

SOM- Department of Obstetrics and Gynecology	TITLE: Records Retention Policy – Research, MCGHI Health Records and Other MCG Departmental Records	Policy: IS003
Department Guideline	Date: August 19, 2005	Rev. 0
Approvals:		
Chairman/Date	Dept. Manager/Date	

The URL for the MCG Policy is: <http://www.mcg.edu/research/policy/records.html>

I. Medical College of Georgia Policy on the Ownership and Retention of Scholarly / Research Records

The ownership and responsibility for retaining scholarly/research records generated by Medical College of Georgia faculty, staff and students is an issue of increasing importance. Georgia state law contains specific requirements for state agencies, such as MCG, to maintain and produce records generated by its personnel (see, e.g., O.C.G.A. 50-18-70 et seq.). Additionally, federal laws and regulations governing federally funded research mandate awardee institutions to retain original records and to provide them upon request (see, 42 C.F.R. sec. 50.102 and 45 C.F.R. Part 74, Subpart D). This policy on ownership and retention of records has been adopted in order to provide guidance for MCG faculty, postgraduate trainees, students, and employees concerning the ownership and retention of scholarly/research records generated by them during the course of their employment or enrollment.

1. This policy shall apply to all MCG faculty, postgraduate trainees, staff and students.
2. The term "scholarly/research record" as used in this policy, shall mean any and all documents, slides, photographs, specimens, data, computer based information, videotapes, or any other information, whether recorded in a written, electronic or other format, and which is produced in the creation, testing or evaluation of any product or process and which is produced within the scope of an individual's employment or enrollment at the Medical College of Georgia. The term "scholarly/research record" shall include any intellectual property rights embodied in such records, subject to the provisions of the Medical College of Georgia Intellectual Property Policy.
3. All scholarly/research records generated or produced by an MCG faculty member, student or employee during the course of his/her employment or enrollment shall be the property of Medical College of Georgia.
4. Responsibility for proper collection and a system for retention of scholarly/research records resides with the faculty member (principal investigator or author). Faculty members are responsible for records created and maintained by trainees, students, or staff whom they mentor/supervise. Departmental chairpersons share responsibility for assuring proper maintenance and storage of scholarly/research records. Any person creating or maintaining a scholarly/research record shall be responsible for complying with any applicable laws, rules or regulations and with generally accepted standards of scholarly/research conduct. Compliance with specific record creation and

retention requirements mandated by contract, grant, statute or regulation is expected. The obligation to maintain records subject to this policy shall remain in effect for a period of four years from the date of their creation, unless otherwise specifically required (for example by a study sponsor) or agreed to by MCG.

5. Original scholarly/research records shall remain upon the premises of the Medical College of Georgia unless otherwise authorized by MCG. In the event an individual ceases to be either employed or enrolled at the Medical College of Georgia, copies of any and all research records created by that employee or student will be made available upon request. Refer to Administration Policies and Procedures of the Medical College of Georgia (Policy number 1.2.12; Records Management) for additional information.

II. How long do study records need to be stored following study closure? Our study has been over for about three years. How long do we have to store this stuff?

Per FDA 21 CFR312.62 Investigator record keeping and record retention:

- a. Disposition of drug
- b. Case histories. An investigator is required to prepare and maintain adequate and accurate case histories designed to record all observations and other data pertinent to the investigation on each individual treated with the investigational drug or employed as a control in the investigation.
- c. Record retention. An investigator shall retain records required to be maintained under this part for a period of 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 2 years after the investigation is discontinued and FDA is notified.

ICH Guidelines recommend 15 years. Contact the sponsor and ask if they can store the documents after the two-year obligation is met. Some will store the information or they will provide written documentation to destroy the records.

We currently have no policy on record retention, other than the FDA regulation. We are in the process of preparing a SOP for this. As far as budgetary information, this is an investigator decision.

The CFR regulations only apply to those studies under FDA jurisdiction.

III. MCGHI Retention of Medical Health Records

The link to view this policy is listed as:

http://hi.mcg.edu/printer/intranet/aboutus/PDFPolicies/06_15.pdf

**IV. Medical College of Georgia Administrative Policies and Procedures
Office of Primary Responsibility: Controller's Division No. 1.2.12**

The URL for the MCG Policy is: <http://www.mcg.edu/Policies/1212.html>

Records Management

Purpose

To present this Institution's policy of Records Management, and to describe the responsibilities of Records Management Officers.

Policy

All institutions of the University System of Georgia have adopted a systematic program of Records Management. This institution will receive general instructions from the Board of Regents, who represent all institutions in liaison with the Secretary of State. All schools and divisions of the Medical College of Georgia are expected to cooperate with and assist the appointed Records Management Officer in the performance of his responsibility.

Responsibilities

1. Establish and maintain an active and continuing program for the economical and efficient management of records.
2. Implement approved records disposition standards received from the Board of Regents concerning records common in use to all institutions.
3. Develop and recommend disposition standards for records peculiar to local functions and activities.
4. Provide staff assistance in the operation of the local records holding area and insure that records are properly packed prior to movement from an office area to the local holding area.
5. Review and evaluate microfilm projects in accordance with standards published by the Secretary of State.
6. Evaluate requests for filing equipment and supplies to provide for procurement of the most economical and efficient filing equipment and supplies in accordance with published standards and forward to Records Management Officer, Board of Regents.
7. Provide staff assistance to budget unit administrators concerning filing methods, records retention periods and the ultimate disposition and destruction of records.
8. Prepare and submit a report of status and progress of Records Management as of 30 June each year. The report should be forwarded to the Records Management Officer of the Board of Regents within five working days after close of the reporting period.

Date 1 July 1972/Rev. No. 82-1/Rev. Date 1 July 1981/1.2.12