Proposal Number: _____

McNeese State University
Human Subjects Institutional Review Board
APPLICATION FOR REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS

For HSIRB approval, submit your proposal to: Dr. Peggy Wolfe, McNeese State University HSIRB, College of Nursing and Health Professions, Box 90415, Lake Charles, LA 70609. Materials may also be submitted electronically to pwolfe@mcneese.edu. If you have questions or wish to check the status of your proposal, please call Dr. Peggy Wolfe at 337-475-5822. **ALL APPLICATIONS MUST BE TYPED.**

Please fill in this application form completely. [Do not state, "refer to pages in proposal" for requested information.] Attach additional information to this form only after the space available for response to a given question has been used.

RESPONSIBLE FACULTY OR STAFF SUPERVISOR/INVESTIGATOR:

_____

DEPARTMENT AND CAMPUS ADDRESS:

_____

_____

PHONE: _____
EMAIL: _____

NAME OF INVESTIGATOR(S) (if different):

_____

DEPARTMENT AND CAMPUS ADDRESS:

_____

_____

PHONE: _____
EMAIL: _____

☐ **Thesis**
☐ **Research Project**

TITLE OF PROPOSAL/PROJECT:

_____

In making this application, I certify that I have read and understood the guidelines and procedures developed by McNeese State University for the protection of human subjects and that I will comply with both the letter and the spirit of the University's policies. I further acknowledge my responsibility to report any significant changes in the protocol involving human subjects and to obtain written approval from the Human Subjects Institutional Review Board for these changes prior to making these changes. I understand that HSIRB approval extends for one year, and if the project continues beyond the date of approval, then I will notify the HSIRB and request a renewal.

_____ _____ _____ _____
Instructor's Signature **Date** **Student's Signature** **Date**

For Thesis:

_____ _____
Graduate School Dean's Signature **Date**

This proposal has been reviewed and approved by McNeese State University Human Subjects Institutional Review Board for compliance with the Code of Federal Regulations 45 CFR 46, Protection of Human Subjects and as amended.

_____ _____
Approved: **Date**
HSIRB Chair's Signature

Proposal Number: _____

TITLE OF PROPOSAL/PROJECT:

_____

1. **IS THIS A:**
   - ☐ New Project
   - ☐ Continuation
   - ☐ Renewal _____
   - ☐ Change in Procedure for a Continuing Project _____

2. **FUNDING:** **Funding Agency:**
   - ☐ Externally Funded _____
   - ☐ Internally Funded _____
   - ☐ No internal funds or external funds are requested

3. **DATE ON WHICH YOU PLAN TO BEGIN DATA COLLECTION:** _____

4. **ANTICIPATED DATE OF COMPLETION FOR PROJECTS/PROPOSALS:** _____

5. **STATUS OF PRINCIPAL INVESTIGATOR:**
   - ☐ Faculty
   - ☐ Staff
   - ☐ Graduate Student
   - ☐ Undergraduate Student ____

NOTE: Students, be sure to include the required letter from your supervising professor--see checklist at the end of this application. Students who are conducting research of an invasive nature must ensure that their project/proposal has close faculty supervision and that raw data will be secured and destroyed.

6. EXEMPT/EXPEDITED REVIEW: If you are applying for Exempt or Expedited status, indicate the category by which the study qualifies for exempt or expedited status in the Rationale section below. (See the General Guidelines in the HSIRB Policy - A. Exempt/Expedited/Full Review)

- ☐ Exempt
- ☐ Expedited
- ☐ Uncertain

RATIONALE (see CATEGORIES of exempt/expedited review in "Guidelines"):

7. ABSTRACT: Summarize the research in abstract form; include the purpose(s) of the study, hypotheses/research questions, sampling procedure, subjects, data collection tools/procedures, and interventions/treatments as appropriate. The abstract can be identical or similar to the summary required when submitting to the funding source. Briefly outline, in particular, what will be done to research subjects.

8. SUBJECT POPULATION:

a. Will any of the following be <u>primary</u> subjects (subjects selected specifically for their status indicated below):

	Yes	No		Yes	No
Minors	☐	☐	Minorities	☐	☐
Institutionalize Persons	☐	☐	Low Income Persons	☐	☐
Pregnant Women	☐	☐	Physically Disabled	☐	☐
Women of Childbearing Age	☐	☐	Emotionally Disabled	☐	☐
MSU Students	☐	☐	Incompetent or Those with Diminished Capacity	☐	☐
University Students (Non-MSU Students)	☐	☐			

b. Number of subjects, including controls: _____

c. Are you associated with the subjects (e.g., your students, employees, subordinates, or patients)?

☐ Yes
☐ No

If yes, explain the nature of the association.

d. How will subjects be contacted and selected?

e. Will research subjects be compensated?

☐ Yes
☐ No

If yes, all information concerning payment, including the amount and schedule of payment, must be set forth in the informed consent form.

f. Will you be advertising for research participants?

☐ Yes
☐ No

If yes, attach a copy of the advertisement you will use. (See the General Guidelines in the HSIRB Policy - B. Advertising)

g. Describe your procedures and safeguards for insuring confidentiality or anonymity of the research subjects.(See the General Guidelines in the HSIRB Policy - C. Anonymity and Confidentiality) Include how data will be secured, reported, and when identifiable raw data will be destroyed.

9. VOLUNTARY PARTICIPATION/INFORMED CONSENT:
Describe your method or procedures for assuring that subject participation is voluntary. If subjects are children and they are capable of assent, describe provisions or provide copies of protocols for soliciting their assent as well as provisions for soliciting permission of their parent(s) or authorized representative.

Describe how and where informed consent will be obtained. A copy of the consent form to be signed by the subject or authorized representative (if applicable) and/or protocols for any explanation to be given to to the subjects should be attached to this application.

If no consent form is to be used, explain the procedure to be used to assure that participation is voluntary. If any information is withheld from subjects, identify and justify the withholding and describe debriefing plan, if any. (See the General Guidelines in the HSIRB Policy - D. Voluntary Participation and Informed Consent)

10. RISK: At what level of risk will the subjects be placed? (See the General Guidelines in the HSIRB Policy - E. Risk/Benefit)

- ☐ Minimal Risk
- ☐ More than Minimal Risk
- ☐ Uncertain_

RISK/BENEFIT RATIO: Describe and assess any potential risks (physical, psychological, social, legal, economic or other) and assess the likelihood and seriousness of such risks. The concept of "risk" includes risks to the subject's dignity and self respect. Justify the risks by assessing the potential benefits to be gained by the individual subjects, as well as benefits which may accrue to society in general as a result of the planned work.

Describe your procedures for protecting against or minimizing potential risks and an assessment of the likely effectiveness of these procedures.

11. CHECKLIST: Check off the items that you have included for the HSIRB review. If not applicable, state N/A.

☐ **Full Review:**

Eight (8) copies of the completed HSIRB application form, including all informed consent forms, questionnaires, tests, and other data collection tools to be used. (See below for specific items included with each form.)

OR

☐ **Exempt or Expedited:**

Three (3) copies of the completed HSIRB application form, including all informed consent forms, questionnaires, tests, and other data collection tools to be used. (See below for specific items included with each form.)

Of these copies, one remains on file with the HSIRB chair, one is sent to your academic dean, and the rest are returned to you.

AND BOTH OF THESE:

☐ One (1) complete copy of the full research proposal. Graduate students should furnish one copy of the "Methods" section of their thesis/dissertation (if available) in lieu of a research proposal. A proposal is a document explaining the purpose and procedures to be used in the study.

☐ A signed statement from the student's major professor/thesis committee chair stating that he/she has reviewed and approves the proposed project.

Each completed form includes:

☐ 1. Complete answers to questions #1 through #10.
☐ 2. A copy of your consent form and/or protocols for eliciting consent or assent, if needed (see questions #8e and #9).
☐ 3. A copy of your advertisement for subjects, if needed (see question #8f).
☐ 4. A copy of any questionnaires, tests, or interviews to be used as data collection tools. If a data collection tool exists only as a computer program, videotape, audio tape etc., a full and complete description of the tool is needed.
☐ 5. Documentation of mandatory HSIRB Training.
- Log on to Citiprogram and register your account at https://www.citiprogram.org.
- Select your affiliation institution: McNeese State University.
- Select and complete the seven modules in the following course: Biomedical Data or Specimen Only.
- Once completed you can print out a certificate of completion.

Adapted from UL Lafayette 04/02/06
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