A. PURPOSE

This Manual Chapter establishes the policy for PHS review and disposition of requests to allow a PHS Contractor’s employee-inventors to acquire title to extramural inventions for which the PHS Contractor elects not to retain title.

B. BACKGROUND

When a Contractor elects not to retain rights in a Subject Invention, the Government, as represented by a PHS Agency, may receive title to the Subject Invention, as provided under 35 U.S.C. § 202(c)(2). If a Contractor does not elect to retain title to a Subject Invention or the Contractor otherwise waives title to the Government, the Federal agency (NIH) may consider and after consultation with the Contractor grant requests for retention of rights by the inventor subject to the provision of 35 U.S.C. § 200 et al. See 35 U.S.C. § 202(d). The Contractor may also request, on behalf of its employee-inventor, permission from the PHS Agency for the employee-inventor to acquire title.

C. POLICY

It is the policy of PHS to allow a Contractor’s employee-inventor to acquire title to subject inventions at the request of the Contractor, when it is determined that granting the request would be in the public interest and conform to PHS policy. Issues considered when making this decision include, without limitation, whether: (1) the invention is sufficiently related to any PHS Agency research to warrant PHS retaining title; (2) the invention has sufficient commercial or public health value to be of interest to the Government; (3) the invention will be appropriately commercialized without PHS involvement; or (4) the grant of the waiver would be consistent with PHS policy and public interest.

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 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 For purposes of making this request, the “Contractor” may be either the Contractor or an employee-inventor of the Contractor subject to 35 U.S.C. § 202(d).
D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective September 23, 2013, and supersedes in its entirety the policy in PHS Technology Transfer Manual Chapter 603, which was first approved on December 18, 2003 and revised on September 20, 2012. 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.