FORM B: APPLICATION FOR USE OF HUMAN SUBJECTS IN RESEARCH

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.

Background and Brief Summary

1. 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.

2. 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.

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

4. What is/are the research questions/hypotheses?

5. 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, and what are his/her qualifications?

Human Subjects

Ages:
Sex:
Race:

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

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

Inclusion/Exclusion Criteria

1. List the criteria for inclusion.

2. List the criteria for exclusion.

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

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

a. __ Posters/Flyers
b. __ Email
c. __ Television
d. __ Radio
e. __ Newspaper Ads
f. __ Internet/Social Media
g. __ Medical Records/Database Review – subjects will be contacted
h. __ Medical Records/Database Review – subjects will not be contacted
i. __ Referrals from healthcare providers
j. __ Other: please explain

5. How will the consenting process take place?

6. Do you plan to enroll yourself, your 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.

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

8. Will there be any deception involved in this protocol? If so, what details of the study will be kept secret from the participants?

Compensation

1. Are subjects being compensated (e.g. monetary compensation, gift cards, gas cards, course extra credit) for being in this study? Compensation includes payment for conditions like time, discomfort, inconvenience.

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

2. Are subjects being reimbursed for travel expenses? Reimbursement includes paying a subject back for expenses like mileage, parking.
        i. If yes, explain the rate/amount of reimbursement.

Risk/Benefit Analysis

1. What are the potential risks for the participant in this 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.

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

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

Data Safety and Monitoring Plan

1. Describe how you will minimize or protect against potential risks to 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.

2. 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.

Bibliography

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.