

**POLICY AND PROCEDURES FOR THE  
PROTECTION OF  
HUMAN RESEARCH SUBJECTS  
AT  
FAYETTEVILLE STATE UNIVERSITY**

**Approved: April 9, 1997**

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## I. INTRODUCTION

Fayetteville State University, in compliance with Federal regulation, Title 45 Code of Federal Regulations Part 46 (revised June 18, 1991) establishes this *Policy and Procedures for the Protection of Human Research Subjects*. This policy and its procedures applies to all research involving human subjects conducted under the auspices of a department, school, or research unit, regardless of funding status.

Every person conducting research involving human subjects at Fayetteville State University is expected to be aware and implement the university's *Policy and Procedures for the Protection of Human Research Subjects*. As a part of the university's primary mission of education, every person involved in any phase of research in which human subjects are included must be educated to the principles and values which govern such research activities.

Included in this document are "Procedures to Conduct Research Involving Human Subjects." Failure to abide by the policy and procedures will be considered a violation and shall be dealt with accordingly.

Regulations extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State of North Carolina law and is not directly regulated by 45CFR46.

## II. SCOPE

There are three basic ethical principles that are particularly relevant to the protection of human subjects. They are: (1) Respect for Persons, (2) Beneficence, and (3) Justice.

- A. Respect for Persons -- recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy (an autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.)
- B. Beneficence -- obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks or harm.
- C. Justice -- fairness in the distribution of research benefits and burdens.

### III. DEFINITION OF TERMS

- X *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- X *Children* are persons who have not attained the legal age (18) for consent to treatments or procedures involved in the research in which the research will be conducted.
- X *Exempt* means the proposed research poses minimal risks to subjects and satisfies other criteria listed in Section V, subsection A, of this document.
- X *Expedited Review* is a review of minimal risk by at least one member of the Human/Animal Rights Committee of a research proposal that meets the criteria of minimal risks as listed in Section V, subsection B of this document.
- X *Guardian* means an individual who is authorized under State of North Carolina law to consent on behalf of a child.
- X *Human Subjects* is a living person about whom a researcher obtains (1) data through intervention or interaction or (2) identifiable private information.
- X *Human/Animal Rights Committee* is duly authorized to review human subjects use.
- X *Informed Consent* is consent to participate in research based on a full and complete information of the research and attendant risk.
- X *Interaction* includes communication or interpersonal contact between investigator and subject.
- X *Intervention* includes physical, social, and behavioral procedures by which data are gathered and manipulations of the subject's environment that are performed for research purposes.
- X *Minimal Risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- X *Parent* means a child's biological or adoptive parent
- X *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.
- X *Research* is a systematic investigation designed to develop or contribute to generalized knowledge.
- X *Vulnerable Subjects* are subjects especially susceptible to coercion or undue influence (including but not limited to the mentally or physically infirm, children, the illiterate, prisoners and parolees, addicts, and the poor).

#### IV. HUMAN/ANIMAL RIGHTS COMMITTEE

The Human Rights in Research Committee (HRRC) is a standing subcommittee of the Research Council. HRRC is composed of five members with varying backgrounds to promote competent and adequate review of research activities commonly conducted by the institution. Specifically, membership is composed of at least one person not affiliated with the University and at least one person whose primary concerns are in a nonscientific area. HRRC 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 HRRC. These individuals are nonvoting.

##### Functions and Operations of HRRC (45CFR46.108 & 109)

X Except when an Expedited Review Procedure is used, HRRC shall review proposed research at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.  
[45CFR46.108(b)]

X Review of Research (45CFR46.109)

HRRC shall:

- A. review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
- B. require that information given to subjects as part of informed consent is in accordance with Federal Regulations, and may require that information, in addition to that specifically mentioned in 45CFR46.116, be given to the subjects when in HRRC's judgment the information would meaningfully add to the protection of the rights and welfare of the subjects.
- C. require documentation of informed consent or may waive documentation in accordance with 45CFR46.117.
- D. notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure HRRC approval of the research activity. If the research activity is disapproved, it shall include in its written notification a statement of the reasons for the disapproval and give the investigator an opportunity to respond in person or in writing.
- E. conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

## V. CRITERIA FOR EXEMPTED, EXPEDITED, AND FULL HRRC REVIEW

Fayetteville State University requires that ALL research involving human subjects must be submitted for review and approval. This includes theses, dissertations, externally and internally funded research, and other types of research.

### A. Exempted from Further HRRC Review

Research is exempted from further HRRC review if it entails no more than A minimal risk@ and falls in one or more of the following categories [45CFR46.101(b), Revised June 18, 1991].

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless: (1) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (2) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedure, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section if: (1) the human subjects are elected or appointed by public officials or candidates for public office; or (2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (1) public benefit or service programs; (2) procedures for obtaining benefits or services under those programs; (3) possible changes in or alternatives to those programs or procedures; or (4) possible changes in methods or levels of payment for benefit or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

HRRC cannot exempt research with children that falls under category 2 above unless such research involves (a) educational tests, or (b) observation of public behavior when the investigator does not participate in the activities being observed.

It is the responsibility of HRRC to ensure that research involving human subjects follow the guidelines established in 45CFR46, especially 46.116, General Requirements for Informed Consent (see Section VII.) This applies to research considered to be exempt from further HRRC review, as well as research given expedited and full review.

Before a proposal is determined to be exempt from further review, HRRC may request additional information about the proposal, and/or may require changes in the consent form, subject recruitment methods, or other aspects of the procedure.

If HRRC requires changes in forms or clarification of other issues, this is not considered an expedited or full review. Research that falls under the exempt category will be exempted from further review following necessary clarifications, and no other action will be needed on the part of the investigator unless there are changes in the research protocol. Exempted research does not require an annual renewal nor progress reports.

#### B. Expedited Review

Non-exempted research is eligible for expedited review if it involved no more than “minimal risk” AND it falls in one or more of the following categories.

1. Voice recordings made for research purposes such as investigations of speech defects.
2. Moderate exercise by healthy volunteers.
3. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
4. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
5. Any other category specifically added to this list by the U.S. Department of Health and Human Services (HHS) and published in the *Federal Register*.

Expedited projects are approved for a period of no more than one year. At the end of that period investigators will be asked to submit a progress report. Continuing projects must be reviewed by HRRC.

C. Full HRRC Review

All other research involving human subjects must undergo full committee review.

**VI. WHAT TO SUBMIT FOR COMMITTEE REVIEW AND WHERE**

(Applies to exempt, expedited, or full committee review)

A. What to Submit:

1. HRRC Application (one original and one copy) (see Appendix) and Computer-based Training (CBT) Certificate (see web site <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp?action=register>)  
NOTE: Student applicants must a copy of their CBT Certificate as well as a copy of their advisor's CBT Certificate.

2. Proposal (include)
  - (a) Introduction (brief)
  - (b) Review of Related Literature (if appropriate)
  - (c) Research Design and Procedures (see Section B below)
  - (d) Informed Consent (if appropriate) (See Section VII)
  - (e) Copy of instrument(s) to be used

B. Research Design and Procedures

To ensure completeness of the research design, the following must be included:

1. Provide a detailed description of the proposed involvement of human subjects in the work as indicated in your research proposal.
  - (a) Describe the characteristics of the subject population, including their anticipate number, age range, and health status.
  - (b) Identify the criteria for inclusion or exclusion of any subpopulation.
  - (c) Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable.
2. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
3. Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.

4. Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternate treatments and procedures that might be advantageous to the subjects.
5. Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
  - (a) Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.
  - (b) Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.
6. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

If HRRC determines that any part of the request for approval is missing, the researcher will be requested to resubmit and include any missing materials. Further, HRRC, in the event of full committee review, may request the researcher to be present at the meeting in which the researcher's proposal is being reviewed.

#### C. Where to Submit

All request for approval must be submitted to Sponsored Research & Programs, located in the Continuing Education Building.

### VII. INFORMED CONSENT

Informed consent must be obtained from each subject who is legally, mentally, and physically able to provide it. The consent must be in written form and signed by the subject (or his/her legally authorized representative) UNLESS HRRC finds either (1) the consent document is the only link between the subject and the research and principle harm would come from a breach of confidentiality, or (2) there is no risk or harm to the subject, other than minimal risk and the study involves no procedures for which written consent is normally required outside of a research setting. For subjects not able to provide informed consent themselves, written informed consent must be obtained from others (e.g., parents, guardians.) Under certain circumstances HRRC may waive the informed consent provision. [45CFR46.116(c)]

The researcher shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

#### A. Written Consent

If consent is written, a copy of the consent form should be included in the proposal. Essential elements of a written consent form are provided below.

A written consent form should include the elements below and it should relate to a specific study. It should not be a standard form. It must be written in simple language so as to be easily

understood by persons with no legal, medical or scientific background. A general rule is that potential subjects must be given all information that might reasonably be expected to influence their willingness to participate. The researcher should provide two (2) copies of the consent form: one for the subject, parent, or guardian to sign and return, and the other for the researcher to keep.

#### Essential Elements of a Written Consent Form

1. A simple descriptive title of the research project.
2. Name and telephone number of the researcher and faculty advisor, if researcher is a student.
3. A statement that the study involves research.
4. An explanation of the general purpose of the research.
5. An explanation of the procedures to be followed.
6. A statement concerning the approximate number of subjects involved in the study.
7. A description of discomfort, risks, or benefits (if any) that can be reasonably expected. (The researcher may choose to describe the importance of the knowledge that may be gained.)
8. A statement concerning the expected duration of the subject's participation (if applicable).
9. A statement of any costs to the subject (if any).
10. A statement, if applicable, about any monetary or other inducements for participation and how these will be prorated.
11. A statement describing how confidentiality will be maintained and who will have access to the data.
12. A statement that the subject is free to refuse to participate or to withdraw from the research activity at any time without penalty and without jeopardy.
13. A statement that the researcher or faculty advisor (include name) may be contacted (list phone number) if the subject has any further questions about the study.
14. A statement containing information about questions or concerns that the subject may have but does not wish to talk with the researcher or faculty advisor. This statement may be similar to the following:

You may contact Kimberlee Hyman of the Sponsored Research office if you have any questions concerning the processing of your Humans Subjects request at 910-672-1569/672-1570 or [khyman@uncfsu.edu](mailto:khyman@uncfsu.edu).

You may contact the Dr. Joseph F. Johnson, Chair of the Human Right Review Committee at the following address or telephone number at any time during this study if you have questions or concerns about your rights as a research subject:

Dr. Joseph F. Johnson  
Fayetteville State University  
1200 Murchison Road  
Fayetteville, NC 28301-4298  
(910) 672-1700 (v) (910) 672-2110 (F) or [jjohnson@uncfsu.edu](mailto:jjohnson@uncfsu.edu) (email)

15. Signature of the subject indicating consent. (Signature of parents or legal guardians for subjects who cannot legally represent themselves.)

16. When appropriate, a simply worded assent form for children who can read and write should be prepared for their signature. This is in addition to the consent form signed by the parent or guardian.

#### B. Oral Consent

When consent is obtained orally, all the applicable elements of informed consent should be verbally explained to the subject before he or she agrees to participate. In addition, HRRC requires that a written document be given to participants in studies that involve oral informed consent. A copy of this document should be included in the proposal. The document should provide a description of the study and also include the name and phone number of the researcher and faculty advisor (if the researcher is a student), and the phone number of the Dean of Graduate Studies. In some questionnaire studies or surveys, this document may be included as a preface to the questionnaire or survey.

### VIII. CHILDREN AS RESEARCH SUBJECTS

A. Children are permitted to be research subjects, according to 45CFR46.406, if:

1. there is no greater than minimal risk, OR
2. An intervention or procedure holds out the prospect of direct benefit for the individual subject, or a monitoring procedure is likely to contribute to the subject's well-being, OR
3. there is only a minor increase over minimal risk and the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the subject's disorder or condition, AND 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 situation.

#### B. Consent by Parents or Guardian

1. According to the Federal regulations, for research falling under #1 and #2 above, the permission of ONE parent is sufficient.

2. Permission from BOTH parents is required for category #3 above unless one parent is deceased, unknown, incompetent or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
3. HRRC requires parental consent to be written.

C. Children's Assent

In addition to parental permission, Federal regulations require in most instances that a child who is sufficiently mature to comprehend his/her participation in the research project be offered the opportunity to give assent. Generally speaking, the Federal government has interpreted this rule as *requiring* assent of children seven years of age or older, and encourages assent of younger children if there is reason to believe it would be meaningful. "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, *absent affirmative agreement*, be construed as assent. Affirmative agreement is necessary. Under some circumstances written assent may be appropriate, but generally verbal assent will be sufficient.

When a written form is used, it should contain a simple explanation of the research project, including possible benefits, risks, and safeguards. A copy of the assent form should be included in the proposal.

If children are involved in the research project, parent(s) or guardian(s) must sign a written consent form regardless of whether there is a child's assent.

## APPENDICES

## CONSENT FORM CHECKLIST

(Approved: September 5, 2000)

**NOTE: This checklist is for your use in the preparation of the consent form.**

	ITEMS	YES	NO	COMMENTS
1	Does the title of this study appear at the top of the consent form?			
2	Does the Consent Form state the general purpose of the study, what the researcher expects to learn?			
3	In the case of students, does the Consent Form state how the study relates to your program of work (project, thesis, dissertation)?			
4	Does the Consent Form indicate to the subject his/her rights to choose to participate?			
5	Is there a statement indicating why and how this subject was selected as a possible participant? Are population and sample clearly identified? Is the number of potential subjects identified?			
6	Does the Consent Form explain the procedure to be followed in implementing the project (time, frequency, nature of information, questions asked, observations made)?			
7	Is there a statement which addressed possible discomforts and inconveniences that the participant might expect?			
8	Does the Consent Form describe any participants risks that are involved in the project? For example, if pregnancy presents a risk, have specific precautions been taken?			
9	If there are any benefits to the subject, is this identified in the Consent Form?			
10	If the project required that any standard treatment is withheld, is this clearly designated in the Consent Form? If alternative treatment are available, are they described?			
11	Is subject confidentiality explained in the Consent Form? Is use of any tapes and other material (e.g. audio tapes, videotapes, photos, use of data for other purpose) explained and the disposition of materials clear?			
12	Are compensation and cost included in the project, and are they identified specifically for the subject?			
13	Does the Consent Form indicate where the subject can contact the investigator to have questions answered?			
14	If the author of the proposed study is a student, is the supervising professor identified and a phone number given?			
15	Does the Consent Form indicate to the subject that he/she can withdraw at any time from the project? Does the Consent Form indicate any procedures that might be necessary for orderly withdrawal from a complex study? Are situations where the subject=s participation can be terminated described?			
16	Does the Consent Form indicate to the subject that he/she is entitled to a written copy of said form?			
17	Does a statement exist expressing that the client=s signature indicated willingness to participate?			
18	Does the Consent Form have a place for subject=s signature, investigator=s signature, parent=s signature (if needed), and dates?			
19	Is there provision for child assent (required for children age 7 and above)?			

**SAMPLE CONSENT FORM**  
**(Approved September 5, 2000)**

**[Title of your study]**

You are invited to participate in a study of **[a brief description of your study]**.

My name is **[put your name in]**, and I am a **[your position with the University, e.g., a faculty member]** at Fayetteville State University, Department of **[your department]**. I hope to gain a better understanding about **[a brief description of what you hope to learn from this study]**. You will be one of **[number]** participants chosen to participate in this study.

If you decide to participate, you may be asked to participate in the following phases of data collection: **[list the phases that the subject will be involved with; give a brief description of each task the subject will have to perform]**. You may decide not to participate in any task or you may decide to not answer any questions on the questionnaire, inventories, or during the interviews that make you feel uncomfortable or embarrassed **[list any other risks that the subject maybe exposed to]**; you may stop your participation at any time during the study. There is **[no monetary compensation or monetary compensation (chose one). If there is monetary compensation or credit given specify the amount.]** for participation in this study. I will make all reasonable efforts to accommodate your schedule and time constraints.

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. Audio tapes and transcription, completed questionnaires, journals, and scores on inventories will be kept under lock and key. All audio tapes and video tapes will be erased following data collection, analysis, and manuscript development. At no time will your name or institution be identified in reports, papers, or publications.

Your decision whether or not to participate will not affect your future relations with Fayetteville State University. If you decide to participate, you are free to discontinue participation at any time.

You are making a decision whether or not to participate. Your signature indicates that you have read the information provided above and that you have decided to participate. You may withdraw at any time after signing this form, should you choose to discontinue your participation in this study.

If you have questions, please ask me. If you have additional questions later, I will be happy to answer them. You can reach me at **[your phone number]** or write me at **[your name and address]**. If you have questions or concerns, at any time during this study, about your rights as a research subject you may contact:

Dr. Joseph F. Johnson, Chair Human Rights and Research Committee  
Fayetteville State University  
Fayetteville, NC 28301-4298  
(910) 672-1700

You may keep a copy of this form.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date

# FAYETTEVILLE STATE UNIVERSITY

## REQUEST FOR APPROVAL FOR THE USE OF HUMAN SUBJECTS IN RESEARCH

### Check Sheet

*Please Type*

<b>Principal Investigator (PI):</b>
<b>Co-Investigator(s):</b>
<b>University:</b>
<b>Department:</b>
<b>Title of Proposed Research:</b>

### Instructions

*Please complete and use as a cover to the request. All materials must be typed and stapled in the upper left hand corner and submitted to Sponsored Research & Programs located in the Continuing Education Building. Please submit a signed original and one copy of all documents.*

1.  Completed and Signed Application (Turn in 1 original and 1 copy)
2.  Certificate(s) of Human Subjects Training (<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp?action=register>) – Mandatory for each submission (PI and Advisor)
3.  Proposal/Research Plan
4.  Informed Consent (if applicable)
5.  Debriefing Statement (if applicable)
6.  Instrument(s)

Check appropriate answer

- Survey
- Educational Test (Cognitive, Diagnostic, Aptitude, Achievement, etc.)
- Other (please explain) \_\_\_\_\_
- Psychological Assessment (Identify) \_\_\_\_\_
- Experimental Manipulation (Identify) \_\_\_\_\_
6.  Other Relevant Materials (please list)
7. Does research involve children?    Yes             No

If yes, in what capacity?

- Educational Tests
- Observation
- Other (please explain briefly)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Department Chair or Dean=s Signature

\_\_\_\_\_  
Date



