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SUNY Downstate IRB & Privacy Board
FORM 13-2: Scientific Reviewer Worksheet
(Version 10.19.2022)
Instructions: 1) Open form in Adobe Reader. 2) Use Fill & Sign tool to complete. 3) Confirm any preformatted fields are correct. 4) Save file. 5) Submit completed form to IRB.
Note: Free Adobe Reader available at: www.adobe.com

Section 1: General Information:

A. Protocol Title:

B. Principle Investigator:

C. Reason for SRC Review:

- ☐ Required by IRB (as indicated in Step 13 of IRB submission website)
- ☐ Required by Dean/Department Chair
- ☐ Requested by PI
- ☐ Other (specify):

D. Additional Information for IRB (optional):

Section 2: Study Design Evaluation:

Consider the following in your review of the Scientific Design and answer questions 1-2:

What is the design of the study?

a) Is the study designed as a feasibility pilot? for proof of concept?
b) Is the study designed for hypothesis generation (i.e., is it exploratory) or is it
c) confirmatory (i.e., a formal hypothesis testing study)?
d) Is the study designed to examine the efficacy/effectiveness of an intervention? If yes, is it designed to examine:
    i. Superiority?
    ii. Non-inferiority?
    iii. Equivalence of the intervention vs. placebo or an alternative intervention?
e) Are the study outcomes and other study variables clearly defined and measurable?

f) If the study employs random allocation to treatment, is the randomization strategy clearly described/appropriate?
g) If the study is observational, does the plan adequately control for bias and confounding?
h) If the objective of the study is to validate a new procedure or questionnaire, is the validation method appropriate?

1. Has the study design been identified and clearly described?

◯ **YES** ◯ **NO** ◯ **N/A**

2. Is the design appropriate to answer the research question(s)?

◯ **YES** ◯ **NO** ◯ **N/A**

Comments on Study Design (optional):

Section 3: Statistical Considerations:

Consider the following in your review of the Statistical Methods and answer question 3

Has a sample size justification been included?

a) Is it adequate for determining statistical power or precision? (i.e., are assumptions properly explained?
b) Has adequate consideration been given to the potential number of study-eligible subjects, within the identified enrollment period?
c) Has adequate consideration been given to potential loss to follow up?
d) Has adequate consideration been given to evaluation and statistical management of potentially missing data?
e) If the study is quantitative and inferential, are the statistical tests described appropriate to test the study hypotheses or to provide adequate estimates of population parameters?
f) If the study is descriptive or qualitative, is the analytic methodology clearly explained

3. Does the study protocol include an adequate statistical plan?

◯ **YES** ◯ **NO** ◯ **N/A**

Comments on Statistical Plan (optional):

Section 3: Other Considerations:

4. Is the protocol likely to yield valid and meaningful information?

◯ **YES** ◯ **NO** ◯ **N/A**

5. **Are the research team's qualifications and facilities sufficient to protect participants and achieve the objectives of the study?**

   ◯ **YES** ◯ **NO** ◯ **N/A**

6. **Do you agree that the study is safe to conduct and that there is a proper monitoring plan in place?**

   ◯ **YES** ◯ **NO** ◯ **N/A**

7. **Based on the elements identified above, (questions 1-6) does the proposed study have scientific merit?**

   ◯ **YES** ◯ **NO** ◯ **N/A**

Section 4: Summary of Comments and Recommendations:

Note: If the SRC will not approve the study, the PI should be given the feedback generated from this reviewer worksheet, so the study can be revised. If the SRC answers "no" to any of the questions, but still wishes to grant approval, justify recommendations for approval.

Section 5: Determination:

◯ **Approve**

◯ **Disapprove**

E-Signature:

SRC Reviewer MUST e-sign this form: 1) Open form in Adobe Reader. 2) Use Fill & Sign tool to complete. 3) Confirm all responses are correct. 4) Click on Red Signature tab to sign. 5) Save file. Note: Free Adobe Reader available at: www.adobe.com