COORDINATION OF RECORDS RETENTION BETWEEN PATIENT MEDICAL RECORDS AND CLINICAL TRIAL RESEARCH RECORDS/0135

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Policy

Patient Medical Records often are used as the supporting record for Clinical Trial Research Records. And in some cases, Clinical Trial Research Records have either caused the creation of, or contributed to, Patient Medical Records. These two records series (types) have become interwoven and the Commonwealth’s records retention schedules defining the length of time these records are to be retained after closure differs for each series.

The purpose of these procedures is to bring into alignment the retention of Patient Medical Records and Clinical Trial Research Records where the two are mutually in use, and to protect the records from the loss of information from each record series (type).

The starting year of 1985 is based on the supposition that Clinical Trial Research Records and Patient Medical Records before 1985 are not connected between records series. Since approximately October 2014, the two records series have been connected in the Electronic Medical Record system.

Procedure

For records dated prior to 1985:
• Patient Medical Records and Clinical Trial Research Records that have been identified as having exceeded the records retention requirement, and for which there is no confirmed connection between Patient Medical Records and Clinical Trial Research Records, each shall be destroyed according to their records series retention.

For records dated between 01/01/85 and 12/31/14, inclusive that have exceeded the records retention requirement:
• Starting in 2015, eligible records dated 30 years prior shall be destroyed according to their records series retention.
• Records eligible for destruction will be processed for destruction after December of each year, in most cases be completed within 6 months and no later than 12 months. Example: Patient Medical Records and Clinical Trial Research Records that have independently met or exceeded their retention as of 1985 may be destroyed in 2015. Records from 1986 for each shall be destroyed in 2016.

For records dated 01/01/2015 and forward, where both Patient Medical Records and Clinical Trial Research Records interact or share a patient, each record shall be retained until the longest retention of either record is satisfied:

Example: The records of a patient who is enrolled in a Clinical Trial Research Project and also being treated at the Medical Center shall be retained until the retention period of both the Clinical Trial Research Project records AND the Patient Medical Record have been satisfied.

• The Electronic Medical Record will contain indicators for those patients participating in one or more Clinical Trials, which shall identify the specific Clinical Trial or Trials involved.

• For Clinical Trial Research Records that are not embedded within Patient Medical Records, the method of determining the satisfaction of the record retention shall depend on sponsor requirements and FDA regulations. (Industry sponsored Clinical Trial Records currently must be retained for 2 years after the drug/device being tested has been approved for marketing by the FDA or after development has been discontinued by the sponsor; furthermore, the sponsor may require, in the protocol or contract, its approval before destruction.)

• For Patient Medical Records, the method of determining compliance with records retention requirements shall be based on yearly reports generated from the electronic patient registration system.

Questions regarding the retention of Medical Center Records shall be addressed by the Medical Center Records Manager. Questions regarding the retention of the Research Records shall be addressed by the University Records Manager.

**Related Information**

Medical Center Policy 0266 – Records Management/Document Retention and Destruction
Virginia GS-120: Health Records
  • 012504: Patient Medical/Dental Records: Adults
  • 012503: Patient Medical/Dental Records: Minors
Virginia GS-111: College and University -
  • 200233: Clinical Trial Projects: Sponsored
  • GS-111; 200233: Clinical Trial Administrative, Data & Participant Records (Industry Sponsored)