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| **Proposal Number:** |  |

**McNeese State University Institutional Review Board**

**APPLICATION FOR REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS**

For IRB approval, submit your proposal to: Dr. Peggy Wolfe, McNeese State University IRB, College of Nursing, Box 90415, Lake Charles, LA 70609. 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.

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| RESPONSIBLE FACULTY OR STAFF SUPERVISOR/INVESTIGATOR: | | |  | NAME OF INVESTIGATOR(S) (if different): | | |
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|  | |  |  |  | |  |
| DEPARTMENT AND CAMPUS ADDRESS: | | |  | DEPARTMENT AND CAMPUS ADDRESS: | | |
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|  |  | |  |  |  | |
| PHONE: |  | |  | PHONE: |  | |
| EMAIL: |  | |  | EMAIL: |  | |

Thesis

Research Project

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| **TITLE OF PROPOSAL/PROJECT:** |
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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 Institutional Review Board for these changes prior to making these changes. I understand that IRB approval extends for one year, and if the project continues beyond the date of approval, then I will notify the IRB and request a renewal.

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|  |  |  |  |  |  |  |
| Instructor’s Signature |  | Date |  | Student’s Signature |  | Date |
|  |  |  |  |  |  |  |
| For Thesis: |  |  |  |  |  |  |
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| Graduate School Dean’s Signature |  | Date |  |  |  |  |

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

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| Approved:  IRB Chair’s Signature |  | Date |  |  |  |  |

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| **Proposal Number:** |  |

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| **TITLE OF PROPOSAL/PROJECT:** |
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**1. IS THIS A:**

New Project

Continuation

Renewal

Change in Procedure for a Continuing Project

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| --- | --- |
| **2. FUNDING:**  Externally Funded | **Funding Agency:** |
| 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. Students who are conducting research of an invasive nature must ensure that their project/proposal has close faculty supervision and how 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 GENERAL GUIDELINES - A. EXEMPT/EXPEDITED 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 primary 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) |  |  |  |  |  |

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| **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 (see Question #8).

**f. Will you be advertising for research participants?**

Yes

No

If yes, attach a copy of the advertisement you will use. (SEE INSTRUCTIONS - B. SUBJECT POPULATION: Advertising)

**g. Describe your procedures and safeguards for insuring confidentiality or anonymity of the research subjects.** (SEE INSTRUCTIONS - C. SUBJECT POPULATION: 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 INSTRUCTIONS - D. VOLUNTARY PARTICIPATION/ INFORMED CONSENT under IRB Specific Guidelines)

**10. RISK: At what level of risk will the subjects be placed?** (SEE INSTRUCTIONS - E. RISK/BENEFIT RATIO, p. 8)

**Minimal Risk More than Minimal Risk**  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 IRB review. If not applicable, state N/A.**

**Full Review:**

A1. ( ) Eight (8) copies of the completed IRB 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:**

A2. ( )

Three (3) copies of the completed IRB 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 IRB chair, one is sent to your academic Dean, and the rest are returned to you.

**AND BOTH OF THESE:**

B. 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.

C. 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. Copy of Certificate of education in responsibilities of researchers to protect human subjects (NIH intramural investigator education certificate is acceptable).

**Adapted from UL Lafayette 04/02/06**

**Revised 07/21/06; 11/14/07; 2/28/12**