A. PURPOSE

This chapter sets forth the procedures used by the National Institutes of Health (NIH) Office of Technology Transfer (NIH OTT) to administer the collection and the distribution of Royalties in compliance with obligations in NIH administered Public Health Service (PHS) license agreements and applicable statutes.

B. BACKGROUND

PHS generally seeks to license inventions to facilitate and attract investment by commercial partners for further research and commercial development of the invention. At the same time, PHS seeks to obtain a fair financial return on the public’s investment through the negotiation of Royalty-bearing licenses with, and obtaining payment of patent expenses, if any, from Licensees. NIH OTT administers the receipt and distribution of Royalties for NIH and the Food and Drug Administration (FDA).

C. DEFINITIONS - For the Purposes of this Procedure

1. *Earned Royalties* - A share of the net sales from the sale of products or services using a licensed technology.
2. *External Audit* – An examination of the financial accounts relating to the sales of the Licensee by an independent auditing firm selected by NIH OTT. The External Audit addresses the Licensee’s compliance with the terms of the license, which may include sales of licensed products and calculation of Earned Royalties.
3. *Institutes and Centers (IC)* – Organizational components of NIH or other PHS agencies that utilize NIH OTT for licensing and patenting activities.
4. *Licensee* - The person, corporation, or institution that enters into a license agreement with PHS.
5. *Royalty(ies)* - All income received from a Licensee as required by the terms of an executed license agreement. Royalties include, but are not limited to Earned Royalties, Short-Paid Royalties and patent cost reimbursement.
6. *Short-paid Royalties* – Small differences between the amount of Royalties a Licensee owes and the actual amount received. The difference may be due to errors in calculation (e.g., rounding errors), use of an incorrect exchange rate for converting foreign currency to U.S. Dollars (USD), or failure to remit sufficient
funds to cover bank wire fees deducted during electronic transfers of funds between banks.

D. PROCEDURES

1. Upon receipt of an executed license agreement, NIH OTT will:
   
a. Review the executed license agreement to identify the license obligations that need to be administered throughout the term of the agreement.

b. Conduct internal data integrity checks or audits of information entered in databases that are utilized by NIH OTT to ensure that negotiated terms are correctly administered.

c. Forward a copy of the executed license agreement to the Licensee and relevant IC Technology Development Coordinator (TDC).

d. Provide appropriate payment notices to the Licensee, including NIH banking depositories.

e. Forward copies of the preliminary Royalties Distribution Form to the appropriate IC TDC and NIH Office of Financial Management (OFM).

2. According to the terms of the license, the NIH OTT will provide written authorization to the IC, inventor or repository to release any materials transferred under the license. The IC TDC, inventor or repository will provide written verification to NIH OTT when the material is shipped. If verification is not received within 30 days of authorizing release, NIH OTT will follow-up with the IC TDC, inventor, or repository about the material release.

3. Depending on the terms of the license, NIH OTT will prepare a patent expense summary report and bill the Licensee for reimbursement of appropriate patent expenses incurred by NIH applicable to the license.

4. On a monthly, semi-annual, and annual basis, NIH OTT, OFM, and IC TDC will reconcile Royalties received to ensure a proper accounting, distribution, and reporting of Royalties collected. Reconciliations will ensure that:

a. License agreement numbers and terms are identified for each payment.

b. Individual and total amounts of Royalties reported to the NIH OTT and deposits posted by the OFM match.

c. Royalties payouts to the ICs, Inter-Institutional Agreement (IIA) Institutions, and inventors will not be withheld due to pending licensing issues for more than two distribution cycles made by OFM.
d. OFM is notified of any misrouted deposit receipts that are not Royalty payments, so that they can be re-routed to the appropriate account, agency, or payee.

e. Overpayment of Royalties by Licensees is identified by NIH OTT. OFM is notified to either refund the Royalty overpayment or to apply the Royalty overpayment to other Royalties owed, whichever is in the best interest of the Federal Government.

f. NIH OTT determines IIA distributions and notifies OFM of any Royalty payouts, as appropriate.

g. OFM will notify each IC of monthly Royalty income and proposed distributions and will schedule Royalty payouts from the U.S. Treasury accordingly. The IC is required to review and confirm distributions to OFM.

5. NIH OTT will monitor and enforce the terms of license agreements. This will include:

a. Collecting sales and progress reports from Licensees and following-up with Licensees when such reports are overdue.

b. Reviewing sales reports received from Licensees. Any sales that do not represent anticipated Earned Royalties or that contain significant fluctuations from previous reports will be identified and investigated to ensure proper reporting. Reports that accurately reflect sales will be certified as acceptable by NIH OTT. This certification does not necessarily exempt a license from being subject to an External Audit, as described in 5.j. below.

c. Imposing additional Royalties as a penalty, consistent with the license and when considered appropriate by NIH OTT on overdue Royalties at a rate of 1% per month (simple interest) from the date originally due, if more than 90 days old.

d. Negotiating payment plans for overdue Royalties when considered appropriate by NIH OTT. Requests for delays in payment or use of installment payment plans may be granted at the discretion of the Director (or designee). It is not in NIH’s interest to pursue Short-paid Royalties that total less than $100 because of the collection costs involved. Therefore, NIH’s Licensee will not be contacted about such Short-paid Royalties until they exceed $100 per license agreement. At such time, OTT will generate a notice for payment to the Licensee explaining the reason for requesting such payment or will add the Short-paid Royalties to the payment notice for the next Royalty payment routinely due with an explanation for the added amount.

e. Negotiating Letters of Agreements (LOAs) with the Licensee when they are willing to pay the delinquent Royalty term but need more than ninety (90) days (but less than one year) to pay, i.e., extended payment plans. LOAs may be
approved at the discretion of the NIH OTT Director (or designee) with notification to the IC(s) TDC(s) when delinquent Royalty term is greater than ninety (90) days.

f. When considered appropriate by NIH OTT, executing a license amendment for Royalty payments that are to be delayed more than one year. License amendments may also be used to resolve disagreements concerning the validity of any license term.

g. Exhausting all reasonable efforts to collect delinquent Royalties before referring collection to the agency’s Debt Collection Office (DCO) after the license is terminated. Documentation of efforts to collect or resolve delinquent Royalties greater than $2,500 will be forwarded to DCO with a request to pursue collection. DCO shall provide the NIH OTT with copies of any correspondence related to an attempt(s) to collect payments.

h. Deciding to suspend efforts to collect Royalty payments relating to delinquent or short paid Royalty terms when it is determined by the NIH OTT that it is in the best interest of the Government. A written request to suspend efforts to collect a Royalty payment will be made by NIH OTT to the NIH OTT Director (or designee) and may be approved on a case-by-case basis.

i. Reviewing annual progress reports from Licensees. Reviews will determine whether the Licensee is demonstrating due diligence in fulfilling commercial development plans. Licensee will be contacted when reporting information deviates from the agreed to plan or benchmark schedule. Benchmark schedules may be updated or modified through an amendment, as appropriate.

j. Contracting with audit firms to perform External Audits on Licensees who report more than $5,000,000 in annual net sales. All licenses over this threshold will be audited, at ICs expense, at least once every 5 years unless reasonable justification is provided not to do so. Requests not to perform an audit will be submitted to the NIH OTT Director (or designee) for review and concurrence or non-concurrence. Determination not to perform an audit will be made by the NIH OTT Director (or designee) after consultation with the IC TDC. NIH OTT will request reimbursement from the Licensee of any expenses resulting from the audit, as appropriate and allowed by the license. NIH OTT will develop the Statement of Work for the audit with input from the IC.

IC’s may request, at their expense, additional External Audits that do not meet the threshold described above. An IC’s request to audit an NIH OTT license must be submitted to the NIH OTT Director (or designee) for approval. A written decision on the audit request will be sent to the requestor within 30 days.

Audit results will be reviewed with the appropriate IC TDC and necessary follow-up will be conducted.
6. NIH OTT will notify the IC TDCs when Royalty payments greater than $2,500 and more or are anticipated to be more than 120 days overdue.

7. Licenses may be terminated by the Licensee or NIH.
   
a. Notices of termination by the Licensee must be submitted in writing to the NIH OTT and in accordance with the terms of the license agreement. The NIH OTT will review the license to identify any outstanding reports or Royalty terms still due and notify the Licensee. As appropriate, the NIH OTT may request a certification of destruction or return of any licensed materials. NIH OTT will notify the appropriate IC(s) when a Licensee has terminated their license.
   
b. NIH has the authority to unilaterally terminate a license according to the terms of the license agreement. However, if the NIH OTT is unable to contact the Licensee and has exhausted reasonable efforts to contact them, the license may be terminated according to the terms of the agreement. In such cases, the termination date will be made effective from the earliest documented unsuccessful attempt of notification.

8. All commercial and financial information obtained in the administration of executed license agreements are treated as privileged and confidential, with the understanding that this information is not subject to disclosure to individuals not involved in the post-license execution administration of the agreement. Any proposed disclosure of these records by the PHS under the Freedom of Information Act, 5 U.S.C. § 552 shall be subject to the pre-disclosure notification requirements of 45 C.F.R. § 5.65(d).

E. CHAPTER REVIEW, RECORDS RETENTION AND DISPOSAL.

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, NIH Records Control Schedule, "Appendix 1, Items 1100-L. This Chapter will be reviewed at least every three (3) years. Specifically, OTT will obtain feedback from the IC TDCs, collect modifications, and submit a final draft to the Technology Transfer Policy Board for review, comment, and approval/disapproval.

F. EFFECTIVE DATE

The procedures set forth in this Manual Chapter are effective September 15, 2011 and supersede in their entirety all procedures in PHS Technology Transfer Manual Chapter 310, which was first approved on 22 March 2007. This Manual Chapter supersedes in its entirety PHS Technology Transfer Manual Chapters 308 (Dated 9/30/94) and 310 (Dated11/13/95).
G. 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

H. REFERENCES

4. Title 5, Section 552 and the Freedom of Information Act, establishes guidelines for the protection and non-disclosure of commercial and financial information obtained in the execution and administration of license agreements. This was further upheld in the United States District Court for the District of Columbia in Civil Action No. 00-1847, Memorandum Opinion, dated March 11, 2002.
6. 31 U.S.C. Chapter 3717; 31 C.F.R. Part 901.2 – Demand Payment
7. 31 U.S.C. Chapter 3717; 31 C.F.R. Part 901.8 - Consider Installments