A. PURPOSE

This Manual Chapter establishes the procedures for the National Institutes of Health’s (NIH) review and disposition of requests for permission by a nonprofit Contractor¹ to assign title to Subject Inventions² to a third party that does not have as one of its primary functions the management of inventions.

B. BACKGROUND

For all non-profit Contractors, 35 U.S.C § 202(c)(7) and 37 C.F.R. § 401.14(k)(1) require 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.

The NIH Office of Technology Transfer (NIH OTT) has been delegated the authority to permit a nonprofit organization to assign "the rights to a Subject Invention in the United States" to organizations which do not have as one of their primary functions the management of inventions. 35 U.S.C. § 202(c)(7). The Contractor must request such a waiver on behalf of its proposed assignee. The following procedures are to be followed in processing and responding to such requests.

C. PROCEDURES

1. OER shall send a copy of the Contractor’s request and supporting information to NIH OTT.

2. The determination to grant or deny approval of assignment, along with any conditions and/or limitations, will be communicated by NIH OTT to OER within twenty (20) business days upon receipt of a complete waiver request. Within five (5) business days

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 (CRADA) 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…”. 
of OER receiving OTT’s determination, OER can send to OTT its comments and/or edits. OTT will seriously consider OER’s comments and/or edits and will issue its final determination within five (5) business days of receiving OER’s comments.

3. Within five (5) business days after receiving NIH’s determination as prepared by OTT (absent extenuating circumstances and notification to NIH OTT), OER will communicate the final OTT determination to the Contractor(s) and will send, at the same time of sending the final determination to the Contractor(s), a copy of OER’s correspondence to OTT. OER will maintain the original request of the Contractor(s), all of OER’s related documents, and those documents submitted by the Contractor(s) through iEdison.

D. EFFECTIVE DATE

The NIH procedures set forth in this Manual Chapter are effective June 20, 2013, and supersede in their entirety the NIH 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, or http://inventions.nih.gov.