RESEARCH STUDY PROTOCOL

Study Title

Name of the Principal Investigator

For research involving human subjects, certain elements must be included with each ‘new’ IRB submission to ensure an effective review by the IRB. The research protocol should address these elements in detail as outlined below. You can write in this document however, all template language and italicized language should be removed prior to submission. If certain section(s) do not apply to your study, state ‘Not Applicable’. If you have any questions, contact the ORA Office at 914-594-2590.

1. Study Design including study procedures & Background
1a. State the specific scientific objectives of the research. Outline the research question/hypothesis of the study. What has been done already in this area of research? [Literature references must be cited in this or at end of this section]

1b. Describe the study design (e.g. Interventional: randomized trial, blinded etc. vs Observational: cohort, cross-sectional, etc.) and the principal variables or outcome measure(s).

List the procedures to be used to accomplish the specific aims of the project. For clinical trials, procedures/tests/interventions that are considered experimental and performed exclusively for research purposes must be identified and clearly differentiated from those that would occur regardless of the research (i.e., standard of care treatment procedures).

2. Research Subject Population:
2a. Number of Subjects
State the total number of subjects expected to participate at this site (if the study involves retrospective chart review, state the number of records and the date range). In the case of multi-center protocols also include the overall total. Explain the reason for choosing this sample size. Include brief information regarding how subjects will be identified for study inclusion (e.g. through medical records, hospital database, office charts etc.). Detailed information on subject identification & recruitment should be discussed in section 7 below.

2b. Gender of Subjects
Equitable inclusion of both men and women in research is important to ensure that both receive an equal share of the benefits of research and that neither bears a disproportionate burden. Therefore, subjects of both genders should be included in the study unless there are appropriate medical and/or scientific reasons for exclusion.

Describe the intended gender distribution of the subjects. If there are any gender-based enrollment restrictions, explain the nature of the restriction(s) and provide justification.

2c. Age of Subjects
State the age range of the subjects. Provide the rationale for selecting this age range. 

**Note:** The age of majority in New York is 18 and special considerations apply to research with children. If you are conducting research with children, please take into account issues relating to consent/assent detailed below in section 7.

**2d. Racial and Ethnic Origin**

The research should include sufficient enrollment of persons of diverse racial/ethnic backgrounds, within the limitations imposed by the population of the study site(s,) to ensure that the benefits and burdens of the research and participation in research are distributed in an equitable manner.

Describe the intended racial and ethnic distribution of the subjects. If there are any enrollment restrictions based upon race or ethnic origin, explain the nature of the restrictions and provide justification.

**3. Inclusion and Exclusion Criteria**

List the inclusion and exclusion criteria for the study and explain.

**4. Data Analysis and Data Monitoring**

Explain sample size derivation and address appropriate power issues. Summarize the statistical/analytical methods to be used for analysis. For studies that involve greater than minimal risk to subjects, a data monitoring plan must be provided. See instructions on the IRB website {LINK} on data monitoring for additional details. In addition, a data safety & monitoring committee may be required to protect the safety and/or welfare of subjects. If you employ a data monitoring committee, provide a detailed description of its operation (i.e., membership, function, frequency of review, stopping rules) or include as a separate attachment.

**5. Data Storage and Confidentiality**

The principal investigator must take all necessary steps to maintain confidentiality of data including coding data and choosing an appropriate and secure data storage mechanism that will prevent unauthorized access to data.

Describe where the research data will be stored during the study and how it will be secured. State who will have access to the data and for how long the study related data will be stored.

**Note:** If any research data with subject identifiers will be released, additional information such as the person(s) or agency to whom the information will be released and the purpose of the release is required. Contact the Director of Human Subjects administration for additional guidance.

**6. Risk/Benefit Assessment**

A risk is a potential harm associated with the research that a reasonable person would likely consider injurious. Risks are not only physical, but can be psychological, sociological, economic
and legal as well. This includes any specific toxicity data from previous related studies in the literature.

Detail the risk that the research presents. If possible, estimate the probability and magnitude of the risks associated with the research. Describe whether these risks are minimal or greater than minimal and explain why.

**6a. Protection against Risks**

Describe how the study design will prevent and/or minimize any potential risks or discomfort. Potential risks and discomforts must be minimized to the greatest extent possible by using procedures such as appropriate training of personnel, monitoring of subjects, withdrawal of the subject upon evidence of difficulty or adverse event (clearly define the withdrawal criteria); and referral for treatment, counseling or other necessary follow-up.

**6b. Potential Benefits to the Subjects**

Describe potential benefit(s), if any, for subjects actually participating in the research. Distinguish these from benefits to the society at large. If there are no anticipated benefits, this should be stated.

*Note: Payment to subjects is not considered to be a benefit of research.*

**7. Subject Identification, Recruitment and Consent/Assent**

*Principal investigators have an ethical and legal obligation to ensure that prospective subjects/subjects’ representatives have sufficient knowledge and comprehension of the elements of informed consent. The information presented to subjects must be clear and provided in a manner to enable subjects to make an informed decision regarding whether or not to participate themselves or allow the participation of others in research.*

**7a. Method of Subject Identification and Recruitment**

Describe the method(s) that will be employed in the identification and recruitment of prospective subjects. Identify the screening process and list the possible criteria for screening failures or subject withdrawal.

*Note: All recruitment materials such as letters, flyers, advertisements, website information etc. must be submitted to the IRB for review and approval.*

**7b. Process of Consent**

Describe who will obtain consent and how the process of informed consent will be structured in such a way that allows for sufficient time and opportunity for rational and thoughtful decision making by the subject OR the subject’s legally authorized representative (LAR) without coercion or undue influence. Identify how and where documentation of consent will be stored. If the study involves children, outline the process for obtaining assent (explicit approval of the child) and consent (permission) from their parent(s) or legally authorized representative (LAR).
Note: Individuals who are authorized to obtain consent must have appropriate credentials. If necessary to use ‘Witness’ and/or translator, these roles should be described in this section. Only the NYMC Standard Consent Form should be used including the boiler plate page of the consent form.

7c. Subject/Legal Representative Comprehension
Describe how it will be determined that the subject/subject’s legally authorized representative (LAR) understood the information that was presented. Outline an adequate plan in place to assure an acceptable level of comprehension before consent is obtained. If children are involved also include a specific plan to assess comprehension during assent.

8. Vulnerable Populations
Children, pregnant women, fetuses, and prisoners are considered vulnerable populations in the federal regulations. However, the elderly, students, employees, and persons with decisional incapacity or those with limited autonomy are also considered vulnerable subjects in need of greater protection
If vulnerable subjects are included, state the additional steps that will be taken for the protection of their rights and welfare.

8a. Subject’s Capacity to Consent (If applicable)
When not all subjects will have the capacity to give informed consent, describe how that will be assessed and who will perform the assessment. State the frequency of these assessments. Describe the anticipated degree of impairment relative to their ability to consent to participate in research. Describe the degree of risk involved with the study since research with persons who have diminished capacity is allowed only for minimal risk or the studies that offer direct benefit.

9. Cost to the subject
Describe and justify any costs that the subject(s) will incur as a result of participating in the study. State who will pay for research procedures versus standard of care procedures associated with the study. If the study employs counseling services or follow-up care, state who will pay for those. THESE?

10. Payment for Participation
The compensation amount provided must be justified and not constitute undue inducement of the subject to participate in research or to continue beyond a point that they would have otherwise withdrawn.

Describe any reimbursements or payments such as cash payments, coupons and gift certificates that the subject(s) will receive for participation and how/when the subjects will receive the payment. List the prerequisite condition(s) that must be fulfilled by subject(s) to receive these payments.