

# UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

## Chapter No. 605A

### NIH Procedures Regarding Requests for Permission to Assign Title to Extramural Subject Inventions Developed by NIH Nonprofit Contractors to Third Parties

#### A. PURPOSE

This Manual Chapter establishes procedures for National Institutes of Health (NIH) Contractors<sup>1</sup> regarding requests for permission to assign title to Subject Inventions<sup>2</sup> to a third party, also referred to as requests for waiver of the prohibition against third party assignment of title. These procedures apply only to requests by NIH nonprofit Contractors.

#### B. BACKGROUND

For all nonprofit Contractors, 35 U.S.C § 202(c)(7) requires that the Funding Agreement include, among other terms, a prohibition of assignment of any Subject Invention to third parties without the approval of the funding agency “except where such assignment is made to an organization which has as one of its primary functions the management of inventions (provided that such assignee shall be subject to the same provisions as the contractor).”

#### C. NIH NONPROFIT CONTRACTOR PROCEDURES

1. The NIH nonprofit Contractor shall submit a request for permission to assign title to a third party to the NIH Office of Extramural Research (OER). Evaluation of the waiver request will **not** begin until the Contractor provides sufficient and detailed information, including the identity of the proposed assignee.
2. Factors that may be considered by the NIH in making a determination include:
  - a. The nature of the technology;
  - b. The explanation of why the assignment is necessary for commercialization of the technology;

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<sup>1</sup> 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). For the purpose of this chapter, Contractor also includes a third party assignees of extramural subject inventions developed by nonprofit contractors.

<sup>2</sup> “Subject Invention” is formally 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...”.

- c. The explanation of why the technology cannot be commercialized through means other than assignment to a third party, such as through exclusive, co-exclusive, or nonexclusive licensing;
  - d. The description of the entity to which the NIH nonprofit Contractor proposes assignment; and,
  - e. The explanation of how the public interest will be protected after assignment of title, including, without limitation, through:
    - i. Agreement by the assignee that the Subject Invention(s) will remain bound by and subject to all of the Government rights reserved under applicable laws and regulations as if the assignee was the original NIH nonprofit Contractor, and
    - ii. Agreement by the assignee that the use and transfer of the Subject Invention(s) will conform with all of the PHS's applicable published policies concerning broad public access to research results (e.g., data, materials);
    - iii. Remedies for failure to comply with conditions placed on the assignment; and,
    - iv. Disposition of the technology in the event the assignee enters bankruptcy, dissolution, or is otherwise unable or unwilling to commercialize the technology.
3. Each granted waiver request shall be subject to reservation by the Government of a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In addition, consistent with statutes, regulations, and PHS policies, the NIH retains sole discretion to add additional conditions, requirements, and/or restrictions (either generally or case-specific) that the NIH deems appropriate.
4. The waiver will become effective upon receipt of confirmatory signatures from both the NIH nonprofit Contractor and the proposed assignee accepting all terms and conditions of the waiver approval.

#### **D. EFFECTIVE DATE**

This chapter is effective September 20, 2012, and supersedes in its entirety the NIH Contractor procedures in PHS Technology Transfer Manual Chapter 605, which was first approved on March 26, 1998. 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.

## **E. 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/contact-us> , or the NIH Office of Extramural Research, Division of Extramural Inventions & Technology Resources, (301) 435-1986, [Edison@nih.gov](mailto:Edison@nih.gov), or <http://inventions.nih.gov>.