Required Documentation for the Conduct of Research Involving Human Subjects

An inspection of required research documents may be conducted by a research sponsor, Contract Research Organization, Einstein IRB 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. Documents should not be maintained exclusively on a flash drive or email archive. The investigator is to keep the original signed copy of the consent form and HIPAA authorization. A copy or second signed original should be provided to the participant and filed with the clinical record.

Required documents are listed below.

I. All Research: (Includes human subjects research that poses only minimal risk to the subject)

1. General Research Protocol Application and all related documents (with signatures)
2. Initial IRB Approval letter
3. Protocol
4. Protocol Amendments
5. IRB Approval letter for each amendment
6. All IRB approved versions of Informed Consent Forms & HIPAA Authorization Forms (unless the consent requirement has been specifically waived by the IRB)
7. Progress Report Form submitted to the IRB and all related documents (with signatures)
8. IRB Recertification letters
9. Deviation Reports submitted to the IRB and IRB acknowledgements
10. Adverse Event Reports submitted to the IRB
11. All monitoring reports (if third party monitoring is done)
12. Subject Identification Log
13. Completed Case Report Forms or Data Collection Forms (as applicable)
14. Original Signed Informed Consent Forms
15. Correspondence with study sponsor or outside agencies (if applicable)

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

All of the above (1-15) and:

16. Data Safety Plan and Reports (if applicable)

III. All Research involving a drug or therapeutic device

All of the above (1-16) and:

17. Delegation of Authority/ Signature Log
18. For Drug Studies: Drug Accountability Log and shipping records (when Investigator is providing the drug to subjects).
19. For Drug Studies: Pharmacy Waiver (if not using the MMC Pharmacy for Drug Storage and Dispensing)
20. For Drug Studies: Investigator’s Brochure or Product Insert
21. For Device Studies: Device Accountability Log and shipping records (when the Investigator provides the device to subjects)
22. For Device Studies: Device Manual
23. Decoding Procedures (if trial is blinded)
24. Instructions (if any) 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 (1-24) and

25. CV – Principal Investigator
26. Source Documents (including, for example, progress notes, physical exams, ecgs, lab reports etc.)
27. For Drug Studies: Form 1572 – Statement of the Investigator
28. For Device Studies: Investigator Agreement
29. CV of Subinvestigators
30. Laboratory normal values for all lab tests used (Outside Labs only) – MMC normal values are available on the MMC Intranet – Department of Pathology
31. Lab certificates for all labs used (Outside Labs only)- MMC Lab Certificates are on file with the Department of Pathology 920-2456