

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 602A

NIH Contractor Procedures for Requesting Waiver of NIH's Right to Obtain Title to Subject Inventions

A. PURPOSE

This Manual Chapter sets forth the procedures for NIH Contractors¹ for requesting waiver of NIH's rights to obtain title to Subject Inventions² when:

- (1) The Contractor initially elects *not* to retain title under 35 U.S.C. § 202(a) and 202(c)(2) (Declines Title);
- (2) The Contractor initially elects to retain title under 35 U.S.C. § 202(a) and § 202(c)(2) but later decides not to file or not to maintain the patent applications on the Subject Invention required by § 202(c)(3) (Abandons Title); and
- (3) The Contractor elects to retain title under 35 U.S.C. § 202(a) and § 202(c)(2) in order to license patentable biological material and does not file for patent protection as required by § 202(c)(3).

These procedures apply only to NIH Contractors.

B. NIH CONTRACTOR PROCEDURES

1. Declining or Abandoning Title

When a NIH Contractor Declines or Abandons Title to a Subject Invention, the NIH has discretion whether to obtain title. In such cases, where the Contractor notifies the NIH of its intent to ensure that the results of the research will be broadly available and reasonably accessible, and agrees in writing to comply with any and all applicable procedures that are available on the iEdison webpage (<https://s-edison.info.nih.gov/iEdison/>), the NIH will generally not obtain title.

¹ Under 35 U.S.C. § 201(c) and 37 C.F.R. § 401.2(b), as expanded by Executive Order 12591 (Apr. 22, 1987), a "Contractor" means any person, business firm, or nonprofit organization that is a party to a Funding Agreement. A "Funding Agreement" means any contract, grant, or cooperative agreement (but not a Cooperative Research And Development Agreement as defined under 15 U.S.C. § 3710a).

² "Subject Invention" is defined in 35 U.S.C. § 201 as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement...".

2. Unpatented Biological Materials

If a Contractor elects to retain title to a Subject Invention comprising a unique research resource (or “research tool”),³ but does not file for or maintain any patents on the Subject Invention, the NIH will not exercise its right to obtain title, provided the Contractor agrees with the following conditions:

- (1) The Contractor must make a written or electronic request to the Division of Extramural Inventions and Technology Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7750, Bethesda, MD 20814-7750;
- (2) Information describing the invention must be made publicly available either through publication in the scientific literature or by other appropriate means;
- (3) The licensing strategy must ensure that the research resource will be made available to the nonprofit research community. Generally, this can be accomplished through nonexclusive licensing, or exclusive licensing for distribution or sale of the materials. If an exclusive license is negotiated for internal use by a for-profit entity, the license must address continuing availability of the material to the nonprofit research community. Any exclusive license must provide for conversion to nonexclusive status or termination of licensee's rights upon failure to comply with the terms addressing continuing availability;
- (4) If an exclusive license is executed, provision must be made for independent maintenance of the material, such as at a national repository, or the originating grantee laboratory;
- (5) The government shall have a worldwide, irrevocable, unlimited royalty free, paid-up license in the material to make, use or distribute, or to have it made, used, or distributed for the Government. Upon request, sufficient quantities of the biological material shall be provided to the Government with such documentation as the Government is needed to preserve, use, and replicate the material to meet PHS needs; and
- (6) If the Contractor fails to fulfill the conditions of paragraphs 1-4 above, NIH shall automatically have the right to: (1) distribute the material, or (2) require the Contractor to comply with the Unique Research Resource requirements of its grant.

³ As stated in the “Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Resources: Final Notice, 64 Fed. Reg. 72,090-72,096 (Dec. 23, 1999) (“NIH Research Tools Policy”): “The term ‘unique research resource’ is used in its broadest sense to embrace the full range of tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines. The terms ‘research tools’ and ‘materials’ are used throughout this document interchangeably with ‘unique research resources.’ Databases and materials subject to copyright, such as software, are also research tools in many contexts.”

See “NIH Procedures for Non-election of Title to Patentable Biological Materials,” NIH Guide, Volume 25, Number 16, May 17, 1996 (<https://s-edison.info.nih.gov/iEdison/biological-materials.jsp>).

C. EFFECTIVE DATE

The procedures set forth in this Manual Chapter are effective September 20, 2012, and supersede in their entirety the NIH Contractor Procedures in PHS Technology Transfer Manual Chapter 602, which was first approved on March 28, 1996. This Manual Chapter is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any other persons.

D. ADDITIONAL INFORMATION

For additional information on this Manual Chapter and related NIH policies, contact the NIH Office of Technology Transfer, (301) 496-7057, or http://www.ott.nih.gov/contactus/contact_us.aspx, or the NIH Office of Extramural Research, Division of Extramural Inventions & Technology Resources, (301) 435-1986, Edison@nih.gov, or <http://inventions.nih.gov>.