BUFFALO STATE
The State University of New York

Institutional Review Board
Sponsored Programs Office, Buckham Hall B-206
1300 Elmwood Avenue, Buffalo, NY 14222
Federalwide Assurance ID#: 00007126

PROTOCOL TEMPLATE FOR APPROVAL TO CONDUCT RESEARCH INVOLVING HUMAN SUBJECTS

Buffalo State College and federal policy (e.g., the Department of Health and Human Services regulations for the Protection of Human Subjects Research) require review and approval of **ALL** research activities involving human subjects. This applies to all faculty, staff, and student research, including that to satisfy the requirements of master's degrees. It is not up to the researcher to determine if the Institutional Review Board (IRB) review is required for any particular research activity. Refer to https://sponsoredprograms.buffalostate.edu/human-participants with questions before starting any research involving human subjects!

The approval of the IRB must be obtained **PRIOR** to the involvement of subjects, including pilot studies. Failure to have human subjects research reviewed and approved by the IRB is a violation of college and federal government policy and could result in a loss of grant funding or other consequences. **The IRB cannot review protocols for projects for which data collection has already begun.**

All proposals submitted will be given a preliminary review within two weeks of the submission date if the researcher provides all necessary information in the Pre-Award and Compliance System (PACS).

Researcher: Click here to enter text.
Email Address: Click here to enter text.
Telephone No.: Click here to enter text.

Faculty Advisor (for student projects): Click here to enter text.
Email Address: Click here to enter text.
Telephone No.: Click here to enter text.

Project Title: Click here to enter text.

Select one: ☐ **6-month Approval** ☐ **12-month Approval**
Please note: Start date will be the date the protocol is approved.

REQUIRED INFORMATION

Please indicate the appropriate answer to <u>all</u> questions.

Question	Yes	No
Will any subject be audio or video recorded? *If yes, this must be addressed in the narrative portion of this application. Further, there must be a separate signature line in the consent form for participants to agree to recording.*	☐	☐
Are you planning to solicit subjects by email or through Blackboard? *If yes, the email or Blackboard announcement must be uploaded to PACS IRB.*	☐	☐
If you are a student, has your faculty advisor approved your project's methodology? ☐N/A *If no, please do not submit until your advisor has fully reviewed this protocol. This approval must be secured prior to this protocol being approved. Approval must be documented in PACS IRB. Once you have added your faculty advisor as a study team member, your faculty advisor must note in the comment section that your protocol has been approved.*	☐	☐
Is this research designed to study typical educational practices (e.g., instruction, classroom management)? If so, will the research be conducted in an established educational setting?	☐ ☐	☐ ☐
If research will be conducted with students in their classroom, will it require any activity that is not part of the normal class? ☐N/A	☐	☐
Will the subjects be anonymous? *(Anonymous means that data is recorded in a way that it can never be linked to the subject it came from. Confidential means that measures will be taken to record the data in a manner that it is not linked to the subject, but a link could potentially be made.)*	☐	☐
Does this research involve the collection or study of existing data, documents, records, pathological or diagnostic specimens where a. their sources are publicly available? b. the data cannot be linked to identifiable subjects?	 ☐ ☐	 ☐ ☐
If subjects will not be identified from public sources or from Buffalo State, will signed approval to recruit subjects, conduct the study, or use existing data be obtained from the designated authority prior to conducting the research? ☐N/A *If you are recruiting participants through the resources of another school, business, etc., you must have a signed site agreement giving you permission to do so.*	☐	☐
Are the subjects minors (less than 18 years of age)?	☐	☐
If subjects are minors, will parental consent be obtained for participation? ☐N/A	☐	☐
Will subjects receive compensation for participating in the research (e.g., money, extra credit toward grades)?	☐	☐
If extra course credit will be given, will students who choose not to participate in the research have alternative opportunities to earn credit? ☐N/A	☐	☐

A. PURPOSE, RESEARCH VARIABLES, AND POPULATION

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

Click here to enter text.

Background – Briefly state the background of the study and identify the main question the current study is intended to address. *For most projects, this should be at least a few paragraphs in length and should reference prior research.*

Click here to enter text.

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

a. Age Range – What is the age range and why was it chosen?

Click here to enter text.

b. Sex – What is the sex of the subjects? If there is a restriction, provide the rationale.

Click here to enter text.

c. Number – What is the estimated number of subjects?

Click here to enter text.

d. Inclusion Criteria – What are the specific inclusion criteria?

Click here to enter text.

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.

Click here to enter text.

f. Vulnerable Subjects – If vulnerable subjects will be included (children, pregnant women, fetuses, prisoners, persons with intellectual disabilities), provide justification of the need to use these subjects in research.

Click here to enter text.

B. METHODS AND PROCEDURES

Methods of Subject Selection – Describe the study's method(s) of identification and recruitment of prospective subjects. Upload a copy of any planned advertisements to the PACS IRB Consent Forms and Recruitment Materials SmartForm.

Click here to enter text.

Study Site – State the location(s) where the study will be conducted. The letter of approval to conduct the study from all non-BSC sites must be uploaded to PACS IRB Supporting Documents SmartForm.

Click here to enter text.

Methods and Procedures Applied to Human Subjects – Describe in detail the study design and all procedures (sequentially) to be applied to subjects. How long will the study take each participant? How many sessions are required? What will participants be required to do? All researchers are expected to follow campus COVID-19 or other health guidelines.

Copies of any instruments to be used, such as surveys, rating scales, or questionnaires, must be uploaded to PACS IRB Supporting Documents SmartForm.

It is the responsibility of the Institutional Review Board to weigh risks and benefits to participants. The scientific merit of each project is of interest only as far as it affects the potential benefits of a study. Accordingly, the IRB may make comments and/or suggestions about scientific methodology to improve the quality of research designs.

Click here to enter text.

C. RISKS/BENEFITS

Potential Risks – Identify the potential risks of the study. Specify the types and levels of risk. *Please note that no study is considered "no risk." Minimal risk is defined as risk not greater than that encountered in everyday life.*

Click here to enter text.

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

Click here to enter text.

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

Click here to enter text.

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.

Click here to enter text.

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.

Click here to enter text.

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

Click here to enter text.

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

Click here to enter text.

D. CONFIDENTIALITY

Describe explicitly how your research records will be stored and how this information will be protected and kept confidential. 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.

Click here to enter text.

E. CONSENT PROCEDURE

How will consent be assured? Studies that are exempt do not always require written informed consent. However, aside from research that only involves observation in public areas, there must be a consent process.

See Informed Consent template at http://sponsoredprograms.buffalostate.edu/suny-rf-pacs-irb-module or in the PACS IRB Library. Upload informed consent form or a consent statement to the Consent Forms and Recruitment Materials SmartForm.

Please note that an informed consent form or a consent statement 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 or Consent Statement should be given to each subject who participates in the study.

Click here to enter text.

F. SECONDARY USE OF DATA

Do you anticipate possibly using these data in a future study? If so, how will data be maintained and protected? Will data be de-identified? What types of studies do you anticipate?

Potential secondary use of data must be addressed in the consent form. If data will not be de-identified in future studies, the researcher may consider requesting broad consent. Broad consent applies only to identifiable data. Researchers requesting broad consent must address why the data may not be de-identified and must address how they will track the affected information. For example, if 10% of participants do not agree to broad consent, how will these participants be excluded from future research? In the case of broad consent, the consent form must include enough of a description of future research that a reasonable person may make an informed decision to consent or not.

If data will be de-identified for use in the future, the researcher should provide an idea of the type of studies that may be involved. Secondary research using de-identified data would typically be reviewed at the exempt level at the time the research that uses the secondary data is conducted.

Check ONE of the following:

___ Data will not be used for any future research.
___ Data, minus any identifying information, may be used in future research studies examining similar topics.
___ Data, with your identifying information, may be used in future research. (If checking this option, you must provide additional information about the future research and provide a separate signature line for consent.)

Click here to enter text.