Record Retention

RESEARCH RECORD RETENTION POLICY

I. AECOM* and North Bronx Healthcare Network Requirements:

State regulations concerning Article 28 facilities require:

1. Medical records to be maintained for a minimum period of six (6) years from the date of discharge for adults, and
2. for minors, three (3) years after the patient's age of majority (18 years) or six (6) years from the date of discharge, whichever is longer. [10NYCRR Section 405.10(a) (3) and 10NYCRR Section 751.7 (j)]
3. In addition, the maximum statue of limitations for medical malpractice litigation is ten (10) years.

NOTE: Legal counsel recommends that research records and informed consent documents be retained for ten (10) years after termination of a research subject's participation in a research study.

*In instances where an AECOM employee conducts research involving MMC patients, the MMC record retention requirements apply.

II. Montefiore Medical Center Requirements (please refer to Montefiore Medical Center Administrative Policy and Procedures JH12.1 and JL10.1):

1. Agreements with pharmaceutical manufacturers, IRB records, protocols and records of trials involving investigational drugs or devices must be retained for a least 2 years after records are no longer needed to support a pre-market approval application, unless otherwise specified in agreement with sponsor or funding source, or 10 years, whichever is longer.
2. Subject/patient records relating to research must be kept for 25 years from date of last activity, or at least 2 years after records are not longer needed to support a pre-market approval application, unless otherwise specified in agreement with sponsor or funding source, whichever is longer.
3. Medical records must be kept for 25 years from the date of last activity.

III. Investigational Drug/Device Research:

FDA regulations 312.62 (b), Sub Part D, require researchers –

1. To prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered an investigational drug or employed as a control in the

investigation.

Case histories include case report forms and supporting data. For example: signed and dated consent forms, progress notes of the physician, the individual's hospital chart and the nurses' notes, etc. The case history of each individual shall document that informed consent was obtained prior to participation in the study.

2. To retain records involving investigational drugs and/or devices for a period of two (2) years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or if no application is to be filed, or if the application is not approved for such indication, until two (2) years after the investigation is discontinued and FDA is notified.

NOTE: Investigators must be aware that when a decision is made to dispose of research records, the disposal must be done in a manner to protect patient confidentiality.

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Approved by JCC 5.07