



Access to Health Information of Individuals

Scope

This policy establishes rules for access to health information of individuals found in archival, manuscript, and image collections in the National Library of Medicine's History of Medicine Division (HMD). The purpose of the policy is to safeguard the health privacy of individuals, while making these holdings available for research to the greatest possible extent.

The creation of this policy was motivated by the implementation in April 2003 of the Privacy Rule [45 CFR 160; 140] of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). While the Library is not a covered entity under HIPAA and therefore not subject to its regulations, the Library nonetheless wishes to establish a policy that reflects the principles of HIPAA's Privacy Rule.

This policy applies to collections that the staff of the Archives and Modern Manuscripts Program have specifically identified as containing health information of individuals. For further clarification, please contact the manuscripts curator of HMD.

Materials also may be restricted under HMD's policy on access to personal information in its archives and manuscript holdings. For this policy, please see Appendix B.

In addition, access to archives and manuscripts may be further restricted by the donors of the materials. To determine whether a collection is restricted, please contact the reference staff or the manuscripts curator of HMD.

1. Access to Archival Materials.

Under certain conditions, HMD may authorize access to archival and manuscript materials that contain health information of individuals:

- A. Materials more than 100 years old are available to all researchers.
- B. Where HMD is able to make a copy of materials with all personal identifiers masked or deleted, the copies are available to all researchers.

- C. If a researcher obtains written authorization for access from the individual of interest, or from his/her legal guardian, the records will be available to that researcher.
- D. Individuals shall have free access to their own health information if contained in HMD collections.

Where none of these circumstances obtains, researchers may apply to HMD for access to such records, in accordance with the following general guidelines:

Access will be granted to qualified persons doing historical and other research, using statistical or quantitative methods, or methods ensuring that no individual shall be able to be identified from the results of the research.

Researchers who are granted access to restricted records shall agree in writing to maintain the confidentiality of the information and to adhere to the conditions of access imposed by HMD.

In addition, all other persons associated with the research project who will have access to personally identifiable information from the records shall agree in writing to maintain confidentiality of the information.

The remainder of this document provides guidance in implementing these guidelines.

2. Conditions of Access.

HMD may impose some or all of the following conditions of access on any project, while additional conditions may be imposed on the use of specific records or on specific projects, at HMD's discretion.

- (1) The records may be used only for the purpose of statistical research, the reporting of aggregate research findings, or in such a way that no individual may be identified using the results of the research. The information may not be used for any other purpose without HMD approval.
- (2) The records and copies of any data elements which permit the identification of an individual or which can be identified with an individual may not be transferred to any person or institution not directly involved with the approved research project.
- (3) Reasonable administrative, technical, and physical safeguards, as approved by HMD, to prevent unauthorized use or disclosure of the information shall be established by the researcher and followed by all persons associated with the research project.
- (4) Collections shall be consulted only at the HMD reading room in Bethesda, Maryland, and not at any other site.
- (5) During the course of the research project, any individually identifiable information in the researcher's notes or in authorized copies of the materials shall be rendered

anonymous by the researcher at the earliest possible time consistent with the purpose of the research project.

(6) Persons who are identified in the materials in the course of research may not be contacted by or on behalf of the researcher. (However, this does not preclude the researcher from contacting a person in advance of gaining access, for the purpose of obtaining access, as specified above under 1.C.)

(7) Prior to publication or public presentation of the data, the final research product(s) shall be provided to HMD for review. HMD's review shall be limited to ensuring that there is no possible identification of individuals in the research findings. HMD will not evaluate the validity of the research findings.

(8) Upon completion of the project, all research notes containing health information of individuals derived from HMD's archival materials, and/or copies of such materials shall, upon completion of the project, be destroyed or returned to HMD, whichever condition HMD has imposed as a condition of access. If the notes and/or copies are destroyed, the researcher shall verify in writing to HMD that the research notes and/or copies have been destroyed.

3. Request for Access.

To obtain access to health information of individuals, researchers should submit a written request to the Archives and Modern Manuscripts Program, History of Medicine Division, National Library of Medicine, Bethesda, MD 20894. Researchers are encouraged to consult with HMD prior to submitting the request. The request must include the following information; a form is provided in Appendix A:

- (1) Name and mailing address.
- (2) Institutional affiliation and position, if applicable.
- (3) List of publications pertinent to topic of the research project.
- (4) References from two persons who have first-hand knowledge of the requester's qualifications to perform the research.
- (5) A statement of the nature of the research to be conducted and any plans for publication or presentation of the research findings.
- (6) A listing of all sources of grant funds supporting the research project or its publication.
- (7) A statement of the methodology to be used.

(8) A statement of the administrative, technical, and physical safeguards to be employed by the researcher to prevent unauthorized use or disclosure of the records.

(9) A listing of the collections and/or items and series titles to be used.

(10) A statement that the researcher will abide by the conditions of access to be prescribed by NLM and that the researcher will assume responsibility for the action of all persons working with the researcher on the project.

The researcher should sign the form and obtain the signatures of all other persons associated with the research project who will have access to personally identifiable information from the records.

4. Access Review Committee.

Requests for access to health information of individuals will be reviewed by HMD's Access Review Committee, which is composed of the Curator (or designate) of the Archives and Modern Manuscripts Program, the Coordinator of Reference Services, and the Head of Images and Archives. The Committee may consult other persons within and outside the Federal Government who are knowledgeable in the research field for assistance in evaluating a request.

The Committee will examine the request to determine:

(1) Whether the requested information is of such a highly sensitive personal nature that disclosure should not be permitted even for statistical or quantitative research.

(2) Whether the methodology proposed by the requester will permit the researcher to obtain the projected research results without revealing personally identifying information.

(3) Whether the research results will be published or presented at an academic or research conference, or a similar venue.

(4) Whether the requester is a researcher who has experience in conducting statistical research projects and publishing articles or books on such research; or a researcher whose presentations and publications demonstrate the ability to protect the privacy of individuals.

(5) Whether the safeguards proposed by the requester will adequately protect the personal information.

(6) Whether HMD has sufficient staff and space available to safeguard privacy as it accommodates the research project.

The decision of the Committee will be made in writing to the requester within 15 workdays after receipt of a completed request. At the discretion of the Committee, the researcher may meet with the Committee to discuss the project and may be asked to revise it to meet the concerns of the Committee.

5. Appeal Process.

Any decision to deny access to requested records may be appealed to the Chief of the History of Medicine Division. Appeals must be made in writing and shall be received within two weeks of notification of the denial.

6. Noncompliance with Conditions of Access.

If HMD discovers that a researcher has violated the confidentiality of information or the conditions of access, HMD shall take steps to revoke the research privileges of the researcher and shall consult with the NIH legal counsel to prevent further disclosure of the health information. HMD may also inform the following persons and organizations of the researcher's failure to follow the conditions of use:

- (1) The institution with which the researcher is affiliated, if applicable.
- (2) Persons who served as references in the application for access.
- (3) Organizations which provided grant funds for the project.
- (4) The sponsor of the publication or public presentation.
- (5) Appropriate professional organizations.

Adopted February 17, 2004; revised May 10, 2004.



Appendix A:

REQUEST FOR ACCESS TO HEALTH INFORMATION OF INDIVIDUALS

1. Name, mailing address, and phone:

2. Institutional affiliation and position, if applicable:

3. Listing of published work (attach separate sheet)

4. References from two persons who have first-hand knowledge of requestor's qualifications to do the research (attach separate sheet)

5. State the nature of the research to be conducted and any plans for publication or presentation of the findings:

6. List all sources of grant funds supporting the research or its publication:

7. State the research methodology to be used:

8. State the administrative, technical, and physical safeguards to be employed to prevent unauthorized use or disclosure of the records:

I hereby agree to maintain the confidentiality of information and to abide by the conditions of access set by the History of Medicine Division, National Library of Medicine, and I will assume responsibility for the action of all persons working with me on the project.

Signature

Date

Printed name

(Please add additional names and signatures as needed.)

Please list below the collections and/or items and series titles to be used:



Appendix B:

RESTRICTIONS ON ACCESS TO PERSONAL INFORMATION FOUND IN ARCHIVES AND MANUSCRIPTS IN THE HISTORY OF MEDICINE DIVISION, NATIONAL LIBRARY OF MEDICINE

(From the Archival Processing Manual, Archives and Modern Manuscripts Program, Images and Archives Section, History of Medicine Division, National Library of Medicine)

This document outlines HMD's policy for restricting access to certain classes of records that contain personal information.

General Considerations

If a donor leaves explicit instructions in the deed of gift to restrict portions of a collection, of course these need to be followed. However, creating an absolute policy for applying periods of restrictions to individual categories of unprocessed records is more problematic. Case-by-case decisions occur more often than not, but this section will attempt to provide some firm categories of materials that are candidates for restriction, periods of restrictions, and guidelines for action if potential restricted materials are encountered during processing. Also, no legal statutes exist that codify specific time periods for restricting particular record formats; privacy laws (Privacy Act of 1974; 5 USC 552a and amendments) exist to generically protect an individual from intrusions into their private lives, to prevent public access to confidential records, and to ensure the accuracy of the information legally collected on individuals. No mechanisms are mandated for the administration and service of these records, however. Those functions are ceded to whichever internal administrative body is responsible for custody of those records. Therefore, archivists must rely on precedent and good professional practice, much as will a court of law if a complaint is adjudicated. If the archivist can point to a documented policy or set of procedures that are applied consistently, liability should be limited.

The U.S. Census Bureau closes its enumerations to the public for 72 years and archivists have generally adopted this period restriction. Increased to 75 years, this period of restriction helps ensure that personal information, if used, will be old enough to have a limited impact on the personal lives to which any information is attached. The Modern Manuscripts Program should be conservative in applying current legal requirements for restricting materials such as patient records or official school records, but should be liberal in promoting local physical access to collection materials. Restriction issues should be discussed with the curator during the development of intellectual series and throughout processing.

Categories of Restricted Materials

Medical records are very sensitive materials and rarely should be accepted as part of a collection. Personal medical records may appear in personal papers collections, in agency or corporate records, as part of legal case files, or as part of a scientific study, and access should be restricted. However, legitimate researchers collecting summary data may be granted limited access to personal medical information. In these cases the researcher must complete a form describing the research, its methodology, and the data's intended use with a signed assurance that no personal information will be gathered or disseminated as part of the research. As an added assurance, copies of the records requested should be copied and personal identifiers such as names or social security numbers redacted. Otherwise, medical records and hospital records are restricted for 100 years from the date of the record, to ensure that the subject has died. Alternately, definitive proof of death will open the record.

Official student records should also not be accepted as part of a collection. The Family Educational Rights and Protection Act (FERPA -- 34 CFR Part 99) protects a student's right to privacy and provides a mechanism to ensure the accuracy of these confidential materials. School records such as official transcripts and official recommendations should be closed for 75 years from the date of the record. Similarly, correspondence (or other form of a request) about grade changes should be closed for 75 years. Other records that document official business of any sort by a professor or a student should be closed for 75 years. Unofficial, personal recommendations or references from a school official or professor regarding a student should not be considered an official school record and need not be restricted.

Personnel records are another troublesome, common record type, oftentimes voluminous in corporate records. Official personnel disputes, evaluations, or complaints are extremely sensitive and should not be considered archival records. If these records do appear in a collection, they should be restricted from the general public. If a company or association uses the NLM as its de facto ongoing archival program (MLA, for instance) there may be instances where we will need to store personnel records for their continued administrative purpose, but they are not to be considered for public consumption if permanently retained. Moreover, modern individual time cards are not considered archival and should be weeded. There may be reason to save examples of older types of time cards, if only to show how record forms changed over time at a company with an extensive history, or reason to sample a series of time cards for informational value.

Fourth, editorial peer reviews of scientific journal submissions are kept secret from the submitting author. In other disciplines, academic debates are usually carried out in various public forums, so the impact of a negative review usually reflects back on the reviewer, not the article's author. In fact, peer reviews provide good insight into the specific nature of an academic debate. And since scientific knowledge changes at such a rapid pace, many arguments often become moot or superseded by ancillary debates. If a manuscript collection contains copies of the various peer reviews submitted as part of the editorial process, they need not be closed to research use, but a copy should be made of the review with the author's name and the article's title redacted. It will then be difficult to trace any negative attacks to a particular individual.

Grant applications present a fifth category with restriction issues. Grant applications for funding scientific research are extremely sensitive materials and those found in archival collections should not be open to the public. Successfully funded grants will be publicized by the granting

agency and it will determine what information is for public consumption. Reviewers or granting agencies may keep copies of the applications for which they are asked to review, but any archival record of the review process should remain private. Grant materials should be restricted for 75 years from the date of the application.

A sixth major record type encountered in AMMP collections are special session board minutes. Many association records have two sets of board minutes: regular meetings that are usually public knowledge; and special session segments of regular board meetings wherein sensitive strategic business and financial decisions are often made and personal/personnel issues regarding board members are debated. The deed of gift should make note of any restrictions of regular board minutes (private associations have every right to restrict these records), but if not, the processing archivist should look for special session minutes or other board records that contain personal issues or private debates.

Lastly, financial and business records often contain personal information that would not normally be public knowledge. But if a donor has included them in the collection, one might assume that the donor has no privacy concerns about personal financial information. However, to be safe the curator should double check with the donor about keeping financial records and offer to return them.

| | RESTRICT ACCESS? | LENGTH OF RESTRICTION |
|---|-------------------------------------|---|
| Peer Reviews for Journal Articles | YES (redact names/title) | Serve redacted version; 75 YEARS (from date of review) |
| Official School Records | YES | 75 YEARS (from record date) [Case-by-case decision for unofficial] |
| Letters of Recommendation | YES | 50 YEARS (if official) [Case-by-case decision for unofficial] |
| Grant Applications | YES | 75 YEARS (from date of application) |
| “Derogatory” or “Private” Material | NO | Case-by-case decision |

| | RESTRICT ACCESS? | LENGTH OF RESTRICTION |
|--|--------------------------------------|--|
| Medical Records | YES | 100 YEARS (from date of record) |
| Curriculum Vitae | NO (redact S.S.N.) | |
| Financial Records | NO | |
| Voting Ballots | YES | 75 YEARS (from date of vote) |
| Personnel records | YES | Permanent |
| Board of Directors Special Sessions | Follow donor's guidelines | Follow donor's guidelines |