Memorial Sloan Kettering Cancer Center

Clinical Research Oversight Committee (C-ROC)
Objectives and Guidance for Review

C-ROC Objective: The C-ROC is charged with performing independent oversight review of research for which certain individual and/or institutional conflicts of interest exist, to protect against even the perception of any lack of objective judgement and/or decision-making that could impact research integrity or research subject welfare.

This includes the review of the following with respect to covered studies, to **assess whether documentation or information reviewed demonstrates that there is actual or potential bias or lack of objective judgement and/or decision-making in the research**:

1. Evaluation of research activity and progress (through review of IRB Continuing Reviews and protocol deviations, DSMC reports and/or reports of adverse events, audit reports if applicable, and other documentation or information if/as applicable and available) to determine if there is any specific indication or evidence of *bias* in enrollment practices, and/or subject data collection, analyses, or reporting (or other study activities)
2. Determination of whether additional information is needed from the study team to inform the C-ROC review and disposition

Bias is defined as a systematic distortion, prejudice or deviation from generally accepted scientific practice or standards, whether in results or inferences.

Key Roles & Responsibilities and Scope Reminder Points:

Conflict of Interest Committee (COIC)	• Reviews individual and institutional interests and determines whether conflicts exist, and if so, if they are manageable • Reviews and approves compelling circumstances • Institutes COI management plans
Clinical Research Oversight Committee (C-ROC)	• **Performs reviews of specific research studies covered under individual and institutional COI management plans that require independent review** • **Determine whether each review demonstrates any actual or potential bias or lack of objective judgement and/or decision-making in the research that could (or has) impact(ed) research integrity or research subject welfare** • **Members' scientific and clinical expertise important to understand study design, aims, and activities in order to appropriately identify bias (or confirm lack thereof)**
Compliance	• Supports the work of the COIC and C-ROC • Provides insight and assistance relative to COIC and C-ROC reviews • Perform routine and more administrative (as opposed to scientific/clinical) compliance monitoring to assess compliance with individual and institutional COI requirements, including management plans; this includes tasks that may inform/assist/compliment the C-ROC in their reviews (e.g., checking that appropriate disclosure language is included in ICFs for covered studies; checking that appropriate COI disclosures have been made in publications, etc.)

General C-ROC Review Guidance:

The Committee should review the documentation available for each project to ensure that:

- The research procedures and methods have been designed according to sound and accepted scientific reasoning
- The research activity has been *conducted* in a manner consistent with standard scientific procedures and in accordance with the approved research protocol
- The research data has been *analyzed* in a manner consistent with standard scientific procedures and in accordance with the approved research protocol
- The research results have been *reported* in a manner which accurately reflects the research data generated and analyzed

Factors to Consider: In conducting this review, please consider the following:

- The nature and magnitude of the Institutional financial interest
- The nature of research conducted and how the ICOI may impact the research or bias the research
- Nature and level of MSK's involvement in the study
- The structure and design of the research, including aspects of the design that could serve as potential controls (e.g., multi-site, blinded, external data safety monitoring board (DSMB));
- Evidence of enrollment practices that deviate in a manner that might indicate inclusion or exclusion bias
- Evidence of systematic bias in data gathering or analyses, including patterns uncovered in reported deviations, adverse events or preliminary statistical analyses, that could indicate bias
- Safeguards in place by institution/investigators to ensure integrity and reduce risks of bias

Conclusions: All conclusions of the C-ROC's review, and any requests for additional information, will be reported out at the C-ROC meeting. A draft template form (evolving and subject to change) for documentation and summary of C-ROC review disposition is included as Appendix A.

If bias is found, Compliance will work with the C-ROC, the COIC, the IRB and others if/as needed to develop a plan for appropriate handling and action.

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Standard Materials Compiled and Made Available to Inform C-ROC Reviews:

ICOI Management Plan Documentation

- Summary information related to nature of institutional interests, related technologies, and IP inventors (File: *CROC – ICOI Entities & Protocols)*
- For each ICOI plan, detailed summary information regarding related interventional, non-interventional, and single patient use protocols related to institutional interests. Summary includes all individual COIs by study (both IP and personal financial interest related), and key study details and dates (File: *CROC – ICOI Entities & Protocols)*
- Copy of ICOI management plan and latest updated Appendix, as applicable
- Documentation of compelling circumstances to perform related interventional research at MSK
- Copy of ICOI notifications sent to participating investigators and study team members

Protocol Specific Documentation (for all human subjects research)

- Current protocol and informed consent form(s) with amendment number and date noted
- Latest IRB continuing review documentation, including continuing review report (including listings of protocol deviations) and IRB approval correspondence.
- DSMC review documentation, including DSMC monitoring form and database report submitted by the study team, and DSMC approval and any correspondence documentation between the DSMC and the study PI
  - For those studies currently under active review by the DSMC, all past year review documentation is included, specified by meeting date
  - If no longer or never under MSK DSMC review, SAE documentation from PIMS included. For those studies previously but no longer under DSMC purview (i.e., closed to accrual or change in sponsor), latest review documentation included with corresponding date
- Any relevant internal or external audit documentation, as applicable, including audit findings report and any corresponding Corrective and Preventive Action (CAPA) plans.

Requests for Additional Information: The Committee may request that Compliance staff gather additional information from the investigators on the Committee's behalf. The Committee may also request to interview the Investigator or members of the study team.