A. PURPOSE

This Manual Chapter sets forth the procedures for the receipt and distribution of Royalties received from the licensing of inventions in which the U.S. Government has an ownership interest and which are administered by the National Institutes of Health (NIH).

B. BACKGROUND

NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability. NIH’s goals are to: (1) foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health; (2) develop, maintain, and renew scientific human and physical resources that will ensure the Nation’s capability to prevent disease; (3) expand the knowledge base in medical and associated sciences in order to enhance the Nation’s economic well-being and ensure a continued high impact on the public investment in research; and (4) to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science. To accomplish its mission and goals some research results must be transferred to the private sector for subsequent commercial development and manufacture in order to make available to the public new or improved products and services. The licensing of inventions is generally an effective means for the transfer of such research results to the private sector.

Under the Stevenson-Wydler Technology Innovation Act of 1980 and as amended, Congress established that assisting U.S. businesses to speed the development of new products and processes is a responsibility of each federal agency. To further this objective, Congress has included incentives for researchers to participate in the technology transfer process that promote and support the expeditious transfer of Federally-owned inventions. These incentives are realized in part through the distribution of Royalties by NIH to inventors.

C. PROCEDURES

NIH, as set forth at 35 USC 207 (a)(2), is authorized to “grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions, Royalty-free or for
Royalties or other consideration and on such terms and conditions as determined appropriate in the public interest.” Any Royalties excluding payments of patent cost reimbursement, that are received by NIH are distributed to the inventor or co-inventors ("Inventor’s Share"), and to the NIH Institute(s) or Center(s) ("ICs” or “IC”) in accordance with 15 U.S.C. 3710c. Royalties are also distributed to non-NIH inventor(s) or co-inventor(s) or entities as required under associated Inter-Institutional Agreement IIA, settlement agreement, or other appropriate agreement.

1. ROYALTY DISTRIBUTION FORM (RDF)

a. After execution of a license agreement, the NIH Office of Technology Transfer (NIH OTT) will provide a preliminary Royalty Distribution Form (RDF) to each of the Technology Development Coordinators (TDCs) of the ICs having inventions listed within the license agreement. The NIH OTT will generally include on the list only those inventors whose inventions have been assigned to the U.S. Government as represented by the Public Health Service. In the case of licensed biological materials inventions, the Employee Invention Report (EIR) will serve as the basis for this calculation.

b. The NIH OTT will send the RDF for every license to the relevant ICs’ TDC, unless the TDC specifies otherwise. The ICs will verify or modify the relative Royalty distribution on the RDF of the Inventor's Share to be paid to each of the inventors whose invention is licensed. If the licensed invention(s) was (were) made in more than one IC, the TDCs for each of the ICs will reach an agreement on the distribution and coordinate their response. The ICs or the lead IC have thirty (30) days from the date the RDF was sent to the ICs to return a fully executed RDF to the NIH OTT. The NIH OTT Senior Royalties Administrator will then forward the signed RDF to the NIH Office of Financial Management (OFM). If the IC does not return the RDF to the NIH OTT within the thirty (30) day period (or notifies NIH OTT of an exception of this 30 day notice period), the NIH OTT will instruct the OFM to use the Default Distribution formula (see section C.2 below). An IC’s written request for changes in the RDF received by the OFM less than thirty (30) days prior to a scheduled payout by the OFM will become effective in subsequent distributions. Errors in Royalty distributions that were not originally identified through the RDF review and approval process or by review of the OFM Royalty Reports, and are determined to affect an inventor(s)’ or an IC’s distributions, will be adjusted retroactively upon written request of the ICs with adjustments made through the requesting ICs’ CAN(s).

2. DETERMINATION OF THE INVENTORS’ RELATIVE SHARE OF ROYALTIES.

There are two options to designate the distribution of Royalties to inventors.

a. EQUAL SHARE DISTRIBUTION OF ROYALTIES AMONG INVENTORS
This is the Default Distribution to distribute Royalties to inventors and is defined below.

Royalties will be distributed for each license agreement among all inventor(s) named on licensed patents, pending patent application(s), and/or EIR. For a set of licensed patent(s), licensed pending patent application(s), or biological materials that name the same inventors and are based on the identical invention disclosure (“Genus”), the inventors will receive an equal share of royalties. If two or more Genera are licensed in one license agreement, each inventor’s name is counted once per Genus in which the inventor is named. Each inventor(s) total share(s) will be determined by the number of times the inventor is named within all of the licensed Genera; divided by the cumulative number of inventor(s) shares among all Genera. For purposes of determining distribution among multiple inventors, the number of patents within a Genus is not considered.

For example, a license agreement identifies 2 Genera. Genus 1 identifies inventors A, B, and C. Genus 2 identifies inventors A, B, and D. Adding the total number of inventors in Genus 1 (3) to the total number of inventors in Genus 2 (3) yields 6 inventors. Inventors A & B are represented twice (once in Genus 1 and once in Genus 2) and each would receive 2/6 of the total Royalties share. Inventor C is named once in Genus 1 and would receive 1/6 share of the Licensed Income. D is named once in Genus 2 and would receive 1/6 share of Royalties.

b. DISTRIBUTION OF ROYALTIES AMONG INVENTORS OTHER THAN BY THE DEFAULT DISTRIBUTION AMONG INVENTORS (Alternate Distribution): The ICs, or inventors with ICs’ approval, may choose an Alternate Distribution of Royalties. Use of an Alternate Distribution may be warranted when, for example, the inventors agree that their relative contributions to the invention was not equal, when some of the patents or patent applications under one license are licensed exclusively and some nonexclusively, or when the result obtained by the Default Distribution does not otherwise appear to be equitable in light of the licensed technology as a whole. In determining an Alternate Distribution among inventors, the ICs’ TDCs will strive to attain a consensus among the inventors and may ask the inventors to sign a distribution agreement reflecting that consensus. However, if a consensus cannot be reached after reasonable attempts to do so, the ICs may either choose the default distribution described in (a) above or designate an Alternate Distribution that is determined to be equitable. The ICs may establish a means of resolving any dispute.

c. Normally, Royalties received will be distributed to all inventors of the inventions encompassed by the license who have assigned their rights to the U.S. Government, as represented by the agency. If the assignment of any invention encompassed by the license changes, then OTT will generate a new
d. There are a variety of circumstances under which the inventors or their relative proportion listed in an RDF may change, including, for example: the licensee amends the license to add or to drop some of the licensed patent applications or patents, an application encompassed by the license becomes abandoned or expired, a new application encompassed by the license such as a Continuation-in-Part is filed, the inventorship of a patent or patent application is corrected, an issued patent is invalidated, or the claims are restricted and a divisional application is not filed on all the original, non-elected claims. OTT will generate a new RDF for the following circumstances: the license agreement is amended, the inventorship of a patent or patent application is corrected, and/or a new patent application encompassed by the license is filed which effects the inventors’ distribution. For any other circumstance, the TDC may initiate a new RDF at the discretion of the IC. TDC initiated RDFs may not be required if the original distribution appears equitable in light of the licensed technology as a whole, or if it is impractical to track changes in patent status.

e. Inter-Institutional Agreements (IIA), Settlement Agreement, or other appropriate agreement, parties will be notified of pending Royalty distributions by the NIH OFM prior to distribution of Royalties. The NIH OTT Royalties Administrator will also provide Royalty calculation information to these parties.

3 RECEIPT OF ROYALTY INCOME:

Licensees submit all Royalty payments to the designated Agent Cashier (the designated U.S. Treasury agent for collection). Payments received directly by the NIH OTT or by an IC will be forwarded to the NIH Agent Cashier. The NIH OFM is designated as the official recipient of payments for the NIH and is responsible for the distribution of Royalties to Inventors and ICs.

4 DISTRIBUTION OF ROYALTY INCOME TO THE INVENTOR(s):

a. 15 U.S.C. 3710c(a)(1)(A)(i) specifies that “(t)he head of the agency or laboratory, or such individual’s designee, shall pay each year the first $2,000, and thereafter at least 15 percent, of the royalties or other payments, other than the payment of patent costs as delineated by a license or assignment agreement, to the inventor or co-inventor’s, if the inventor or co-inventor’s rights are assigned to the United States.”

b. An inventor’s annual Royalty income will accumulate based on the date that the Royalty income is received at the NIH during the fiscal year. In the event that income on more than one license is received on the same day, income from the older license is allocated first. Inventors’ share of Royalties are accumulated and distributed as outlined on the RDF generated for each
Each inventor will receive their share of the first $2,000, their share of the sum of fifteen (15%) of the Royalties received above $2,000 and up to $50,000, and their share of a sum of twenty-five percent (25%) of Royalties received in excess of $50,000. These sums are calculated in chronological order by receipt date, per license, per fiscal year. Distribution of these accumulated funds is reported on a monthly basis and distributed to the inventors biannually on a calendar year basis.

c. The maximum amount any one inventor can receive in a calendar year is $150,000. “Payments made under this section shall not exceed $150,000 each calendar year to any one person, unless the President approves a larger award (with the excess over $150,000 being treated as a Presidential award under section 4504 of title 5.” 15 U.S.C. 3710c(a)(1)(B)(3)).

When an inventor reaches the $150,000 Royalty cap that inventor’s share beyond the cap will be redistributed to all inventors whose accumulated income has not yet reached the cap in the relative proportions stipulated on the RDF. For example, if inventors A, B and C share in relative proportions of 10%, 30%, and 60%, respectively, and inventor C has already reached the cap of $150,000 Royalties, the remaining inventors’ Royalty share is distributed to A and B in relative proportions of 25% and 75% (10/[10+30]) and 30/[10+30]). If all the inventors under a given license reach the Royalty cap, the excess inventors’ share will be added to the ICs’(s)’ share as described at Section 5 below.

d. No minimum or cumulative minimum annual Royalty payments to inventor(s): Inventors are not entitled to receive appropriated funds or Royalties in order to supplement Royalties received on a licensed invention that are insufficient to provide a minimum of $2,000 annual payment to the inventors individually or as a group during any fiscal year or to compensate for payment of less than a $2,000 annual payment during any other fiscal year. In cases where licensees do not comply with the Royalties payment schedule provided under the license agreement and payments are received after the scheduled distribution period, supplemental or early distributions will not be made to inventors. Royalties to inventors will be distributed based on the deposit date identified by the OFM for that particular calendar year. Supplemental distributions of income will be made if it is determined that an inventor or inventors did not receive an appropriate share of the Royalties through an inadvertent accounting error on the part of NIH.

e. It is each inventor's responsibility to keep the NIH OFM apprised of his/her current address, phone number, U.S. social security number, and banking deposit information. Any changes should be provided in writing to the NIH OFM. If reasonable attempts to obtain current information for a particular inventor fail, his/her share of Royalties will be distributed to the appropriate IC(s).
f. Subject to applicable law and provided the inventor or the inventor’s personal representative establishes an appropriate account in the name of the estate, the NIH shall continue to pay the inventor’s share of Royalty payments to such account after the inventor’s death. The NIH OTT Senior Royalties Administrator will request a copy of the death certificate and establish a contact for any future patenting or Royalty issues that may arise. The information will be forwarded to the NIH OFM. Royalty payments will be issued “to the estate of” and the deceased Inventor’s name. Any requests for changes to the payee of the deceased inventor’s Royalties must be provided to the NIH OTT Royalties Administrator and NIH OFM through written probate decision of the court or other appropriate written documentation. Original court documents are not required. The NIH OTT Senior Royalties Administrator can provide to the Personal Representative the status of related license agreements, patent applications and issued patents and an accounting of previous Royalty distributions to the deceased inventor. This information may be provided to assist the Personal Representative in the administration of the estate.

5. DISTRIBUTION OF ROYALTIES TO THE ICs ("ICs’ Share"):

a. The NIH OFM will notify each IC each month the amount of Royalties received from licenses to inventions made by each IC inventors. The ICs have ten (10) business days to review these OFM reports and notify OFM of any irregularities or inconsistencies found. The ICs will determine the distribution of the Royalties remaining after the distribution to inventor(s). An IC share must be obligated or expended by the end two fiscal years following the fiscal year in which the NIH received it.

b. The ICs’ Share may be used for a variety of purposes as follows (15 U.S.C. 3710c(a)(1)(B)):

   (1) to reward scientific, engineering, and technical employees of the laboratory;

   (2) to further scientific exchange among the laboratories of the agency;

   (3) to educate and train employees consistent with the research and development missions and objectives of the agency or laboratory, and to support other activities that increase the potential for transfer of the technology of the laboratories of the agency;

   (4) to pay expenses incidental to the administration and licensing of intellectual property by the agency or laboratory with respect to inventions made at that laboratory, including the fees or other costs for the services of other agencies, persons, or organizations for intellectual
property management and licensing services; or

(5) to support scientific research and development consistent with the research and development missions and objectives of the laboratory.

6. DISTRIBUTION OF PATENT COST REIMBURSEMENT TO ICs.

a. Patent cost reimbursement Royalties are tracked separately from other Royalties, and are not distributed in the same manner as the Royalties addressed by the royalty distribution form (RDF). Inventors do not receive a share of patent cost reimbursement Royalties, so all patent cost reimbursement Royalties are distributed to the IC(s) having contributed to the costs of patent filing.

b. When NIH OTT receives patent cost reimbursement Royalties under a license involving inventions to which more than one IC contributed to patenting costs, NIH OTT will calculate the actual patent expenses paid by each IC up to the time of the license. If the patent cost reimbursements Royalties are not sufficient to reimburse all of the patent expenses of all of the ICs, then OTT will calculate a distribution so that each IC receives a reimbursement amount in proportion to its actual expenses.

For example, a patent reimbursement Royalty of $25,000 is received, which is 50% of the actual patent expenses. IC-A actual expenses were $10,000, IC-B expenses were $40,000, and IC-C did not have patent expenses. In this example, the calculated distribution is $5,000 to IC-A, $20,000 to IC-B and none to IC-C.

c. If ICs desire an alternative distribution of patent cost reimbursement, then NIH OTT Royalties office must be notified within 10 days of receipt of the default distribution RDF. If pursuing alternate IC distribution, the ICs must provide a written agreement to NIH OTT, signed by all ICs receiving funds, delineating the agreed to alternate distribution of patent cost reimbursement royalties.

If NIH OTT does not receive an executed RDF of either the default formula within 10 days of receipt of the default distribution RDF of it being sent to the ICs or for alternate formulas within 21 days of receipt of the default formula, NIH OTT will provide the default formula RDF to NIH OFM so that NIH OFM may make the appropriate distribution.

d. Patent costs may also be recovered through the calculation of IIA royalty sharing based on 15 U.S.C. 3710c(a)(1)(A) recognizing that NIH’s patent costs should be recovered before royalties are paid to the inventors. When royalties are received, the OTT Senior Royalties Administrator determines if
there is an active and related IIA or Royalty Sharing Agreement. If the IIA language allows for the recovery of expenses, the IIA language is reviewed for guidance and takes precedence for the calculation of royalty payouts. If it is determined that there are unreimbursed expenses that can be deducted prior to royalty sharing with an IIA institution, the OTT Senior Royalties Administrator notifies the OFM Royalties Coordinator of the amount of royalties to be identified as patent prosecution recovery. The OFM Royalty Report distributed to the ICs each month for approval identifies the funds as patent prosecution recovery. The patent prosecution recovery funds are distributed to the appropriate IC(s) as stated in paragraphs 61 through 6c above.

D. EFFECTIVE DATE

The procedures set forth in this Manual Chapter are effective March 8, 2012 and supersede in their entirety the procedures in PHS Technology Transfer Manual Chapter 311, which was first approved on January 23, 2002.

E. ADDITIONAL INFORMATION

For more information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 594-7700 or http://www.ott.nih.gov/contact-us