Note that when multiple research methodologies or research involving more than one subject group (e.g., children and their parents) are combined into a single IRB submittal, the recruitment, consent process, research procedures, confidentiality and risks sections may need address the points in some of these sections multiple times. Distinctions must be clearly made for each methodology and subject group.

**Title of Project**

This title must be the same as the title on your application forms, any consent documents and recruitment materials. This title need not be the same as the title of any grant application(s) related to this protocol.

**Purpose:**

Summarize the purpose of the study including the research questions and/or the hypotheses to be tested.

**Participants:**

Describe the population to be recruited for participation in the research.

Give the reason that this subject population was chosen for this study.

If certain groups are to be excluded or restricted from participating, explain why and how. This may be for safety or scientific reasons.

Describe any previous or current interaction between the investigator/research team and the participant population and the procedures put in place to ensure that there can be no real or perceived undue influence.

**Recruitment:**

Describe all potential recruitment processes including location, timing, persons conducting the recruitment, screening processes and any materials to be used. Use references to specific recruitment materials (scripts, flyers, advertisements, letters, etc.) that you provide as appendices to this project description.

When specific populations are to be selected for recruitment, describe how access to the participants or data has been obtained.

**Consent Process:**

Describe the method(s) of consent you plan on using for this study (Signed consent document, Waiver of signed consent where an information sheet is provided in lieu of a consent document, Verbal consent documented by a witness, Request that consent be
waived). Reference to informed consent documents, scripts, information sheets and/or a waiver form contained in an appendix should be made.

If a signed consent document is not obtained, explain why the method used is justified for this specific study both in terms of the regulatory information set out in the waiver of consent form and the methods used to collect the data for this study.

Describe the consent processes and procedures that potential participants will be guided through. Be sure to include a description of who will obtain informed consent (e.g., PI, RA, nurses, other key personnel), in what setting and when it will occur relative to the research procedures.

If participants cannot give a legally effective consent (ex. minors under the age of 18 in NY State, persons with cognitive impairments), address each of the above points in describing how legal permission and/or assent will be obtained.

If English is not the primary language of potential participants, the identity and credentials (academic or practical) of the translator must be specified in the project description.

**Research Procedures:**

Describe specifically what the subjects will do (participate in an interview or focus group, fill out a survey, etc.) and/or how the data will be obtained. Be sure to include information on how long participation will last, who will collect the data or information, where the study data will be collected, the method of data collection (participant observation, survey collection, records review, etc.) and how data will be recorded (notes, video taping, etc.).

**Compensation:**

Describe the type of compensation (monetary, class credit, etc.), if any, that subjects will receive for participation in the study. Be certain to explain any prorating system that will be used for participants who do not complete the study.

Details of any alternate methods for obtaining compensation along with the methods of presenting these options to potential participants must be given where participation in the research or an alternative process is required of the potential subjects (ex. When class credit is given for research, an alternative must be given to participation in the research project).

**Confidentiality:**

Describe how participants’ data will be handled, indicating how the study data is obtained (anonymously, confidentially, or semi-confidentially or publicly), recorded by the investigator (anonymously, coded or identifiably), how it is later either coded and/or de-identified, and finally how and when it is to be destroyed or placed in a permanent repository. Make certain that all data is accounted for.
Persons having access to the data and the period of time relative to data collection that any records are to be kept must also be specified. This is especially important for identifiable records such as audio or video tapes.

Describe any additional procedures for protecting the confidentiality of the subjects’ responses including if the PI has plans to obtain a certificate of confidentiality to keep data from being subpoenaed.

Risks:

Overall Risk Level. Describe the level of risk to be encountered by subjects as GREATER THAN MINIMAL or NO GREATER THAN MINIMAL and justify this assessment.

Describe and evaluate the level (e.g. minimal or [slightly] greater than minimal) of any physical, psychological, social, legal, employment, loss of confidentiality or other risks for participants.

Risk Minimization: Discuss the efforts taken to minimize risks (if any) including any special training, education or skills that key study personnel possess or will obtain.

Adverse Events: Discuss potential adverse events (if any), procedures for dealing with adverse events and/or minimizing consequences of an adverse event.

Benefits:

Describe any direct benefits to subjects along with any indirect benefits and how likely the study is to yield generalizable knowledge. A discussion of why it is worth exposing human participants to even minimal risks associated with the study should also be presented.

Deception:

If deception is a necessary aspect of the project, give a full explanation of the deception and justification for its use. Include an indication of the degree of deception (mild, moderate, severe), and a description of the debriefing process.

If no deception is involved in the research, simply state, “No deception is used in this research protocol.”

Appendices:

Include all supplementary information (consent forms, screening instruments, survey/interview questions, data collection forms used by participants) as appendices and make sure that all portions of your submittal are consistent.