

Respond to each of the following items or questions. Provide enough detail so the reviewers will be able to judge how well your study protects human subjects.

If any item listed on this form is not applicable, enter N/A. Do not leave any required items blank.



Additional Uploads Required

In addition to answering these questions, some protocols will require supporting documentation including but not limited to Informed Consent, Minor Assent, Survey Consent, copies of surveys or questionnaires, interview guides, recruitment materials, or site permission letters. These documents should be uploaded directly to the protocol homepage on Axiom Mentor.



No question answered yet.

* Has another IRB approved this protocol? If YES, list the name and contact information and upload documentation from the IRB which includes their approval of this protocol.

Answer Required

Answer

* Are there any study sponsors, grants, or contracts associated with this protocol? If yes, list the name and contact information of the agencies involved and attach documentation from the agency regarding this protocol.

Answer Required

Answer

* Provide a brief description of the proposed study (i.e. purpose, problem to be investigated).

Answer Required

Answer

* What is the hypothesis to be tested?

Answer Required

Answer

* What are your qualifications for conducting the study? (i.e. what is your experience with the procedures and instrumentation to be used in this study?) If you are a student, what is your status, who is your faculty advisor, what are his/her qualifications?)

Answer Required

Answer

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No question answered yet.

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* Ages:

Answer Required

Answer

* Sex:

Answer Required

Answer

* Race:

Answer Required

Answer

* Provide a target number of subjects needed to complete the protocol. Include sample size estimate/power analysis if performed.

Answer Required

Answer

* Describe the expected rate of screen failure/dropouts/withdrawals from all sites.

Answer Required

Answer

 No question answered yet.

* List the criteria for inclusion.

Answer Required

Answer

* List the criteria for exclusion.

Answer Required

Answer

* List any restrictions on the use of drugs or other treatments.

Answer Required

Answer

* How will participants be recruited? Check all that apply. *Attach all recruiting material for review.*

- Options:**
1. Posters/Flyers
 2. Email
 3. Television
 4. Radio
 5. Newspaper Ads
 6. Internet/Social Media
 7. Medical Records/Database Review - subjects will be contacted
 8. Medical Records/Database Review - subjects will not be contacted
 9. Referrals from other health care providers
 10. Other - please explain.

Answer Required

Answer

* How will the consenting process take place?

Answer Required

Answer

* Do you plan to enroll yourself, your own students, patients, staff, employees, or other personnel listed on this protocol or students, patients, staff, employees of any of the other personnel listed on this protocol?

- a. If yes, which groups?
- b. If yes, explain how these potential subjects will be recruited to avoid the appearance of coercion.

Answer Required

Answer

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What will be done in the protocol? Provide a detailed list of step-by-step procedures. Be specific about the methods, instrumentation, and type of data collected.

Answer Required

Answer

* What details of the study are best kept secret from the participants? Will there be any deception involved in this protocol?

Answer Required

Answer



Payment Required Questions Unanswered: 2

i Total possible compensation should reflect the true value of the total possible dollar amount per participant for involvement in this study.

i No question answered yet.

* Are subjects being compensated for being in this study? Compensation includes payment for things like time, discomfort, inconvenience.

- Options:**
1. No
 2. Yes

Answer Required

Answer

If yes, what is the total compensation to be given over the duration of the protocol? Explain the compensation plan.

Answer

* Are subjects being reimbursed for travel expenses? Reimbursement includes paying a subject back for expenses like mileage, parking.

- Options:**
1. No
 2. Yes

Answer Required


Answer

If yes, explain the rate/amount of reimbursement.

Answer

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⌵ Risk/Benefit Analysis Required Questions Unanswered: 3

 No question answered yet.

* What are the potential risks for the participant in the study? Risks could be physical, psychological, social, legal, etc. and may result from your experimental procedures or your methods of obtaining, handling, or reporting data.

Answer Required

Answer

* Describe other methods that were considered that would reduce or eliminate these risks and explain why they will not be used.

Answer Required

Answer


* What are the potential benefits for the participant as well as benefits which may occur to society in general as a result of this study?

Answer Required

Answer

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🔒 Data Safety and Monitoring Plan **Required Questions Unanswered: 2**

 No question answered yet.

* Describe how you will minimize or protect against potential risks for subjects throughout the study.

- a. Describe emergency procedures, confidentiality safeguards, debriefing procedures, security measures for storing data, etc.
- b. Identify all personnel involved in the study, their role, their qualifications, and their access to the data.

Answer Required

Answer


* Provide the names and contact information of experts in your field (not including the investigators) with whom the committee members could communicate to discuss the potential risks of your procedures.

Answer Required

Answer



🔒 Bibliography **Required Questions Unanswered: 1**

 No question answered yet.

* Bibliography

Answer Required

Answer

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