I. Policy:
   A. Albert Einstein College of Medicine of Yeshiva University (Einstein) (FWA00000140) and the Montefiore Medical Center (MMC) (FWA00002558) have designated the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) #1 (IRB00000781) as an IRB for Phase III cancer cooperative group trials and the NCI CIRB #2 (IRB00004296) as an IRB for pediatric cooperative group trials, as participants in the CIRB Initiative.
   B. Einstein and Montefiore will perform local institution functions outlined in the “Division of responsibilities between NCI’s Central IRB and Participating Local Institutions” and will rely on the NCI CIRB to fulfill stated responsibilities (http://www.ncicirb.org/CIRB_SOPs.pdf).
   C. The CIRB’s primary function is initial and continuing review of protocols, amendments and external adverse event reports.
   D. For the purpose of this policy, either of the Einstein IRBs (East or West) can serve as the ‘Local IRB (LIRB)’ whose primary responsibility is to conduct review with consideration to local context and oversight of local performance, that includes: review of the informed consent document, progress reports, amendments and internal adverse event reports.
   E. The Adult and Pediatric CIRB and the LIRB share regulatory responsibilities.
   F. The LIRB review will be known as ‘facilitated review’ and will be conducted by one scientific LIRB voting member. The LIRB will ensure compliance with standard administrative requirements and the appropriateness of the informed consent document, in accordance with the following guidelines:
      1. Local boilerplate additions to the informed consent dealing with state and local law, institutional requirements or LIRB policies may be added to the local consent document.
      2. LIRB may make minor word substitutions or additions in the ICD particularly to facilitate better comprehension by the local population, as long as the proposed changes do not alter the meaning of the CIRB approved consents.
      3. Revisions/changes to the local consent form other than those described above require full board review at the local level, and facilitated review may not be used.
      4. The LIRB retains the authority to accept or reject a ‘facilitated review’ on a protocol-by-protocol basis and may require Full Board Review.
   G. The Einstein IRB agrees to accept the facilitated review of the Primary LIRB.

II. Overview of the CIRB:
   A. The CIRB provides an innovative approach to human subject protection through a "facilitated review" process that streamlines local IRB reviews of adult and pediatric national multi-center cancer treatment trials.
   B. The CIRB is composed of individuals who represent a broad range of oncology scientific and nonscientific disciplines. These may include oncology physicians, nurses, patient representatives, pharmacists, ethicists and attorneys. None of the members, or the Chairs, are NCI employees.
   C. The Adult CIRB meets twice a month and currently reviews all Phase 3 Cooperative Group trials from the ACOSOG, CALGB, ECOG, GOG, NCCTG, NCIC CTG, NSABP, RTOG, and SWOG, as well as any other protocols opened in the Cancer Trials Support Unit (CTSU).
   D. The Pediatric CIRB meets monthly and currently reviews all CTEP-sponsored Pilot, Phase 2, and Phase 3 COG clinical trials. Upon request from the Division of Cancer Prevention (DCP), the Pediatric CIRB may review DCP-sponsored trials.
III. Procedures:
   A. Initial Review
      1. Principal Investigator responsibilities: After determining if he/she wants to participate in a CIRB reviewed adult phase III or pediatric pilot, phase II or phase III cancer cooperative group trial, PI or designee:
         a. Downloads and prints out the following documents from the Participants’ Area of the CIRB website (http://www.ncicirb.org): the CIRB protocol, informed consent document(s) and approval letter.
         b. Completes the appropriate LIRB’s Research Application, inserts CIRB approved elements into the LIRB consent template to comply with local requirements.
         c. Submits all materials simultaneously to the PRMC and the LIRB for facilitated review.
      2. LIRB facilitated review responsibilities: Designated staff member will:
         a. Print the CIRB minutes, scientific and non-scientific review materials from the CIRB web site. Immediately conduct administrative review to ensure all appropriate materials are available. Ensure that the consent document contains the local template elements. Follow up on local administrative requirements.
         b. Forward the materials to 1 voting LIRB member, preferably a member whose primary specialty is Oncology, and/or Chairman for facilitated review to determine: to accept the CIRB review, accept with minor modifications, or not accept the CIRB review. (If uncertain whether minor modifications meet CIRB requirements, staff member will confirm with CIRB.)
         c. Ensure that all administrative/facilitated review requirements are met, and accept CIRB approval on the CIRB website.
         d. Send the PI the written notification that the CIRB approval is affirmed, and the stamped consent document(s). The consent document approval stamp will reflect the LIRB approval date and the CIRB expiration date. (The initial approval period for the local PI will be less than 365 days. Thereafter, the CIRB approval/expiration dates will reflect the LIRB full recertification period.)
         e. Update the LIRB database, and include the transaction on the upcoming LIRB Committee Agenda for the membership’s information.

   B. Continuing Review:
      1. PI or designee responsibilities:
         a. Download and print out all the documents from the Participants’ Area of the CIRB website (http://www.ncicirb.org), including informed consent and recertification letter.
         b. Complete the appropriate LIRB’s Progress Report Form, including CIRB related documents, and submit to the LIRB for facilitated review.

   C. Amendments:
      1. PI/designee and LIRB responsibilities:
         a. Will confirm that an amendment posted on the Group website has been CIRB approved before sending to the LIRB.
         b. The LIRB’s standard Amendment Procedure remains in force and the procedures outlined in Section III, A. apply.
D. Adverse Event Reports:
   1. PI/designee and LIRB responsibilities:
      a. The LIRB Internal and External Adverse Event Report Policies and
         Procedures remain in force and all reports require LIRB review.