Application for Review of Research Involving Human Subjects:

Expedited and Full Review Instructions & Form

Before completing this form, please be sure to check whether your research qualifies for exemption from IRB review (refer to the exempt research categories provided on the *Application for Exemption* form available on the RSCC IRB webpage). If your research qualifies as exempt, you do not need to complete this form! Instead, please complete the *Application for Exemption* form.

If your research does not qualify for an exemption, please submit your application to the Director of Institutional Research. Please be sure to answer all sections, marking "N/A" when a section does not apply to your research. Form begins on page 3.

I. **PROPOSED CATEGORY OF REVIEW**

Please refer to the handouts *Research Eligible for Expedited Review*, and *An Overview of the Three Research Classifications Used by the IRB* (available on the RSCC IRB webpage). Please specify the appropriate category of your research (i.e., expedited or full). Please briefly provide a rationale for the proposed category of review.

II. **EXTERNAL FUNDING**

If this project is not externally funded, type "N/A" and proceed to Section III.

If external funding is sought or was obtained for this project, please provide the following information:

1. Grant/Contract Submission Deadline/Award Date
2. Funding Agency
3. Sponsor ID Number (if known)

III. **RESEARCH OBJECTIVES**

Provide a brief description of the research objectives of your study.

IV. **DESCRIPTION AND SOURCE OF RESEARCH PARTICIPANTS**

How will you recruit/solicit participants for this study? Describe your participants. Describe the criteria (e.g., age, gender) for selection and exclusion. Approximately how many participants will you collect data from?

Explain the rationale for using any special groups, such as children, pregnant women, prisoners, students, cognitively impaired, institutionalized individuals, or any participants whose ability to give voluntary and informed consent may be questioned. Give a rationale for projects that restrict participants based on gender, age, etc.

Identify the source of your participants (school systems, hospitals, colleges and universities, private companies, religious groups, governmental entities, community groups, etc.) and describe the methods for recruiting participants. *Letters of permission are required from entities other than Roane State.* Letters of permission should authorize the investigators to contact potential participants, to use the facilities, or obtain records of that entity. These letters must accompany your application at the time of submission for review.

Disclose any relationship between researchers and participants - such as, teacher/student; employer/employee; or superintendent/principal/teacher.

If an incentive is to be used, identify the incentive for participation, payment procedures, and provide a rationale for using the incentive. Please keep in mind that highly valued incentives may be considered coercive by the IRB.

V. **METHODS AND PROCEDURES**

Please describe the research methods and data collection procedures you will use. Include descriptions of experimental manipulations, tests or measures, surveys, interviews, observations, photography, and video and audio recordings. *A copy of any tests, surveys, or other instruments should be included along with this application.*

If the project involves audio taping, videotaping or photography of participants, explain the need for these methods and describe how the data will be used. Describe how the film or tapes will be stored, and when and how they will be destroyed. Identify the individuals who will have access to the tapes or film, and on what basis they will have access. If the tapes or film are to be used in the future, explain the procedures for obtaining participants' informed consent for those uses, and the conditions under which the tapes or film would be used.

Describe how you will analyze and interpret the data.

VI. SPECIFIC RISKS AND PROTECTION MEASURES

Estimate the nature and amount of potential risk, stress, or discomfort for your participants. Describe the precautions you will take to reduce any of these risks. Describe whether your data is confidential or anonymous. Note that anonymity is only possible if the investigator cannot discover the participant's identity from data collected. In either case, describe how you will maintain the confidentiality of the participants' data. Identify security measures, such as limiting access to data, purging identification information from data, securing files, and other appropriate measures. Who has access to the data you collect? Where and how will the data be stored? All research documents (including data) should be stored for a period of at least three years after the research has been completed.

VII. BENEFITS

Evaluate the reasonableness of the risks stated in Section VI in relation to the anticipated benefits (e.g., desired outcomes), if any, to the participants and/or to society. If the risks are minimal, please state that the risks are minimal and include a statement of anticipated benefits. *Note that in most research projects, the only relevant benefits are those that contribute to generalizable knowledge in a field of research.* In these cases, participant benefits are incidental. Please do not inflate the significance of incidental benefits to participants in your application or your informed consent procedures.

Please note that payment for participation in research is an incentive for participation, and should *not* be considered a "benefit" of the research.

VIII. METHODS FOR OBTAINING "INFORMED CONSENT" FROM PARTICIPANTS

Please state the methods you will use to obtain informed consent, assent, or permission (if applicable) from participants or participants' legally authorized representatives. Clearly describe how you will seek consent from participants in a manner that allows them sufficient opportunity to consider whether to participate, and that minimizes the possibility of coercion or undue influence. **Please attach a copy of your informed consent letter or information sheet for IRB review. A sample consent form, and a template for creating consent forms, is available on the Office of Institutional Effectiveness and Research web page.** Please indicate how you will store signed consent documents. Signed consent documents must be kept on the Roane State campus for three years (e.g., in your office, or your advisor's office) following completion of the research.

IX. QUALIFICATIONS OF THE INVESTIGATOR(S)

Investigators must specify their relevant qualifications and those of other investigators involved in this project to perform the proposed research. Include qualifications of personnel working on portions of the research where special training, certification, or licensing is required for the performance of their tasks.

X. RESEARCH STUDY CHAIR/FACULTY ADVISOR

If applicable, please list the name, mailing address, phone number, and e-mail address for the chair or faculty advisor of this research project.

XI. IRB APPROVAL FROM ANOTHER INSTITUTION

If you are affiliated with another institution with a functioning IRB, please provide a copy of your IRB approval letter from that institution.

Application for Review of Research Involving Human Subjects: Expedited and Full Review

Research Study Title:

Proposed Start Date for Study: **Proposed End Date:**

Principal Investigator:

Institution, Organization, or Department:

Mailing Address:

Phone Number: **Email Address:**

Co-Investigator(s):

Institution, Organization, or Department:

Mailing Address:

Phone Number: **Email Address:**

I. PROPOSED CATEGORY OF REVIEW

Expedited ☐ **Full Review** ☐

II. EXTERNAL FUNDING

III. RESEARCH OBJECTIVES

IV. DESCRIPTION AND SOURCE OF RESEARCH PARTICIPANTS

V. METHODS AND PROCEDURES

VI. SPECIFIC RISKS AND PROTECTION MEASURES

VII. BENEFITS

VIII. METHODS FOR OBTAINING "INFORMED CONSENT" FROM PARTICIPANTS

IX. QUALIFICATIONS OF THE INVESTIGATOR(S)

X. RESEARCH STUDY CHAIR/FACULTY ADVISOR

XI. IRB APPROVAL FROM ANOTHER INSTITUTION (attach form)

XII. PRINCIPAL INVESTIGATOR'S ASSURANCES

(Please keep these assurances in your signed document.)

1. I certify that all of the information in this application is complete and correct to the best of my knowledge.
2. I understand, as Principal Investigator, that I have ultimate responsibility for the conduct and ethical performance of this study, the protection of the rights and welfare of all research participants, and that I will adhere to the RSCC IRB policy.
3. I certify that all individuals involved with the conduct of this study are qualified to carry out their specified roles and responsibilities and all will be in compliance with the collection and analysis of research data.
4. I agree to comply with the RSCC IRB policy, as well as all applicable federal, state and local laws regarding the protection of human subjects.
5. I agree to obtain informed consent in writing from all research participants, unless this requirement is waived by the RSCC IRB.
6. If I am unavailable to direct this research personally, I agree to arrange for a co-investigator to assume direct responsibility in my absence.
7. I will prepare and submit a Continuing Review Form to the IRB before the approval period has expired if it is necessary to continue this research project beyond the one-year time period approved by the RSCC IRB.
8. I will prepare and submit a final/close-out report (Change of Status Form) upon completion of this research project.

Principal Investigator (Printed):

Signature of Principal Investigator: **Date**:

IRB Approval (For Internal Use Only)

The IRB certifies that this research study meets the criteria for the following type of review:

Exempt Expedited Full Review

This IRB Director and/or the IRB Committee approval/disapproval actions are as follows with regard to this research study application:

Approved without reservation Yes No

Approved with minor modifications (feedback provided)

Approval deferred pending resubmission of the application with requested materials (feedback provided)

Disapproved (feedback provided)

If the project is not approved, the investigator can revise and resubmit the project or appeal the IRB's decision through the IRB chair.

Institutional Review Board Chair Name:

Signature of Institutional Review Board Chair:

Date:

IRB APPROVAL #:
***RESEARCH END DATE IS ONE YEAR AFTER THE IRB DATE LISTED ABOVE.**