research that requires approval of the DHHS Secretary, the study must either be (i) related to the research participant's status as a ward, or (ii) be conducted in schools, camps, hospitals, institutions or similar settings in which the majority of children involved as participants are not wards (OHRP: 45 CFR 46.406-409). The FUIRB is required to appoint an advocate for each child who is a ward. The advocate is required to have the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's participation in the research and who is not associated in any way with the research, the investigator or the guardian organization. The requirement for an advocate is in addition to gaining permission from any other person acting on behalf of the child as guardian or in *loco parentis*.

Subpart D of 45 CFR Part 46 requires the FUIRB to classify research involving children into one of the four following categories relating to the risks and benefits of the proposed research:

1. research involving no greater than minimal risk;

2. research involving greater than minimal risk, but presenting the prospect of direct benefit to individual participants. Research in this category is approvable by the FUIRB, provided: (i) the risk is justified by the anticipated benefit to the subjects; (ii) the relationship of risk to benefit is at least as favorable as any alternative approach; and (iii) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardian;
3. research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield important generalizable knowledge about the participant's disorder or condition. Research in this category is approvable by the FUIRB provided: (i) the risk represents a minor increase over minimal risk; (ii) the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; (iii) the intervention or procedures is likely to yield generalizable knowledge about the participants' disorder or condition which is of vital importance for the understanding or amelioration of the participants' disorder or condition; and (iv) adequate provisions are made for soliciting assent of the children and permission of the parents or guardians;
4. research not otherwise approvable that presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children. This section provides a mechanism for the approval of research not falling under one of the three previous categories. The research must be approved by the Secretary of the Department of Health and Human Services (DHHS) if it is to be funded by the DHHS, after consultation with a panel of experts, and the panel must find that the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a significant problem affecting the health and welfare of children.

When assessing risk to children and evaluating a research project proposing to involve children, the FUIRB will consider the following issues:

1. Is the participation of children as research participants justified in this particular instance?
2. If this research question can be addressed initially in adults, has this work been conducted?
3. Have results from any adult research indicated that the proposed research would benefit, or at least would not be harmful to children?
4. Has every effort been made to ensure that a parent is present when the research intervention is conducted? This will not only comfort the child, but will enable the parent to exercise the right to end the child's participation in the research project at any time. Investigators should note that in some cases (e.g., research into sensitive personal matters, physical examination of adolescents, research into abuse, etc.) it may not be appropriate to have a parent present. If a parent will not be present during the course of the project, has the investigator clearly stated why in the protocol?
5. Are the personnel involved in the research, and the facility in which the research will be conducted, knowledgeable about and sensitive to the physical and psychological needs of the children and their families?
6. Have the investigators taken into account the child-participant's previous experience with illness and medical intervention? Some children may be able to cope with stresses of research better than others as a result of previous experiences with medicine. Younger, "less experienced" children may be unprepared for participation in a research study.
7. How the investigator determined the number of children to be enrolled for the study. Investigators should justify the number of subjects they propose to study. Biomedical Investigators should always plan to involve the fewest number of children necessary to obtain statistically significant data from which valid conclusions can be drawn.
8. Whether the proposed techniques are the least invasive (physically and psychologically) in order to obtain the information for the study.

9. Have the investigators clearly defined how the assent of the child-participants will be obtained?
10. For research involving medical intervention the FUIRB will consider previous research with animals. The investigator should indicate whether the animal research is completed and the results to date.

All personnel working with children must be familiar with State laws requiring reports of suspected child abuse or neglect.

Research with undergraduate college students, in which the students are under 18 years of age, must adhere to guidelines regarding research with minors. Specifically, researchers must obtain informed consent from one or both custodial parents, and the participant, prior to involvement of the student in the research endeavor, as specified in section XI of the FU IRB Guidebook concerning research with children and minors

The FUIRB cannot approve research that exposes children as research participants to more than minimal risk and does not satisfy the conditions outlined above. The federal regulations; however, provide a process for seeking approval for such research from the DHHS Secretary. Please contact the FUIRB chair for information about this process.

Terminally Ill Patients

Patients with a terminal illness may be willing to “try anything” that might offer hope of either a cure or a slowing of the disease process. Others, aware that nothing further can be done to cure their disease, might fear abandonment by the medical establishment and agree to participate in research as a means of maintaining contact with physicians expert in treating their condition. On the other hand, many terminally ill individuals are willing to submit to considerable discomfort and risk for the possible benefit of future patients suffering from the same condition, and will volunteer for Phase I clinical trials or basic research about their particular condition in hopes of helping other, similarly situated patients in the future.

Investigators should be sensitive to these matters and explain with care and clarity the likelihood (or lack thereof) that research participants will experience any personal medical benefit from their participation in a particular study. This is especially important in Phase I drug studies, since the research is designed to evaluate a potential treatment for their illness and as a result, may obscure the fact that the dosage research participants will be given is not expected to produce a therapeutic result.

At the same time, it is important not to treat terminally ill patients as incompetent or incapable of autonomous decision-making, just because they are critically ill.

Students

Students have traditionally served as subjects for behavioral and biomedical research. The obvious concern is that their participation may not be truly voluntary, because of a desire to appear particularly cooperative or highly motivated or because participation in research is a course requirement.

Various procedures have been suggested to reduce the possibility of unintended coercion, while still permitting students to participate as subjects in research. These include the following:

1. Posting FUIRB approved advertisements throughout the university to recruit subjects from a broad base of students;
2. Avoiding any personal solicitations of student by faculty, graduate assistants or fellow students;

3. Providing a number of research projects from which to choose, if participating as a subject in a research investigation can be used as a course requirement;
4. Providing alternative and equal methods for meeting course credit (or extra credit) requirements, such as attending a series of research presentations by faculty, writing a brief paper or conducting one's own research.

Student Assistants

Because students are often involved, in very detailed ways, in research at undergraduate institutions, confidentiality takes on unique concerns. Researchers who use or supervise undergraduate students who are then collecting data from fellow students must assure all of the following:

1. Student assistants are certified by the FUIRB. This includes 1) completion of the NIH tutorial, 2) having read and understood the *Belmont Report* [appendix 2], and 3) read and understood the **Responsibilities of the Investigator Prior To and After Project Approval**, which is described in section XII of this Guidebook.
2. Students are aware of the need for confidentiality concerning a participant's involvement in research. This includes an understanding that the assistant will not discuss with anyone not officially (i.e., recognized by the FUIRB) affiliated with the investigation any aspect of the study that involves identification of any participant.
3. To maximize confidentiality, the investigators (i.e., faculty, student etc) will discuss participants and the obtained data in a way that ensures anonymity.
4. Participants will be made aware in the Informed Consent document that student assistants will be involved in the investigation, and made aware of those efforts taken to assure anonymity and confidentiality.

Employees

University employees, such as office staff or lab technicians, are similar to students in that they are vulnerable to perceive, even if not intended, pressures so as to appear cooperative and supportive of their supervisor's work. Accordingly, many of the same procedures (described above) to reduce the likelihood of coercion in recruiting procedures include employees from the investigator's own lab or office. The FUIRB; however, will reconsider policy on a case-by-case basis.

Prisoners

Prisoners are considered vulnerable because they are in a restrictive, institutional environment that affords little opportunity for making choices, earning money, communicating with outsiders or obtaining medical care. The National Commission for Protection of Human Subjects found that prisoners often volunteer for medical research as a means of access to a competent medical examination, because health care may be inadequate in some prisons. The same could be true of behaviorally related research.

Because their autonomy is limited, prisoners may participate only in certain categories of research, and special precautions are needed to assure that their consent to participate in the research is both knowing and voluntary (OHRP: 45 CFR 46.302).

Categories of Research in Which Prisoners May Participate

1. Studies of the possible causes, effects and process of incarceration and criminal behavior, if those studies present no more than minimal risk or inconvenience to the subjects.
2. Studies of prisons as institutions, or of prisoners as incarcerated persons, if those studies present no more than minimal risk or inconvenience to the subjects;
3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual

assaults) provided that the study may proceed only after the Secretary of DHHS has consulted with appropriate experts including experts in penology, medicine and ethics and published notice, in the Federal Register, of their intent to approve such research.

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

Note: DHHS biomedical or behavioral research protocols involving the use of prisoners MUST fall into one of the above categories.

Additional Responsibilities/Duties of the FUIRB

Prior to reviewing any protocol involving the use of prisoners as participants, the IRB must have at least one member who is a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity. Once the membership is established, the IRB is then required to first confirm that the proposed study fits within one of the permissible categories of research described above. Once the permissible category is established, the IRB will determine whether:

1. any advantages that prisoners may realize as a result of participating in the research, when compared to the general living conditions within the prison, are not so great as to impair prisoners' ability to weigh the risks and benefits of participation and freely choose whether or not to participate;
2. the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
3. procedures for selecting subjects within the prison are equitable, and free from arbitrary manipulation by prison authorities or prisoners;
4. control subjects will be selected randomly from among the group of eligible volunteers, unless the principal investigator justifies, in writing, a different procedure;
5. the information presented during recruitment and consent procedures is in a language, and level of complexity, understandable to the subject population;
6. the IRB is assured that the parole board will not take research participation into account in making decisions about parole, and each prisoner is informed in advance that participation will have no effect on the possibility of parole;
7. if medical follow up is necessary to protect the health and welfare of the subjects, adequate provision is made for such care, taking into account the varying length of prisoners' sentences, and for informing participants of this fact.
8. insure the appropriateness of deception and disclosure failures

The institution is required to certify to the Secretary of DHHS, in such form and manner as the Secretary may require, that the duties of the IRB have been fulfilled.

For research conducted or supported by DHHS involving prisoners, two actions must occur; (i) the institution must certify to the Secretary of DHHS (via OHRP) that it has reviewed and approved the research in accordance with the above and (ii) the Secretary of OHRP must determine that the proposed research fall within one of the categories of permissible research identified above.

For each protocol involving prisoners, the investigator will complete a form identifying the permissible category or research. The minutes of the convened FUIRB meeting will specifically address the

discussion determining the appropriate category selected by the FUIRB members and the accomplishment of the additional responsibilities/duties as outlined above.

XII. RESPONSIBILITIES OF THE INVESTIGATOR PRIOR TO AND AFTER PROJECT APPROVAL

In order for any investigator to begin their research involving humans as participants, the investigator will:

1. acknowledge and accept their responsibility for protecting the rights and welfare of human research participants and for complying with all applicable provisions of Furman University's FWA with OHRP. This is accomplished by signing the certification on FUIRB Form A. **This may be accomplished only after meeting all education requirements of the FUIRB (see section VII)**
2. Make an initial determination, to be confirmed or changed by the FUIRB, of the appropriate review category by completing FUIRB Form A.
3. Be responsible for ensuring that all personnel have been adequately trained in the conduct of human participant research.
4. Ensure that all key personnel involved in human participant research have successfully completed the educational program of the FUIRB (see section VII).
5. Ensure that only procedures in the FUIRB approved protocol are conducted (including the consent process) and /or supervised by the listed investigator or other authorized personnel.
6. Notify the FUIRB in writing if the investigator or other key personnel have changed during the approved review period.
7. Provide the FUIRB with the appropriate information on the research protocol including initial information, notification of subsequent modifications, terminations and adverse reactions.
8. Provide a copy of the FUIRB approved informed consent document to each research participant at the time of consent unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in accordance with the Record Retention section (below).
9. Promptly submit proposed changes in previously approved human subject research activities to the FUIRB. The proposed changes will not be initiated without FUIRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
10. Report the progress of approved research to the FUIRB as often as, and in the manner prescribed, by the approving IRB on the basis of risks to subjects, but not less than one-year from the date of board approval.
11. Immediately report to the FUIRB the death of a research participant, regardless of cause, within one (1) working day.
12. Promptly report to the FUIRB any injuries, adverse events or other unanticipated problems involving risks to subjects or others, within two (2) working days.
13. Promptly report to the FUIRB any significant findings that become known in the course of the research that might affect the willingness of a research participant to continue to participate in the study, or prevent a person from joining the study.
14. Ensure FUIRB approval is in place for the use of data collection procedures (including sampling and device approval) during the provision of emergency medical care. Otherwise, the investigator will not seek to obtain research credit for, or use data from, patient interventions that constituted the provisions of emergency medical care.

15. Ensure that no research (including modifications/amendments to already approved protocols) will be initiated (except Emergency Use) until FUIRB approval is received.
16. Ensure the timely completion and submission of the continuing review report; it is the responsibility the principal investigator to ensure that continuing review is completed and approved by the FUIRB prior to protocol expiration date.
17. Maintain confidentiality of all records related to the project.
18. Report in writing to the FUIRB any severe adverse reaction or injury arising during the conduct of an FUIRB-approved protocol.
19. Notify the FUIRB in writing when the study has been completed.

The FUIRB will mail original correspondence only to the investigator. It is the responsibility of the investigator to ensure that copies of the FUIRB's letters are distributed to appropriate individuals (e.g., grant and contract administrators, departmental administrators, granting agencies, sponsors, participants, etc.).

XIII. COMPONENTS OF PROTOCOL

To Submit A Full Review Requires The Following Items:

1. Completed and signed FUIRB Form A

This form is considered to be the cover page of the protocol. Students conducting research **MUST** indicate their advisor's approval of the protocol by having the advisor sign and date this form. (Note: A student as an investigator on a full board protocol review must attend, along with their advisor, the FUIRB meeting at which the protocol will be reviewed, if attendance is requested by the Chair).

2. Proposal/ Application

If a proposal/application is submitted for funding either internally or to an external sponsor, the protocol must include a complete copy of all pertinent information.

3. Project aims and methodology (what, why, how, and who)

A description of the project, purpose of the project, procedures used in the project, participant population for the project (criteria for inclusion/exclusion including the attempts made to include women and members of minority groups), recruitment procedures of project and how confidentiality of data will be maintained throughout and following the project (including where the data is kept, who has access to the data and how the data is secured). The following list provides areas of explanation within this section of the protocol.

- a. Background and prior pertinent experimental findings or animal data, if any, concerning the current project. This is especially important in protocols for studies of investigational drugs or devices.
- b. Purpose or hypothesis of the study as related to section a, including knowledge to be gained.
- c. Complete description of the project's procedures and methodologies.
- d. The anticipated duration of the protocol.
- e. Location(s) where the research is to be conducted.
- f. Description of all experimental controls and placebos.
- g. The type and number of research participants, including method of participant selection, randomization, and inclusion/exclusion criteria, if any.
- h. Description of statistical analysis to which the data will be subjected. This allows the FUIRB to ensure that the study will produce statistically valid conclusions to justify the research on human participants.

- i. Incentives to participants: Study participants may be offered reasonable, but not coercive, incentives to participate in a project. All projects that promise to provide incentives to participants must include details regarding how the incentives will be provided within the protocol and consent form. The reasonableness of the amount offered will depend on the degree of discomfort the participants experience, the invasiveness of the procedure or investigation, the character of the research, the population likely to be attracted by the protocol, the method in which the protocol will be advertised, the amount of time a participant is expected to devote to the protocol, and related considerations. In addition, such protocols and consents should either (i) describe the plan for pro-rated distribution of incentives to participants if they choose to withdraw voluntarily from the protocol or if, upon the suggestion of a physician investigator, early withdrawal is necessary or (ii) provide justification(s) to why prorated distribution of incentives is not being offered to the participants.
- j. Procedures, which will be used to maintain confidentiality of research and participant information.
- k. Bibliographic references to support the hypothesis and the justification for the use of human participants and in particular the inclusion of vulnerable populations.
- l. A description of recruiting methods (i.e., advertisements, physician referrals). If advertisements are to be used, indicate where they will be placed and who will handle responses to them. Note: In general, finder's fees are not permitted by the FUIRB. A detailed explanation is necessary with the protocol.
- m. If applicable, the protocol should clarify whether female participants will be asked to take a pregnancy test before and, as applicable, during the study.
- n. As applicable, provide a rationale for excluding women, minorities and/or children from participation. It is a policy of National Institutes of Health that all research involving human participants includes women, minorities and children. All protocols that explicitly exclude any of these populations must provide sufficient rationale for the exclusion. Sufficient rationale might include a discussion of the inappropriate study population with respect to the health of the participants or the purpose of the research. The expectation that additional costs may be incurred by including women, minorities and children cannot be a reason for excluding these populations. Note: Protocols involving children must conform to the requirements of 45 CFR 46 Subpart D.

4. Risks and Benefits

This section describes the potential risks to participants and how the experimental design will minimize those risks, and a description of the anticipated benefits, whether to the individual or to the body of science.

5. Informed Consent

- a. Explain the methods to be used in obtaining and recording the informed consent of the research participants. The recommended informed consent format is appended. Written consent of the research participant is strongly recommended. If the investigator feels that a verbal consent procedure is more appropriate for the population and circumstances, an explanation for the deviation from the preferred procedure is required along with a written version of the consent monologue. Whether written or verbal, the basic elements of informed consent must be present as outlined.

All of the following should be considered for inclusion in the investigation Informed Consent document (OHRP Chapter 3, Informed Consent). The omission of any of the following should either be clearly evident or justified by the investigator.

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

- experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
 3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
 4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; or a statement indicating that currently, there are no alternative strategies available.
 5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 6. For research involving minimal risk or greater than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
 7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
 8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
 9. A statement regarding the potential costs to participants incurred as a result of their involvement, including but not limited to the expense of travel, time lost and work absence. If there are "no cost," this should be stated.

The regulations further provide that the following additional information be provided to subjects, where appropriate:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.
7. Use of student research assistants.

Researchers should obtain a signed consent agreement from each participant in which the participant's signature is clearly linked to the consent agreement. Investigators must be careful to maintain confidentiality when collecting informed consent (e.g., in many cases, a list of signatures would violate confidentiality). Investigators should be prepared to provide a copy of the signed agreement to each participant.

A. Deception and Incomplete Disclosure (i.e., Failure to Disclose). Research conducted in which the information concerning the true purpose of the study is withheld, or in which the investigators give the participants false information (e.g., about their performance or some other aspect of the research)

requires that the subject's consent not be fully informed. While it may be argued that deception should not be used in any circumstance, some research questions require that certain information be withheld or altered. In all cases, the FUIRB and the investigators should practice common sense in determining the appropriateness of deceptive practices.

In dealing with the issue of deception or incomplete disclosure, the FUIRB will consider each of the following concerns (see OHRP Guidebook, Chapter 3):

1. Is deception or incomplete disclosure necessary in order to answer the stated research question(s)? Deceptive practices that are not necessary to the specific goals of the research investigation should not be used.
2. Are there means for answering the research question(s) that would not require deception or incomplete disclosure? Researchers should justify their use of deception or incomplete disclosure relative to alternative research designs.
3. Does the risk incurred as a result of the deception or incomplete disclosure constitute **minimal risk** (see section V on minimal risk)?
4. Are the rights and welfare of any participant compromised as the result of the research design? This would include violation of the participant's common right to privacy.
5. Are there appropriate means for eliminating or minimizing the effects of the deception or incomplete disclosure? (i.e., debriefing). Researchers should provide a description or copy of the debriefing procedure to be used in the investigation.
6. Is there a potential for adverse effects being created as the result of the debriefing procedure? Researchers should consider the implications of procedures implemented in order to eliminate or minimize the effects of deceptive practices. In some cases the effects of deception may be made more risky as the result of debriefing, in which case it may be best to omit a debriefing procedure. In all cases, the participant must experience no risk beyond minimal as a result of the initial deceptive procedure or follow-up debriefing procedure.
7. Following debriefing, participants will be given the option of having their data withheld from subsequent analysis and stricken from the data set. The option of withholding provided data must be explained to the participant in the informed consent document.

All use of human participants at Furman University is subject to approval or sanction by the FUIRB concerning the appropriateness and potential harm of deceptive practices.

XIV. RESPONSIBILITIES OF FUIRB FOLLOWING PROJECT APPROVAL

A. Reporting Adverse Experiences

1. **Importance.** Prompt, full and accurate reporting of adverse experiences is a major responsibility of investigators, intended to prevent unnecessary harm to other current and future research participants, and to provide to sponsors, FDA, OHRP and the FUIRB information to make decisions about the research which is under way, such as whether the risk/benefit ratio has changed. Newly discovered, including unanticipated, risks also may necessitate revising the informed consent.

2. **Reporting Requirements.** FDA regulations for trials of new drugs and medical devices require the principal investigator to report serious adverse experiences to the trial sponsor and the FDA immediately. Other adverse experiences, including unanticipated adverse experiences, must be reported within various time periods. In each instance, a copy of the principal investigator's FDA/sponsor report must be submitted to the FUIRB within three (3) working days of making the required report. For research in which FDA reporting is not required, all adverse experience, including unanticipated adverse experiences, must be reported to the FUIRB, within five (5) working days, or earlier if required by the sponsor. The principal investigator must also submit to the FUIRB within five (5) working days from

date of submission, copies of any reports of adverse experiences submitted to the sponsor, FDA or any other organization, agency or individual which describes the clinical management of the adverse experience. The principal investigator must also submit to the FUIRB copies of any unanticipated adverse experience reports that may have occurred at other investigative centers, reported by the sponsor, within five (5) working days of their receipt. With each Adverse Event Report that is submitted to the FUIRB, the principal investigator must also attach a completed Adverse Event Report form and a copy of the currently approved (date-stamped) consent form. If the principal investigator feels that they adverse event requires a change to the consent form, a copy should be submitted with the changes underlined.

3. **Failure To Comply.** When a principal investigator fails to comply with any of these requirements of the above section, he or she will initially be warned by a letter from the FUIRB, with copies to the principal investigator's department Chair and the Vice President and Dean of Academic Affairs. A second violation will result in a letter to the study's sponsor (if appropriate). After further violations, research will be suspended or terminated by the FUIRB in accordance with guidelines found below, and the principal investigator may be subject to disciplinary action pursuant to appropriate Furman University, OHRP, federal, state and local laws and regulations.

An Adverse Effects Report form is included in Appendix 1 of this document.

B. Proposed Changes In Research.

1. **Proposal.** A principal investigator who desires to make a change in a research activity during the period of which the FUIRB approval has already been given, including making a change in the principal investigator, must submit to the FUIRB, Form A of the FUIRB protocol and a written proposal including a complete description of the changes. If the proposed change necessitates a modification in the consent form, a revised consent form should be attached to this submission. For revisions of the protocol (or consent form), two (2) copies must be submitted, one copy with changes highlighted and the other copy without highlights. If deletions have been made, a copy of the original protocol (or consent form) with highlights or deleted sections must be submitted, as well as a copy of the revised protocol.

Faculty, staff or students who fail to comply with the FUIRB Guidelines, as established in this manual, will be subject to investigation by a subcommittee of the FUIRB committee or by the office of the Vice President and Dean of Academic Affairs. Any findings by either of these groups will require adjudication according to the Faculty Staff Handbook.

The FUIRB has the authority to stop any research by institutional members if it is found that there is deviation from the protocols set forth in this manual.

XV. RECORD RETENTION

Investigator Records

Investigators are required to maintain a research file. The requirements for a research file include but are not limited to, all correspondence with the FUIRB and the sponsor (as applicable), and documentation of participant eligibility as well as a copy of the signed consent and assent forms obtained from all research participants participating in and/or who have participated in the protocol regardless of whether or not the subjects completed the study. The research file should also contain any data derived from the study. This file will act as the investigator's documentation regarding the proper performance of the study. This information is subject to review by the FUIRB, Internal Audit, federal, state or local authorities, sponsors and authorized individuals as appropriate to ensure proper performance of the study. To determine data retention requirements, see applicable sponsor guidelines.

Note: All signed consent forms and other materials (e.g., audio or video tapes) must be maintained in a secure location as described in the approved protocol and for an additional three (3) years beyond the completion of the project unless extended by the FUIRB.

FUIRB Records

The FUIRB keeps permanent records of all its proceedings, including minutes of each meeting, all correspondence and all submitted protocols (including proposals where applicable), modifications, advertisements, consent forms, survey instruments, continuing reviews, statements of significant findings provided to subjects and a list of FUIRB members. These records will be maintained for at least a period of three (3) years beyond the completion of the project. All FUIRB records are accessible for inspection and reproduction by appropriate authorized individuals and agencies.

**Adverse Effects Report
FUIRB**

If an adverse event or accident occurs to a subject during research, this report should arrive in the office of the FUIRB Chair (Dr. Ray Moss) within 24 hours of the event.

Date: _____ IRB#: _____

Investigator(s): _____

IRB Proposal Title: _____

Date and Place of Event: _____

Did the event result in medical treatment? _____ No _____ Yes

If "yes," where?

Give a description of the adverse event as determined by the investigator. (Use back of form if more space is needed.)

Any follow-up action taken:

Individual Reporting Event: _____
Signature Date

Principal Investigator:
(and/or Advisor) _____
Signature Date

IRB Use Only

- _____ Continue study as submitted and approved by FUIRB
- _____ Changes recommended
- _____ Report sent to Institutional Officials: (Date) __/__/__
- _____ Discuss with principal investigator

Chair, FUIRB Date

Appendix 2

**Informed Consent
(An Example)**

Title of Study: Communication Technology and Social Interaction.

I, _____, by agreeing to participate in the investigation, entitled, “Communication Technology and Social Interaction”, which is being conducted by Professor Beth Pontari of the Furman Psychology Department, understand that,

1. The purpose of the study is to investigate how new forms of technology may influence social interaction. It is being conducted to determine how, depending on the type of communication device (e.g., telephone versus email), people interact with others, and how friends’ involvement in such social interactions varies.
2. I understand that the study will take approximately 60 minutes to complete.
3. I understand that if I am enrolled in PSY 21, I will be given research credit for participation.
4. I understand that I might interact with another student through different mediums of communication, or that I might observe my friend having an interaction with another student. I will also complete questionnaires that address my reactions to the study, and my opinions, preferences, and attitudes.
5. The benefit of the investigation is the opportunity to receive partial course credit in psychology and to gain experience with the process of research in psychology.
6. Because this procedure requires verbal participants, it is not possible to do the investigation with nonhuman subjects.
7. All information is being collected with complete anonymity. At no time in the investigation will my name be associated with obtained data.
8. I understand that some of the details of this study may not be made known to me until my experimental session is completed. I realize at the completion of the study that I have the option of withholding the responses that I have provided from subsequent analysis.
9. This study makes use of student research assistants, who are educated in the importance and practice of anonymity and confidentiality. They are Susan LaGrone, Stan Sulkowski, and Katie Sweeny.
10. Questions regarding this investigation can be directed to Dr. Beth Pontari, Department of Psychology, Furman University. Email: beth.pontari@furman.edu, or phone: 294-2149.
11. Participation in this investigation is completely voluntary. Participants may choose to terminate their involvement at any time during the investigation without penalty.

Participant Date

Witness Date

Experimenter Date

Appendix 3

The Belmont Report

Office of the Secretary
Ethical Principles and Guidelines for the Protection of
Human Subjects of Research
The National Commission for the Protection of Human Subjects of
Biomedical and Behavioral Research
April 18, 1979

AGENCY: Department of Health, Education, and Welfare.

ACTION: Notice of Report for Public Comment.

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

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

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

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

Members of the Commission

Kenneth John Ryan, M.D., Chairman, Chief of Staff, Boston Hospital for Women.
Joseph V. Brady, Ph.D., Professor of Behavioral Biology, Johns Hopkins University.
Robert E. Cooke, M.D., President, Medical College of Pennsylvania.
Dorothy I. Height, President, National Council of Negro Women, Inc.
Albert R. Jonsen, Ph.D., Associate Professor of Bioethics, University of California at
San Francisco.
Patricia King, J.D., Associate Professor of Law, Georgetown University Law Center.
Karen Lebacqz, Ph.D., Associate Professor of Christian Ethics, Pacific School of
Religion.
*** David W. Louisell, J.D., Professor of Law, University of California at Berkeley.
Donald W. Seldin, M.D., Professor and Chairman, Department of Internal Medicine,
University of Texas at Dallas.
*** Eliot Stellar, Ph.D., Provost of the University and Professor of Physiological
Psychology, University of
Pennsylvania.
*** Robert H. Turtle, LL.B., Attorney, VomBaur, Coburn, Simmons & Turtle,
Washington, D.C.
*** Deceased.

Ethical Principles & Guidelines for Research Involving Human Subjects (THE BELMONT REPORT)

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

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

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

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

A. Boundaries Between Practice and Research

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

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

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.⁽³⁾

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule

is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

B. Basic Ethical Principles

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

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

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

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

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

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

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

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

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

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

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

C. Applications

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

1. Informed Consent. -- Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied. While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

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

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

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

purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare. Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

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

other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.

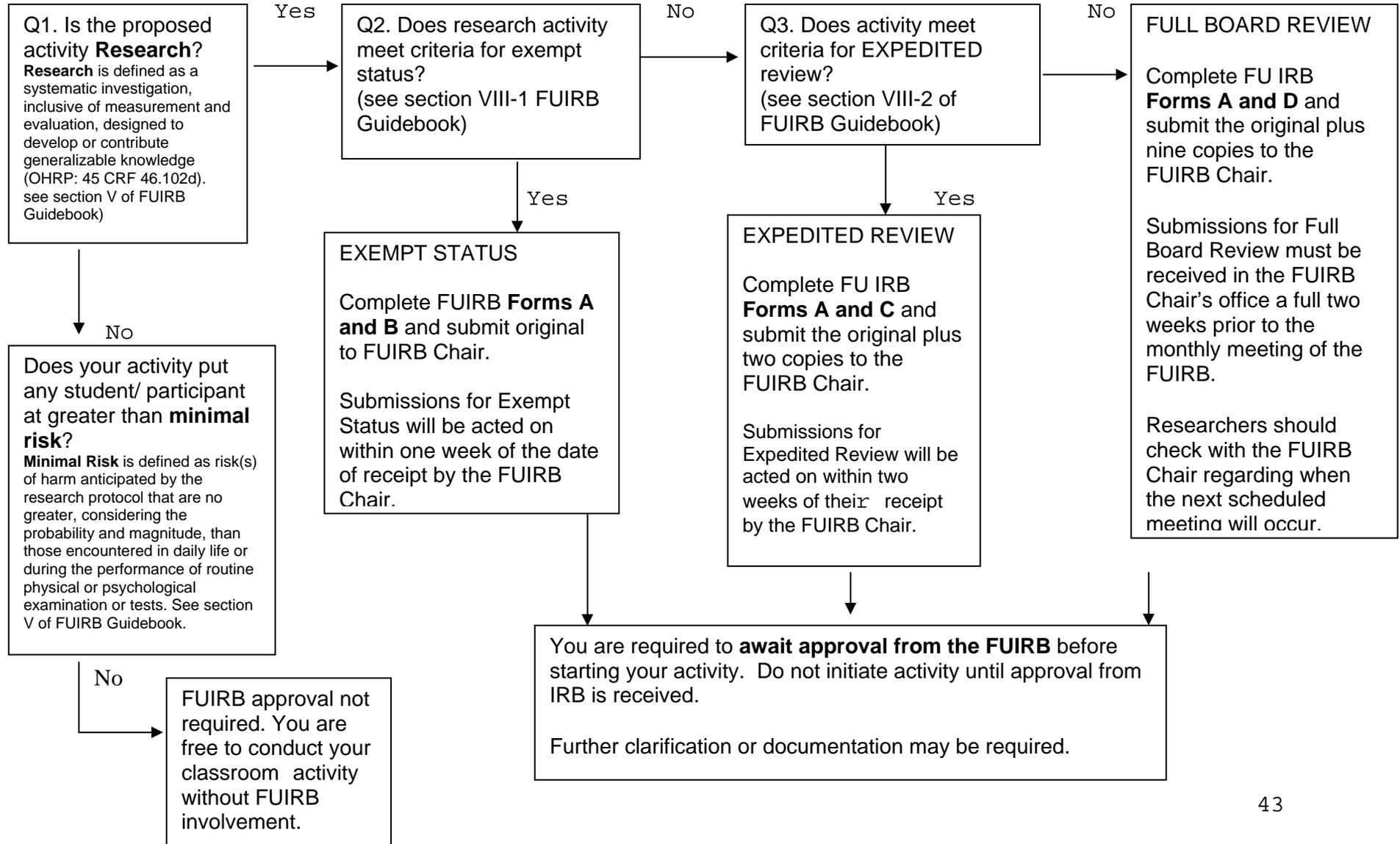
(3) Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be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

National Institutes of Health
Bethesda, Maryland 20892

Appendix 4

Decision Flowchart

Decision Tree for How to Proceed with Review and Approval of Research Involving Human Participants.
Furman University Institutional Review Board



Furman University IRB Form
Institutional Review Board for the Protection of Human Participants

FORM A
Project Description
(45 CFR 46)
USE OF HUMAN PARTICIPANTS
STATEMENT BY PRINCIPAL INVESTIGATOR OR ACTIVITY DIRECTOR

A. Principal Investigator/Activity Director: _____

B. Activity Title: _____

C. Department: _____ Telephone Ext: _____

D. Student Investigators: _____

E. Sponsoring Agency (NIH, NSF, etc.): _____

Funds Awarded: Yes / No Funds Applied For: Yes / No

F. Date Submitted to Furman University IRB: _____

G. Furman IRB registration number of Activity Director: _____

Furman University adheres to the Code of Federal Regulation, Title 45 (Public Welfare) concerning research with human participants, Part 46 (Protection of Human Subjects).

1. TYPE OF SUBMISSION: _____ New
_____ Continuation (appendix X)
_____ Renewal (please include signed FUIRB approval from original submission)
_____ Modification (provide explanation/justification)
Previous approval date: _____

2. TYPE OF REVIEW: _____ Exempt – Form B (see sec X; X)
_____ Expedited – Form C (see sec X; X)
_____ Full review – Form D (see sec X; X)

3. DURATION OF INVESTIGATION: (Protocol must be reviewed annually or frequently if required by the FUIRB)

Proposed Starting Date of Research Activity: _____

Expected Duration of Research Activity: _____ Ending date: _____

4. PARTICIPANTS:

- | | |
|--|--|
| <input type="checkbox"/> Students | <input type="checkbox"/> Prisoners, incarcerated subjects |
| <input type="checkbox"/> Minors (students under 18) | <input type="checkbox"/> Normal adult volunteers |
| <input type="checkbox"/> Patients as experimental subjects | <input type="checkbox"/> Persons who first language is not English |
| <input type="checkbox"/> Patients as controls | <input type="checkbox"/> Geriatrics |
| <input type="checkbox"/> Pregnant women or fetuses | <input type="checkbox"/> Minority |
| <input type="checkbox"/> Mentally disabled | <input type="checkbox"/> Other (please specify) _____ |
| <input type="checkbox"/> Children/Infants (circle) | _____ |

_____ TOTAL ANTICIPATED PARTICIPANTS

5. PROCEDURES: (check all that apply; ATTACH relevant materials, such as questionnaires, interview schedule, instruments, etc.)

- | | |
|--|---|
| <input type="checkbox"/> Survey, questionnaire(s) | <input type="checkbox"/> Investigational drug* |
| <input type="checkbox"/> Interview: phone/in-person | <input type="checkbox"/> Approval drug, New use* |
| <input type="checkbox"/> Medical or other personal records | <input type="checkbox"/> Investigation device (attach relevant information) |
| <input type="checkbox"/> Filming, taping, recording | <input type="checkbox"/> Placebo |
| <input type="checkbox"/> Observation | <input type="checkbox"/> Ionizing Radiation (attach CURRENT approval) |
| <input type="checkbox"/> Participant observation | <input type="checkbox"/> Venipuncture |
| <input type="checkbox"/> Anthropological fieldwork | <input type="checkbox"/> Surgery |
| <input type="checkbox"/> Psychological Intervention | <input type="checkbox"/> Payment of Subjects |
| <input type="checkbox"/> Incomplete disclosure of purpose | <input type="checkbox"/> Other body fluids, excreta |
| <input type="checkbox"/> Class project | <input type="checkbox"/> Other procedure _____ |
| *FDA approval certification required | _____ |

6. Location(s) where research will be conducted.

_____ Principal Investigator or Activity Director's Signature	_____ Date
_____ Faculty Advisor's Signature (if different than above)	_____ Date
_____ Department Chair's Signature	_____ Date

FORM D - Full Review
 (45 CFR 46)
 USE OF HUMAN PARTICIPANTS
 STATEMENT BY PRINCIPAL INVESTIGATOR OR ACTIVITY DIRECTOR

1. Associate or Collaborating Investigator(s), excluding student assistants:

Name	Institution	Address	Tel.#	Fax #
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1. Describe the Nature of the Research Activity (Please use language that can be understood by reviewers outside of your discipline.). Provide enough detail to adequately and accurately represent the proposed investigation. Include description of each of the following concerns:

- (a) Relevant background research with bibliography
- (b) Purpose and methodology.
- (c) Requirements for the participant population.
 Explain the rationale, if the population includes a special group such as prisoners, children, mentally disabled, or those whose ability to give informed consent may be in question.
- (d) Identify those procedures in which a human participant is used which depart from common and established activities, or which increase the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.
- (e) Describe any potential risks--physical, psychological, social, legal, etc., and assess the likelihood and seriousness of such risks.
- (f) Anticipated statistical analyses to be conducted on the obtained data.

2. If electronic or stressful instrumentation is to be used, provide the name of the manufacturer, the model number, and appropriate specifications of the device, as well as how it is to be used on the participants.

3. a. Is the Activity Director contributing to the design or conduct of the study Yes / No

b. Do you expect your name (Activity Director) to appear on a presentation of publication resulting from this study? Yes / No

c. Please describe the specific role of the Activity Director in this research activity:

4. Where are the subjects of this research activity located?

5. If the research activity is taking place elsewhere (not at Furman University), will you have direct contact or intervention with the human subjects?

Yes / No

Has the activity been reviewed and approved by an Institutional Review Board (IRB) elsewhere?

Yes / No

If "yes," specify which IRB and when reviewed:

6. What kind of human samples or data are being collected?

(e.g., questionnaire responses, private information, blood or tissue samples, etc.)

Will you be:

collecting samples/data

Yes / No

receiving samples/data

Yes / No

sending samples/data

Yes / No

7. Do the samples or data:

a. already exist?

Yes / No

b. Or are they being collected for the express purpose of this study?

Yes / No

c. Or a combination of (a) and (b)?

Yes / No

Please specify

8. Do the samples or data come from any individual(s) who may need special safeguards (e.g., individuals under 18 years of age, pregnant women, handicapped persons, prisoners, etc.)?

Yes / No

If "yes," please specify

9. Are the samples or data you expect to collect, receive or send anonymous?

Yes / No

If "yes" your proposal may be eligible for IRB Exemption.

If "no," explain how the anonymity of your participants will be assured.

10. Does your research design involve, in any way, the conveying of Instructions or other information that is deceptive or misleading?

Yes / No

If "yes," explain (a) why the deception is necessary to successful completion of the Investigation and (b) how the participants will be protected from any potential harm occurring as a result of this deception.

Include a copy of your debriefing statement/procedure (see section XX of FUIRB Guidebook).

11. Is participation in the activity completely voluntary? Yes / No

If "No," explain.

12. May any participant withdraw from the activity at any time without penalty? Yes / No

If NO, explain.

13. Is any kind of incentive offered to the participant? Yes / No

If YES, explain the type and amount.

14. Describe subject recruitment procedures.

15. Describe procedures for maintaining participant confidentiality.

16. Describe debriefing procedure. Include copy of debriefing statement.

Submit the original plus 10 copies of Form A and D, your consent form*, debriefing statement and any other supporting materials to Dr. Ray Moss, Chair, Furman University Institutional Review Board, PAC 4E (HES), Furman University.

* See section XX of the FUIRB Guidebook for a description of appropriate consent form preparations.

FORM C
Expedited Review
(45 CFR 46.110)
USE OF HUMAN PARTICIPANTS
STATEMENT BY PRINCIPAL INVESTIGATOR OR ACTIVITY DIRECTOR

Research activities that (1) present no more risk to human subjects, and (2) involves only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review process, as authorized by 45 CFR 46.110 and 21 CFR 56.110. Please refer to Section X of the Furman University IRB Guidebook to determine the criteria for expedited review prior to completing Form B.

1. Associate or Collaborating Investigator(s), excluding student assistants:

Name	Institution	Address	Tel.#	Fax #

2. Describe the Nature of the Research Activity (Please use language that can be understood by reviewers outside of your discipline.). Provide enough detail to adequately and accurately represent the proposed investigation. Include description of each of the following concerns:

- (a) Relevant background research with bibliography
- (b) Purpose and methodology.
- (c) Requirements for the participant population.
Explain the rationale, if the population includes a special group such as prisoners, children, mentally disabled, or those whose ability to give informed consent may be in question.
- (d) Identify those procedures in which a human participant is used which depart from common and established activities, or which increase the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.
- (e) Describe and assess any potential risks--physical, psychological, social, legal, etc., and assess the likelihood and seriousness of such risks.
- (f) Anticipated statistical analyses to be conducted on the obtained data.

3. Provide a copy of any and all Consent Forms to be used in this investigation.

4. Provide copies of any instruments or other documents that will be used in this investigation.

For expedited review, submit the original plus Form A and other supporting materials to Dr. Ray Moss, Chair, Furman University Institutional Review Board, PAC 4E (HES), Furman University.

FORM B
Exempt Research
(45 CFR 46.101)
USE OF HUMAN PARTICIPANTS
STATEMENT BY PRINCIPAL INVESTIGATOR OR ACTIVITY DIRECTOR

Use of human participants that does not involve research may be exempt from IRB review. Nonetheless, institutional policy requires that all protocols believed by the investigator to be exempt, be reviewed by the IRB office to certify whether the research in fact qualifies for exempt status. Please read FU IRB Guidebook, section X prior to completing Form B.

1. Describe the nature of your project and the specific involvement of human participants.
2. Explain why your proposed project constitutes Exempt Research.

Submit the original plus 1 copy of this form to Dr. Ray Moss, Chair, Furman University Institutional Review Board. PAC 4E (HES), Furman University.