Human Subjects Research Review Committee
ITC, Biotechnology Building, Room 2204
Tel. (607) 777 – 3818
Fax: (607) 777 – 5025
hsrrc@binghamton.edu

Protocol Narrative for IRB Review

Copies of this application form and other IRB resources can also be found at:
https://www.binghamton.edu/research/compliance/humansubjects/irbpacs.html

1. STUDY TITLE:

2. PRINCIPAL INVESTIGATOR

Name:	
Classification	☐ **Student** ☐ **Faculty** ☐ **Staff** ☐ **Other, describe:**
Email:	
Contact Number(s):	
Co-Investigators:	

3. ADVISOR/FACULTY SUPERVISOR OF STUDENT PRINCIPAL INVESTIGATOR
This is required information for all applications that are not directly written/submitted by a faculty member

☐ Not applicable; or complete below:

Name:	
University phone number:	
Faculty e-mail address:	

☐ I have attached the faculty advisor letter to my application indicating my faculty advisor has reviewed and approved my proposed research.

4. RESEARCH DATES AND LOCATION

NOTE: Initial contact cannot occur until after IRB Approval. Initial approval is for one year only for full board and expedited studies. An Annual Continuing Review Request Form must be completed for full board and expedited studies lasting more than a year.

Approximate Start Date:	
Approximate End Date:	
Location(s):	

5. EXEMPT REVIEW CATEGORIES [45 CFR 46 - §46.101(b)]

This research protocol submission involves no more than minimal risk to human subjects nor vulnerable populations and therefore is to be considered Exempt based on the Exemption # [ ] (please choose one of the six categories below. Leave this box blank if your study does not qualify for exempt review).

1. Research will be conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or (b) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods. Children are involved; however, the researcher will not participate in the activities being observed.

2. Research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless the subjects can be identified directly or through identifiers linked to the subjects and disclosure of responses could reasonably place the subjects at risk or criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

3. Research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under item (2) above, if (a) the subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) that the confidentiality or other personally identifiable information will be maintained throughout the research and thereafter.

4. Research will involve 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.

5. Research and demonstration projects which are conducted by or subject to the approval of federal agency sponsoring the research, and which are designed to study, evaluate or otherwise examine (a) public benefit or service programs, (b) procedures for obtaining benefits 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.

6. Taste and food quality evaluation and consumer acceptance studies, if (a) wholesome foods without additives are consumed, or if (b) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

6. EXPLAIN WHETHER OR NOT THE RESEARCH WILL INVOLVE POPULATIONS VULNERABLE TO COERCION OR UNDUE INFLUENCE

The following populations are considered vulnerable populations:

- Individuals with diminished mental/physical capacity
- Children
- Pregnant women
- Fetuses, neonates
- Economically/educationally disadvantaged persons
- Prisoners
- Racial/ethnic minorities
- Students and employees
- Terminally ill
- AIDS/HIV+

If vulnerable population is recruited, provide a description of additional safeguards included to protect their rights and welfare and describe the consent process.

7. USE OF OTHER INFORMATION

Other than the information and data created and produced by this research project, will the researcher(s) have access to records or to other forms of information (including previous research data) about the human subjects participating in this research?

☐ **Yes**
☐ **No**

If yes, please explain here.

If yes, provide in an appendix signed permission letter(s) from the agency/researchers holding and providing access to such records and information.

8. HUMAN SUBJECT CHARACTERISTICS

a. Indicate estimated number of subjects to be studied of each gender and their expected (estimate if necessary) age range. You may amend the table below to accommodate your study's population (e.g., separate adult from child subjects).

Gender	**Number**	**Age Range**
Female		
Male		
Transgender (*if applicable*)		

b. Describe the inclusion/exclusion criteria for the human subjects (e.g., all individuals over the age of 18).

c. Describe any other human subject characteristics common to participants that are relevant to being selected as a potential participant or relevant to the research question.

9. RECRUITING SOURCE(S)

a. Identify the source(s) and location (e.g., hospitals, institutions, schools, classes, shopping malls, etc.) from which subjects will be recruited into the research.

b. Submit original letters of approval from all participating organizations (from the appropriate official of the organization/department or the faculty of any class section) in which the research will be conducted. Letters must be on their official letterhead and indicate specific classes, units, etc. that are being affected. Please ensure that the exact title of your research, your name, and a statement of involvement of the participating organization(s) are included.

☐ I have attached the letter(s) of approval
☐ Not applicable

c. International Research

- All materials, including consent forms must be provided in English and in the language of the country where the research is being conducted.
- Documentation of permission from local authorities, co-investigators, or foreign institutions is required before approval can be granted.

Please list the country, whether or not it is being done in collaboration with another institution, and the name of the institution.

10. RECRUITMENT PROCESS AND INFORMED CONSENT

a. Describe in chronological and numerical order the detail process you will use to invite people to participate in your research. Include complete and numbered step-by-step sequence of specific events from initial approach to the point where you have obtained informed consent.

Recruitment Process:

Informed Consent Process:

NOTE: Upload a script, flyer, email, or any other materials to be used to announce the research opportunity.

☐ I have attached the recruitment materials
☐ Not applicable

b. Attach proposed informed consent form(s) as an appendix. Include all required elements of informed consent (please use the template provided on our website).

☐ I have attached the informed consent form(s)
☐ Not applicable

c. **Fill this section only if you are requesting a waiver of documentation (signature) of consent.** If you are requesting to waive written documentation of consent (i.e., not obtaining signature) please check one of the two justifications below *and* answer the question regarding FDA:

☐ (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; **or**

☐ (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., telephone survey).

FDA regulated research does not allow waiver of written documentation of consent. Is this research FDA-regulated? ☐ Yes ☐ No

d. **Fill this section only if you are requesting a waiver of the elements (contents) of consent**. If you are requesting to omit or alter of one or more of the elements (i.e., content/information) of informed consent (e.g., omitting the study procedure section), you must answer YES to all four items below:

Does this research involve no more than minimal risk to the participants?
☐ Yes ☐ No
Please describe:

The waiver or alteration will not adversely affect the rights and welfare of the participants.
☐ Yes ☐ No
Please describe:

The research could not practicably be carried out without the waiver or alteration.
☐ Yes ☐ No
Please describe:

Whenever appropriate, participants will be provided with additional pertinent information after participation.
☐ Yes ☐ No
Please describe:

Identify the element(s) that for which a request to alter or waive is sought:

If a waiver is being requested, researchers are still required to provide participants with verbal information or a written document which contains all the necessary elements of consent. The researcher must provide to the HSRRC a copy of the verbal or written consent document that will be given to the participants. Include this document with your application.

11. HUMAN SUBJECT PARTICIPATION/STUDY PROCEDURE

a. Describe what you will do with the human subjects once informed consent has been obtained. Include complete and numbered step-by-step, sequential detail regarding what will happen to the subjects when the research procedures are carried out. Provide separate descriptions for each unique group of subjects if two or more groups are participating.

b. Is this a clinical trial?

☐ Yes ☐ No

It is the policy of the NIH policy that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials are to complete training in Good Clinical Practice (GCP), in addition to the human subjects research training (e.g., Social/Behavioral or Biomedical) required for all researchers.

c. If your study is a clinical trial, please contact the HSRRC regarding registering your study in ClinicalTrials.gov.

d. Are you using a device?

☐ Yes ☐ No

If any mechanical devices or electrodes are attached to the subject, please describe the locations and the steps taken to minimize the possibility of electrical interactions or mechanical stress:

Please contact the HSRRC if you have any question or concern regarding any device or electrodes used in the study.

e. If your research involves the collection and/or analysis of biological specimens or exposure to biohazardous materials, please contact the Research Compliance Office at rescomp@binghamton.edu. For more information, please visit https://www.binghamton.edu/research/compliance/institutionalbiosafety.html

f. What data will be collected?

- ☐ Data from questionnaires/survey
- ☐ Data from interviews
- ☐ Data from observational coding
- ☐ Data from billing records
- ☐ Data from medical charts
- ☐ Data from audio/video/photography
- ☐ Data from quality improvement records
- ☐ Data from clinical laboratory results
- ☐ Data from public health records
- ☐ Data from physiological measurements
- ☐ Data from databases
- ☐ Data from educational records

Will data not listed above be used? If so, please list: _____

12. DEBRIEFING OF SUBJECTS AFTER PARTICIPATION

☐ Not applicable; or describe the nature of any debriefing of subjects *after* they have completed the procedures and upload the debriefing document in PACS.

13. POTENTIAL RISKS

a. Please check *yes* or *no* to the following questions:

(i) Does the study manipulate physical, psychological, or social variables such as sensory deprivation, physical stimuli, or psychological stress? ☐ Yes ☐ No
If yes, explain

(ii) Does the study probe for or present any materials which subjects might consider sensitive, offensive, threatening, or degrading? ☐ Yes ☐ No
If yes, explain

(iii) Does the study involve the collection of information that may be reportable to authorities and/or prosecutable under the law? ☐ Yes ☐ No
If yes, explain

(iv) Does the study collect information that might render the subjects prosecutable under the law? ☐ Yes ☐ No
If yes, explain

(v) Does the study involve major changes in diet, exercise or sleep? ☐ Yes ☐ No
If yes, explain

(vi) Does the study use deception? ☐ Yes ☐ No
If yes, explain

b. Describe the potential risks, harm, discomfort, or inconvenience, however minimal. It can be said that everything has a risk. *Number each risk so that you can address how you are minimizing each risk in item 12 below.*
**All potential risks explained here must be mentioned in the Informed Consent.*

14. PROTECTING AGAINST OR MINIMIZING POTENTIAL RISKS

c. Describe the measures you will take to protect against or to minimize each numbered risk noted above (#11b).
**All risk mitigation measures explained here must be mentioned in the Informed Consent.*

a. Describe security and storage, and disposal of research materials by completing the items below.

i. Physical records/data (e.g., paper copies of the signed informed consent):

a) Who will have access:

b) Where will they be stored:

c) What security measures will be taken:

ii. Electronic records/data (e.g., digital data files, scanned signed informed consent):

a) Who will have access:

b) Where will they be stored:

c) What security measures will be taken:

iii. Will audio/video recordings be collected as part of the research? If so ensure that it is mentioned in sections 11a and f.

a) Who will have access:

b) Where will they be stored:

c) What security measures will be taken:

d) Will the recordings be shared in any dissemination or publication:

Binghamton University requires all research data to be retained for 3 years. However, depending on the study, IRB may require the research data to be retained for a longer period of time.

b. Security and storage

☐ I will store both consent forms and raw data in a secure location for 3 years or the required amount of time as per the IRB after completion of the research.

Describe location and security.

Describe who will have access.

c. Disposal of research materials

What will happen to the consent forms and raw data after the 3-year period?

☐ I will destroy the consent forms and the raw data after 3 *years* or the required amount of time as per the IRB.

or explain alternative.

d. A Data and Safety Monitoring Plan are required when a study is more than minimal risk and involves an intervention. If your research project includes a medical, pharmacological, or behavioral intervention or therapy intended to improve the physical or mental health of the subject, please include the Data and Safety Monitoring Plan. This Plan is to include includes a Data and Safety Monitoring Board, "stop rules," and explicit provisions for reporting adverse events to the Binghamton HSRRC. Please contact the HSRRC for guidance, as needed.

☐ Not applicable

Data and Safety Monitoring Plan:

15. BENEFITS

a. Describe any <u>direct</u> benefits to the subject(s), which may reasonably be expected from the research.

b. Describe any compensation to the subject(s) and the conditions under which it is to be awarded (all compensation must be pro-rata). Explain how and when participants will be compensated and whether or not a full compensation will be given even if participants partially complete or withdraw from the study.

Payments to human subjects are considered nonemployee compensation and, as such, are subject to Internal Revenue Service (IRS) requirements for miscellaneous income reporting. If a subject earns $600 or over in a calendar year as a research subject, these earnings will be reported to the Internal Revenue Service.

c. Describe benefits, if any, to others, and the expected gain in generalizable knowledge including summary of research findings where appropriate for professionals and participating organizations.

16. DATA COLLECTION INSTRUMENTS/MATERIALS APPENDIX

a. Attach a copy of all tests, questionnaires, surveys, or other instruments and materials to be used in PACS. If using an online survey, provide an active link to the survey as well.

☐ I have attached a copy of the instruments/materials
☐ Not applicable

b. List here each test, questionnaire, survey, or other instruments and materials to be used, providing full publication/bibliographic information.

c. If you have adapted or made changes in any of these materials, indicate the changes.

d. Indicate which instruments, or portions of instruments, you have created.

e. Do you have copyright permission to use the questionnaire? Yes ☐ No ☐
If no, explain.

17. RESEARCHER QUALIFICATIONS: Briefly describe the training and experience that qualifies you to carry out the proposed research.

18. RESEARCH KNOWLEDGE

a. Describe the contribution of the knowledge for the betterment of the society and the scientific community. Please mention existing literature in this field of research.

b. Describe how knowledge obtained by this study will be distributed (i.e. published, presented at conferences, etc.).

19. CONFLICT OF INTEREST

The HHS regulations at 45 CFR part 46 use the term "investigator" to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of the HHS regulations, OHRP interprets an "investigator" to be any individual who is involved in conducting human subjects research studies. Such involvement would include:

- obtaining information about living individuals by intervening or interacting with them for research purposes;
- obtaining identifiable private information about living individuals for research purposes;
- obtaining the voluntary informed consent of individuals to be subjects in research; and
- studying, interpreting, or analyzing identifiable private information or data for research purposes.

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research studies are conducted by more than one investigator, and usually one investigator is designated the "principal investigator" with overall responsibilities for the study. In every human subjects research study, investigators have certain responsibilities regarding the ethical treatment of human subjects**.**

1. Does any investigator who is involved in the design, conduct, or reporting of the study, their spouse, or dependent children have a proprietary or financial interest related to the research? ("Financial interest" refers to any financial interest in the sponsor, product, or service being tested, or any financial interest in a competitor of the sponsor, product, or service being tested.)
   Yes ☐ No ☐
2. Does any investigator who is involved in the design, conduct, or reporting of the study, their spouse, or dependent children have any ownership interest, stock options, or other financial interest related to the research that
   1) exceeds $5,000 when aggregated? Yes ☐ No ☐
   2) is not publicly traded on stock exchange? Yes ☐ No ☐
   3) involves arrangements in which the value of the ownership interests will be affected by the outcome of the research? Yes ☐ No ☐
   4) exceeds 5% interest in any one single entity when aggregated for the spouse or dependent children? Yes ☐ No ☐
3. Does any investigator who is involved in the design, conduct, or reporting of the study, their spouse, or dependent children have any compensation related to the research that
   1) exceeds $5,000 in the past year, when aggregated? Yes ☐ No ☐
   2) involves arrangements in which the amount of compensation will be affected by the outcome of the research? Yes ☐ No ☐

20. REFERENCES

Provide a reference list of all sources *cited or otherwise identified in this application*.

21. SUBMISSION

Documents requiring letterhead and signatures, such as agency approval letters or faculty supervisor statement, please upload them to PACS along with your other application materials.

For information on how to submit applications, please contact: hsrrc@binghamton.edu or 607-777-3818/