UNITED STATES PUBLIC HEALTH SERVICE
TECHNOLOGY TRANSFER PROCEDURE MANUAL

Chapter No. 606.1

NIH Internal Procedures for Handling Requests for Reconsiderations and Appeals of Certain Extramural Waiver Decisions

A. PURPOSE

This Manual Chapter describes the internal procedures for handling requests for reconsideration and appeals of an NIH decision denying: (1) a request for waiver of the U.S. manufacturing requirement, under 35 U.S.C. § 204, in exclusive licenses to use or sell a Contractor’s Subject Invention in the United States; and (2) a request for permission by a nonprofit Contractor1 to assign title to a Subject Invention2 to a third party.

B. BACKGROUND

The NIH decision or determination concerning the denial of a Contractor’s request for waiver of the U.S. manufacturing requirement or permission for third party assignment3 is final unless the procedures for requests for reconsideration and appeals set forth below are initiated.

C. NIH INTERNAL PROCEDURES

1. Requests for Reconsideration

   a. Upon receipt of a request for reconsideration, the NIH Office of Extramural Research, Division of Extramural Inventions & Technology Resources (OER) shall transmit the request to the NIH Office of Technology Transfer (NIH OTT) within five (5) business days. If NIH OTT first receives a request for reconsideration it shall transmit the request to OER within five (5) business days.

   b. The NIH Office of Technology Transfer (NIH OTT) shall review the case and make a decision regarding action to be taken. NIH OTT may seek advice and information from any source, including OER; the Contractor; the NIH funding Institute or Center; NIH OTT employees; the NIH Office of the General Counsel;

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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). For the purpose of this chapter, Contractor also includes third party assignees of extramural subject inventions developed by nonprofit contractors.

2 “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…”.

3 Request for assignments of title to third parties are also referred to as requests for waiver of the prohibition against third party assignment of title.
or other NIH employees.

c. NIH OTT shall provide OER with a draft of the NIH decision prepared by OTT and will seriously consider OER’s comments with respect to its proposed determination.

d. Within fifty (50) calendar days of receiving the request for reconsideration, or, if additional information is required, within fifty (50) days of NIH receiving such additional information, NIH OTT shall transmit the final NIH decision to OER.

e. Within five (5) business days of receiving NIH OTT's final decision, OER will communicate the NIH decision to the Contractor and will send a copy to the NIH OTT.

2. Appeals

a. Pursuant to 37 C.F.R. § 401.11, upon receipt of an appeal, OER shall transmit the request to the NIH Office of Technology Transfer (NIH OTT) within five (5) business days. If NIH OTT first receives a request for appeal it shall transmit the request to OER within five (5) business days.

b. The Deputy Director for Intramural Research and the Deputy Director for Extramural Research may confer with respect to consideration of the appeal.

c. The NIH Director shall make the final decision of any appeal

d. Within five (5) business days of receiving the NIH decision from the NIH Director, NIH OTT will communicate the NIH decision to the Contractor and will send a copy to OER.

e. Judicial review is available as the law permits.

D. EFFECTIVE DATE

The NIH internal procedures set forth in this Manual Chapter are effective September 23, 2013, and supersede in their entirety the NIH internal procedures in PHS Technology Transfer Manual Chapter 606, which was first approved on March 26, 1998.

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, or http://inventions.nih.gov.