Required Documentation for the Conduct of Research Involving Human Subjects

An inspection of required regulatory documents may be conducted by the Montefiore Medical Center Office of Research and Sponsored Programs, the IRB of record, research sponsor, Contract Research Organization, or Regulatory Agency, such as the FDA or OHRP. These documents serve to demonstratethe compliance of the investigator with accepted standards of research practice and applicable regulatory and institutional requirements.

The following documents must be maintained by the investigator as applicable to each clinical trial. Theprinted regulatory binder is to be organized in sections as listed below. In some cases, the institution may require investigators to use a designated electronic document management system that complies with the standards outlined in 21 CFR Part 11.

Some documents may be stored in a central or master binder (for example, study staff CVs or labinformation). The location of the master file should be noted in the study regulatory binder.

Questions about these guidelines should be directed to irb@einsteinmed.org

1. Study Protocol and amendments
2. Investigator's Brochure, Product Insert or Device Manual
3. Informed Consent Documents
4. Advertisements and other recruitment material
5. Case Report Forms (blank)
6. All IRB submission forms, including Initial IRB application and annual IRB progress reportapplications
7. IRB approvals, acknowledgements and correspondence (may be filed here or with the corresponding documents above)
8. Investigator Qualification Documentation
    - Updated investigator and sub-investigator CVs
    - A clinical (dental, medical, etc.) license for the PI and co-investigators, if licensed
    - Other qualifications, as required
9. Delegation of Authority Log
    - Delegation of Authority and Signature Log
10. Clinical Research and Study Training
    - Study specific training
    - Dangerous Goods Shipping Training – IATA (if applicable)
    - Lab safety training (if applicable)
11. Screening/Enrollment Log
    - Enrollment Log/Subject identification Log
    - Screening Log (no identifying information if subjects have not consented)
12. Investigational Product
    - Shipping records for investigational products and trial related materials

- Sample of label attached to investigational product (when product is not FDA approved)
- Investigational product disposition and accountability, or memo as to where records arelocated (e.g., research pharmacy) and who is maintaining accountability logs
- Unmasking procedures for blinded trials
    - *And additionally when the research is investigator initiated (PI is sponsor)*
- Master randomization list (file so that blind is not compromised)

13. Laboratory Documentation
    - Clinical Laboratory Improvement Amendments [CLIA] Certification
    - College of American Pathologists [CAP] Certification
    - Normal-range values for each test
    - Lab Director's CV, may be required if lab assessments are experimental
14. Specimen Tracking Log
15. Adverse Events/Protocol Deviations
    - AEs reported to the sponsor
    - Adverse Device Effects and Complaints reported to sponsor
    - Protocol Deviations reports to the sponsor
    - IND Safety Reports and UADE reports received
    - Reportable Events (AEs, deviations and Unanticipated Problems) submitted to the IRBand corresponding acknowledgements
16. Clinical Site Monitoring Visits
    - Site visit log
    - Trial initiation monitoring report
    - Monitoring Reports
17. Sponsor Correspondence/communication
18. FDA Documentation
    - FDA Form 1572 (drug trial)
    - Investigator Agreement (device trial)
    - Financial Disclosure Forms for PI and subinvestigators
        - *And additionally when the investigator is the IND/IDE holder:*
    - Initial IND/IDE Application, FDA acknowledgement of receipt, comments, numberassigned and "Study May Proceed" confirmation
    - Amendments to the application
    - Annual Progress Reports
    - Form 3674, Certification of Registration to ClinicalTrials.gov (drug trials only)
    - Closeout/withdrawal application
19. Data and Safety Monitoring Documents

- DSMB/C correspondence and determinations
    - *And additionally when the research is investigator initiated (PI is sponsor):*
- IRB approved data safety and monitoring plan
- DSMB/C Reports and/or meeting minutes
- Documentation of any systematic data safety reviews carried out by PI or IndependentSafety Monitor

20. Other Documents

- Certificate(s) of Confidentiality (for non-NIH research, no documentation needed for NIH sponsored research)
- Information related to CT.gov registration
- Letters of Understanding/Confidentiality Agreements
- Data Sharing Agreements
- Material Transfer Agreements
- Signed agreements between parties (i.e., sponsors/investigators)
- Substantive correspondence with any party regarding the study conduct
- Notes to File
- Grant application
- Other study documents