



CENTRAL METHODOLOGY REVIEW COMMITTEE (CMRC) PROCESS (PILOT PHASE)

PURPOSE:

The Central Scientific Review Committee (CMRC) evaluates Downstate human research protocols noted below to ensure they meet acceptable standards for study methods, research design, and statistical analysis.

CRITERIA & INSTRUCTIONS FOR SUBMITTING A RESEARCH PROTOCOL FOR CMRC REVIEW:

Review the criteria and follow the instructions for submitting the CMRC Request Form which available on the form. The CMRC Request Form is posted at [Step 7 on the IRB submission website](#).

Contact the Downstate IRB at IRB@downstate.edu for additional guidance, as needed. Include a copy of the draft protocol.

CMRC REVIEW PROCESS:

1. The **CMRC Coordinator** does the following:
 - a. Tracks availability of CMRC reviewers (see item 3 a below) on the CMRC calendar.
 - b. Enters the protocol into the CMRC Log.
 - c. Creates a protocol folder on the CMRC One Drive folder. This is available to all CMRC members.
 - d. Confirms protocol meets the criteria for CMRC review.
 - i. Consults with IRB Office as needed for confirmation. If the study does not meet the criteria for CMRC review, a note is added to the CMRC log and the PI is notified.
 - ii. If it meets the criteria for CMRC review, acknowledges receipt by sending a confirmation e-mail to the PI within 1 business day of receipt.
 - e. Assigns the review to two CMRC reviewers, including one biostatistician within 1 business day of receipt.
 - f. Coordinates a Zoom interview with the PI and CMRC reviewers. This should be tentatively targeted for 1 to 2 weeks after submission. All parties should confirm availability. Note: Additional time may be needed

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- by the parties depending on their workload; however, the CMRC review can be reassigned to another CMRC review, if needed.
- g. Reaches out to the CMRC Co-Chair for guidance on assignment when needed; however, reviewers are assigned in advance on the CMRC log.
 - h. Re-assigns the study to another CMRC member if a reviewer discloses a conflict.
 - i. Monitors turnaround time and submits reminders to CMRC reviewers as needed. Tracks the final turnaround time and issues quality improvement surveys designed by the CMRC.
 - j. Sets up CMRC meetings as needed or when requested by the CMRC members for a specific protocol review (after consulting or confirming with Co-Chair) or when requested by a Co-Chair.
1. The **CMRC Members** follow the instructions on the CMRC Review and Certification form. This form is available at [Step 7 on the IRB submission website](#).
 2. The **CMRC Administrator** does the following:
 - a. Helps establish the CMRC process with the Co-Chairs.
 - b. Trains the CMRC coordinator.
 - c. Serves as a back-up to the CMRC coordinator.

Note: The IRB Associate Administrators may assist with any of the above as needed.

FREQUENTLY ASKED QUESTIONS REGARDING CMRC REVIEW:

Q1: How do I fill out and sign the form using Adobe Reader?

A1: Do the following:

1. Save the form on your desktop with the name of your choice.
2. Download [Adobe Reader](#) if you do not have it on your computer.
3. Open Adobe Reader.
4. Click "Fill & Sign."
5. Select the file that was saved in step 1.
6. Fill out the form.
7. Click on the red tab in the Signature box and follow prompts.

Q2: Is CMRC review required for studies overseen by an external IRB such as a commercial IRB or sIRB?

A2: No. CMRC review is not required for studies sent to a Reviewing (External) IRB reviewing research under an IRB Reliance Agreement.

Q3: Can the CMRC review other studies that are not required to go to the CMRC?

A3: No. The CMRC does not have the capacity to provide a consultation service and cannot review other studies. It is recommended that investigators obtain a mentor or consultant or collaborate with others when needed.

Q4: What is the role of a Dean or a Department Chair when reviewing a study submitted to the CMRC?

A4: None. They do not need to review the study before it is submitted to the CMRC. The Dean or Department Chair determines merit, value, operational impact, feasibility, institutional efficiency, and whether the research fits within the scope of the mission of Downstate at the time the study is submitted to the Downstate IRB. The PI should consult the Dean or a Department Chair if they have any questions on whether they would have any concerns with conducting the research at Downstate.

Q5: Is the Departmental and College level Scientific Review Committee (SRC) still required by the IRB?

A5: No, this is NOT required by the IRB. SRC review is not required by the Downstate IRB for any study undergoing CMRC review, *including those reviewed during the pilot phase*. SRC review may be valuable for other types of studies and may or may not be required by the Department Chair or Dean. The PI should consult with the Department Chair or Dean if they have any questions about their requirements for SRC review.

Q6: Does the CMRC provide guidance on the requirements of Downstate IRB?

A6: No. The IRB is responsible for protecting the rights and welfare of research participants, ensuring the ethical conduct of the research, evaluating risks, and achieving regulatory and policy compliance. Questions regarding IRB requirements must be directed to the Downstate IRB.

Q7: Is the CMRC part of the IRB or part of the Department or College review?

A7: No. The CMRC review is independent from the review of the Dean/Department Chair and the IRB.

Q8: Can the Downstate IRB require CMRC review of other studies?

A8: Yes. The Downstate IRB can require CMRC review for any study which appears to be methodologically flawed, *including during the pilot phase*.

Q9: What is being done to monitor the quality of the CMRC?

A9: At any time, the PI may provide feedback or direct questions to CMRC@downstate.edu. For quality improvement purposes, the CMRC may send out surveys from time to time to ask about the quality of the CMRC review and process. This is optional; however, input is appreciated.

Q10: Can the PI appeal the decision of the CMRC?

A10: If the PI disagrees with any of the required changes by the CMRC, (s)he should appeal the decision to the CMRC in writing to CMRC@downstate.edu. The Downstate IRB will serve as the final arbiter of any discrepancies, concerns, or controverted issues, when an appeal cannot be resolved.