

individuals who participate as subjects in the research project specified in the Certificate while the Certificate is in effect. The authorization applies to all persons who, in the performance of their duties in connection with the research project, have access to information which would identify the subjects of the research. Persons so authorized may not, at any time, be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify the research subjects encompassed by the Certificate, except in those circumstances specified in paragraph (b) of this section.

(b) A Confidentiality Certificate granted under this part does not authorize any person to refuse to reveal the name or other identifying characteristics of any research subject in the following circumstances:

(1) The subject (or, if he or she is legally incompetent, his or her guardian) consents, in writing, to the disclosure of such information,

(2) Authorized personnel of DHHS request such information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See 45 CFR 5.71 for confidentiality standards imposed on such DHHS personnel), or

(3) Release of such information is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or the regulations promulgated thereunder (title 21, Code of Federal Regulations).

(c) Neither a Confidentiality Certificate nor the regulations of this part govern the voluntary disclosure of identifying characteristics of research subjects.

#### § 2a.8 Termination.

(a) A Confidentiality Certificate is in effect from the date of its issuance until the effective date of its termination. The effective date of termination shall be the earlier of:

(1) The expiration date set forth in the Confidentiality Certificate; or

(2) Ten days from the date of mailing a Notice of Cancellation to the applicant, pursuant to a determination by the Secretary that the research project

has been completed or discontinued or that retention of the Confidentiality Certificate is otherwise no longer necessary or desirable.

(b) A Notice of Cancellation shall include: an identification of the Confidentiality Certificate to which it applies; the effective date of its termination; and the grounds for cancellation. Upon receipt of a Notice of Cancellation the applicant shall return the Confidentiality Certificate to the Secretary.

(c) Any termination of a Confidentiality Certificate pursuant to this section is operative only with respect to the names and other identifying characteristics of individuals who begin their participation as research subjects after the effective date of such termination. (See § 2a.4(k) requiring researchers to notify subjects who enter the project after the termination of the Confidentiality Certificate of termination of the Certificate). The protection afforded by a Confidentiality Certificate is permanent with respect to subjects who participated in research during any time the authorization was in effect.

### PART 3 [RESERVED]

### PART 4—NATIONAL LIBRARY OF MEDICINE

Sec.

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#### § 4.1 Programs to which these regulations apply.

(a) The regulations of this part govern access to the National Library of Medicine's facilities and library collections and the availability of its bibliographic, reproduction, reference, and

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related services. These functions are performed by the Library directly for the benefit of the general public and health-sciences professionals as required by sections 465(b) (3)–(6) of the Act (42 U.S.C. 286(b) (3)–(6)).

(b) The regulations of this part do not apply to:

(1) The Library's internal functions relating to the acquisition and preservation of materials and the organization of these materials as required by sections 465(b) (1) and (2) of the Act (42 U.S.C. 286(b) (1) and (2)).

(2) The availability of "records" under the Freedom of Information Act or the Privacy Act of 1974 (5 U.S.C. 552, 552a). These matters are covered in 45 CFR parts 5 and 5b.

(3) Federal assistance for medical libraries and other purposes which are authorized by sections 469–477 of the Act (42 U.S.C. 286b to 286b–8). (See parts 59a, 61 and 64 of this chapter.)

(4) The availability of facilities, collections, and related services of Regional Medical Libraries established or maintained under the authority in section 475 of the Act (42 U.S.C. 286b–6). (See part 59a, subpart B of this chapter.)

### § 4.2 Definitions.

As used in this part:

*Act* means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

*Collections* means all books, periodicals, prints, audiovisual materials, films, videotapes, recordings, manuscripts, and other resource materials of the library. It does not include data processing tapes or programs used solely for internal processing activities to generate reference materials, nor does it include "records" of the Library as defined in 45 CFR 5.5. Records of the Library are available in accordance with the regulations under the Freedom of Information Act and Privacy Act of 1974. (See 45 CFR parts 5 and 5b.)

*Director* means the Director of the National Library of Medicine or the Director's delegate.

*Health-sciences professional* means any person engaged in: (1) The administration of health activities; (2) the provision of health services; or (3) research, teaching, or education concerned with the advancement of medicine or other

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sciences related to health or improvement of the public health.

*Historical collection* means: (1) Materials in the collections published or printed prior to 1914; (2) manuscripts and prints; (3) the archival film collection; and (4) other materials of the collections which, because of age, or unique or unusual value, require special handling, storage, or protection for their preservation, as determined by the Director.

*Library* means the National Library of Medicine, established by section 465 of the Act (42 U.S.C. 286).

*Regional Medical Library* means a medical library established or maintained as a regional medical library under section 475 of the Act (42 U.S.C. 286b–6).

### § 4.3 Purpose of the Library.

The purpose of the Library is to assist the advancement of medical and related sciences and aid the dissemination and exchange of scientific and other information important to the progress of medicine and the public health. The Library acquires and maintains library materials pertinent to medicine, including audiovisual materials; compiles, publishes, and disseminates catalogs, indices, and bibliographies of these materials, as appropriate; makes available materials, through loan or otherwise; provides reference and other assistance to research; and engages in other activities in furtherance of this purpose.

### § 4.4 Use of Library facilities.

(a) *General*. The Library facilities are available to any person seeking to make use of the collections. The Director may prescribe reasonable rules to assure the most effective use of facilities by health-sciences professionals and to protect the collections from misuse or damage. These rules must be consistent with the regulations in this part and applicable Department regulations and policies on nondiscrimination.

(b) *Reading rooms*. Public reading rooms are available for obtaining and reading materials from the collections. The Director may prescribe reasonable rules designed to provide adequate