The Drew RCMI Clinical Research Advisory Committee (RCAC)

RCAC Membership

Lee Irons (Research Center Administrator; RCAC Chair)
Mayer Davidson, M.D.
Theodore Friedman, M.D., Ph.D.
Esther Hernandez, R.N. (Research Subjects Advocate)
Stanley Hsia, M.D.
Dulcie Kermah, M.P.H.
David Martins, M.D., M.S.
Melba Miller, R.N.
Keith Norris, M.D. (non-voting)
Laurice Pitts, L.V.N.
Atam Singh, M.D.

RCAC Responsibilities

To set general policies governing the Drew Clinical Research Center; to review the operations of the clinical research program, including the core laboratories; to evaluate proposed research projects for utilization of CRC resources; to assist the Program Director (Keith Norris, M.D.) in allocating resources; to implement NIH policies on the inclusion of women, minorities, and children as study subjects; to conduct periodic reviews of all CRC operations to ensure that resources are used for the most scientifically justified and relevant projects; to work closely with the Program Director to proactively address investigator resource needs; to encourage CRC use by junior investigators, or others who are not currently using it; to provide outreach to investigators at institutions that do not have a CRC; to request NCRR funds (competitive renewal, noncompetitive renewal, supplements); to approve all rebudgeting requests once funds have been awarded.

RCAC Subcommittees

Scientific Review Subcommittee

Mayer Davidson, M.D. (chair)
Ted Friedman, M.D., Ph.D.
Keith Norris, M.D.

Responsibilities: To review the scientific validity and completeness of proposed clinical research protocols; to communicate with the IRB and IACUC regarding protocols involving human and animal research subjects; to report its scientific evaluation of protocols to the RCAC which has final authority to approve or deny investigator requests for utilization of the CRC.

Data and Safety Monitoring Board (DSMB)

David Martins, M.D., M.S. (chair)
Esther Hernandez, R.N. (RSA)
Kermah, M.P.H. (Biostatistician)
Martin Lee, Ph.D. (Sr. Biostatistician)

Responsibilities: To evaluate the data safety and monitoring plans of proposed protocols; to provide guidance to investigators in developing and implementing sound data safety
and monitoring plans; to provide an institutional resource for investigators (not limited to those utilizing the CRC) who require an objective panel to conduct periodic assessments of research in progress, with special reference to data quality and integrity; participant recruitment, accrual and retention; risk-benefit ratio; adverse events; and related issues.

**Hormone Assay Subcommittee**

Stanley Hsia, M.D. (chair)
Indrani Sinha-Hikim, Ph.D. (Sr. Research Associate)

Responsibilities: To develop policy and procedures regarding investigator utilization of the CRC’s hormone assay laboratory; to review investigator requests for utilization of the hormone assay laboratory.

**Logistics & Ancillary Procedures Subcommittee**

Lee Irons (chair)
David Martins, M.D., M.S.
Melba Miller, R.N.
Laurice Pitts, L.V.N.

Responsibilities: To review proposed protocols to determine whether the CRC has the resources to perform the study; to coordinate study implementation with CRC nursing staff; to develop policy and procedures regarding the charge-back system for investigator utilization of CRC resources; to review investigator requests for utilization of routine and specialized CRC resources; to approve special requests for utilization of CRC resources at reduced charge-back rates.

**RCAC Meetings**

The first RCAC meeting was held on September 20, 2004. Generally, the RCAC meets every 6 to 8 weeks. RCAC meetings are typically on a Friday from 8:30 a.m. to 10:00 a.m. in Hawkins # 3059. Official minutes are kept, documenting all reports to the RCAC and all recommendations made by the RCAC.

**Contact**

Additional information is available online at [www.cdrewu.edu/rcmi](http://www.cdrewu.edu/rcmi).
To apply to utilize the Drew CRC, contact the RCAC Chair:

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Last Revised 4/29/05