**Streamlyne: IRB Protocol**

**Questionnaire**

1. **Protocol Summary Interview (Complete)**

What are your study's objectives? Please state each objective in a separate manner and, after each objective, present a simple rationale for the proposed objective.

What are the possible benefits to your study? Please present, in a separate manner, the study benefits as they correspond to each study objective presented above.

What site(s) will be used in your study? Note that you must upload a Study Site Approval Letter in the Protocol Attachments section for each study site that you identify.

What is the proposed time period for the study? Please state in years and/or months.

Please describe your recruitment procedures. Note that all Recruitment Documentation, such as advertisements, flyers, posters, etc., must be uploaded to the Protocol Attachments section.

Please describe the characteristics of the subject population. Include information on gender, age, ethnic background, and health status.

Please describe the Subject Inclusion Criteria. Please be as specific as possible.

Please describe the Subject Exclusion Criteria. Please be as specific as possible. Remember that Exclusion Criteria are related to any subject that fulfills all Inclusion Criteria but has a characteristic -- that could be a confounding variable, for instance -- that makes him/her not suitable for the research. If one study criteria is, "to be Hispanic and able to consent," for instance, please do not state, as Exclusion Criteria, "to be not Hispanic and unable to consent."

Please describe investigational methods and procedures. Your description MUST include details about the study design, independent and dependent variables, instruments, statistical plan per objective, quality control methods, limitations, biases, and methods to minimize bias. Note that copies of each instrument (surveys, scales, etc.) must be uploaded in the Protocol Attachments section. Additionally, if your description of the statistical plan exceeds half a page, please upload a copy of the statistical plan to the Protocol Attachments section in addition to the description provided here.

What are the possible risks and discomforts to subjects, as described on the consent form? Please include expected frequency and severity of adverse reactions or risks. Be sure to state if the research activities involve no more than 'Minimal Risk.' If so, state each one separately. Submissions stating 'this study implies no risk' are not acceptable.

Please describe the special precautions to minimize risks or hazards. Please state, in a separate manner, the special precautions as they apply to each possible risk or discomfort stated above. Please take into consideration that discomfort can be influenced by factors such as study content and participant time commitment. Investigators must consider consequences to participants' mental/emotional state, level of fatigue, etc.

Please describe the measures taken to protect confidentiality. Please address the following questions in your response: Who is responsible for each component of each protocol? When will data be shared and how? How will you protect the data? How long will the data be stored once the study is finished? How will you dispose of data once the study is finished?

1. **PI Submission Interview (Complete)**

Is this study generalized or non-generalized? (Yes/No)

If non-generalized, is the study a pilot study or an exploratory study? (If the study is generalized, type 'N/A'.)

What is your sample size?

How did you calculate your sample size? Include alpha/beta values, errors or differences, confidence intervals, baseline values such as incidence, prevalence, and median values as they apply to the study, including a percentage of margin of error, etc.

What is the age range of your subjects?

What is the source of your subjects?

Does your study propose remuneration for participants by test and/or study? (Yes/No)

In your judgement, might the procedures place the subject at more than minimal risk? (Yes/No)

In your judgement, are the proposed research procedures apart from and beyond the diagnostic and therapeutic needs of the subject? (Yes/No)

Will the procedures involve administration of new drugs, which have not been approved formerly? (Yes/No)

Will the procedures involve an Investigational Device? (Yes/No)

Does the study include questionnaires with sensitive areas, for example alcohol/drug abuse, sexual behavior, HIV status, etc.? (Yes/No)

Does the protocol involve Biohazard risk? (Yes/No)

I agree to use procedures with respect to safeguard human subjects involved in this research. (Yes/No)

If changes in investigative procedures involving human subjects are called for during the research program covered by this application, I shall seek prior approval for the changes from the IRB and I shall agree to follow their recommendations. (Yes/No)

I further agree to report to the IRB, if applicable, any complications or unanticipated or adverse events with respect to human subjects. (Yes/No)

I also understand that I must submit a renewal application annually. (Yes/No)

1. **Data Sharing (Complete)**

Will this application include Data Sharing? (Yes/No)

How will you be sharing the data? Describe the method of data transfer.