DOWNSTATE
HEALTH SCIENCES UNIVERSITY

CENTRAL METHODOLOGY REVIEW COMMITTEE (CMRC)
REVIEW REQUEST FORM

INVESTIGATOR INSTRUCTIONS:

1. Confirm the protocol requires CMRC submission (see page 2 for criteria).
2. Develop the Research Protocol using one of the Downstate IRB Protocol templates (posted at Step 7 of the IRB Electronic Submission Process webpage).
    a. The CMRC and IRB has revised the Downstate protocol template for this pilot phase. Use one of the Downstate protocol templates or one of the NIH templates posted on the IRB website.
    b. Include all elements in the protocol template or indicate N/A.
3. **Open, fill, and sign this form with Adobe Reader** (https://get.adobe.com/reader/).
4. Submit the following to CMRC@downstate.edu prior to submission to the Downstate IRB.
    a. The Research Protocol (noted above).
    b. Data collection tools, including surveys.
    c. CMRC Review Request Form (this form), e-signed by PI.
    d. If applicable, provide communication from the Downstate IRB that indicates CMRC review is required.
    IMPORTANT TIP: To avoid delays with the IRB submission, the PI should work on other requirements for IRB review during the CMRC review process, such as the IRB application, informed consent, etc., as these are not submitted to the CMRC.
5. Review confirmation e-mail from CMRC Coordinator for any additional instructions.
6. Correspond directly with the CMRC reviewers and/or CMRC Coordinator.
    a. Attend a Zoom interview (scheduled about 1-2 weeks after submission).
    b. The CMRC will 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 reviewers, the need to consult with others, and the availability and responsiveness of the PI.
    c. Respond to the CMRC in a timely manner. Iterative changes may be required. Revise the protocol based on CMRC review, if requested.
7. Review the CMRC certification, once received and consider any additional recommendations.
8. Submit the CMRC certification to the Downstate IRB along with the final protocol during the IRB submission process. The PI may submit a CMRC certified protocol to the Downstate IRB 2 weeks after the normal deadline posted on the IRB website.
9. It is recommended that the PI provide feedback to the CMRC.
10. Refer to CMRC Process for additional information

CHECK CRITERIA FOR CMRC REVIEW:

Prior to submitting the Downstate IRB application (Form 11-A2 or Form 11-A1, in the case of some deception research) to the Downstate IRB, Investigators must submit their human research protocol[1-2] to the CMRC when it meets one or more of the following criteria:

☐ 1. A drug, biologic, or medical device is the object of the study[3].

☐ 2. Includes prospective specimen collection.

☐ 3. Non-exempt[4] human research with inclusion criteria for the prospective enrollment[5] of one or more of the following populations: pregnant women, pregnant persons, human fetuses, neonates, prisoners, children, individuals with physical disabilities, individuals with mental disabilities or cognitive impairments, economically disadvantaged, socially disadvantaged, terminally ill or very sick, under-represented populations, under-served communities, people of diverse backgrounds, or institutionalized persons (persons in correctional facilities, nursing homes or mental health facilities). This category **does not include** the following activities when the study qualifies for expedited IRB review: educational tests, surveys, interview procedures, focus groups, observations of public behavior, or benign behavioral interventions.

☐ 4. Involves deception research (full research purpose is not disclosed to participant).

☐ 5. Any study not otherwise described above which requires Full Board review by the Downstate IRB. Consult with the IRB for guidance, if needed.

☐ 6. If CMRC review is required by the Downstate IRB (include a copy of the IRB communication).

FOOTNOTES:

1) Contact the Downstate IRB at IRB@downstate.edu for additional guidance, as needed. Include a copy of the draft protocol. Do not submit sponsored generated protocols to the CMRC for research which require review by a Reviewing (external) IRB via an agreement such as an IRB Reliance Agreement (e.g., multi-site studies which are sponsored by industry; conducted or supported by a federal agency or federal department; or overseen by the NCI CIRB).

2) Research protocols submitted to the Downstate IRB that are peer reviewed and funded through a Federal Department/Agency are recommended (not required) for Central Methodology Research Committee (CMRC) review; however, the IRB has the option to refer the protocol for CMRC review if necessary for IRB approval. The IRB submission must include a data analytic plan and the grant application that was used to receive the award to verify congruency.

3) This category includes clinical investigations of investigational agents to determine their safety or effectiveness and research on FDA approved agents to further clarify efficacy and/or sensitivity. This category does not include studies that use an FDA approved/marketed medical device to measure what the device is designed to measure; nor does this category include studies involving an FDA approved/licensed agent that is used per indication in a clinic or the review of medical records about an agent.

4) This category does not include studies which qualify for exempt review by the IRB. Exempt research, for example, includes research involving ONLY one or more of the following activities: adult surveys, educational tests, adult interviews, observations of public behavior of adults, data collection (chart reviews, secondary data), normal educational practices (instructional strategies, techniques, curricula, classroom management), or benign behavioral interventions with adults.

5) This criterion does not apply to unplanned or incidental enrollment of these populations.

STUDY INFORMATION:

TITLE:

PI:

Downstate E-Mail for PI:

Best Phone # for PI:

Department or College:

Study Coordinator (if applicable):

Downstate E-Mail for Study Coordinator (if applicable):

Remarks (optional):

Date:

PI e-Signature: