POLICY STATEMENT

Clinical research auditing is performed as set forth in this Policy, to ensure subject safety, protection of subject rights, verification of accurate and complete data collection, identification of deficiencies and development and implementation of appropriate corrective action plans. In addition, auditing is conducted to ensure compliance by Principal Investigators (PIs) with applicable Einstein and Montefiore policies and procedures, policies and procedures of the reviewing IRB, ICH Good Clinical Practice guidelines, and OHRP and FDA requirements. Audits of the Institutional Review Board (IRB) may be conducted under this Policy to ensure that the IRB is adhering to federal regulations governing human subject research.

SCOPE

The requirements of this Policy apply to all employees and other individuals involved in clinical research being performed at Einstein and Montefiore under the jurisdiction of the BRANY IRB, Einstein Montefiore IRB, or a central IRB. The PI maintains ultimate responsibility for compliance with the requirements of this Policy. With respect to clinical research performed at the North Bronx Healthcare Network under oversight of the Einstein-Montefiore IRB, the Associate Director of Research Auditing shall, on a regular and ad hoc basis, confer with research leadership at NBHN to ensure that auditing and reporting are performed in compliance with this Policy. In addition, as determined by the Research Integrity Officer(s), audits of clinical research under the oversight of the Einstein-Montefiore IRB performed at NBHN and/or Yeshiva University may also be conducted.
RESEARCH AUDITORS

Under the direction of the Research Integrity Officers for Einstein and Montefiore and the Montefiore Research Compliance Officer, clinical research auditing is conducted by the Associate Director of Research Auditing and the clinical research auditors at Einstein and Montefiore (collectively, the “Research Auditors”).

SELECTION OF STUDIES TO AUDIT: A clinical research auditing work plan will be developed on an annual basis and will be updated as needed. The work plan will be developed jointly by the Research Integrity Officers for Einstein and Montefiore, the Montefiore Research Compliance Officer, the Associate Director of Research Auditing, Director of the Einstein-Montefiore IRB, and the Research Auditors. Studies are selected for audit both judgmentally and randomly. The Research Auditor may elect to audit one particular study, selected studies, or all studies of a particular PI or department as a group. Factors considered in the selection of studies to audit include but are not limited to:

a. Risk level of the research interventions;
b. Studies with significant risk but no direct benefit;
c. Studies involving vulnerable population(s) and/or sensitive data;
d. Studies that are investigator-initiated;
e. Studies with higher than predicted accrual rates;
f. Studies in which the local PI is the IND or IDE holder;
g. Studies with new or early career investigators;
h. Studies for which Einstein or Montefiore owns an intellectual property and/or licensing interest;
i. Studies presenting other risks as determined by the Research Auditor.

THE AUDIT PROCESS

1. All research personnel involved in clinical research at Montefiore and Einstein are required to cooperate with audit notifications and requests for documents and other information by the Research Auditors and to assist the Research Auditors as needed, including remaining available throughout the audit for questions or discussion. Failure to respond or otherwise cooperate shall be referred to the applicable IRB and Research Integrity Officer for handling.
2. Except in the case of audits for cause, the PI and study team will receive three to five weeks advance notice in anticipation of an audit. Notification will be communicated via email describing the audit process and how the study documents should be prepared for inspection. Prior to the audit, the PI and study team are responsible for:

   a. Reserving a work space for the Auditor during the scheduled audit dates, ensuring computer access for the Auditors use with access to the electronic medical record and internet, as applicable.

   b. Gathering all research records described in the policy “Required Documentation for the Conduct of Research Involving Human Subjects” and making them available for review.

3. All requested study-related documentation must be printed out and organized as described in the formal audit notification.

4. During the audit, a review of the Regulatory Binder will be conducted to ensure compliance. For each subject reviewed, an Audit Review Form will be completed. The Research Auditor will review medical records and research files to verify compliance with the IRB-approved protocol and applicable research policies and regulations. Pharmacy and laboratories, as well as additional documentation, may be reviewed/inspected as applicable. The Research Auditor may also conduct a review of all protocol-mandated drug accountability records.

5. If subject safety issues and/or suspected research misconduct is observed during an audit, the Research Auditor will immediately notify the Associate Director of Research Auditing and the IRB, for review and escalation to the Research Integrity Officers for Einstein and Montefiore, the Research Compliance Officer, and others as applicable, who may take immediate action, including closure of accrual and/or conduct or suspension of the protocol, if deemed necessary.

6. An exit interview will take place promptly following completion of the audit. During the exit interview, the Research Auditor will communicate preliminary audit findings to the PI and the study team and present the findings. The exit interview is an opportunity for addressing questions that have come up during the audit, generating suggestions and recommendations for correcting issues of non-compliance, and identifying strategies for future process improvement. Findings requiring immediate
attention will be communicated at the time of the audit.

7. A signed Final Audit Report, identifying all positive and negative audit findings, will be sent via secure email to the PI and the study team following the exit interview. The Research Integrity Officers for Einstein and Montefiore, the Director of the Einstein-Montefiore IRB and the Research Compliance Officer will also be copied on the final report email. The PI should sign the audit report where indicated to acknowledge that all items requiring follow-up have been addressed, and return the signed copy to the Research Auditor.

8. A written response from the PI is required if findings of the audit require additional information or corrective action. The response should include, as requested by the Research Auditor, a detailed explanation describing the root cause for the violation and a detailed corrective action plan to decrease the risk of the non-compliant event or issue from happening again in the future. The Research Auditor will notify the Associate Director of Research Auditing of a PI’s failure to respond and the matter will be referred to the Research Integrity Officers for Einstein and Montefiore for further action. If a protocol amendment is proposed as a result of the audit findings, the PI will be required to submit the proposed amendment with the signed final audit report for review and approval by the Associate Director of Research Auditing before submission to the reviewing IRB. If protocol deviations are identified that require reporting to the IRB, copies of the completed Reportable Event form(s) shall be submitted with the written response.

AUDITS OF BRANY STUDIES

Both the PI and BRANY shall notify the Associate Director of Research Auditing at the time the PI receives notification of a planned audit. BRANY will immediately notify the Associate Director of Research Auditing of any adverse findings, so that the Associate Director of Research Auditing can be involved in mitigation and development of the corrective action plan, and so that notification can be made to the Research Integrity Officer(s) and/or Research Compliance Officer. If Montefiore conducts an audit of a study reviewed by BRANY, Montefiore shall notify BRANY at the time the PI receives notification of the planned audit.
AUDIT OF THE IRB

Under the direction of the Research Integrity Officers for Einstein and Montefiore, audits of the IRB may be conducted pursuant to this Policy. During the IRB audit, the Research Auditor may review:

a. Records of IRB membership;
b. IRB procedures and guidelines;
c. Minutes of IRB meetings, to confirm that required findings were recorded;
d. Documents that demonstrate that studies were properly classified by the IRB in accordance with 45 CFR 46;
e. Documents related to selected studies given by the study team to the IRB (e.g. progress reports);
f. Documents related to the studies sent by the IRB to the study team (e.g. approved consent forms);
g. IRB approval documents and conditions of approval; and
h. Any other materials reasonably requested by the Research Auditor.

CONFIDENTIALITY

All clinical research audit reports, findings and other information are to be kept confidential and shall not be disclosed without prior approval of the Associate Director of Research Auditing. Clinical research audit reports are not part of the clinical research record and should be filed separately by the PI.

CONTACT INFORMATION

Contact Kathleen O’Connor, Associate Director of Research Auditing, for any questions you may have about this Policy.