INFORMED CONSENT

***Title of Study***

***Summary of Key Information***

“Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.”

**Key information should include the following:**

1. The fact that consent is being sought for research and that participation is voluntary

2. The purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research

3. The reasonably foreseeable risks or discomforts to the prospective subject

4. The benefits to the prospective subject or to others that may reasonably be expected from the research

5. Appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the prospective subject.

# Name and title of Researcher (INCLUDE UNIVERSITY AFFILIATION, Positions, AND DEGREES):

Department/Room Number:

Telephone Number:

Email:

# Study Location(s):

# PURPOSE OF STUDY

The purpose of this research study is to *(complete this sentence) Example: “to explore attitudes of first-generation Americans regarding education.”*

# DO NOT INCLUDE YOUR HYPOTHESIS ON THIS FORM.

# PARTICIPANTS

***Inclusion/Exclusion Criteria***

You are eligible to participate in this study if you *(complete this sentence or use a bulleted list of inclusion criteria) Examples include, “are at least 18 years of age or older,” “have been clinically diagnosed with depression.”*

*Approximate Number of Participants*

“The approximate number of people who will participate in this study is \_\_\_\_\_\_\_.”

# PROCEDURES

The following procedures will occur *(Explain the research procedures in chronological order; include the expected duration of each procedure(s) to be completed at the visit. You may provide a visit schedule to assist the participant.)*

# RISKS AND DISCOMFORTS

The possible risks and/or discomforts associated with the procedures described in this study. Please note that no study is truly “no risk” and the lowest category is minimal. *(For example,* *risks are minimal and no greater than those encountered in everyday life. Make sure to consider all risks – psychological, social, economic, legal and physical.)*

# BENEFITS

The possible benefits you may experience from the procedures described in this study include *(Complete this sentence) Example: a better attention span. [If no direct benefit to the subject is anticipated, delete the above statement and insert –* You will not directly benefit from participation in this study.] Include a statement of the overall benefits to society.

# COMPENSATION:

Provide information on financial payments or reimbursement of expenses. Indicate if full payment is given if the subject withdraws from participation in the research study.

# CONFIDENTIALITY

All information obtained in this study is strictly confidential unless disclosure is required by law. In addition, the Human Research Ethics Board, the sponsor of the study (e.g. NIH, FDA, etc.), and University or government officials responsible for monitoring this study may inspect these records.

Examples include **(please choose one)**:

* All identifiable information about you will be removed, with only a code to identify you. The code that links your name to the data will be kept separate from the study data.
* Data will be recorded anonymously, which means no one, including the research team, can identify you from the study data.
* Identifiable information about you will be kept with the study data.

# DATA STORAGE

Your research records will be stored in the following manner: (Complete this sentence. Also, specify the level of privacy afforded to subject data.)

This information will be protected and kept confidential in the following manner: (Complete this sentence.) Examples include:

* All study data will be kept under lock and key and only authorized research team members will have access to it.
* All data stored electronically will be stored on a secure network server, or on portable devices, such as a laptop with encryption (special software) and password protection. Any hard copies will be shredded and disposed of.

# IF YOU HAVE QUESTIONS

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the researcher at \_\_\_\_\_\_\_\_\_\_\_\_.

*For questions about your rights as a research participant, contact the State University of New York at New Paltz Human Research Ethics Board (which is a group of people who review the research to protect your rights) at 845-257-3282.*

*The Human Research Ethics Board of the State University of New York at New Paltz has determined that this research meets the criteria for human subjects according to Federal guidelines.*

# VOLUNTARY PARTICIPATION STATEMENT

Your participation in this project is voluntary. Even after you agree to participate in the research or sign the informed consent document, you may decide to leave the study at any time without penalty or loss of benefits to which you may otherwise have been entitled. I will retain and analyze the information you have provided up until the point you have left the study unless you request that your data be excluded from any analysis and/or destroyed.

***SIGNATURES***

Your signature documents your permission to take part in this research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature of participant Date***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Printed name of participant***

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature of researcher Date***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Printed name of researcher***

**Please Note: Additional consent elements may be necessary based on the nature of your research. See the Informed Consent SOP for further information.**

1. **A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.**
2. **Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent.**
3. **Any additional costs to the subject that may result from participation in the research.**
4. **The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;**
5. **A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;**
6. **The approximate number of participants involved in the study.**
7. **A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;**
8. **A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions; and**
9. **For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).**
10. **Research Involving More than Minimal Risk (include only if applicable):
When more than minimal risk is anticipated you must include an explanation as to whether any compensation and/or treatments are available if injury occurs and if so, what they consist of or where further information may be obtained. This may include treatments such as referrals for counseling services, intervention services or hotline references.**
11. **Photographing or Audio/Video Recording of participants (include only if applicable):
Include a statement that audio and/or video-recording devices will be used, if applicable. You must state how the photos or recordings will be used, what settings context outside of study, e.g., conferences, presentations, education/classroom use, promotional materials, electronic online posting distribution. You may want to provide participants with the ability to opt in or out of any mode of utilization. This can be done through a checklist on the consent form. Caution interview participants before the interview begins to avoid mentioning the names of or identifying information about third parties. If identifying information is mentioned inadvertently, the taping should be stopped immediately, the identifying information erased, and the caution repeated before taping resumes. Please provide a separate line on the consent form for the participants to agree to each session to be photographed or recorded.
Suggested Text if applicable:
*“Please sign below if you are willing to have this interview recorded (specify audio or video). You may still participate in this study if you are not willing to have the interview recorded.”***
12. **REQUIREMENTS SPECIFICALLY FOR CLINICAL TRIALS: All research involving clinical trials must post, to a federal website, a copy of the HREB-approved version of the consent form that was used for enrollment purposes for each clinical trial conducted or supported by a federal department or agency. §46.102(b) defines “clinical trial” to mean “a research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.”**
13. **REQUIREMENTS FOR BROAD CONSENT FOR THE STORAGE, MAINTENANCE, AND SECONDARY RESEARCH USE OF PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS.**

**Broad consent will provide participants with a choice to say no to storage, maintenance, and secondary research. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the use of identifiable private information or identifiable biospecimens.**

**46.116(b)(9) indicates that researchers must include one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:**

**(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or**

**(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.**

# The requirements for broad consent include:

* **All of the requirements for consent are described above.**
* **A general description of the types of research that may be conducted with identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;**
* **A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;**
* **A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);**
* **Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private**