

UNIVERSITY OF ARKANSAS, Fayetteville

POLICY AND PROCEDURES GOVERNING RESEARCH WITH HUMAN SUBJECTS

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# UNIVERSITY OF ARKANSAS, Fayetteville

## POLICY AND PROCEDURES GOVERNING RESEARCH WITH HUMAN SUBJECTS

### 1.0 DEFINITIONS

As used in this document, and unless the context clearly requires otherwise, the following terms shall have these meanings:

#### 1.01 Consent

Consent shall mean legally effective and informed consent obtained from each subject or the subject's legal representative, and shall normally be in writing unless the research involves no more than minimal risk and consent can be reasonably inferred or waiver is otherwise proper under these policies and procedures. In the case of research involving a minor, consent shall be obtained from a parent or legal guardian as well. Consent must be obtained under circumstances that offer the subject or representative sufficient opportunity to consider whether the subject should or should not participate, and should not include exculpatory language through which the subject or representative is made to waive or appear to waive any legal rights, or to release the Researcher or the University or its agents from liability for negligence or other wrongdoing. The specifics of informed consent are outlined in Section 5.0.

#### 1.02 Human Subjects Committee

A Human Subjects Committee (HSC) shall consist of those persons selected from a given Department, School or College in accordance with Institutional Review Board (IRB) requirements which operates under policies approved by the IRB, and which is authorized to review and approve certain research protocols involving human subjects.

#### 1.03 IRB

The IRB is the University Institutional Review Board.

#### 1.04 IRB Program Manager

The IRB Program Manager shall be that individual designated by the Director of Research and Sponsored Programs to serve as such for the IRB.

#### 1.05 Protocol

Protocol means the written report from the Researcher to be provided to the Human Subjects Committee and/or the IRB from which compliance with these policies and procedures can be ascertained.

### 1.06 Regulations

Regulations means those regulations for the Protection of Human Research Subjects which are codified at 45 CFR § 46, as the same may be amended from time to time.

### 1.07 Research

Research means study in which a Researcher obtains data through intervention or interaction with human subjects, or identifiable private information about such subjects. It specifically includes the gathering of information about or directly from human subjects, whether or not the information is intended to be published or disseminated, except that use of large, publicly available archival data about human subjects shall not be covered if there is no personally identifiable information that could link the subjects to responses. In addition, it specifically excludes information obtained through any and all accepted and established service relationships, such as the normal physician-patient, professor-student, and client-professional relationships where the patient, student or client is receiving aid or services consistent with accepted and established practice, and the contact is intended only to meet his or her own personal needs.

### 1.08 Minimal Risk

Risk refers to the risks of harm reasonably to be anticipated in connection with proposed research. Research will be deemed to involve no more than minimal risk if it does not increase the subjects' risk of harm, either in probability or magnitude, beyond those risks which are inherent in ordinary daily living.

### 1.09 Unit Executive Officer

The Executive Officer of various academic units at the University (e.g., College Dean, Department Chair)

### 1.10 Vulnerable Population

Vulnerable Population shall refer to any group of human subjects who are likely to be compromised in their ability to make decisions in their best interests. This term shall include those persons who suffer from a mental disability such as a psychiatric disorder (e.g., organic and functional psychoses, neuroses, personality or behavioral disorders, senility) or developmental disorder (e.g., mental retardation), persons under the influence of or dependant on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, persons with severely disabling physical handicaps, prisoners, and some children. It also specifically includes pregnant women and fetuses.

## 2.0 APPLICABILITY OF POLICY

### 2.01 General Applicability

This policy and the attendant procedures apply to all research involving human subjects which fits into any one or more of the following categories:

- a) It is sponsored by the University.
- b) It is conducted by or under the supervision or control of university employees in connection with their institutional responsibilities.
- c) It is conducted by or under the supervision or control of university employees or students using any property or facility of the University.
- d) It involves the use of the University's non-public information to identify or contact subjects or potential subjects.

Research which is subject to these policies and procedures includes the gathering of information about or directly from human subjects, whether or not the information is intended to be published or disseminated.

### 2.02 Statement in the Faculty Handbook

The current Faculty Handbook gives the following description of the responsibilities of the IRB:

Recommends policies, and monitors their implementation, on the use of human beings as subjects for physical, mental, and social experimentation in and out of class. Policies recommended are in keeping with the guidelines established by the U.S. Department of Health and Human Services, other federal agencies, and the Belmont Report.

Protocols for the use of human subjects in research and in class experiments, whether funded internally or externally, must be approved by the IRB or in accordance with IRB policies and procedures prior to the implementation of the human subject protocol. IRB approval may be for one year (maximum) or shorter intervals as determined by the IRB. Approval, denial or the withholding of approval pending modification to the protocol is at the sole discretion of the IRB. Violation of procedures and approved protocols can result in the loss of funding from the sponsoring agency or the University of Arkansas and may be interpreted as scientific misconduct.

The Vice Chancellor for Academic Affairs shall appoint members to the IRB so that the membership complies with 45 CFR 46, as the same shall be amended from time to time, and so that it includes one community representative, one graduate student, and faculty members as follows: one non-scientist, two or three members from the College of Education and Health Professions, two or three members from the Fulbright College of Arts and Sciences, one member from the Walton College of Business Administration, one member from the Bumpers College of Agricultural, Food and Life Sciences, one member from the College of Engineering, one member from the School of Architecture, and one member from the School of Law. The Director of the University Health Services will be an *ex officio* (voting) member and the Director or his/her designated representative of the Office of Research and Sponsored Programs will be an *ex officio* (non-voting) member.

In addition to the foregoing individuals, the IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

The Vice Chancellor for Academic Affairs will designate a chairperson from the faculty members.

### **3.0 STATEMENT OF PRINCIPLES**

#### **3.01 General Statement of Principles**

The University is guided by the ethical principles regarding human subject research as set forth in The Nuremberg Code and the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report"). The University acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research.

#### **3.02 Background**

The procedures and rules for the ethical treatment of human participants in research are founded on two codes of behavior. The Nuremberg Code (U.S. Government, 1947) was formulated during the War Crimes Trials following World War II as a standard for judging the physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. Widely adopted by investigators conducting studies on human beings, it has

served as a prototype for many later codes, all of which are intended to insure that research involving human subjects will be carried out in an ethical manner.

The second set of principles was developed by the National Commission for the Protection of Human subjects in Biomedical and Behavioral Research in order to provide a basis on which specific rules could be formulated, criticized, and interpreted. These principles are discussed in what has become known as The Belmont Report (1978). The important sections of The Belmont Principles and The Nuremberg Code are reproduced below (emphasis added). These documents, as well as others cited later (e.g., 45 CFR 46 as amended), may be reviewed in the Office of Research and Sponsored Programs (RSSP), or on-line at: <http://www.uark.edu/admin/rsspinfo/irb/irb.html>

### 3.03 The Belmont Principles

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

#### a) 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.

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.

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

#### b) Beneficence

People are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms. Learning

what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be forgone 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.

c) Justice

Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. The selection of research subjects needs to be scrutinized in order to determine whether some 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.

### 3.04 The Nuremberg Code

- a) The voluntary consent of the human subject is absolutely essential.
- b) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
- c) The experiment should be so designed and based on the results of animal experimentation and a knowledge of the nature and history of the disease or other problem under study so that the anticipated results will justify the performance of the experiment.

- d) The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
- e) No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur — except perhaps in those experiments where experimental physicians also serve as subjects.
- f) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
- g) Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
- h) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
- i) During the course of the experiment, the human subject should be at liberty to bring the experiment to an end if she or he has reached the physical or mental state where continuation of the experiment seems to him or her to be impossible.
- j) During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage if she or he has probable cause to believe, in the exercise of good faith, superior skill, and careful judgment required of her or him, that a continuation of the experiment is likely to result in injury, disability, or death of the experimental subject.

### 3.05 Responsibilities of People Involved in Human Subjects Research

The responsibility for the protection of human subjects of research is distributed among several parties: Researchers, the Human Subjects Committees, the IRB, the Unit Executive Officer, sponsoring agencies, the subjects themselves, and those who control access to subjects. The following subsections deal with responsibilities of those people who are or may be on campus.

#### a) Researchers

The primary responsibility for the day-to-day assurance for protection of the rights and welfare of human subjects lies with the individuals responsible for the conduct of the activity. Specifically, the Researchers are responsible for:

- I. the research design;
- II. adherence to ethical codes and applicable policies and procedures of the University, the sponsoring agency, and cooperating institutions, if any;
- III. training and supervision of staff and students participating in the research;
- IV. obtaining informed consent from subjects;
- V. providing information required and taking all steps in initial and continuing review of research involving human subjects;
- VI. retaining required records;
- VII. obtaining the prior approval of the IRB (or IRB-approved Human Subject Committees) for the initiation of and changes in research protocols involving human subjects as required by these policies and procedures; and
- VIII. prompt reporting to the IRB of unanticipated problems involving risks to human subjects or others.

b) Unit Executive Officer

The Unit Executive Officer has the responsibility to:

- I. assure that faculty, staff, and students in the Unit are kept informed of the University policy and procedures and of their responsibilities for protecting the rights and welfare of human subjects involved in research;
- II. assure that the Unit review process and Human Subject Committee, if any, operates within IRB-approved guidelines;
- III. assure that for any course offered by the Unit in which participation of the registrants as human subjects is expected, notification to this effect is given in the course description in the official University catalogs; and
- IV. report promptly to the IRB any unanticipated problems involving risks to human subjects or others.

c) IRB and Human Subjects Committees

The IRB and IRB-approved Human Subject Committees are responsible for:

- I. initial and continuing review of research involving human subjects;
- II. ascertaining acceptability of proposed research protocols in terms of institutional commitments, applicable law, and standards of professional conduct and practice;
- III. documentation of such review in conformity with applicable law, regulations, and policies; and
- IV. provision of advice and counsel to investigators engaged in research involving human subjects.

In addition, the IRB has responsibility for:

- V. developing policy, procedures, information, and instructions;
- VI. adjudicating differences and reviewing problems regarding the rights and welfare of human subjects arising in research involving human subjects;
- VII. assuring compliance with externally imposed policies and regulations;
- VIII. reporting to the appropriate funding agency unanticipated problems involving risks to human subjects and others; and
- IX. reporting to the appropriate University officers and to appropriate funding agency any serious or continuing non-compliance by investigators with the requirements and determination of the IRB.

d) Human Subjects

Human subjects who participate in research should:

- I. consider carefully the decision to participate in research;
- II. ask questions freely;
- III. recognize that they are free to withdraw from participation at any time;

- IV. notify the investigator promptly of adverse effects of participation; and
- V. take unresolved complaints or concerns about their participation in research to the Unit Executive Officer and, if the matter remains unresolved, to the Chair of the IRB.

#### **4.0 REQUIREMENTS FOR APPROVAL OF RESEARCH GENERALLY**

Research involving human subjects may only be approved if the following requirements are met:

- a) The risk of harm to human subjects is minimized. Either the Research must involve no more than minimal risk, or, if greater risks of harm are involved, they cannot be avoided and they bear a reasonable relationship to the anticipated benefits to the subjects.
- b) Selection of subjects is equitable.
- c) Informed consent has been obtained and documented in accordance with Section 5.0 of these policies and procedures.
- d) Data will be monitored to ensure the safety of subjects.
- e) All data will be kept confidential as necessary to protect the subjects' privacy, or the protocol provides other adequate assurances that subjects' privacy will not be needlessly compromised.
- f) If the Research includes vulnerable populations, the special provisions of Sections 11.0 to 14.0, as the case may be, are also satisfied.
- g) Research by University students is to be conducted only under the supervision of a faculty member or administrator, who has signed the Protocol form to attest to that responsibility.

#### **5.0 REQUIREMENTS FOR CONSENT**

##### 5.01 Requirement of Informed Consent.

All Researchers are responsible for obtaining informed consent in accordance with 45 CFR § 46.116, and for ensuring that no human subject will be involved in the research prior to the obtaining of the consent. Unless otherwise authorized by the applicable Human Subjects

Review Committee or the IRB, Researchers are responsible for ensuring that legally effective informed consent shall:

- a) be obtained from the subject or the subject's legally authorized representative;
- b) be in language understandable to the subject or the representative;
- c) be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
- d) not include exculpatory language where the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or which releases or appears to release the investigator, the sponsor, the University or its agents from liability for negligence.

#### 5.02 Basic Elements of Informed Consent

The basic elements of informed consent must include:

- a) a statement that the study involves research;
- b) identification of the Researchers, including their institutional affiliation, and the means by which they may be reached (e.g., address, telephone number(s));
- c) an explanation of the purposes of the research;
- d) the expected duration of the subject's participation;
- e) a description of the procedures to be followed;
- f) identification of any novel and/or uncommon procedure;
- g) a description of any reasonably foreseeable risks or discomforts to the subject;
- h) a description of any benefits which may reasonably be expected from the research;
- i) if appropriate, a disclosure of alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

- j) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- k) for research involving more than minimal risk, an explanation of any compensation or treatment available if injury occurs;
- l) an explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject;
- m) a statement that participation is voluntary, and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; and
- n) a statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

#### 5.03 Additional Requirements That May be Imposed

Additional elements of informed consent may be required at the request of the IRB. These may include:

- a) a statement that particular procedures may involve risks to the subject that are currently unforeseeable;
- b) anticipated circumstances under which the subject's participation may be terminated by the Researcher without regard to the subject's consent;
- c) any additional costs to the subject that may result from participation in the research;
- d) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- e) 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
- f) the approximate number of subjects involved in the study.

#### 5.04 Waiver or Alteration of Informed Consent

In its discretion, the IRB or Human Subjects Committee may approve a consent procedure which differs from the one described above in the following situations:

- a) The research is conducted for the purpose of demonstrating or evaluating federal, state, or local benefit or service programs which are not themselves research programs, or procedures for obtaining benefits or services under these programs, or possible changes in or alterations to these programs or procedures.
- b) Survey or questionnaire research satisfying the requirements for Human Subjects Committee Review under Article 9.02 may rely on the return of the completed instrument as evidence of informed consent so long as the instrument itself or a cover letter: i) informs subjects that they are being asked to participate in research; ii) provides a description of the extent and expected duration of their participation; iii) includes a statement that their participation is voluntary; and iv) assures confidentiality or anonymity of responses.
- c) The research could not be carried out practicably without the waiver or alteration.
- d) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. (In this event, each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern).
- e) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- f) The research meets all of the following requirements: i) the research involves no more than minimal risk to subjects; ii) the waiver or alteration will not adversely affect the rights and welfare of the subjects; and iii) whenever appropriate the subjects will be provided with additional pertinent information after participation.

#### 5.05 Documentation of Consent

- a) The Researcher is responsible for ensuring that informed consent is documented on a written form approved by the IRB or the Human Subject Committee and signed by the subject or the subject's legally authorized representative, unless this requirement is waived by the IRB or the Human Subjects Committee. Subjects should receive a copy of the consent form.

- b) The information should be presented in such a way that it takes into consideration the characteristics of potential subjects regarding developmental skills, reading ability, life experiences, and cultural influences. There should be a provision for nonreaders or people whose primary language is not English. Additional consultation from representatives of such groups may be sought by the IRB to evaluate the clarity of the information presented to subjects.
- c) The Researcher has two options for using a consent form. They are: i) a written consent document with the elements listed above in Sections 5.02 and 5.03, as applicable, which is read by or to the subject or the subject's legally authorized representative prior to signing; or ii) a short form written consent document stating that the basic elements have been presented orally to the subject or the subject's legally authorized representative.
- d) The short form may be used provided that: i) a witness is present at the oral presentation, ii) the short form is signed by the subject or the representative, iii) the witness signs both the short form and a copy of the written summary of the oral presentation, iv) the person(s) obtaining consent signs a copy of the summary, v) a copy of both the short form and summary is given to the subject or the representative, and vi) the written summary of what is to be said to the subject or the representative receives prior IRB or Human Subjects Committee approval.
- e) The IRB or Human Subjects Committee may require that an observer be present for the consent process and the research.
- f) The Researcher is responsible for maintaining the signed informed consent documents in a depository approved by the IRB or Human Subjects Committee for at least three years after the end of the research project.

#### 5.06 Special Procedures Required Where Children are Subjects

- a) The IRB or Human Subjects Committee shall determine that adequate provisions are made soliciting the assent of children who are subjects of research when, in the judgment of the IRB or Human Subject Committee, the children are capable of providing assent. In determining whether children are capable of assenting, the IRB or Human Subjects Committee shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol or for each child, as the IRB or Human Subjects Committee deems appropriate. The information the child will be presented, and the

manner in which it is presented, should conform to the child's age, maturity, and psychological state.

- b) When children are involved as subjects in research, the IRB or Human Subjects Committee shall determine that adequate provisions are made for soliciting the permission of each child's parent or guardian. The permission of one parent is sufficient for research to be conducted where (i) the research does not involve greater than minimal risk, or (ii) the research involves greater than minimal risk, but presents the prospect of direct benefit to individual subjects.
- c) Permission of both parents must be obtained (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child) when children are involved in (i) research involving greater than minimal risk and no direct benefit to individual subjects, but likely to lead to generalizable information about the child's disorder or condition, or (ii) research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health of children and permission is to be obtained from parents.
- d) The IRB or Human Subjects Committee may waive consent of parent(s) or guardian if the IRB or Human Subjects Committee determines that (i) a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children), and (ii) the waiver is not inconsistent with federal, state, or local laws, and (iii) an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.

## **6.0 REQUIREMENTS FOR HUMAN SUBJECTS COMMITTEES**

### **6.01 Authority to Establish**

Any Department, School or College may establish a Human Subjects Committee to review Human Research Protocols to ensure compliance with these policies and procedures. No Department, School or College is required by these procedures to establish such a committee. However, the procedures for review solely by such a committee (Section 9.02) are only available where such a committee has been established.

### **6.02 Published Procedures Required**

In order to qualify as a Human Subject Committee under these policies and procedures, the Committee must establish and publish procedures pursuant to which it will operate. Such procedures must, at a minimum, be consistent with this document and must require the use of the Protocol Form and Research Approval forms which appear in the appendices to this document. In addition, such procedures must prohibit any Researcher from reviewing his or her own research.

### 6.03 Composition

A Human Subjects Committee must consist of at least three members, one of whom shall be designated as Chair of the Committee. At all times, at least one member of the committee must have had at least two years experience sitting on the IRB or a Human Subjects Committee. (For academic years 1999-2000 and 2000-2001, this will mean two years service on an established Departmental Review Committee which existed before the implementation of these policies and procedures.)

### 6.04 IRB Approval Required

Before a Human Subjects Committee is authorized to function under these policies and procedures, the procedures under which the committee proposes to operate shall be provided in writing on the form entitled Authority to Establish Unit Human Subjects Committee to the IRB for review. Only after such procedures are approved in writing by the IRB shall the Human Subjects Committee be authorized to conduct the reviews described in this document.

In addition, all Forms submitted to the IRB by any such committee are subject to being audited by the IRB, and if a Human Subjects Committee, after written notification, persists in violating these policies or procedures, the committee's authority to approve research may be limited, suspended, or terminated, at the discretion of the IRB.

## **7.0 REQUIREMENTS FOR THE IRB**

### 7.01 Composition

The Vice Chancellor for Academic Affairs shall appoint members to the IRB so that the membership complies with 45 CFR 46, as the same shall be amended from time to time, and so that it includes one community representative, one graduate student, and faculty members as follows: one non-scientist, two or three members from the College of Education and Health Professions, two or three members from the Fulbright College of Arts and Sciences, one member from the Walton College of Business Administration, one member from the Bumpers College of Agricultural, Food and Life Sciences, one member from the College of

Engineering, one member from the School of Architecture, and one member from the School of Law. The Director of the University Health Services will be an *ex officio* (voting) member and the Director or his/her designated representative of the Office of Research and Sponsored Programs will be an *ex officio* (non-voting) member.

In addition to the foregoing individuals, the IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

## 7.02 Terms

Members of the IRB shall serve for five year terms, unless they are selected to fill a vacancy which occurs during the middle of a term. Terms shall expire on a staggered basis to ensure that there are always some experienced members of the IRB serving.

## 7.03 Chair of the IRB

The Vice Chancellor shall designate one member of the IRB to serve as the Chair. In the event that the Chair shall be unable to continue his or her term and resigns from the IRB, the Vice Chancellor shall designate a replacement to serve as Chair. In the event that the Chair is temporarily unable to serve, or is unable to attend one or more meetings of the IRB, the IRB itself may select an acting Chair by majority vote of those present and voting, to act during the Chair's absence.

## 7.04 Designation of Members to Work With Specific Human Subjects Committees or Academic Units

The Chair of the IRB shall, on an annual basis, designate specific members of the IRB to work with specific Human Subjects Committees or Academic Units. Every Human Subjects Committee or Academic Unit shall have at least one and, in the discretion of the Chair, more IRB members specifically designated to work with the Committee or Unit. The sole function of this association shall be to ensure that the Protocol and Research Approval Forms are sent by the IRB Program Manager to specific IRB members for review.

Only IRB members with at least one full year experience on the IRB shall be assigned to work with specific Human Subjects Committees or Academic Units in this capacity.

## 7.05 Meetings

The IRB shall meet at least twice each year. As soon as practicable after the start of each academic year, the IRB Chair and IRB Program Manager will determine suitable meeting times, and will announce when meetings are to be held. In no event will there be fewer than two scheduled meetings for the IRB during any academic year. In addition, the Chair shall schedule a meeting to be held within 20 working days' after receipt of any properly formatted and documented request for full review.

IRB members are to be given at least five working days notice of meetings in written form, which notice must include copies of all research protocols which are to be considered at that meeting, as well as a general notice of the other purposes for which such meeting is called.

### 7.06 Procedures for Conducting Business at Meetings

In order to conduct business, at least 50 percent of the total active members serving on the IRB (excluding those members who are on leave or sabbatical during the semester in question) must be present. If at least 50 percent of such members are present, any and all business may be properly conducted.

The Chair shall govern the meeting.

Whenever the IRB is conducting a full review of a research protocol, at least one Researcher shall be present to answer questions about the protocol. Deliberations of the IRB, however, are generally to be conducted without the Researcher present.

If the protocol is approved, the IRB will notify the Researcher in writing as soon as reasonably possible. If the protocol is not approved, the IRB will provide the Researcher with an explanation of why approval was not granted, with any requested modifications or revisions. Revised protocols are to be reviewed by the IRB within 10 working days after receipt of the revised materials.

## **8.0 LEVELS OF REVIEW**

The University shall recognize the following levels of review for Research:

- a) Instructor or Administrator Review
- b) Human Subjects Committee Review
- c) Expedited IRB Review
- d) Full IRB Review
- e) Appellate Review

## **9.0 REQUIREMENTS FOR EACH LEVEL OF REVIEW**

### **9.01 Instructor or Administrator Review**

Any research which the Instructor or Administrator responsible for the research reasonably believes satisfies all of the following criteria:

- a) The research is conducted under the supervision of an Instructor for a class project or involves program evaluation conducted by or under the supervision of an Administrator for the purpose of furthering academic or administrative goals.
- b) The research is not conducted, supported or otherwise subject to regulation by any federal department or agency.
- c) No subjects who are members of vulnerable populations are involved with the exception of University of Arkansas students who would be vulnerable solely because they are under 18 years of age.
- d) The research involves no more than minimal risk to subjects and any such risk is clearly outweighed by the benefits of the research.
- e) The results of research are not to be published or disseminated; rather, the research is being conducted with the intent of furthering reasonable educational or administrative goals.
- f) No records which identify the subjects by name or would permit such identification to be made are to be kept beyond 30 days past the end of the academic semester in which the research takes place.
- g) Implied or actual consent is obtained from all subjects.

### **9.02 Human Subjects Committee Review**

Any research which is reviewed by a Human Subjects Committee and meets all of the following conditions is exempt from further review:

- a) The research is not conducted, supported or otherwise subject to regulation by any federal department or agency.

- b) No subjects who are members of vulnerable populations are involved. For this purpose, students enrolled at the University of Arkansas shall not be deemed to be children, even if they are under the age of 18.
- c) The research involves no more than minimal risk which is clearly outweighed by the benefits of the research.
- d) Implied or actual consent is obtained from all subjects or their representatives (in addition to any consent obtained from a parent or guardian of a child).
- e) The research fits into at least one of the following categories:
  - 1) The research satisfies the requirements for instructor or administrator review, but the Researcher has elected Human Subjects Committee review or the rules of the academic Unit require such review.
  - 2) The research is conducted in commonly accepted educational settings, and involves normal educational practices, such as research on instructional strategies or the effectiveness of techniques, curricula, or classroom management methods.
  - 3) The research uses educational tests (cognitive, diagnostic, aptitude, achievement), and information is recorded in such a manner that subjects cannot be identified or if subjects can be identified there is no possibility that their responses could place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing.
  - 4) The research: (i) does not involve children; and (ii) involves surveys and/or interviews, unless the survey involves sensitive aspects of the subject's own behavior or there is the possibility that subjects can be identified and their responses could place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing.
  - 5) The research involves observation of public behavior, and does not involve the observation of children unless the Researcher does not participate in the activities being observed.
  - 6) The research involves taste and food quality evaluation and consumer acceptance studies, and either (i) wholesome foods without additives are consumed or (ii) any food ingredients are at or below the level and

for a use found to be safe, and any agricultural chemical or environmental contaminants are at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

- 7) The research involves only the collection or study of existing data, documents, records, which are publicly available and the information is recorded by the researcher in such a manner that the subjects cannot be identified.
- 8) The research involves only minor changes in previously approved research not involving any increase in risk to subjects.
- 9) The research involves the study of data previously obtained in compliance with this policy and these procedures (whether or not in a manner which originally required Instructor or Administrator review, Human Subjects Committee approval or IRB approval), but which is to be used in a new way, without any risk that subjects can be identified.

### 9.03 Expedited IRB Review

Any research which is reviewed by a Human Subjects Committee and receives preliminary approval for expedited review, and which meets all of the following conditions or any research which is submitted directly to the IRB because there is no Human Subjects Committee and which meets all of the following conditions:

- a) The research involves no more than minimal risk which is clearly outweighed by the benefits of the research.
- b) Implied or actual consent is obtained from all subjects or their representatives (in addition to any consent obtained from a parent or guardian of a child).
- c) There is no possibility that subjects can be identified or their responses could 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 are implemented so that any risks related to invasion of privacy or breach of confidentiality are no greater than minimal.

- d) The research fits into one or more of the following categories and the Human Subjects Committee has clearly indicated its opinion as to which of these categories the research fits into:
- 1) The research satisfies the requirements for Instructor or Administrator review, but the Researcher or the academic Unit has elected IRB review.
  - 2) Clinical studies of drugs for which an investigational new drug application (21 CFR Part 312) is not required; or clinical studies of medical devices for which an investigation device exemption application (21 CFR Part 812) is not required or the medical device is cleared/approved for marketing and is being used in accordance with its cleared/approved labeling.
  - 3) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    - a) From healthy, nonpregnant adults who weigh at least 100 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an eight week period and collection may not occur more frequently than two times per week; or
    - b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight week period and collection may not occur more frequently than two times per week.
  - 4) Prospective collection of biological specimens for research purposes by non-invasive means.

Examples: (i) hair and nail clippings in a non-disfiguring manner; (ii) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (iii) permanent teeth if routine patient care indicates a need for extraction; (iv) excreta and external secretions (including sweat); (v) uncannulated saliva collected either in an unstimulated fashion or by chewing gum-base or wax or by applying a dilute citric solution to the tongue; (vi) placenta removed at delivery; (vii) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (viii) supra- and subgingival dental plaque and calculus,

provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

(ix) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (x) sputum collected after saline mist nebulization.

- 5) Collection of data through non-invasive 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: (i) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (ii) weighing or testing sensory acuity; (iii) magnetic resonance imaging; (iv) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; and (v) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual, or if individual may voluntarily cease exercise at any time.

- 6) 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).
- 7) Collection of data from voice, video, digital, or image recordings made for research purposes.
- 8) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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

#### 9.04 Full IRB Review

Any of the following research requires full IRB review:

- a) Research involving more than a minimal level of risk to the subjects;
- b) Research not qualifying for a lesser level of review; or
- c) Research where the Researcher, the Human Subjects Committee, or the Chair of the IRB requests full review.

#### 9.05 Appellate Review

An ad hoc appeal Appellate Institutional Review Board may be established by the Vice Chancellor for Academic Affairs to act as an appeal body when a Researcher chooses to appeal a decision made by the IRB.

## 10.0 PROCEDURES FOR REVIEW

### 10.01 Process for Instructor or Administrator Review

- a) Research projects which are subject to review only by the Instructor or Administrator under Section 9.01 need not be forwarded to the IRB.
- b) The Human Subjects Committee in the department, school or college with which the Researcher is affiliated may impose review requirements and/or require that records be kept. The Researcher is responsible for checking with the Human Subjects Committee or, if none, the Unit Executive in question to ensure compliance with any such requirements.

### 10.02 Process for Human Subjects Committee Review

- a) Research projects which are subject to review by the Human Subjects Committee Review must be submitted in writing by the Researcher on the Protocol Form which appears in Appendix A to this document, before the research begins.
- b) The Human Subjects Committee must review the protocol in a timely fashion, giving the Researcher an opportunity to appear before the Committee, at the option of the Researcher. Before final consideration of the protocol, a determination on the ethical considerations and the scientific merit of the research must be made by the Human Subjects Committee itself.
- c) If the Human Subjects Committee determines that the research qualifies for review by the Human Subjects Committee and is exempt from further review, the Research Approval Form shall be signed by the Chair of the Human Subjects Committee, unless the Chair has an interest in the research in which case any member of the Human Subjects Committee may sign the Form. Research may begin as soon as the Researcher receives a signed copy of the Research Approval Form. The Human Subjects Committee shall immediately send a copy of the Protocol Form together with an executed copy of the Research Approval Form to the IRB Program Manager.
- d) If the Human Subjects Committee determines that the research requires Expedited Review or Full Review by the IRB, or cannot decide what type of review the research requires, the procedures applicable to Expedited or Full Review, as the case may be, shall apply. The Human Subjects Committee may

not disapprove the research, and if it declines to approve the research, it must submit the protocol for review by the IRB if the Researcher so requests.

- e) In any event, should the IRB elect to review any protocol and find that the research does not comply with the policies and procedures in this document, the IRB may require the Researcher to stop the research or to change the way in which the research is conducted, notwithstanding prior approval by a Human Subjects Committee.

### 10.03 Process for Expedited Review

- a) Research projects which are subject to review by the IRB shall be submitted in writing by the Researcher, on the Protocol Form which appears in Appendix A to this document, to the Human Subjects Committee if there is one sitting in the applicable department, school or college, or if there is no such committee, directly to the IRB Program Manager. This submission must be complete and approval received from the IRB before the research begins.
- b) If the Protocol Form is submitted to a Human Subjects Committee, and that Committee determines that the research qualifies for Expedited Review by the IRB, the form shall so indicate. In this case, the form may be signed by any sitting member of the Human Subjects Committee, specifically indicating the reason why the Human Subjects Committee believes the research is entitled to expedited status. The Human Subjects Committee shall immediately send a copy of the Protocol Form together with the Research Approval Form to the IRB Program Manager, who sends it to that member of the IRB specifically designated to work with that HSC by the IRB Chair. After review, the designated IRB member forwards the Protocol and Research Approval forms to the IRB Program Manager. Research may not begin until the Researcher receives a signed copy of the Research Approval Form from the IRB.
- c) If the Protocol Form instead is submitted directly to the IRB Program Manager, the Protocol shall be assigned to a specifically designated member of the IRB, who shall review the Protocol, and may sign the Approval Form on behalf of the IRB, specifically indicating the reason why the research is entitled to expedited status. The signed form shall be returned to the IRB Program Manager, who shall keep a copy and send a copy to the Researcher. In this case, research may not begin until the Researcher receives the signed copy of the Research Approval Form from the IRB.

- d) The designated member of the IRB may not disapprove the research, and if the reviewer declines to approve the research, he or she must submit the protocol for review by the IRB if the Researcher so requests.

#### 10.04 Process for Full IRB Review

- a) Research projects which the Researcher, the Human Subjects Committee, or the IRB member assigned to review a protocol believes are subject to Full review must be submitted to the IRB Program Manager in writing by the Researcher, on the Protocol Form which appears in Appendix A to this document. Any research involving more than minimal risk must be submitted for full review. This submission must be complete and approval received before the research begins.
- b) The IRB shall be convened, and shall evaluate whether the research should be approved. The IRB shall have full authority to require modifications to the protocol as a condition for approval. The full IRB may disapprove research projects, subject to the right of appeal as provided herein. Research may not begin until the Researcher receives a signed copy of the Research Approval Form from the IRB.

#### 10.05 Process for Appeal

Any appeal shall be to an ad hoc review board established by the Vice Chancellor for Academic Affairs as provided herein. Such appeal shall be governed by such rules and procedures as the ad hoc review board may establish.

### **11.0 SPECIAL REQUIREMENTS FOR RESEARCH INVOLVING CHILDREN**

#### 11.01 Special Requirements for Consent

All research involving children must satisfy the special consent requirements of Section 5.06.

#### 11.02 Criteria for Approval by the IRB

- a) When children are included in research involving not greater than minimal risk, the IRB or Human Subjects Committee must find that adequate provisions are made for soliciting the assent of children and the permission of their parents.
- b) When children are included in research in which the IRB finds that more than minimal risk is presented by an intervention or procedure that holds out the prospect of direct benefit to the individual subject or by a monitoring procedure that is likely to contribute to the subject's well-being, the IRB must find that (i) the risk is justified by the anticipated benefit to the subjects; and (ii) the relation of

the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (iii) adequate provisions are made for soliciting the assent of children and permission of their parents and guardians.

- c) When children are included in research in which the IRB finds that more than minimal risk is presented by an intervention or procedure that does not hold out the prospect of direct benefit to the individual subject, or by a monitoring procedure that is not likely to contribute to the subject's well-being, the IRB must find that (i) the risk represents a minor increase over minimal risk; and (ii) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; and (iii) the intervention or procedure is likely to yield generalizable information about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the subject's disorder or condition; and (iv) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.
- d) When children are included in plans for research not otherwise approvable, (i) the IRB must find that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and (ii) the appropriate funding agency must make a similar determination; and (iii) the research must be conducted in accordance with sound ethical principles; and (iv) adequate provisions must be made for soliciting the assent of children and the permission of their parents or guardians.
- e) The requirements for children who are wards of the state or any other agency, institution, or entity do not differ from those for other children if the research involves no more than minimal risk. If the research involves greater than minimal risk but presents the prospect of direct benefit to individual subjects, the IRB may require appointment of an advocate for each child who is a ward in addition to any other individual acting on behalf of the child as guardian or *in loco parentis*. Children who are wards of the state or any other agency, institution, or entity can be included in research described in subsections c) and d) above only if the research is related to their status as wards, or is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

## 12.0 SPECIAL REQUIREMENTS FOR RESEARCH INVOLVING FETUSES, PREGNANT WOMEN, AND HUMAN *IN VITRO* FERTILIZATION

### 12.01 IRB Approval Required

Only the full IRB can approve research involving fetuses, pregnant women, and human *in vitro* fertilization.

12.02 General Limitations The only conditions under which research involving fetuses, pregnant women, and human *in vitro* fertilization is permitted are the following:

- a) Appropriate studies in animals and nonpregnant individuals have been completed;
- b) The purpose of the research is to meet the health needs of the mother of the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the research;
- c) Individuals engaged in the research will have no part in (i) any decisions as to the timing, method, and procedures used to terminate the pregnancy; and (ii) determining the viability of the fetus at the termination of the pregnancy;
- d) No procedural changes that may cause greater than minimal risk to the fetus or the pregnant women will be introduced into the procedure for terminating the pregnancy solely in the interest of the research; and
- e) No inducements, monetary or otherwise, may be offered to terminate the pregnancy for purposes of the research.

### 12.03 Additional Criteria for IRB Approval For Research Directed Toward Pregnant Women as Subjects

No pregnant woman may be involved as a subject in research unless:

- a) The risk to the fetus is minimal; or
- b) The purpose of the research is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimal extent necessary to meet such needs and the mother and father are legally competent and have given their informed consent after having been fully informed regarding the possible impact on the fetus, except that the father's informed consent need not be secured if:

- i) the purpose of the research is to meet the health needs of the mother; or ii) his identity or whereabouts cannot reasonably be ascertained; or iii) he is not reasonably available; or iv) the pregnancy resulted from rape.

#### 12.04 Additional Criteria For IRB Approval of Research Directed Toward Fetuses in Utero as Subjects

No fetus *in utero* may be involved as a subject in any research unless:

- a) The purpose of the research is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs; or
- b) The risk to the fetus imposed by the research is minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means.
- c) Such research may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (i) his identity or whereabouts cannot reasonably be ascertained; or (ii) he is not reasonably available; or (iii) the pregnancy results from rape.

#### 12.05 Additional Criteria for IRB Approval For Research Directed Toward Fetuses *Ex Utero*, Including Nonviable Fetuses, as Subjects

Until it has been ascertained whether a fetus *ex utero* is viable, a fetus *ex utero* may not be involved as a subject in research unless:

- a) There will be no added risk to the fetus resulting from the research and the purpose of the activity is the development of important biomedical knowledge that cannot be obtained by other means; or
- b) The purpose of the research is to enhance the possibility of survival of the particular fetus to the point of viability.
- c) No nonviable fetus may be involved as a subject in research unless: (i) vital functions of the fetus will not be artificially maintained; and (ii) experimental research, which of itself would terminate the heartbeat or respiration of the fetus, will not be employed, and (iii) the purpose of the research is the

development of important biomedical knowledge that cannot be obtained by other means.

- d) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the research only to the extent permitted by the other requirements listed above.
- e) Such research may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (i) his identity or whereabouts cannot reasonably be ascertained; or (ii) he is not reasonably available; or (iii) the pregnancy resulted from rape.
- f) Activities involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable state or local laws regarding such research.

#### 12.06 Modification or Waiver of Specific Requirements

Upon the request of a Researcher and with the approval of the IRB, the relevant federal agency may modify or waive specific requirements listed above in consultation with appropriate agencies and experts, and after reasonable opportunity for public comment.

### **13.0 SPECIAL REQUIREMENTS FOR RESEARCH INVOLVING INDIVIDUALS WITH COGNITIVE IMPAIRMENTS**

#### 13.01 IRB Approval Required

Only the IRB can approve research involving individuals with cognitive impairments.

#### 13.02 Special Concerns Where Research Involves Individuals with Cognitive Impairments

In determining whether a proposal involving individuals with may be exempt or expedited, the Researcher, the Human Subjects Committee, and the IRB will consider the issues of the Belmont Report with regard to a subject's autonomy and the risk to the subject. Decisions will be made on a case-by-case basis in accordance with the spirit and directions of the Belmont Report, and Researchers should not assume that such proposals will automatically be treated as exempt or expedited. Researchers are reminded that the consent of the subject is required, if possible, and where the subject is too impaired to give true informed consent, the guardian's consent must also be obtained. Even where the subject is too impaired to give consent,

however, efforts must be made to ensure that the subject is participating voluntarily, and the research must be terminated whenever the subject chooses not to continue.

### 13.03 Research Eligible for Expedited Review

Research involving individuals with cognitive impairments as subjects may, at the option of the Chair of the IRB, be approved on an expedited basis under Section 9.0 if the Research fits into one or more of the following categories. All other research involving individuals with cognitive impairments as subjects must be reviewed by the Full IRB.

- a) Research conducted in established or commonly accepted educational settings, involving normal education practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of, or the comparison among instructional techniques, curricula, or classroom management methods.
- b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to subjects.
- c) Survey or interview procedures.
- d) Observational research.

## **14.0 SPECIAL REQUIREMENTS FOR RESEARCH INVOLVING PRISONERS AS SUBJECTS**

### 14.01 IRB Approval Required

Only the IRB can approve research involving prisoners as subjects.

### 14.02 Definition of Prisoner within this Context

The term prisoner refers to any individual involuntarily confined or detained in a penal institution. It is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

### 14.03 Special Considerations When Research Involves Prisoners

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary or uncoerced decision whether to participate in research, additional safeguards are provided to prisoners involved as subjects of research.

#### 14.04 Composition of IRB when Prisoners are Involved

In addition to the criteria for IRB membership composition specified above, an IRB reviewing research involving prisoners will also meet the following requirements:

- a) A majority of the IRB members (exclusive of prisoner members) will have no association with the prison(s) involved, apart from their membership on the IRB; and
- b) At least one member of the IRB will be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.

#### 14.05 Permitted Research Involving Prisoners

Biomedical or behavioral research may involve prisoners as subjects only if the institution responsible for the conduct of the research has certified that the IRB has approved the research; and the proposed research involves solely the following:

- a) The study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
- b) The study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
- c) The study of conditions particularly affecting prisoners as a class, provided that the study may proceed only after relevant federal agencies have consulted with appropriate experts and published notice of their intent to approve such research; or
- d) The study of 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 these studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after relevant federal agencies have consulted with appropriate experts and published notice of their intent to approve such research.

- e) Except as provided in (a)-(d) of this section, biomedical or behavioral research may not involve prisoners as subjects.

#### 14.06 Additional Duties of IRB When Prisoners are Involved

In addition to the conditions specified for permissible research above, and in addition to all other responsibilities detailed for the IRB, the IRB will review and approve research involving prisoners only if it finds that:

- a) Any possible advantage accruing to the prisoner through his/her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such magnitude that his/her ability to weigh the risks of research against the value of such advantages in the limited choice environment of the prison is impaired;
- b) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- c) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the investigator provides to the IRB in writing justification for following some other procedure, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- d) The information is presented in language understandable to the subject population;
- e) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his/her parole; and
- f) Where the IRB finds that there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

## 15.0 REFERENCES

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Department of Health and Human Services, National Institute of Health, Office of Protection from Research Risks. (1983). "Protection of Human Subjects," Code of Federal Regulations. 45 CFR 46 Washington, DC.

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Trials of War Criminals Before the Nuremberg Military Tribunals. (1947). Superintendent of Documents, Washington, DC: U.S. Government Printing Office.

## 16.0 APPENDICES: FORMS

Appendix A — Protocol Form

Appendix B — Protocol Approval Form

Appendix C — Authority to Establish Unit Human Subjects Committee

Appendix D — Example of an Informed Consent Form

Appendix E — Continuing Review for IRB Approved Projects

## **APPENDIX A — PROTOCOL FORM**

**INSTITUTIONAL REVIEW BOARD  
UNIVERSITY OF ARKANSAS  
PROTOCOL FORM**

"The University Institutional Review Board is responsible for recommending policies and monitoring their implementation on the use of human beings as subjects for physical, mental, and social experimentation in and out of class. . . . Protocols for the use of human subjects in research, and in class experiments, whether funded internally or externally, must be approved by the IRB prior to the implementation of the human subject protocol. . . . Violation of procedures and approved protocols can result in the loss of funding by the sponsoring agency or the University of Arkansas and may be interpreted as 'scientific misconduct.'" (*Faculty Handbook*, p. 3-25).

Supply the information requested in items 1-14 as appropriate. **Type** entries in the spaces provided using additional pages as needed. In accordance with college/departamental policy, submit the original **and** one (1) copy of this completed protocol form and all attached materials to the appropriate Human Subjects Committee. In absence of an IRB-authorized Human Subjects Committee, submit the original **and** one (1) copy of this completed protocol form and all attached materials to the IRB Program Manager, Carol Rodlun, E214B ANSC.

1. Title of Project \_\_\_\_\_  
\_\_\_\_\_

2. (Students **must** have a faculty member supervise the research. The faculty member must sign this form and all researchers and the faculty advisor should provide a campus phone number.)

	Name	Department	Campus Address	Campus Phone
Principal Researcher	_____			
_____	_____			
Co-Researcher	_____			
_____	_____			
Co-Researcher	_____			
_____	_____			
Co-Researcher	_____			
_____	_____			
Faculty Advisor	_____			
_____	_____			

3. Researcher(s) status. Check all that apply.  
 Faculty    Staff    Graduate Student(s)    Undergraduate Student(s)

4. Project type  
 Faculty Research    Thesis/dissertation    Class Project    Independent Study    Honors Project

5. Is the project receiving extramural funding?  
 No    Yes. Specify the source of funds \_\_\_\_\_



\_\_\_\_\_ Children under 14

\_\_\_\_\_ Children 14-17

\_\_\_\_\_ UofA students  
(18yrs and older)

\_\_\_\_\_ Adult non-students

8. Anticipated dates for contact with participants:

First Contact \_\_\_\_\_

Last Contact \_\_\_\_\_

9. Informed Consent procedures: The following information must be included in any procedure: purpose of the research; identification of researchers and their institutional affiliation; expected duration of the subject's/respondent's participation; how confidentiality will be ensured; that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits.

Signed informed consent will be obtained. **Attach copy of form.**

Modified informed consent will be obtained. **Attach copy of form.**

Other method (e.g., implied consent). **Please explain on attached sheet.**

Not applicable to this project. **Please explain on attached sheet.**

10. Confidentiality of Data: All data collected that can be associated with a subject/respondent must remain confidential. Describe the methods to be used to ensure the confidentiality of data obtained.

11. Will participants in the research be exposed to more than minimal risk? Minimal risk is defined as risks of harm not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Other than the contribution of new knowledge, describe the countervailing benefits of this research.

No  Yes. Describe any such risks or discomforts associated with the study and precautions that will be taken to minimize them.

12. Check all of the following that apply to the proposed research and supply the information requested on attached sheets:

- A. Deception of or withholding information from participants. Justify the use of deception or the withholding of information. Describe the debriefing procedure: how and when will the subject be informed of the deception and/or the information withheld?
- B. Medical clearance necessary prior to participation. Describe the procedures and note the safety precautions to be taken.
- C. Samples (blood, tissue, etc.) from participants. Describe the procedures and note the safety precautions to be taken.
- D. Administration of substances (foods, drugs, etc.) to participants. Describe the procedures and note the safety precautions to be taken.
- E. Physical exercise or conditioning for subjects. Describe the procedures and note the safety precautions to be taken.
- F. Research involving children. How will informed consent from parents or legally authorized representatives as well as from subjects be obtained?
- G. Research involving pregnant women or fetuses. How will informed consent be obtained from both parents?
- H. Research involving participants in institutions (prisoners, mentally disabled, etc.). Specify agencies or institutions involved. Attach letters of approval.
- I. Research approved by an IRB at another institution. Specify agencies or institutions involved. Attach letters of approval.
- J. Research that must be approved by another institution or agency. Specify agencies or institutions involved. Attach letters of approval.

13. Checklist for Attachments

The following are attached:

- Consent form (if applicable) or
- Letter to participants, written instructions, and/or script of oral protocols indicating clearly the information in item #9.
- Letter(s) of approval from cooperating institution(s) and/or other IRB approvals (if applicable)
- Data collection instruments

14. Signatures

I/we agree to provide the proper surveillance of this project to insure that the rights and welfare of the human subjects/respondents are protected. I/we will report any adverse reactions to the committee. Additions to or changes in research procedures after the project has been approved will be submitted to the committee for review. I/we agree to request renewal of approval for any project when subject/respondent contact continues more than one year.

Principal Researcher \_\_\_\_\_ Date \_\_\_\_\_

Co-Researcher \_\_\_\_\_ Date \_\_\_\_\_

Co-Researcher \_\_\_\_\_ Date \_\_\_\_\_

Co-Researcher \_\_\_\_\_ Date \_\_\_\_\_

Faculty Advisor \_\_\_\_\_ Date \_\_\_\_\_

## **APPENDIX B — PROTOCOL APPROVAL FORM**

**PROTOCOL APPROVAL FORM**

(To be returned to IRB Program Manager with copy of completed protocol form and attachments)

**Human Subjects Committee use only** (In absence of IRB-authorized Human Subjects Committee, send protocol to IRB)

Recommended Review Status

**F** Human Subjects Committee can approve as exempt because this research fits in the following category of research as described in section 9.02 of the IRB policies and procedures (**cite reasons for exemption**): \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Signature:

For the Human Subjects Committee \_\_\_\_\_

\_\_\_\_\_

\*\*\*\*\*  
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**F** Expedited Review by a designated member of the IRB because this research fits in the following category of research as described in section 9.03 of the IRB policies and procedures (**cite reasons for expedited status**): \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Signature:

Recommendation for expedited review( for the IRB) \_\_\_\_\_ Date \_\_\_\_\_

\_\_\_\_\_

\*\*\*\*\*

**F** Requires Full Review by the IRB

Signature:

For the Human Subjects Committee \_\_\_\_\_ Date \_\_\_\_\_

\_\_\_\_\_

**IRB/RSSP Use Only**

Project Number \_\_\_\_\_

Received RSSP \_\_\_\_\_

Sent to: \_\_\_\_\_ Date: \_\_\_\_\_

Final Status:

**F** Determined to be **Exempt** because this research fits in the following category of research as described in section 9.02 of the IRB policies and procedures (cite reasons for exemption): \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**F** Approved as **Expedited** under Section 9.03 of the IRB policies and procedures because (cite reasons for expedited status) \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_.

Signature: \_\_\_\_\_ Date \_\_\_\_\_  
IRB (for the Committee)

**F** Approved by **Full** review of the IRB as meeting requirements of Institutional Policies and Procedures

Signature: \_\_\_\_\_ Date \_\_\_\_\_  
IRB Chairperson

## **APPENDIX C**

### **AUTHORITY TO ESTABLISH UNIT HUMAN SUBJECTS COMMITTEE**

# AUTHORITY TO ESTABLISH UNIT HUMAN SUBJECTS COMMITTEE

To comply with the revised *University of Arkansas Policy and Procedures Governing Human Subjects Research* (1999), academic units (which may be either a college, a school, or a department) may establish Human Subject Committees (HSC) which have authority to review human subjects protocols for the purpose of ascertaining whether such research is to 1) be exempt from Institutional Review Board (IRB) review, or 2) should be forwarded to the IRB with the recommendation for either expedited or full review. Such HSC will be recognized by the IRB only after this form has been completed and returned to and approved by the IRB.

1. List the members of the HSC (*note that the HSC must consist of at least 2 members, one of which should have at least 2 year's experience sitting on the IRB or a HSC or, for academic years 1999-2000 and 2000-01, two years service on an established Departmental Review Committee which existed before the implementation of the 1999 Policies and Procedures*). Please indicate who is designated as the chairperson (if applicable).

_____	_____
_____	_____
_____	_____

2. Briefly describe, and attach to this form, the policies and procedures of the unit's HSC. Please address the following points:

- a. Does the HSC have a regular meeting scheduled to review the unit's submitted protocols or does it meet as needed?
- b. Does the HSC review the protocols as a group or does one member generally perform the review and sign for the HSC? Is there a procedure for how protocols are assign to members?
- c. Is it the department's policy that protocols **MUST** be submitted to the HSC first before forwarding to IRB (in cases where IRB review is required for research to proceed)? If it is mandatory, any protocols submitted to the IRB without appropriate HSC signatures will be returned to the investigator.
- d. What procedure is in place to assure that protocols will **not** be reviewed by a HSC member listed as a researcher or a faculty advisor?

3. By signing below the Unit Executive assures the IRB that:

- a. All HSC members have access to the most current version of U of A's Policies and Procedures concerning research with human subjects and will strictly adhere to them when reviewing protocols,
- b. The HSC will verify that all protocols include all the appropriate signatures with the understanding that at least one faculty member must be listed (and sign) as either a researcher or an advisor,
- c. That the protocol includes a copy of the document by which informed consent is obtained from participants and a copy of the data collection instrument in the case of a questionnaire or test, or a list of example questions or script in the case of research involving interviews. Where the data collection involve other methods, assure that enough details are submitted with the protocol so that the reviewer can adequately evaluate the degree of risk the subject will be subjected to.

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Signature of Unit Executive \_\_\_\_\_ Date \_\_\_\_\_

Approval of IRB \_\_\_\_\_ Date \_\_\_\_\_

(IRB Chairperson)

**APPENDIX D — EXAMPLE OF AN INFORMED CONSENT FORM**

## INFORMED CONSENT

*Title:* The Effects of Using a Computer Simulation in Geriatric Nursing on the Knowledge and Attitudes of Nursing Students

<i>Investigator(s):</i> Sally Mae Jones, M. S. N., Graduate Student June S. Smith, Ph.D., Faculty Advisor University of Arkansas College of Everything Important Department of All the Good Stuff 100 Important Building Fayetteville, AR 72701-1201 479-1-575-3333	Rosemary Ruff, Director Research & Sponsored Programs Research Compliance University of Arkansas 120 Ozark Hall Fayetteville, AR 72701-1201 479-575-3845 rruff @uark.edu
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*Description:* The present study will investigate what effect using a computer simulation in geriatric nursing has on student knowledge and attitudes. You will be assigned to one of two groups. You will be asked to complete a short survey of attitudes toward learning about and working with computers. You may be assigned to a group which will complete a computer simulation in geriatric nursing using the computers in one of the College of Education and Health Professions computer labs. If you are assigned to this group, you will complete the computer attitude survey a second time. All participants will then complete a 20-item multiple choice exam on a case study in geriatric nursing. Those participants who did not complete the computer simulation as part of the experiment will then have the opportunity to do so.

*Risks and Benefits:* The benefits include contributing to the knowledge base of the effects of computers on knowledge and attitudes. Use of the computer simulation will also give you experience reviewing information included in the Geriatric Nursing course. There are no anticipated risks to participating in the study.

*Voluntary Participation:* Your participation in the research is completely voluntary. There are no payments for college credits for participating.

*Confidentiality:* You will be assigned a code number that will be used to match the knowledge and attitudes surveys. All information will be recorded anonymously. Only the researcher will know your name, but will not divulge it or identify your answers to anyone. All information will be held in the strictest of confidence. Results from the research will be reported as aggregate data.

*Right to Withdraw:* You are free to refuse to participate in the research and to withdraw from this study at any time. Your decision to withdraw will bring no negative consequences — no penalty to you.

*Informed Consent:* I, \_\_\_\_\_, have read the description,  
(please print)

including the purpose of the study, the procedures to be used, the potential risks and side effects, the confidentiality, as well as the option to withdraw from the study at any time. Each of these items has been explained to me by the investigator. The investigator has answered all of my questions regarding the study, and I believe I understand what is involved. My signature below indicates that I freely agree to participate in this experimental study and that I have received a copy of this agreement from the investigator.

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Signature	Date
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**NOTE TO INVESTIGATOR(S):** If the study includes children, you must not only have the consent of the parents or guardians, but also the consent of the children from the time they are old enough to give it (around 4 or 5 years of age). Below age 7 or 8, consent may be verbal.

## **APPENDIX E — CONTINUING REVIEW FOR IRB APPROVED PROJECTS**

**CONTINUING REVIEW FOR IRB APPROVED PROJECTS**

TO: Researcher's Name [faculty and/or student]

FROM: Whoever, Program Manager  
Institutional Review Board (IRB)

SUBJECT: Request for Continuation Review for Protocol Number 00000: "Title of Protocol" approved on month 00, 200?

***Complete the following:***

1. Study has been completed; please terminate approval. Yes\_\_\_ No\_\_\_ (If "yes," you do not have to complete the rest of the form but **please return it to IRB Program Manager.**)

***Complete the following items if "No" was check for item #1:***

2. Anticipated ending date of research project \_\_\_\_\_.
3. Number of subjects enrolled to date \_\_\_\_\_.
4. Estimated number of additional participants \_\_\_\_\_.
5. Have any adverse events occurred during the conduct of the research that have not yet been reported the IRB? Yes \_\_\_ No \_\_\_ (If yes, attach a detailed description.)
6. Have any unanticipated problems occurred involving risks to the subjects or others? Yes \_\_\_ No \_\_\_ (If yes, attach a detailed description.)
7. Have any subjects withdrawn from the research? Yes \_\_\_ No \_\_\_ (If yes, attach a detailed description.)
8. Have there been any complaints about the research? Yes \_\_\_ No \_\_\_ (If yes, attach a detailed description.)
9. Have any significant new findings developed during the course of the research which may relate to the subjects willingness to continue to participate? Yes \_\_\_ No \_\_\_ (If yes, attach a description of the new findings and discuss their implications for subject participation.)
10. If there have been any changes in key personnel since your last review, please attach a sheet listing those changes and the following information for each person: Name, Address, Phone Number, and Responsibility in Project.
11. If substantive changes need to be made in the original protocol, on additional sheets describe briefly the changes and explain why they are essential. **NOTE: No changes in the research procedures should have occurred without previous IRB review. Approval from the IRB must be obtained before implementing any changes.**

***Attachments***

1. Two copies of this completed form
2. Two copies of the currently approved consent form, cover letter and survey instrument (if applicable).
3. Two copies of correspondence concerning any modifications to the protocol that have been approved by the IRB since this study was initiated.

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Received by RSSP \_\_\_\_\_

Approved \_\_\_\_\_ Date \_\_\_\_\_  
(IRB Reviewer)