A. PURPOSE

This Manual Chapter establishes procedures for the National Institutes of Health’s (NIH) review and disposition of NIH Contractors' requests for waiver of the U.S. manufacturing requirement under 35 U.S.C. § 204 in exclusive licenses for their Subject Inventions. These procedures apply only to requests by NIH Contractors.

B. BACKGROUND

When a Contractor grants an exclusive license to a Subject Invention in the United States, 35 U.S.C. § 204 and 37 C.F.R § 401.14(a)(i) require that the licensee agrees “that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States.” The agency that funded the Subject Invention may, on a case-by-case basis, waive this requirement upon a showing by the Contractor “that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture the Subject Invention substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.”

The NIH Office of Technology Transfer (NIH OTT) has been delegated the authority to waive the U.S. manufacturing requirement under 35 U.S.C. § 204. The Contractor must request such a waiver on behalf of its proposed exclusive licensee. The following procedures are to be followed in processing and responding to such Contractor’s requests.

C. NIH PROCEDURES

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

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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 purposes of this Chapter, assignees of the original Contractor will be treated as if they were the original Contractor.

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…”. 
2. The determination to grant or deny approval of the request, along with any specific conditions and/or limitations, will be communicated by NIH OTT to OER within twenty (20) business days of receipt of a complete waiver request. Within five (5) business days 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 final determination as prepared by OTT (absent extenuating circumstances and notification to NIH OTT), OER will communicate the final NIH’s determination to the Contractor(s) and will send to OTT, at the same time of sending the final determination to the Contractor(s), a copy of OER’s correspondence to the Contractor(s). OER will maintain the original request regarding the waiver of the U.S. manufacturing requirement, 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 604, 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.