Central Methodology Review Committee (CMRC)
REVIEWER WORKSHEET & CERTIFICATION

CMRC REVIEWER INSTRUCTIONS:

1. Attempt to complete the initial review of a CMRC submission within 2 to 3 weeks; however, this turnaround time is dependent on the workload of the reviewer, the need to consult with others, and the availability and responsiveness of the PI.
2. Carry out protocol review and certification process in a professional and diligent manner.
3. Notify the CMRC Coordinator via CMRC@downstate.edu if
   a. if review will be delayed,
   b. there is a need to assign it to another reviewer, or
   c. if unavailable to conduct reviews on an extended period of time, such as vacation or heavy workload outside of the CMRC.
4. Request feedback from other CMRC members or consultants as needed.
5. Request a CMRC committee review when needed, after consulting or confirming with Co-Chair.
6. To avoid confusion is best to have just one CMRC member communicate with the PI, as needed. The communicating CMRC member is determined by the reviewers assigned to the group; however, this is typically the biostatistician.
7. The CMRC member that is designated to communicate with the PI contacts the PI with recommendations and requirements. This may be an iterative process using any method that is convenient to the reviewers. Simple changes may be requested without this form or formally requested with this form.
8. Open, fill, and sign form with Adobe Reader (https://get.adobe.com/reader/)
9. Once the protocol is deemed to be ready for IRB submission, the CMRC member sends the certification to BOTH the PI and CMRC@downstate.edu to complete the process. The CMRC coordinator will update the CMRC log.

Version 3.21.24

PART I: Protocol Information (Completed by CMRC Coordinator)
(See request form for additional information)

CMRC #:

TITLE:

PI:

Remarks (Optional):

PART II: CMRC Review (Completed by CMRC Reviewers)

Study Design:

General considerations to answer questions 1-2 (below):

- Are the background information, rationale, and significance clear?
- Are the supporting literature citations accessible and appropriate, when applicable?
- Is the problem statement and/or purpose clear?
- Have the investigators clearly conceptualized a strategy to achieve the goals of the study?
- Are the implications of the research clear?
- What is the design of the study?
    - Is the study designed as a feasibility pilot? for proof of concept?
    - Is the study designed for hypothesis generation (i.e., is it exploratory) or is it confirmatory (i.e., a formal hypothesis testing study)?
    - Is the study designed to examine the efficacy/effectiveness of an intervention?
        - If yes, is it designed to examine:
            - Superiority
            - Non-inferiority or
            - Equivalence of the intervention vs. placebo or an alternative intervention?
- Are the study variables to be collected clearly defined and measurable?
- If the study employs random allocation to treatment, is the randomization strategy clearly described/appropriate?
- If the study is observational, does the plan adequately control for bias and confounding?
- If the objective of the study is to validate a new procedure or questionnaire, is the validation method appropriate?
- Are the research methods consistent with the research questions/hypothesis, design, setting, sampling, intervention, data collection, analysis, etc?
- Are the procedures complete (e.g., could another researcher replicate the study)?
- Are the inclusion and exclusion criteria clearly defined and relevant?
- Are the collection of variables clearly listed (review data collection tools)?
- Can the PI answer the research questions or objectives based on the data collection and study design?
- Is there adequate access to the required study population?
- Are there any logistical concerns?
- Are all of the study design pieces linked together appropriately?
- Is the study feasible given SUNY Downstate resources and study population?

Study Design Evaluation:	Yes	No	N/A	Comments
1. Has the study design been identified and clearly described?	☐	☐	☐	

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

Statistical Plan:
General considerations when answering question 3 (below): • Has a sample size justification been included? • Is it adequate for determining statistical power or precision (i.e., are assumptions properly explained)? • Has adequate consideration been given to the potential number of study-eligible subjects, within the identified enrollment period? • Has adequate consideration been given to potential loss to follow-up? • Has adequate consideration been given to evaluation and statistical management of potentially missing data? • 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? • If the study is descriptive or qualitative, is the analytic methodology clearly explained? ***Examples of statistical problems that could affect CMRC certification:*** • *Sample size is larger than needed to reach the study objectives.* • *Sample size is too small to reach the study objectives.* • *Deficiencies that may result in the ability to achieve meaningful results, such as problems with randomization (if applicable), study design structure, proposed statistical analysis, clearly defined endpoint variables, clearly defined aims, provisions for blinding (if applicable).* • *Lack of, or inappropriateness, of power or precision analysis, which decreases the likelihood of developing knowledge to the point that risks are no longer reasonable.* ***Examples of statistical problems that usually do NOT affect CMRC certification:*** • *If the study involves no greater than minimal risk, statistical issues would likely have no effect on certification.* • *The qualifications of the person who will perform the data analysis.* • *Lack of power or precision analysis that does not affect certification.*

Statistical Plan Evaluation:	**Yes**	**No**	**N/A**	**Comments**
3. Does the study protocol include an adequate statistical plan?	☐	☐	☐	

PART III: CMRC Determinations (Completed by CMRC Reviewer)
(Skip this section if ready to certify without recommendations or comments)

☐ **Check here to indicate the investigator made changes to the protocol to the satisfaction of the CMRC team** (include a copy of the final protocol with this certificate).

☐ **Recommendations (optional):** The PI may make changes to the protocol and submit to the IRB.

☐ **If the CMRC reviewer answers "no" to any of the above questions (1, 2, or 3), but still wishes to certify the study, please provide a justification:**

Other Comments:

PART IV: CMRC Certification (Completed by CMRC Reviewer)

The CMRC certifies this protocol is ready for submission to the Downstate IRB by signing below.
(Complete below and e-mail the certification to the PI and CMRC@downstate.edu)

Certified by (CMRC Member Name):

Date of Certification:

CMRC E-Signature: