



THE RESEARCH FOUNDATION
The State University of New York

Protocol # _____

**PROPOSAL ABSTRACT FOR RESEARCH
INVOLVING HUMAN SUBJECTS**

Request for Expedited Review Request for Full Board Review Request for Continuation

Researcher/Project Director: _____ Ext.: _____

Building/Room No.: _____ E-mail: _____

Faculty Sponsor (for student projects): _____

Project Title: _____

Project Dates: _____ to _____ Date of Submission: _____

Check one: Thesis Dissertation Faculty Research Student Research

Project Funding Source: _____

Please use the following format and place a \checkmark next to each to indicate that the information is complete and attached to this form.

A. PURPOSE, RESEARCH VARIABLES, AND POPULATION

Purpose of the study – State concisely and realistically what the study is intended to accomplish.

Background – Briefly state the background of the study and identify the main question the current study is intended to address.

Characteristics of the Subject Population – The following information should be provided:

- a. Age Range – What is the age range and why was it chosen?
- b. Sex – What is the sex of the subjects? If there is a restriction, provide the rationale.
- c. Number – What is the estimated number of subjects?
- d. Inclusion Criteria – What are the specific inclusion criteria?
- e. Exclusion Criteria – What are the specific exclusion criteria? Clear rationale should be provided for the exclusion of any particular population group, unless the title of the study reflects the restricted population range.
- f. Vulnerable Subjects – If vulnerable subjects will be included (children, pregnant women, fetuses, prisoners, mentally disabled persons), provide justification of the need to use these subjects in research.

B. METHODS AND PROCEDURES

Methods of Subject Selection – Describe the study’s method(s) of identification and recruitment of prospective subjects. Provide a copy of any planned advertisements.

Study Site – State the location(s) where the study will be conducted. Include the letter of approval to conduct the study from all non-BSC sites.

Methods and Procedures Applied to Human Subjects – Describe in detail the study design and all procedures (sequentially) to be applied to subjects. Attach copies of any instruments to be used, such as surveys, rating scales, or questionnaires.

C. RISKS/BENEFITS

Potential Risks – Identify the potential risks of the study. Specify the types and levels of risk.

Protection Against Risks – For all studies involving greater than minimal risk, specify the procedures for preventing or minimizing any potential risks.

Potential Benefits – Describe any potential non-monetary benefits of the study, both for subjects and for society in general.

Compensation for Participation – Describe any monetary or other forms of compensation which will be provided to subjects, and any conditions which must be fulfilled to receive compensation.

Alternatives to Participation – Describe any alternatives to participation in the study which might be advantageous to the subject. If the subjects are to receive academic credit for research participation, describe the alternatives available to earn equivalent academic credit.

Information Withheld – Identify the nature of any information to be purposely withheld from subjects, and provide justification for the non-disclosure.

Debriefing – Describe the procedure for post-study debriefing of subjects.

D. CONFIDENTIALITY

Describe explicitly how confidentiality of data will be maintained. If any information with subject identifiers will be released, specify the recipients. Include a statement that all data will be retained for at least three years in compliance with federal regulations.

E. COPY OF CONSENT FORM

See attached Sample Consent Form. Please note that an informed consent form addresses five critical points: 1) subject participation in the study is voluntary (provide a description of the procedure to be used if choosing not to participate); 2) a statement of the subject’s right to withdraw at any time and a clear description of the procedures for withdrawal from the study without penalty; 3) subjects are informed of the level of risk (from ‘minimal risk’ through the level appropriate to the study) and the means of protecting the subjects from known risks or minimizing the risk; 4) confidentiality is ensured; and 5) the means by which confidentiality is to be ensured is elucidated. While it is not mandatory that an Informed Consent Form is identical to the example, the five points listed above are critical elements of any form an investigator may develop. It is important to include sufficient specific information regarding the purpose and nature of your study to ensure that subjects are fully informed. A copy of the Informed Consent Form should be given to each subject who participates in the study. Please note: the IRB will not accept “blanket waivers” of the right to privacy. Subjects (or their legal agents) must sign a consent form for each research study.

Mailed surveys ordinarily receive expedited reviews and do not need consent forms except when one of the following conditions prevail: 1) the person’s name or other identifier is known to the researcher; or 2) the content of the survey puts the respondent at risk for emotional, physical, or other types of distress. If an informed consent form is not required, the researcher should use a cover letter to potential subjects which addresses all the elements of informed consent previously described. Please include a copy of this cover letter with your protocol.

**CRITERIA FOR APPROVAL FOR CONTINUATION
OF A RESEARCH PROTOCOL**

The Federal Regulations requires that an IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. Therefore, in order for the request for continuation to be properly evaluated, it should not merely be a re-submittal of the original protocol, but rather a summary of the research conducted to date. At a minimum the request for continuation should include:

- ▶ Request for extension
- ▶ Number of participants involved to date
- ▶ A description of any modifications being made to the study design
- ▶ A copy of the research instrument indicating any changes, if any, that are being made
- ▶ A copy of the consent form indicating any changes, if any, that being made
- ▶ An explanation of any adverse events or subject complaints during the previous approval period
- ▶ A brief summary of the findings to date

Number of subjects requested _____

Method (i.e., questionnaire, video/audio, observation, etc.) _____

Population (i.e., adults, minors, institutionalized, etc.) _____

Keyword (i.e., Family Health, Marine Biology, Speech Pathology, etc.) _____

The project identified above may be approved through an expedited review procedure because the research activities involve no more than minimal RISK as defined above, and the involvement of human subjects will be limited to one or more of the following:

- Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risk associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- Prospective collection of biological specimens for research purposes by noninvasive means.

- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt).
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt).
- Continuing review of research previously approved by the convened IRB as follows:
 - a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. Where no subjects have been enrolled and no additional risks have been identified; or
 - c. Where the remaining research activities are limited to data analysis.
- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Project Director's Certification
Program Involving HUMAN SUBJECTS

The proposed investigation (*research or training program*) involves the use of human subjects and I am submitting the complete application form and description of the project to the Institutional Review Board for Research Involving Human Subjects.

If the Board grants approval of this application, I agree to:

1. Abide by any conditions or changes in the project required by the Board.
2. Report to the Board any change in the research plan which affects the method of using human subjects before such change is instituted.
3. Report to the Board any problems which arise in connection with the use of human subjects.
4. Seek advice of the Board whenever I believe such advice is necessary or would be helpful.
5. Secure the informed, written consent of all human subjects participating in the project.
6. Cooperate with the Board designated in its effort to provide a continuing review after investigations have been initiated.

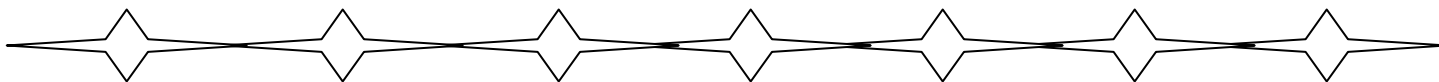
I have reviewed the Federal and State regulations concerning the use of human subjects in research and training programs and the guidelines of the State University College at Buffalo. I agree to abide by the regulations and guidelines aforementioned and will adhere to policies and procedures described in my application. I understand that changes to the research must be approved by the IRB before they are implemented.

Signature of Project Director

Signature of Department Chairperson

Date

Date



ACTION OF REVIEW BOARD

The Institutional Review Board for Research Involving Human Subjects has reviewed this application to ascertain whether or not the proposed project:

1. Provides adequate safeguards of the rights and welfare of human subjects involved in the investigations;
2. Uses appropriate methods to obtain informed, written consent;
3. Indicates that the potential benefits of the investigation substantially outweigh the risk involved.

BOARD DISPOSITION: Approved Disapproved Requested additional information

Chairperson, Institutional Review Board

Date