Appendix C: IRB Application Form

Cover Sheet - The cover sheet provides basic information regarding the study under consideration and the principal investigator(s).

Student:	
Date:	
Address:	
Phone:	
Email:	
Faculty Chair:	
Degree:	
Project Title:	
Submission #1:	
Submission #2 (include rationale for 2nd attempt):	

Proposal Narrative - The proposal narrative is a detailed description of the study. Each of the sections in the narrative needs to be completed, or if a section does not apply write "N/A." Each of these sections contains critical information that allows the reviewer to evaluate the study. These sections need to be written in lay language, avoiding jargon and acronyms. Failure to follow these rules causes delays in processing the submission. The responses to these questions allow the IRB to quickly place the study in the appropriate review category (exempt, expedited, or full review). These questions have been developed to decrease the response time of the IRB.

Introduction

Describe the project, including how it will impact the practice of Public Health. Describe the purpose of the research and explain what the subjects are asked to do. Use simple terms and language understood by a person unfamiliar with the area of interest. Area-specific jargon should be avoided or explicitly explained. If using existing data or records, explain the sources of the data and the means of access to the data.

The broad purpose of this project is to . . .

Project Duration

State the starting date of the DrPH process through the expected completion date.

Research Questions

The primary research question for the proposed study is:

The sub-questions are:

1.
2.
3.

Subject Population

The subject population consists of: Number: Male_____Female _____Total_____Age Range: ___to ___

Special Characteristics

(e.g., student, teacher, administrator): _____

Location of Subjects

If research is conducted through community agencies written documentation of approval and cooperation from such an agency or school should accompany this application.

Recruitment

a. Describe how subjects are identified or recruited. Attach recruitment information, (i.e., advertisement, bulletin board notices, recruitment letters, etc.).
b. If subjects are chosen from records, indicate who gave approval for use of the records. If records and private medical or student records, provide the protocol for securing consent of the subjects of the records and approval from the custodian of the records.
c. Who makes the initial contact with subjects? Describe how contact is made.
d. Do subjects receive inducements before, or rewards after the study? (Include this information in your consent documents.)
e. If subjects are school children and class time is used to collect data, describe in detail the activity planned for non-participant. Who supervises those children? (This information must be included in the consent form.)

Confidentiality of Data

The researcher alone would keep and have access to any documents regarding the data provided by the participants. The Informed Consent form to be signed by each of the participants would state such particulars.

a. Describe provisions made to maintain confidentiality of data. Who has access to data?
b. Where is data stored and safeguarded for five years? If tape recordings are created, explain who has access and how the tapes are retained.

Approvals

The signatures below certify that:

1. The information provided in this application form is correct
2. The learner (researcher) must seek and obtain prior written approval from the IRB Committee for any substantive modification in the proposal.
3. Unexpected or otherwise significant adverse events in the course of this study must be promptly reported.

4. Any significant new findings which develop during the course of this study which may affect the risks and benefits to participation must be reported in writing to the IRB Committee and to the subjects.
5. The research may not be initiated until final written approval is granted.

This research, once approved, is subject to continuing review and approval by the IRB. The student/researcher must maintain records of this research according to IRB guidelines. If these conditions are not met, approval of this research could be suspended.

[Type Name]_____ _____
Student Date

As Faculty Chair of the DrPH Project Team, I attest that the proposal submitted is prepared for IRB approval.

[Type Name]_____ _____
Faculty Chair Date

Completed form and attachments should be submitted to your Faculty Chair.