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TITLE 45—PUBLIC WELFARE

Subtitle A—Department of Health, Education, and Welfare, General Administration

PART 6—INVENTIONS AND PATENTS (GENERAL)

PART 7—EMPLOYEE INVENTIONS

PART 8—INVENTIONS RESULTING FROM RESEARCH GRANTS, FELLOWSHIP AWARDS, AND OTHER RESEARCH ARRANGEMENTS

The following parts are new. They represent a revision of Department rules and policies relating to inventions which are made by Department employees having a relation to their official duties or with some contribution from the Government or which arise from research or related activities assisted by grants or otherwise under programs administered by the Department.

PART 6—INVENTIONS AND PATENTS (GENERAL)

Sec.
6.0 Definitions.

NOTE: PARTS 6 AND 7 APPLICABLE TO GOVERNMENT EMPLOYEE INVENTIONS

PARTS 6 AND 8 APPLICABLE TO INVENTIONS RESULTING FROM RESEARCH GRANTS, FELLOWSHIP AWARDS, AND OTHER RESEARCH ARRANGEMENTS.

Sec.
6.1 General policy.
6.2 Publication or patenting of inventions.
6.3 Government-owned patents; licensing; dedication to the public.
6.4 Central records; confidentiality.
6.5 Procedures relating to employee and grantee inventions.
6.6 Issuance of patents on non-fee basis; certification of public interest.

AUTHORITY: §§ 6.0 to 6.6 issued under Reorg. Plan No. 1 of 1953, 18 F. R. 2053; 3 CFR 1953 Supp. E. O. 10096, 15 F. R. 391; 3 CFR, 1950 Supp.

§ 6.0 *Definitions.* As used in Parts 6, 7, and 8 of this subtitle:

(a) "Department" means the Department of Health, Education, and Welfare.

(b) "Secretary" means the Secretary of Health, Education, and Welfare.

(c) "Head of constituent organization" includes the Surgeon General of the Public Health Service, the Commissioner of Education, Commissioner of Social Security, Commissioner of Food and Drugs, the Director of Vocational Rehabilitation, and the Superintendent of Saint Elizabeths Hospital.

§ 6.1 *General policy.* Inventions developed through the resources and activities of the Department are a potential resource of great value to the public health and welfare. It is the policy of the Department:

(a) To safeguard the public interest in inventions developed by Department employees, contractors and grantees with the aid of public funds and facilities;

(b) To encourage and recognize individual and cooperative achievement in research and investigations; and

(c) To establish a procedure, consistent with pertinent statutes, Executive orders and general Government regulations, for the determination of rights and obligations relating to the patenting of inventions.

§ 6.2 *Publication or patenting of inventions.* It is the general policy of the Department that the results of Department research should be made widely, promptly and freely available to other research workers and to the public. This availability can generally be adequately preserved by the dedication of a Government-owned invention to the public through publication. Determinations to file a domestic patent application on inventions in which the Department has an interest will be made only if the circumstances indicate that this is desirable in the public interest, and if it is practicable to do so. Department determinations not to apply for a domestic patent on employee inventions are subject to review and approval by the Chairman of the Government Patents Board. Except where deemed necessary for protecting the patent claim, the fact that a patent application has been or may be filed will not require any departure from normal policy regarding the dissemination of the results of Department research.

§ 6.3 *Government-owned patents; licensing; dedication to the public.* All licenses under patents and pending patent applications for the administration of which the Department is responsible shall be issued by the Secretary. Licenses will be royalty-free, revocable and nonexclusive. Except in unusual cases when determined upon recommendation of the head of the constituent organization that unconditional licensing would be contrary to the public interest, licenses will be issued to all applicants and will contain no limitations or standards relating to the quality of the products to be manufactured, sold, or distributed thereunder. To reduce the need for individual license applications, patents held for unconditional licensing shall be dedicated to the public as may be feasible.

§ 6.4 *Central records; confidentiality.* Central files and records shall be maintained of all inventions, patents, and licenses in which the Department has an interest, together with a record of all licenses issued by the Department under such patents. Invention reports required from employees or others for the purpose of obtaining determinations of ownership, and documents and information obtained for the purpose of prosecuting patent applications shall be confidential and shall be disclosed only as required for official purposes or with the consent of the inventor.

§ 6.5 *Procedures relating to employee and grantee inventions.* The Department Patents Officer, with the approval of the Department Patents Board, and the heads of constituent organizations within their respective areas of responsibility, are authorized to issue such procedures and bulletins and take such other actions as may be necessary or desirable to supplement the provisions of Parts 7 and 8 of this subtitle.

§ 6.6 *Issuance of patents on non-fee basis; certification of public interest.* For the purpose of an application for a patent to issue under the non-fee provisions of the Patent Code (35 U. S. C. 266), a certification that an invention is used, or is likely to be used, in the public interest may be executed in behalf of the Secretary by the head of the constituent organization having administrative jurisdiction over the inventor.

PART 7—EMPLOYEE INVENTIONS

Sec.
7.0 Who are employees.
7.1 Duty of employee to report inventions.
7.2 Determination as to patentability.
7.3 Determination as to domestic rights.
7.4 Option to acquire foreign rights.
7.5 Determination as to patenting.
7.6 Department review and determination.
7.7 Notice to employee of determination.
7.8 Employee's right of appeal.

AUTHORITY: §§ 7.0 to 7.8 issued under Reorg. Plan No. 1 of 1953, 18 F. R. 2053; 3 CFR, 1953 Supp. E. O. 10096, 15 F. R. 391; 3 CFR, 1950 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 Chairman of the Government Patents Board, that to include him or them would be impracticable or inequitable, giving 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.

§ 7.1 *Duty of employee to report inventions.* Any Department employee is required to report promptly to the constituent organization in which he is employed any 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. Reports of inventions (except for cases as to which it is decided by the appropriate office or constituent organization, with the concurrence of the Department Patents Officer, that it does not appear they are or may be patentable) shall be forwarded through appropriate channels to the head of the office or constituent organization having administrative jurisdiction over the inventor at the time the invention was made. Thereafter they shall be forwarded with the related administrative recommendations and determinations to the Department Patents Officer.

§ 7.2 *Determination as to patentability.* Upon receiving a report of an employee invention, the head of the appropriate office or constituent organization shall make in writing the decision on behalf of the Department as to whether the results of the research, development, or other activity constitute an invention or inventions which may be patentable.

§ 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 head of the appropriate office or constituent organization, in accordance with the provisions of Executive Order 10096 and Government-wide regulations issued thereunder by the Chairman of the Government Patents Board, as follows:

(a) The Government as represented by the Secretary 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 Chairman, 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, in the terms thereof, to appear, where practicable, in any patent, domestic or foreign, which may issue on such invention.

(c) In applying the provisions of paragraps (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 conduct 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 the facts or circumstances attendant upon the conditions under which any particular invention is made and, notwithstanding the foregoing, shall not preclude a determination that the invention falls within the provisions of paragraph (d) of this section.

(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.

§ 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 Chairman of the Government Patents Board, 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-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.

§ 7.5 *Determination as to patenting.* When the head of the appropriate office, or constituent organization determines in accordance with the provisions of §§ 7.3 and 7.4, that the Government has rights in a patentable invention:

(a) He shall also determine whether the Department should seek to obtain a domestic patent thereon, or whether it shall be published or other action taken in the public interest, giving his reasons therefor; and

(b) He shall further recommend in writing whether the invention should receive foreign patent protection or be published abroad and, if affirmative, should specify the foreign jurisdictions in which action is recommended, giving reasons therefor, and should indicate, if possible, its immediate or future industrial, commercial, or other value, including particularly its value to public health.

§ 7.6 *Department review and determination.* The determination by the head of an office or constituent organization of the ownership of domestic or foreign rights in an invention by a Department employee shall constitute the decision of the Department unless, upon review, the Department Patents Officer questions the consistency of the determination with applicable law or regulations or with Department policy. Any question, unresolved after consultation with the originating unit, will be submitted by the Department Patents Officer to the Department Patents Board which shall either affirm or reverse the determination or return the same to the head of the constituent organization or office for further action. If the Board proposes to determine, or to approve a determination, that the invention shall be required to be assigned to the Government, it may in its discretion afford the employee an opportunity of a hearing.

§ 7.7 *Notice to employee of determination.* The appropriate office or constituent organization shall notify each employee-inventor in writing, of the Department's determination and of his right of appeal, if any. In the case of determinations made by the Department Patents Board, the notification shall be made by the Department Patents Officer. 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.

§ 7.8 *Employee's right of appeal.* An employee who is aggrieved by a determination of the Department may appeal to the Chairman of the Government Patents Board, pursuant to section 4 (d) of Executive Order 10096 and regulations issued thereunder, by filing a written appeal with the Chairman, in quadruplicate, and a copy of the appeal with the Department Patents Officer, within 30 days (or such longer period as the Chairman may, for good cause, fix in any case) after receiving written notice of such determination.

PART 8—INVENTIONS RESULTING FROM RESEARCH GRANTS, FELLOWSHIP AWARDS, AND OTHER RESEARCH ARRANGEMENTS

Sec.

8.0 Policy.
8.1 Conditions to be included in research grants.
8.2 Determination as to domestic rights.
8.3 Licenses to the Government.
8.4 Option to acquire foreign rights.
8.5 Arrangements other than grants; fellowships.

AUTHORITY: §§ 8.0 to 8.5 issued under Reorg. Plan No. 1 of 1953 (18 F. R. 2053; 3 CFR, 1953 Supp., E. O. 9865; 12 F. R. 3907; 3 CFR, 1947 Supp., E. O. 10096, 15 F. R. 391; 3 CFR, 1950 Supp.

§ 8.0 *Policy.* (a) The Department of Health, Education, and Welfare each year is expending large sums in the form of grants for research. These grants are made primarily by the Public Health Service in carrying out its broad responsibility under the Public Health Service Act to promote and coordinate research in the field of health and to make available information concerning such research and its practical application. The scientific and technological advances attributable, in varying degrees to this expenditure of public funds frequently include patentable inventions.

(b) The Department, as a matter of policy, takes the position that the results of research supported by grants of public moneys should be utilized in the manner which would best serve the public interest. It is believed that the public interest will in general be best served if inventive advances resulting therefrom are made freely available to the Government, to science, to industry, and to the general public.

(c) On the other hand, in some cases it may be advisable to permit a utilization of the patent process in order to foster an adequate commercial development to make a new invention widely available. Moreover, it is recognized that inventions frequently arise in the course of research activities which also receive substantial support from other sources, as well as from the Federal grant. It would not be consistent with the cooperative nature of such activities to attribute a particular invention primarily to support received from any one source. In all these cases the Department has a responsibility to see that the public use of the fruits of the research will not be unduly restricted or denied.

(d) The following conditions have been adopted to govern the treatment of inventions made in these various types of situations. They are designed to afford suitable protection to the public interest while giving appropriate recognition to the legitimate interests of others who have contributed to the invention.

§ 8.1 *Conditions to be included in research grants.* Subject to legislative directives or Executive orders providing otherwise, all grants in aid of research shall provide as a condition that any invention arising out of the activities assisted by the grant shall be promptly and fully reported, and shall provide, as the head of the constituent unit may determine, either

(a) That the ownership and manner of disposition of all rights in and to such invention shall be subject to determination by the head of the constituent unit responsible for the grant, or

(b) That the ownership and disposition of all domestic rights shall be left for determination by the grantee institution in accordance with the grantee's established policies and procedures, with such modifications as may be agreed upon and specified in the grant, provided the head of the constituent unit finds that these are such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties, and provided the Government shall receive a royalty-free license, with a right to issue sublicenses as provided in § 8.3, under any patent applied for or obtained upon the invention.

(c) Wherever practicable, any arrangement with the grantee pursuant to paragraph (b) of this section shall provide in accordance with Executive Order 9865 that there be reserved to the Government an option, for a period to be prescribed, to file foreign patent applications upon the invention.

§ 8.2 *Determination as to domestic rights.* Rights in any invention not subject to disposition by the grantee pursuant to paragraph (b) of § 8.1 are for determination by the head of the constituent organization as follows:

(a) If he finds that there is adequate assurance that the invention will either be effectively dedicated to the public, or that any patent which may be obtained thereunder will be generally available for royalty-free and nonexclusive licensing, the effectuation of these results may be left to the grantee.

(b) If he finds that the invention will thereby be more adequately and quickly developed for widest use and that there are satisfactory safeguards against unreasonable royalties and repressive practices, the invention may be assigned to a competent organization for development and administration for the term of the patent or such lesser period as may be deemed necessary.

(c) If he finds that the interest of another contributing Government agency is paramount to the interest of the Department of Health, Education, and Welfare, or when otherwise legally required or in the public interest, the invention may be left for disposition by that agency in accordance with its own policy.

(d) In all other cases, he shall require that all domestic rights in the invention shall be assigned to the United States unless he determines that the invention is of such doubtful importance or the Government's equity in the invention is so minor that protective measures, except as provided in § 8.3, are not necessary in the public interest.

§ 8.3 *Licenses to the Government.* Any arrangement or determination as to the disposition of rights in inventions pursuant to § 8.1 or § 8.2 shall require that there be reserved under any patent application or patent thereon, domestic or foreign, a nonexclusive, irrevocable, royalty-free license to the Government with power to sublicense for all governmental purposes.

§ 8.4 *Option to acquire foreign rights.* In any case where it is determined that all domestic rights should be assigned to the Government, there shall be reserved to the Government, pursuant to Executive Order 9865 and Government-wide regulations issued thereunder, an option to require the assignment of all rights in the invention in all or in any specified foreign countries. In any 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 Chairman of the Government Patents Board, 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-free license to the Government for all governmental purposes, including the power to sublicense for all governmental purposes.

§ 8.5 *Arrangements other than grants; fellowships.* In the event of an invention arising from research activities assisted by the Department, other than inventions by Government employees or inventions arising from activities assisted by a research grant, ownership thereof shall be governed by the terms of the agreement or contract and shall be in accordance with any applicable law or regulation. In the discretion of the head of the responsible constituent organization, the award of a fellowship to a person not a Government employee, as so defined, may provide for the reporting of any invention made during the term thereof, and for its disposition in accordance with the provisions of paragraph (a) of § 8.1, or for its disposition by the institution at which the research was performed in accordance with its established policies, if applicable to such an invention, which (with any agreed modifications of such policies) meet the requirements of paragraph (b) or (c) of such section.

Since these parts deal with matters of internal management or personnel, and with grants, benefits, or contracts, notice of proposed rule-making is not required.

Dated: September 8, 1955.

[SEAL] ROSWELL B. PERKINS,
Acting Secretary.

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TITLE 45—PUBLIC WELFARE

Subtitle A—Department of Health, Education, and Welfare, General Administration

PART 8—INVENTIONS RESULTING FROM RESEARCH GRANTS, FELLOWSHIP AWARDS, AND CONTRACTS FOR RESEARCH

MISCELLANEOUS AMENDMENTS

1. The title of Part 8 is amended to read as set forth above.

2. Section 8.5 is amended to read as follows:

§ 8.5 *Fellowships.* In the discretion of the head of the responsible constituent organization, the award of a fellowship to a person not a Government employee may provide for the reporting of any invention made during the term thereof, and for its disposition in accordance with the provisions of paragraph (a) of § 8.1, or for its disposition by the institution at which the research was performed in accordance with its established policies, if applicable to such an invention, which meet the requirements of paragraph (b) of such section.

3. Part 8 is further amended by the addition of the following section:

§ 8.6 *Contracts for research.* Contracts for research, whether or not with nonprofit organizations, shall provide that any invention first conceived or actually reduced to practice in the course of the performance of the contract shall be promptly and fully reported to the head of the constituent organization responsible for the contract, for determination by him as to the manner of disposition of all rights in and to such invention, including the right to require assignment of all rights to the United States or dedication to the public. In the exercise of this power the organization head will be guided by the policy specified in § 8.2 with respect to grants.

4. Part 8 is further amended by the addition of the following new section:

§ 8.7 *Cancer chemotherapy industrial research contracts.* Notwithstanding the provisions of § 8.6, the Surgeon General in the negotiation of contracts with other than nonprofit organizations for the cancer chemotherapy research program shall be subject only to such limitations and alternatives as the Secretary may approve for such program.

5. Section 8.3 is hereby amended to read:

§ 8.3 *Licenses to the Government.* Any arrangement or determination as to the disposition of rights in inventions pursuant to § 8.1, § 8.2, § 8.5 or § 8.6 shall require that there be reserved under any patent application or patent thereon, domestic or foreign, a nonexclusive, irrevocable, royalty-free license to the Government with power to sublicense for all governmental purposes.

Effective date. These amendments shall be effective upon date of publication in the FEDERAL REGISTER. Since they deal with grants, benefits, or contracts, notice of proposed rule making is not required.

(Reorg. Plan No. 1 of 1953, 18 F. R. 2053; 3 CFR, 1953 Supp.)

Dated: November 26, 1957.

[SEAL] M. B. FOLSOM,
Secretary.

[F. R. Doc. 57-10017; Filed, Dec. 3, 1957; 8:48 a. m.]

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February 27, 1958

TITLE 45—PUBLIC WELFARE

Subtitle A—Department of Health, Education, and Welfare, General Administration

PART 8—INVENTIONS RESULTING FROM RESEARCH GRANTS, FELLOWSHIP AWARDS, AND CONTRACTS FOR RESEARCH

CONTRACTS FOR RESEARCH

Section 8.6 is amended to read as follows:

§ 8.6 *Contracts for research.* (a) Contracts for research, with other than nonprofit institutions, shall provide that any invention first conceived or actually reduced to practice in the course of the performance of the contract shall be promptly and fully reported to the head of the constituent organization responsible for the contract, for determination by him as to the manner of disposition of all rights in and to such invention, including the right to require assignment of all rights to the United States or dedication to the public. In the exercise of this power the organization head will be guided by the policy specified in § 8.2 with respect to grants.

(b) Contracts for research with nonprofit institutions shall contain provisions as in paragraph (a) of this section except that, if it is determined that the institution's policies and procedures are acceptable as meeting the requirements of § 8.1 (b) with respect to grants, the contract may provide, with such special stipulations in the contract as may be deemed necessary in the public interest, for leaving the ownership and disposition of all domestic rights for determination by the contracting institution in accordance with such policies and procedures.

Effective date. This amendment to be effective upon date of publication. Since it deals with grants and contracts notice of proposed rule making is not required.

(Reorg. Plan No. 1 of 1953, 18 F. R. 2053; 3 CFR 1953 Supp.)

Dated: February 21, 1958.

[SEAL] M. B. FOLSOM,
Secretary.

[F. R. Doc. 58-1466; Filed, Feb. 26, 1958; 8:46 a. m.]