THE RESEARCH FOUNDATION
The State University of New York

Protocol # _____

PROPOSAL ABSTRACT FOR RESEARCH
INVOLVING HUMAN SUBJECTS

Certificate of Exemption

Researcher/Project Director: Joseph L. Zawicki Ext.: 3800

Building/Room No.: Science #130 E-mail: zawickjl@buffalostate.edu

Faculty Sponsor (for student projects): _____

Project Title: Item Analysis Training Efficacy

Project Dates: 05/07/10 to 05/07/11 Date of Submission: 05/05/10

Check one: ☐ Thesis ☐ Dissertation ☑ Faculty Research ☐ Student Research

Project Funding Source: NA

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, FACULTY SPONSORS 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

Requested Information

Please use the following format and place a √ 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 (IF APPLICABLE)**

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.

Number of subjects requested 50-250

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

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

Keyword (i.e., Family Health, Marine Biology, Speech Pathology, **etc.**) assessment analysis

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I certify that the project identified above, in which the only involvement of human subjects will be in one or more of the categories checked below, is exempt from IRB review and approval.

☑ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
- a.) research on regular and special educational instructional strategies, or
- b.) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, UNLESS
- a.) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND
- b.) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior that is not exempt under (2), if:
- a.) the human subjects are elected or appointed public officials or candidates for public office; or
- b.) federal statute(s) require(s) without exemption that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

☐ Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:
- a.) public benefit or service programs;
- b.) procedures for obtaining benefits or services or services under those programs;
- c.) possible changes in or alternatives to those programs or procedures; or
- d.) possible changes in methods or levels of payment for benefits or services under those programs.

Certification of Project Director:

I have reviewed the Federal regulation concerning the use of human subjects in research and training programs, and the guidelines of at the State University College at Buffalo. I agree to abide by these policies.

_____ May 5, 2010

Signature of Project Director *Date*

Faculty Sponsor Approval:

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Signature of Faculty Sponsor *Date*

Research Foundation Approval:

_____ _____

Signature of RF Operations Manager or Designee *Date*