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of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

(6) Where Federal agencies having the power to subpoena other Federal agencies' records, such as the Internal Revenue Service or the Civil Rights Commission, issue a subpoena to the Department for records in this system of records, the Department will make such records available.

(7) Where a contract between a component of the Department and a labor organization recognized under E.O. 11491 provides that the agency will disclose personal records relevant to the organization's mission, records in this system of records may be disclosed to such organization.

(8) Where the appropriate official of the Department, pursuant to the Department's Freedom of Information Regulation determines that it is in the public interest to disclose a record which is otherwise exempt from mandatory disclosure, disclosure may be made from this system of records.

(9) The Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

(10)-(99) [Reserved]

(100) To the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

(101) To individuals and organizations, deemed qualified by the Secretary to carry out specific research solely for the purpose of carrying out such research.

(102) To organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

(103) Disclosures in the course of employee discipline or competence determination proceedings.

### APPENDIX C TO PART 5b—DELEGATIONS OF AUTHORITY [RESERVED]

### PART 6 [RESERVED]

### PART 7—EMPLOYEE INVENTIONS

Sec.

- 7.0 Who are employees.
- 7.1 Duty of employee to report inventions.
- 7.3 Determination as to domestic rights.
- 7.4 Option to acquire foreign rights.

## 45 CFR Subtitle A (10-1-24 Edition)

- 7.7 Notice to employee of determination.
- 7.8 Employee's right of appeal.

AUTHORITY: Reorg. Plan No. 1 of 1953, 18 FR 2053; 3 CFR 1953 Supp. E.O. 10096, 15 FR 391; 3 CFR. 1950 Supp. and E.O. 10930, 26 FR 2583; 3 CFR 1961 Supp.

### § 7.0 Who are employees.

As used in this part, the term *Government employee* means any officer or employee, civilian or military, except such part-time employees or part-time consultants as may be excluded therefrom by a determination made in writing by the head of the employee's office or constituent organization, pursuant to an exemption approved by the Commissioner of Patents that to include him or them would be impracticable or inequitable, given the reasons therefor. A person shall not be considered to be a part-time employee or part-time consultant for this purpose unless the terms of his employment contemplate that he shall work for less than the minimum number of hours per day, or less than a minimum number of days per week, or less than the minimum number of weeks per year, regularly required of full-time employees of his class.

[27 FR 7986, Aug. 10, 1962]

### § 7.1 Duty of employee to report inventions.

Every Department employee is required to report to the Assistant Secretary (Health and Scientific Affairs) in accordance with the procedures established therefor, every invention made by him (whether or not jointly with others) which bears any relation to his official duties or which was made in whole or in any part during working hours, or with any contribution of Government facilities, equipment, material, funds, or information, or of time or services of other Government employees on official duty.

[31 FR 12842, Oct. 1, 1966]

### § 7.3 Determination as to domestic rights.

The determination of the ownership of the domestic right, title, and interest in and to an invention which is or

may be patentable, made by a Government employee while under the administrative jurisdiction of the Department, shall be made in writing by the Assistant Secretary (Health and Scientific Affairs), in accordance with the provisions of Executive Order 10096 and Government-wide regulations issued thereunder by the Commissioner of Patents as follows:

(a) The Government as represented by the Assistant Secretary (Health and Scientific Affairs) shall obtain the entire domestic right, title and interest in and to all inventions made by any Government employee (1) during working hours, or (2) with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government employees on official duty, or (3) which bear a direct relation to or are made in consequence of the official duties of the inventor.

(b) In any case where the contribution of the Government, as measured by any one or more of the criteria set forth in paragraph (a) of this section, to the invention is insufficient equitably to justify a requirement of assignment to the Government of the entire domestic right, title and interest in and to such invention, or in any case where the Government has insufficient interest in an invention to obtain the entire domestic right, title, and interest therein (although the Government could obtain same under paragraph (a) of this section), the Department, subject to the approval of the Commissioner, shall leave title to such invention in the employee, subject, however, to the reservation to the Government of a nonexclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes, such reservation to appear, where practicable, in any patent, domestic or foreign, which may issue on such invention.

(c) In applying the provisions of paragraphs (a) and (b) of this section, to the facts and circumstances relating to the making of any particular invention, it shall be presumed that an invention made by an employee who is employed or assigned (1) to invent or improve or perfect any art, machine, manufacture, or composition of matter, (2) to con-

duct or perform research, development work, or both, (3) to supervise, direct, coordinate, or review Government financed or conducted research, development work, or both, or (4) to act in a liaison capacity among governmental or nongovernmental agencies or individuals engaged in such work, falls within the provisions of paragraph (a) of this section, and it shall be presumed that any invention made by any other employee falls within the provisions of paragraph (b) of this section. Either presumption may be rebutted by a showing of the facts and circumstances and shall not preclude a determination that these facts and circumstances justify leaving the entire right, title and interest in and to the invention in the Government employee, subject to law.

(d) In any case wherein the Government neither (1) obtains the entire domestic right, title and interest in and to an invention pursuant to the provisions of paragraph (a) of this section, nor (2) reserves a nonexclusive, irrevocable, royalty-free license in the invention, with power to grant licenses for all governmental purposes, pursuant to the provisions of paragraph (b) of this section, the Government shall leave the entire right, title and interest in and to the invention in the Government employee, subject to law.

[27 FR 7986, Aug. 10, 1962, as amended at 31 FR 12842, Nov. 1, 1966]

#### **§ 7.4 Option to acquire foreign rights.**

In any case where it is determined that all domestic rights should be assigned to the Government, it shall further be determined, pursuant to Executive Order 9865 and Government-wide regulations issued thereunder, that the Government shall reserve an option to require the assignment of such rights in all or in any specified foreign countries. In case where the inventor is not required to assign the patent rights in any foreign country or countries to the Government or the Government fails to exercise its option within such period of time as may be provided by regulations issued by the Commissioner of Patents, any application for a patent which may be filed in such country or countries by the inventor or his assignee shall nevertheless be subject to a nonexclusive, irrevocable, royalty-

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free license to the Government for all governmental purposes, including the power to issue sublicenses for use in behalf of the Government and/or in furtherance of the foreign policies of the Government.

[27 FR 7987, Aug. 10, 1962]

### § 7.7 Notice to employee of determination.

The employee-inventor shall be notified in writing of the Department's determination of the rights to his invention and of his right of appeal, if any. Notice need not be given if the employee stated in writing that he would agree to the determination of ownership which was in fact made.

[31 FR 12842, Oct. 1, 1966]

### § 7.8 Employee's right of appeal.

An employee who is aggrieved by a determination of the Department may appeal to the Commissioner of Patents, pursuant to section 4(d) of Executive Order 10096, as amended by Executive Order 10930, and regulations issued thereunder, by filing a written appeal with the Commissioner, in duplicate, and a copy of the appeal with the Assistant Secretary (Health and Scientific Affairs), within 30 days (or such longer period as the Commissioner may, for good cause, fix in any case) after receiving written notice of such determination.

[27 FR 7986, Aug. 10, 1962, as amended at 31 FR 12842, Oct. 1, 1966]

## PART 9—USE OF HHS RESEARCH FACILITIES BY ACADEMIC SCIENTISTS, ENGINEERS, AND STUDENTS

Sec.

- 9.1 Purpose.
- 9.2 Policy.
- 9.3 Delegations of authority.
- 9.4 Criteria.
- 9.5 Restrictions.

AUTHORITY: 27 Stat. 395, as amended; 20 U.S.C. 91.

SOURCE: 34 FR 18938, Nov. 27, 1969, unless otherwise noted.

## 45 CFR Subtitle A (10-1-24 Edition)

### § 9.1 Purpose.

To enhance the availability of DHHS scientific research and study facilities to academic scientists, engineers, and qualified students.

### § 9.2 Policy.

It is the policy of the Department of Health and Human Services in accordance with the policy of the President announced on February 21, 1969, to make research and study facilities of the Department readily available to the scientific community, especially qualified academic scientists and engineers. Unique, unusual, and expensive-to-duplicate facilities at laboratories and other study and research facilities of the Department will be made available to the national scientific community, to the maximum extent practical without serious detriment to the missions of those facilities. It is also the policy of the Department to permit qualified students and graduates of institutions of learning in the several States, and territories, as well as the District of Columbia, to use study and research facilities of the Department. When such facilities are used by academic scientists, engineers, and students, the costs incurred for the operation of the unique or unusual research facilities, as well as of the other facilities, should be funded by the operating agency responsible for the operation of that facility, except for any significant incremental costs incurred in support of research not directly related to an HHS mission.

### § 9.3 Delegations of authority.

(a) The heads of operating agencies are delegated authority for negotiations and decisions as to the use of Department facilities by qualified academic scientists, engineers, and students.

(b) The heads of operating agencies may (and are encouraged to) redelegate to the heads of their respective component organizations, with the power to further redelegate to laboratory directors, the authority for negotiations and decisions as to the use of departmental facilities. Appropriate use shall be made of advisory groups in formulating their decisions.