Institutional Review Board
Protocol # [number will be provided by IRB after pre-review]

Human Participants Research Review Form

Instructions:

Each question is very specific; please respond ONLY to the question being asked. Mark any sections that do not apply to your protocol as N/A.

As of July 1, 2018, proposals will only be accepted via the online PACS system. Please upload each supporting document separately onto the designated SmartForm page.

SECTION ONE: SUMMARY INFORMATION

1. Basic Information:

Principal Investigator:	Click or tap here to enter text.
Phone:	Click or tap here to enter text.
Email:	Click or tap here to enter text.
Status:	☐**Undergraduate Student** ☐**Graduate Student** ☐**Faculty/Staff**
Department:	Click or tap here to enter text.
Advisor Name & Department:	Click or tap here to enter text.
Advisor Email:	Click or tap here to enter text.
Research Category:	☐**Exempt** ☐**Expedited** ☐**Full Board Review**

2. Project Title:

Click or tap here to enter text.

3. How do you intend to use the information gathered?
(e.g., thesis, campus presentation, conference presentation, possible publication, etc.):

Click or tap here to enter text.

4. Consultants or Co-Investigators, Institutional/Department Affiliations & Status:

Click or tap here to enter text.

4a. If working with a co-investigator external to [redacted], you must include the following supporting document:

☐**CITI or NIH certification for any external collaborator who will have direct contact with participants**

5. Research assistants (if any):

Click or tap here to enter text.

6. Study Timelines:

Estimated start date:	Click or tap here to enter text.
Will this project be completed within one calendar year?	☐**YES** ☐**NO**

7. Setting—List all facilities/sites where you will be collecting data. Include physical address(es).

Click or tap here to enter text.

7a. If research is taking place at an external institution or agency (e.g., not within the College at Brockport), you must include the following supporting documents in the appendix:

☐**Letter, e-mail or verbal script used to solicit support from external institution or agency**
☐**Form H—Letter of Support from External Institution or Agency**

SECTION TWO: PROTOCOL NARRATIVE/INSTRUMENTS

8. Describe the purpose, specific aims, or objectives of your research project such that it can be understood by a reviewer outside of your academic discipline. (1-2 paragraphs)

Click or tap here to enter text.

9. State the research question(s) or the hypothesis to be tested.

Click or tap here to enter text.

10. Summarize relevant existing data, literature, past and ongoing studies, and how your study ties in with these. Use in-text citations where appropriate. (2 paragraphs minimum)

Click or tap here to enter text.

11. Provide a list of the references cited above.

Click or tap here to enter text.

12. Research Design: ☐**Quantitative** ☐**Qualitative**

13. Specify the research design (e.g., experimental, correlational, case study, etc.):

Click or tap here to enter text.

14. How will this research design answer your research questions(s)? (1-3 sentences)

Click or tap here to enter text.

15. Will deception procedures be used in this study? ☐**Yes** ☐**No**
If yes, attach Form G in appendix.

16. Will data collection be audio-/video- recorded? ☐**Audio** ☐**Video** ☐**No**

16a. Alternative data collection methods if participants do not consent to audio- or video-recording:

Click or tap here to enter text.

17. Instruments:

- ☐ **N/A *secondary analysis of existing data**
- ☐ **Created by researcher / Interview**
- ☐ **Existing instrument in public domain**
- ☐ **Existing instrument not in public domain**
- ☐ **Adapted from existing instrument**
- ☐ **Created by researcher / Interview**

18. Please list each instrument with a description and citation, if applicable. Attach the specific instruments as well as permission to use each instrument in the appendix.

Click or tap here to enter text.

19. Link to instrument if using online platform (e.g., Qualtrics):

Click or tap here to enter text.

20. For research taking place in a classroom or educational setting ONLY: Describe in detail the activities planned for non-participants (if applicable) and explain where both participants and non-participants will be during the research activities.

Click or tap here to enter text.

SECTION THREE: PARTICIPANT SELECTION & RECRUITMENT

21. Participant Information and Recruitment Process

Indicate the maximum total number of participants that will be recruited or records that will be reviewed. **Bear in mind that all recruited participants must have an equal opportunity to participate in the study.**	Click or tap here to enter text.
Age Range of Participants (check all that apply):	☐**Under 18** ☐**18 or over** ☐**N/A**

22. Indicate whether you will <u>specifically target</u> any of the following vulnerable populations in your study:

- ☐**N/A**
- ☐**Students of principal investigator (PI) or staff/research team**
- ☐**Students (K-12) in an educational setting (in class or at school)**
- ☐**Employees supervised by PI, research member or research sponsor**
- ☐**Prisoners**
- ☐**Refugees**
- ☐**Non-English speaking individuals**
- ☐**Limited or non-readers**
- ☐**Economically/educationally disadvantaged individuals**
- ☐**Wards of the state (e.g., foster children)**
- ☐**Institutionalized patients/residents**
- ☐**Individuals with impaired decision-making capacity**
- ☐**Other – Explain below:**

Click or tap here to enter text.

23. If you checked any of the boxes above, describe the additional precautions that will be taken to protect these individuals from coercion or undue influence <u>during the recruitment and/or consent process</u>:

Click or tap here to enter text.

24. Describe any criteria that define who will be *included in* your study and provide a rationale:

Click or tap here to enter text.

25. Describe any criteria that define who will be *excluded from* your study and provide a rationale:

Click or tap here to enter text.

26. Describe *screening procedures* for determining participants' eligibility, if applicable. Screening refers to determining if prospective participants meet the inclusion and exclusion criteria described above.

Click or tap here to enter text.

27. Check all recruitment methods/materials you plan to use. Attach all recruitment materials in the appendix.

- ☐**N/A *secondary analysis of existing data**
- ☐**Recruitment letter**
- ☐**Recruitment e-mail**
- ☐**Flier**
- ☐**Verbal script**
- ☐**Tabling**
- ☐**Social media posting (specify platform)**
- ☐**Other materials/methods—explain below:**

Click or tap here to enter text.

28. Describe when, where and how potential participants will be recruited. Be specific.

Click or tap here to enter text.

SECTION FOUR: INFORMED CONSENT/MINOR ASSENT

29. For expedited and exempt studies, you may request to <u>waive documented/signed consent</u> if one of the following options applies:

- **<u>Option 1</u>:** The only record linking the participant and the research is the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether they want documentation linking them with the research and their wishes will govern. The research is not subject to FDA regulations.
- **<u>Option 2</u>:** The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of research context.

Click or tap here to enter text.

Is a <u>waiver of documented/signed consent</u> requested? ☐**YES** ☐**NO**

29a. If YES, which of the above option applies? ☐ **1** ☐ **2** ☐ **3**

30. Informed Consent Process—Check all methods you plan to use:

- ☐**N/A *secondary analysis of existing data**
- ☐**Online consent (e.g., clicking to indicate consent, electronic signature, digital signature)**
- ☐**In person**
- ☐**By regular mail, including interoffice mail**
- ☐**By e-mail**
- ☐**By phone**
- ☐**Other method—explain below:**

Click or tap here to enter text.

31. Describe in detail how, when and where you will seek informed consent from participants (or from participants' legally authorized representative), keeping in mind that exempt studies still require a statement of consent to be shared with prospective participants. Attach consent documents in appendix.

Click or tap here to enter text.

32. Minor Assent Process—If working with children, describe in detail how, when and where you will seek minor assent. Attach assent documents in the appendix.

Click or tap here to enter text.

33. In special cases, you may request to <u>waive or alter</u> the informed consent process if ALL of the following apply:

- **Research is no more than minimal risk;**
- **Research could not be carried out without requested waiver/alteration;**
- **Waiver/alteration will not adversely affect the rights and welfare of participants; AND**
- **When appropriate, additional information will be provided to participants after they have completed the study.**

Is a <u>waiver or alteration</u> of informed consent requested? ☐**YES** ☐**NO**

33a. If YES—explain below:

Click or tap here to enter text.

SECTION FIVE: METHODS & PROCEDURES

34. Provide a detailed description of the methods and procedures to be followed during this research project, including the role(s) of the researcher and research assistants.

As applicable, provide: a) data collection timeline, b) number and duration of study visits, c) overall follow-up time, d) total time participants will be enrolled in the study, and e) procedures for member-checking. You may wish to include a table or chart showing the research timeline.

Provide enough detail so that a reviewer outside of your discipline will understand the research. Depending on the nature of your research, response length may range from 1-2 paragraph to multiple pages.

<u>There is no need to include detailed participant recruitment, screening or consent procedures in your response, as these have already been addressed within the proposal form.</u>

Click or tap here to enter text.

SECTION SIX: COMPENSATION & RISK MANAGEMENT

35. Compensation/Incentives – Form of compensation:

- ☐ **N/A**
- ☐ **Cash**
- ☐ **Check**
- ☐ **Gift card/gift certificate**
- ☐ **Voucher**
- ☒ **Raffles/lotteries**
- ☐ **Course/extra credit**
- ☐ **Other – explain below:**

Click or tap here to enter text.

36. Describe compensation and how participants should be compensated. Include how you will document compensation.

Click or tap here to enter text.

37. Risks—Indicate possible risks for participants, including the minimal risk of time spent participating and potential risks to privacy and confidentiality:

Click or tap here to enter text.

37a. Describe precautions to be taken to minimize or eliminate these risks:

Click or tap here to enter text.

37b. Benefits—State any direct personal benefits to participants—if any—keeping in mind that most social and behavioral research does not offer any direct personal benefits:

Click or tap here to enter text.

SECTION SEVEN: PRIVACY & CONFIDENTIALITY

38. Privacy and Confidentiality—List any personal identifiers to be collected, including IP addresses: [Note: Some online survey platforms can provide data without IP addresses]

Click or tap here to enter text.

39. Coding—If using pseudonyms, numbering or another coding system, explain how a master list connecting codes to participant names will be protected (check as many as apply):

- ☐ **N/A Not using coding**
- ☐ **N/A Using coding, but not maintaining master list connecting codes to names**
- ☐ **In password-protected file on password-protected device (using different passwords)**
- ☐ **Encrypted file**
- ☐ **In locked drawer (separate from data storage)**
- ☐ **Other—explain below:**

Click or tap here to enter text.

39a. Explain how non-investigators will be prevented from accessing participants' identifiable information.

Click or tap here to enter text.

40. Results will be reported: ☐**Individually, using coding or pseudonyms**
☐**As aggregate data**
☐**Other—explain below:**

Click or tap here to enter text.

41. Will identifiable data be retained once data collection is complete? ☐**YES** ☐**NO**
If yes—explain below:

Click or tap here to enter text.

42. Provide *physical location* where the identifiable data and IRB documentation will be kept during the research and after the study has been closed. The repository should include, at minimum, copies of IRB correspondence as well as signed consent documents. This documentation should be maintained for a minimum of 3 years after the study has been closed.

Document type:	**Storage location (street address, building, room number, etc.):**
Identifiable data & signed consent forms	☐**N/A** ***While study is active:*** Click or tap here to enter text. ***After study has been closed:*** Click or tap here to enter text.
Copies of IRB correspondence/documentation (approval letters, continuation/modification approvals, approved protocol with all attachments)	***While study is active:*** Click or tap here to enter text. ***After study has been closed:*** Click or tap here to enter text.

43. Method of destroying identifiable data and IRB documentation (after a minimum of 3 years per SUNY regulations):

Identifiable data & signed consent forms	☐**N/A** ☐**Delete files** ☐**Shred paper** ☐**Other–explain below:**
Copies of IRB correspondence/documentation (approval letters, continuation/modification approvals, approved protocol with all attachments)	☐**Delete files** ☐**Shred paper** ☐**Other–explain below:**

44. Timeline for destroying identifiable data and IRB documentation:

Identifiable data & signed consent forms	☐**N/A** ☐**3 years (minimum per SUNY regulations)** ☐**Other–explain below:**

Copies of IRB correspondence/documentation (approval letters, continuation/modification approvals, approved protocol with all attachments)	**☐3 years (minimum per SUNY regulations)** **☐Other–explain below:**

SECTION EIGHT: SUPPORTING DOCUMENTS

Check the supporting documents included in protocol submission:

- **☐Recruitment notices, letters, e-mails, fliers, scripts, etc.**
- **☐Form A—Informed consent/assent document(s)**
- **☐CITI certification for College at Brockport PI, co-PI(s) and research assistants**
- **☐CITI or NIH certification for any external collaborators**
- **☐Any survey instruments, psychological tests, interview forms, interview protocols, etc.**
- **☐Written permission to use testing instrument**
- **☐Instructions to participants for use of instrument**
- **Forms C-J:**
  - **☐C—Minor assent document, if applicable**
  - **☐D —Research Using Specialized Equipment**
  - **☐E—Research Involving Psychological Intervention**
  - **☐F—Research Involving Physiological Intervention**
  - **☐G—Research Involving Deception**
  - **☐Letter, e-mail or verbal script used to solicit support from external institution or agency**
  - **☐Form H—Letter of Support from External Institution or Agency**
  - **☐Form J—Student as Principal Investigator**
- **☐Other—explain below:**

Click or tap here to enter text.

SECTION NINE: INVESTIGATOR'S PLEDGE

By submitting this protocol, you certify that you accept responsibility for and will follow the ethical guidelines set forth by the Belmont Report, Declaration of Helsinki, the Nuremberg Code and the Ethical Principles of the American Psychological Association (if applicable), as well as by The College at Brockport. You have the requisite funding, credentials and training, if needed, to carry out all procedures involved in this protocol.

Submitting the protocol also affirms that the information you have provided concerning the procedures to be taken for the protection of human participants is correct; no other procedures will be used in this project; you will seek and obtain prior approval from the IRB for any modification in this project; and you will promptly report any unexpected or otherwise significant adverse effects encountered in the course of this study to the IRB.