THE RESEARCH FOUNDATION
The State University of New York

Protocol # _____

PROPOSAL ABSTRACT FOR RESEARCH INVOLVING HUMAN SUBJECTS

Request for Continuation

☐ Expedited Review ☐ Full Board Review

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: _____

Research Involving Human Subjects Training Programs

In June 2000 PHS revised its' policy related to human subject protection and mandated that all key personnel involved in PHS-funded human subject research must receive formal instruction in human subject protection. The Federal Wide Assurance (FWA) that Buffalo State College currently has on file with the Office of Human Research Protections (OHRP) further stipulates that the same standards that are applied to federally-funded research will also be applicable to all nonfederal, departmental, and student research conducted at Buffalo State. Therefore, in order to satisfy this requirement, ALL individuals who are involved in research that involves human subjects at Buffalo State College are required to participate in a training program. If you completed human subject training, please attach your certificate to this form. If you still require training, please refer to the Research Foundation website:

http://www.rf.buffalostate.edu/rf/research_compliance/human_subjects/index.htm

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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, non-pregnant 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 of 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 non-research 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 of 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 Faculty Sponsor

_____ _____

Date | Date

_____

Signature of Faculty Chair

_____

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