Required Documentation for the Conduct of Research Involving Human Subjects

An inspection of required research documents may be conducted by the Montefiore Medical Center Office of Research and Sponsored Programs, the BRANY or Einstein IRB, research sponsor, Contract Research Organization, or Regulatory Agency, such as the FDA or OHRP. These inspections are part of the process to confirm the validity of the trial conduct, the integrity of data collected and confirm that any unanticipated problems have been properly reported.

Required documents are those which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator with accepted standards of research practice and applicable regulatory and institutional requirements.

Terms:

OHRP: The Office for Human Research Protections (OHRP) is involved in the protection of the rights, welfare, and well being of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).
FDA Regulated Product: FDA regulated products include but are not limited to human drugs, devices, therapeutic biologicals, vaccines, tissue, blood, and other products derived from living sources, instruments or products used for treating or diagnosing disease
IND: The clinical investigation of a drug that is not marketed requires submission of an Investigational New Drug (IND) application to FDA. The clinical investigation of a marketed drug requires submission of an IND application to FDA unless the clinical investigation meets certain conditions.
IDE: An investigational device exemption (IDE) allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data.
Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Required documents should be maintained by the investigator in printed form or on a secure server. Generally, all medical records that support clinical trial data are expected to be printed and filed with the research records. All study documents must be maintained in accordance with Montefiore-Einstein research, record retention, and privacy and security requirements.

Required documents are listed below.

I. All Research where subject consent is required by the IRB: (Includes human subjects research that poses only minimal risk to the subject)

1. All IRB correspondence, including original IRB application, all IRB submissions, and all IRB approvals.
2. All versions of the protocol and all amendments (protocol signatures where required)
3. Subject Identification and Enrollment Log
4. Screening Log
5. All original signed consent and assent forms
6. Completed Data Collection forms or Case Report forms
7. Completed Adverse Event Logs
8. Completed Protocol Deviation Logs
9. All monitoring reports (if 3rd party monitoring is performed)
10. All substantive communication with the study sponsor - all emails should be printed (if applicable)
11. Documentation of IATA training (if biological samples are shipped)

II. All Research involving greater than minimal risk to the subject:

All of the above (1-11) and:

12. Delegation of Authority Log
13. Documentation that shows the PI or qualified sub-I reviewed all entry criteria and approved subject entry into the study
14. Informed Consent Note for each subject enrolled
15. Data Safety Plan and Reports (if applicable)

III. All Research involving a drug, therapeutic device or study procedure determined by the IRB to be greater than minimal risk

All of the above (1-15) and:

16. For Drug Studies: Drug Accountability Log and shipping records
17. For Drug Studies: Pharmacy Waiver (if not using the MMC Pharmacy for Drug Storage and Dispensing)
18. For Drug Studies: Investigator's Brochure or Product Insert
19. For Device Studies: Device Accountability Log and shipping records (when the Investigator provides the device to subjects)
20. For Device Studies: Device Manual
21. Unblinding Procedures (if applicable)
22. Instructions for handling of investigational products

IV. All research involving a FDA regulated product with an IND/IDE (PI is not IND/IDE holder)

All of the above (1-22) and:

23. For Drug Studies: signed Form 1572 – Statement of the Investigator
24. For Device Studies: signed Investigator Agreement
25. CVs for PI and Subinvestigators
26. Laboratory normal values for all lab tests used (Outside Labs only) – MMC normal values are available on the MMC Intranet – Department of Pathology
27. Lab certificates for all labs used (Outside Labs only)- MMC Lab Certificates are on file with the Department of Pathology 920-2456