

Institutional Review Board: Human Rights in Research Committee (HRRC)

**Application for the Use of Human Subjects in
Research**

**Fayetteville State University
Office of Sponsored Research and Programs
Office: 910-672-1570
www.uncfsu.edu/research**

[2009-2010]

I. Instructions: 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. A signed original and one copy of all documents is required. Omission of documents will yield an incomplete application and prolong your review process. **Responses are rendered within 14 business day to the Principal Investigator.**

<p>Principal Investigator (PI): This individual assumes overall responsibility for 1) development and submission of this IRB application, 2) obtainment of legally effective informed consent and assent (as applicable) from prospective subjects by <u>all</u> authorized personnel listed on this IRB application, 3) the performance of research interventions, and 4) the presentation or publication of the data.</p>		
<p>PI Status: (check one): <input type="checkbox"/> FSU Faculty <input type="checkbox"/> FSU Staff <input type="checkbox"/> FSU Undergraduate Student <input type="checkbox"/> FSU Graduate Student <input type="checkbox"/> Visiting Scholar <input type="checkbox"/> Non FSU Affiliation (Specify Institution): (Complete appropriate section below)</p>		
<p>Office Location or Mailing Address: (This is the address where all IRB correspondence will be sent.)</p>		
<p>Department:</p>		
<p>Project Title:</p>		
<p>Phone Number: ()</p>		<p>University Email:</p>
<p>Co-Investigator #1:</p>		<p>Department:</p>
<p>Co Investigator #2:</p>		<p>Department:</p>
<p>Study Personnel: These individuals are not involved in the development and submission of the application to the IRB, but may be involved in conducting procedures and obtainment of legally effective informed consent/assent. All participating personnel must have sufficient knowledge about the protocol to facilitate effective interaction with the subject as well as complete the Human Subjects Training. If personnel have not been identified please list TBD in the Name column.</p>		
Names (or TBD*)	Position	Department
<p>Is funding being sought for this research? <input type="checkbox"/> Yes <input type="checkbox"/> No Funding Source(s): _____</p> <p>If yes, you must (1) submit a complete copy of that proposal as soon as it is available and (2) provide one copy of the funding announcement and all relevant forms, instructions, etc., with your original copy of this application. Does the funding agency require notification of Institutional Review Board approval? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Project period dates _____ to _____</p> <p><i>This is required information, must be future dates - after you have received final IRB approval to conduct your research.</i></p>		
<p>Other Institutional Review Boards Does the research involve another institution or site? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>- If yes, please list all institutions and sites: _____</p> <p>- Has any other IRB approved this project? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please provide a copy of the approval letter with this application. If No, will any other IRB be asked for approval? <input type="checkbox"/> Yes (please specify which IRB) <input type="checkbox"/> No</p>		
<p>Certificate(s) of Human Subjects Training All Principal Investigators, Faculty Advisors, Co-Investigators, Research Assistants, Graduate Assistants, personnel and volunteers associated with the study must complete the training. NOTE: certificates from the following locations will be accepted: <input type="checkbox"/> NIH Office of Extramural Research - http://phrp.nihtraining.com</p> <p style="margin-left: 20px;"><input type="checkbox"/> Office of Human Rights Protection - http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp</p> <p style="margin-left: 20px;"><input type="checkbox"/> Collaborative Institutional Training Initiative (CITI) – subscription is required</p>		

 Principal Investigator's Signature

 Date

The activity described herein is in conformity with the standards set by our department and I assure that he Principal Investigator has met all departmental requirements for review and approval of this research.

 Department Chair's or Dean's Signature

 Date

II. COMPLETE THIS SECTION IF THE PRINCIPAL INVESTIGATOR IS A GRADUATE STUDENT (NOTE: Graduate Faculty Status is required for all Thesis/Dissertation Chair or Advisors.)

Check one: Thesis Dissertation Other _____

Has the Thesis/Dissertation Committee approved the proposal? Yes Date Approved: ____/____/____ No

Name of Thesis/Dissertation Advisor: _____

Advisor's Department: _____ Advisor's Phone No.: _____

III. COMPLETE THIS SECTION IF THE PRINCIPAL INVESTIGATOR IS AN UNDERGRADUATE STUDENT

Check one: Class Project/Paper Honors Project Independent Study Other _____

Name of Research Supervisor/Class Instructor: _____

Department: _____ Phone No.: _____

Course Name (if applicable): _____

IV. INVESTIGATOR ASSURANCES AND AFFIRMATION OF COMPLIANCE:

I agree to follow the procedures outlined in the summary description and any attachments to ensure that the rights and welfare of human participants in my project are properly protected. I understand that the study will not commence until I have received approval of these procedures from the IRB: HRRC; I have complied with any required modifications in connection with that approval. I understand that additions to or changes in the procedures involving human participants, or any problems with the rights or welfare of the human participants must be promptly reported to the IRB. I further understand that if the project continues for more than one year from the approval date, it must be re-submitted as a renewal application.

***NOTE:** You (the investigator/researcher) are required to notify the IRB:HRRC if any substantive changes are made in your research prospectus/protocol, if any unanticipated adverse events are experienced by subjects during your research, and when your project has ended. **Important:** If your project lasts longer than one year, you (the investigator/researcher) are required to notify the Office of Sponsored Research and Programs in writing of *Notice of Project Ending* or *Request for Continuation* at the end of each year. See the OSRP website for the proper form at <http://uncfsu.edu/research> Failure to notify the IRB of the above may result in disciplinary action under the FSU campus student and faculty misconduct policy. You are required to keep copies of the informed consent forms and data for at least three years.

***(Required for all Investigators):** I affirm the accuracy of this application, and I accept responsibility for the conduct of this research, the supervision of human participants, and maintenance of informed consent documentation as required by the IRB: HRRC.

Investigator's Signature

Date

Co-investigator's Signature

Date

V. APPROVAL OF FACULTY ADVISOR/SPONSOR

***(Required for all faculty advisors)** By signing - you as Faculty Advisor affirm the accuracy of your students application and accept responsibility for the conduct of this research, the supervision of the researcher (student) in ethical conduct of research, and maintenance of informed consent documentation as required by the IRB.

Supervisor or Committee Chair Signature (for student investigator)

Date

VI. DESCRIPTION OF PARTICIPANTS: Anticipated Number to Enroll (if applicable): _____ Gender: Males Females

Please check all that apply

- Fayetteville State University employees/students
- Prisoners – include authorization from appropriate correctional department(s)
- Minors (17 years of age or younger)- include child's assent and parent's consent forms
- Pregnant Women
- Vulnerable populations, which include, but are not limited to persons with physical or mental disabilities, cognitive impairments (including persons in institutions)
- Use of Protected Health Information
- Non English speaking subjects
- Persons otherwise dependent on the researcher (such as students of the researchers, etc.)
- Students in a school system. Name of School/System _____
- Other populations (explain) _____
- Existing Data (specify source) _____
 - ___ Data already collected for another research study
 - ___ Data already collected for administrative purposes (e.g., Medicare data, hospital discharge data)
 - ___ Medical records (custodian may also require form, e.g., HD-974 if UNC-Health Care System)
 - ___ Electronic information from clinical database (custodian may also require form)
 - ___ Patient specimens (tissues, blood, serum, surgical discards, etc.)
 - ___ Other (specify): _____

Which of the following best describes your proposed activity?

- Program evaluation?
- QI/QA for internal purposes?
- Training grants?
- Other? Explain _____
- Class projects for educational purposes only?
- Center or core grants (to establish infrastructure)?
- Demonstration projects?

VII. IDENTIFIERS: (check all of the identifiers that will be collected and associated with your study).

- a. ___ Names
- b. ___ Telephone numbers
- c. ___ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
- d. ___ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code
- e. ___ Fax numbers
- f. ___ Electronic mail addresses
- g. ___ Social security numbers
- h. ___ Medical record numbers
- i. ___ Health plan beneficiary numbers
- j. ___ Account numbers
- k. ___ Certificate/license numbers
- l. ___ Vehicle identifiers and serial numbers (VIN), including license plate numbers
- m. ___ Device identifiers and serial numbers (e.g., implanted medical device)
- n. ___ Web universal resource locators (URLs)
- o. ___ Internet protocol (IP) address numbers
- p. ___ Biometric identifiers, including finger and voice prints
- q. ___ Full face photographic images and any comparable images
- r. ___ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher
- s. ___ **NONE** of the above

VIII. DO NOT COMPLETE THIS SECTION - For Sponsored Research & Programs Use Only

Proposal Number: 2010 P _____

Date Received: _____ / _____ / _____

Date Reviewed: _____ / _____ / _____

Name of Reviewer: _____

Review Status:

Does NOT meet the federal definition of research

Exempted Categories: 1 2 3 4 5 6

Expedited Categories: 1 2 3 4 5 6 7

FULL COMMITTEE REVIEW ACTION

APPROVED: Chairman or Designee of HRRC DATE: _____

CONDITIONALLY APPROVED: Chairman or Designee of HRRC DATE: _____

NOT APPROVED Chairman or Designee of HRRC DATE: _____

Explanation/Notes/Comments: (Use reverse side if necessary)

VIX. Please REMOVE the information within the blue brackets and only provide your response in that area. Do not copy chapters associated with your thesis or dissertation to the application. All information must be incorporated into the application itself. Use as many separate sheets of paper as you need to respond fully respond to the questions in this section to minimize delays in your review.

A. PURPOSE AND RATIONALE:

[Provide a summary of the background information, state the research question(s), and tell why the study is needed. If there is no external funding proposal, provide a rationale and literature review, including references. If a complete rationale and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here.]

B. RESEARCH SUBJECTS:

[Information is required even if existing data is being used. Describe the sources of potential participants, recruitment strategies, and how and where you will contact them. If participants are chosen from records please describe of the type of records as well as documentation of approval for use of the records. Describe all relevant characteristics of the participants with regard to age, ethnic background, sex, institutional status (i.e., patients or prisoners), and their general state of mental and physical health. Attach a copy of any and all recruitment materials to be used e.g. advertisements, bulletin board notices, email scripts, letters, phone scripts, or URLs. Explain who will approach subjects to take part in the research and what will be done to protect the subjects' privacy in this process. Clarify if participants will receive any inducements before or rewards after the research study (stipends, gift cards, reimbursement for travel or parking, etc.) and the source of sponsorship. Be aware that payment over a certain amount may require the collection of the subjects' Social Security Numbers. Describe the subjects about whom personal information will be collected. Where active recruitment is required, please describe inclusion and exclusion criteria. Where the research involves extraction or collection of personal information, please describe from whom the information will be obtained and what it will include.]

C. STUDY DESIGN, METHODOLOGY AND PROCEDURES:

[Describe the research study and if applicable all personnel to be associated with the study. Explain expertise of Investigator, any co-investigators or other key personnel listed in the application, and how it relates to their specific roles on the study team. Discuss the study design (including hypotheses and/or research questions); study procedures; sequential description of what subjects will be asked to do; assignment of subjects to various arms of the study if applicable; how data are to be collected (questionnaire, interview, focus group or specific procedure such as physical examination, venipuncture, etc.). Include information on who will collect data, who will conduct procedures or measurements. Indicate the number and duration of contacts with each subject and location; outcome measurements; and follow-up procedures. Attach a copy of all questionnaires, interview guides, instruments and flyers. If applicable, please provide documentation of use authorization from instrument create or proof of purchase.]

D. DATA ANALYSIS:

[Describe the data to be used for the research study to include, if applicable, an explanation of the type of identifiers that will be collected. Tell how the qualitative and/or quantitative data will be analyzed. Explain how the sample size is sufficient to achieve the study aims. This might include a formal power calculation or explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies). Letters of authorization from agency officials must be included.]

E. CONFIDENTIALITY OF DATA:

[Describe procedures for maintaining confidentiality of the data you will collect or will receive. What procedures will be used to safeguard identifiable records of individuals and protect the confidentiality and

privacy of participants? If this is not possible, state why. Describe how you will protect the data from access by those not authorized. How will data be transmitted among research personnel? Where relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs). Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. Describe your plan to destroy identifiers, if you will do so.]

F. RISKS AND BENEFITS:

[Describe in detail the immediate or long-range risks to participants, if any, that may arise from the procedures used in this study. Risks may be embarrassment, physical, psychological, social, legal, or economic. They would include side effects, risks of placebo, risks of normal treatment delay, etc. Indicate any precautions that will be taken to minimize these risks. Describe what will be done to minimize these risks. Describe procedures for follow-up, when necessary, such as when subjects are found to be in need of medical or psychological referral. If there is no direct interaction with subjects, and risk is limited to breach of confidentiality (e.g., for existing data), state this. Also describe the anticipated benefits to participants and to society from the knowledge that may be reasonably expected to result from this study. If there is no direct benefit to the individual subject, say so here and in the consent form (if there is a consent form). Do not list monetary payment or other compensation as a benefit.]

G. INFORMED CONSENT:

[Informed consent can be in either written or oral format. If you request a waiver of informed written informed consent, please state your justifications (Please note that waiver of informed consent is only granted in limited circumstances and therefore an informed consent should always be prepared and submitted with your application on University letterhead). If an oral consent is planned, attach a copy of the text of the statement. The consent should include identification of 1) the researcher(s), 2) explanation of the nature and purpose of the study and the research method, 2) duration of research participation, 3) a description of how confidentiality/anonymity will be maintained, 4) mention of participants' right to withdraw their participation and their data from the study at any time without penalty, 5) information about the reasonably foreseeable risks and benefits (If there are no foreseeable risks and benefits please state so), 6) the voluntary nature of his or her participation, 7) who to contact regarding questions about participants' rights or injuries, 8) and a statement that the research has been approved by the Institutional Review Board at Fayetteville State University. Attach a copy of the written informed consent, web script or oral informed consent, with this application. For Non-English speaking subjects please include a translation of the informed consent in their language. (See OSRP Informed Consent checklist and other sample forms at www.uncfsu.edu/research). Non-English tools must be accompanied by a letter from an authorized translator of its accuracy.]

H. Protected Health Information (PHI):

[If the researcher needs to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a *limited waiver of HIPAA authorization*. If this applies to your study, please provide the following information: (a) Under this limited waiver, you are allowed to access and use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects; (b)What information are you planning to collect for this purpose? (c) How will confidentiality/privacy be protected prior to ascertaining desire to participate? (d) When and how will you destroy the contact information if an individual declines participation?]

I. DEBRIEFING STATEMENT:

[The participants also should be debriefed about their behavioral response(s) to the study. In the debriefing statement describe the reason(s) for conducting the research, the way to obtain the general results of the study, and the person(s) and/or professional resources to contact if the participant has any questions or concerns as a result of his/her participation.]

- J. **GENERALIZABLE KNOWLEDGE:** Will the proposed activity result in the development of or contribution to generalizable knowledge? _____ yes _____ no If no, please explain.
[Generalizable knowledge might include information presented to a broader audience or published with the intent of drawing scientific conclusions or increasing the body of scientific knowledge. This would not typically describe projects that are intended solely for internal assessment purposes, such as quality improvement, quality assurance, and program evaluations.]