1. Summary

a) Provide a brief summary of the scope of work of this project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.

2. Purpose

a) Describe the purpose for the proposed project as well as the hypotheses/research questions to be examined.

b) What do the investigators hope to learn from this project?

3. Procedures

a) Describe in chronological order of event(s) how the activities will be conducted, providing information about all procedures (e.g. interventions/interactions with subjects, data collection, photographing, audio and video recording), including follow up procedures.

i) Be sure to identify what procedures are experimental and what are standard of care or established practice for the condition/situation.

b) Explain who will conduct the procedures and where and when they will take place. Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study. Include how the data will be collected (i.e. in person or online).

i) Indicate that the instruments used are in the public domain or provide appropriate documentation of permission to use each scale.

c) For school-based activities where class time is used, describe in detail the activities planned for non-subjects and explain where both subjects and nonsubjects will be located during the activities.

d) State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in attachments section

e) Will audio or video taping of individuals occur? Will photographs of individuals be taken? Describe what will become of the apes/photographs (e.g., shown at scientific meetings, erased, etc.).

f) Will the proposed research involve the use of existing data/specimens? If so, check all that apply:

- ☐ **i. The research involves data from publicly available sources**
- ☐ **ii. That data will be recorded by the investigator in such a manner that subjects cannot be identified.**
- ☐ **iii. Any link to identifying information has been destroyed**
- ☐ **iv. N/A**

4.Background and additional procedures

a. Relevant Background: Discuss the present knowledge, appropriate literature and rationale for conducting the research. Include the rationale for the selected subject population.

b. **Describe the statistical methods of the research and plans for analysis of the data (i.e. planned statistics, justification of sample size, etc.).**

c. **Alternative Procedures. Describe any alternatives to participating in the research. (e.g., standard of care treatment, etc.). Any standard treatment that is being withheld must be disclosed. This information must be included in the consent form.**

d. **Will subjects be followed after their active participation is complete?** Yes No

If yes, explain why and describe how:

e. **Will subjects have access to the study treatment/procedure after completing the study?** Yes No

If yes, explain why and describe how:

f. **Do any of the following apply.**

i. **Will subjects be audio recorded?** Yes No

ii. **Will subjects be videotaped?** Yes No

iii. **Will subjects be photographed?** Yes No

If yes to i, ii or iii, explain the collection process and use of such media.

(Explicit consent must be obtained for use of these methods for Expedited and Full Board studies.)

8. Risks (Input N/A if not applicable)

US Department of Health & Human Services (HHS) Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

b) **Describe all known risks or discomforts associated with study procedures whether physical, psychological or social (e.g., pain, stress, invasion of privacy, breach of confidentiality) noting probability and magnitude of potential harm. Specify the risks(s) associated with each research procedure or test.**

c) **Describe the procedures or safeguards in place to protect against or minimize potential risks (e.g., referral to psychological counseling resources).**

10. Procedures to Maintain Confidentiality

Which of the following types of data will you work with:

☐ **Identifiable**
Information is considered to be identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person or investigator

could ascertain the identities of individuals. Therefore, even though a dataset may have been stripped of direct identifiers (names, addresses, student ID numbers, etc.), it may still be possible to identify an individual through a combination of other characteristics (e.g., age, gender, ethnicity, and place of employment).

☐ **Anonymous**
Data are anonymous if no one, not even the researcher, can connect the data to the person who provided it--no identifying information is collected from the individual. Investigators must be aware, however, that even if no direct identifiers (name, address, student ID, etc.) are collected, identification of a participant may be possible from unique individual characteristics (indirect identifiers). For example, a participant who is a member of a certain ethnic group or who was studied because of distinctive personal accomplishments or medical history might be identifiable from even a large data pool.

☐ **De-identified**
If the dataset has been stripped of all identifying information and there is no way that it could be linked back to the subjects from whom it was originally collected (through a key to a coding system or by any other means). Note: This also applies if the source of the data is identifiable but the data collected is not.

☐ **Coded**
This refers to data that have been stripped of all direct subject identifiers, but in this case each record has its own study ID or code, which is linked to identifiable information such as name or medical record number. The linking file must be separate from the coded data set. This linking file may be held by someone on the study team (e.g. the PI) or it could be held by someone outside of the study team (e.g. researcher at another institution). A coded data set may include limited identifiers under HIPAA. Of note, the code itself may not contain identifiers such as subject initials or medical record number.

a) **If information derived from the study will be provided to the subject's personal physician, a government agency, or any other person or group (other than the research team), describe to whom the information will be given and the nature of the information, if applicable.** ☑ **N/A**

b) **Explain how you will protect subjects' privacy.**
Note: Privacy refers to persons and their interest in controlling the access of others to themselves. For example, based on their privacy interest's people want to control:
- **The time and place where they give information.**
- **The nature of the information they give.**
- **The nature of the experiences that are given to them.**
- **Who receives and can use the information.**

For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy-counseling center that is clearly identified as such by signs on the front of the building. Please keep this definition in mind as you respond to this item.

c) **Describe how you will maintain the confidentiality of subjects' information.**
Note: Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others (without permission) in ways that are inconsistent with the understanding of the original disclosure. Please keep this definition in mind as you respond to this item.

d) **Who will have access to study records or specimens? (Please identify specific team members by name.)**

e) **If you plan to use existing data, records or specimens, what is the source of the data/records/specimens, and how will you access them?**

NOTE: "Existing" means data or specimens collected (i.e., on the shelf) prior to the IRB application submission. It includes data or specimens collected for research and non-research activities.

i) Explain why, where, in what format, and for how long data/specimens will be retained.

11. Consent Information

11 a & b only apply to exempt applications

a) How will subjects be informed of procedures, intent of the study, and potential risks to them?

b) How will subjects be informed they may withdraw at any time without penalty?