UNITED STATES PUBLIC HEALTH SERVICE
TECHNOLOGY TRANSFER PROCEDURE MANUAL

Chapter No. 201.1

Procedures for Reporting Employee Inventions to the NIH Office of Technology Transfer

A. PURPOSE

This Manual Chapter sets forth the procedures for reporting inventions from the research Institutes and Centers (ICs) of the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) to the NIH Office of Technology Transfer (NIH OTT).

B. BACKGROUND

The Employee Invention Report (EIR) form is used by NIH and FDA to document inventions made by Personnel.1 Personnel must report and assign to the Government all rights in inventions made during working hours, or with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government employees on official duty, or which bear a direct relation to or are made in consequence of the official duties of the inventor. In certain circumstances, contractors may be obligated to assign inventions to the Government under the terms of the contract, e.g., a Declaration of Exceptional Circumstances or waiver of title to the Government.

Public disclosure of an invention before a patent application has been filed may jeopardize development of the technology by limiting patent rights. Therefore, it is important to submit an EIR as early as feasible; for example, investigators need not wait until a scientific paper is ready to be sent for publication, or an oral/poster presentation is scheduled.

Late EIR submission negatively affects NIH OTT’s ability to perform effective patenting and licensing services for the ICs and the FDA. Late submission may result in increased costs and less than optimal analysis of the reported invention. In order to ensure that the number of late EIR submissions is kept to a minimum and reserved for cases of legitimate, unavoidable emergency situations, the ICs and the FDA should comply with the following standard procedures. Adherence to these procedures will confer substantial benefits to the ICs and the FDA by improving NIH OTT’s ability to secure, in an orderly fashion, the necessary protection of Government intellectual property rights, which are critical to the optimal commercialization of technology.

1 For purposes of this Chapter, “Personnel” includes all individuals who are required either by law (see, e.g., Executive Order 10096, 45 C.F.R. Part 7, and 37 C.F.R. Part 501), by policy (see, e.g., NIH Policy Manual, Chapter 2300-308-1 – “Guest Researcher/Special Volunteer Programs”), or by the terms of a written agreement (e.g., a contract with an explicit clause) to assign rights to the inventions to the Government.
C. PROCEDURES

1. EIR Submission Content

The inventor shall, with the advice and guidance of the IC/FDA Technology Development Coordinator (TDC), complete the EIR.

a. An EIR submission must include enough information to enable the NIH OTT to make a reasonable assessment of the technology and select an appropriate patenting and licensing strategy in view of relevant PHS policies. Specifically, an EIR submission should include, at a minimum (where applicable), the following items:

   (1) A written request for specific NIH OTT action;
   (2) A completed EIR form, signed by at least the lead inventor and the IC/FDA TDC, which includes the affiliation(s) of each inventor at the time of conception;
   (3) A description of the technology (which may be included in the EIR and/or in a manuscript provided to NIH OTT);
   (4) Any available draft or published manuscript;
   (5) Copies of related agreements, such as MTAs, CDAs or CTAs;
   (6) Indication of possible CRADA subject invention, if applicable; and
   (7) Any known related references.

b. Inventions Potentially Not Owned by the Government: An inventor may report an invention to the NIH OTT indicating that the inventor believes that such invention should not be assigned to the Government because it was (i) not made in whole or in part during working hours; (ii) not made with any contribution of Government facilities, equipment, material, funds, or information; and (iii) not using the time or services of other Government employees on official duties. (Such an EIR must, nevertheless, be signed by the appropriate TDC.) The reporting of such inventions will protect the personnel’s rights by providing documentation that the invention is not the property of the Government.

c. Cover Memo: In addition to the EIR itself, the IC/TDC should prepare a cover memo. A suggested template “cover memo” is attached as Attachment 1. The cover memo must indicate if the IC/FDA has made a determination to support initial patent prosecution activities. In order to assist an IC/FDA to form its opinion of an invention, the cover memo may request that NIH OTT conduct a patentability/marketability review as soon as practicable. If the IC/FDA includes in the memo authorization to spend IC funds to file an initial patent application or to conduct an art search, the IC must include a Common Accounting Number (CAN) against which those expenses can be billed. A cover memo indicating that the IC/FDA does not support patent prosecution for the attached EIR may include a request for waiver of rights to the inventor.
d. Coordination Among Parties

(1) For inventions made by inventors working at multiple components of the NIH and/or FDA, the ICs/FDA are responsible for notifying each other, for coordinating among themselves, and for determining which will be the “Lead” for general interactions with the NIH OTT. The Lead IC/FDA will send the EIR submission to NIH OTT, and will provide the CAN against which patenting costs will be charged if applicable.

(2) The NIH OTT is responsible for notifying potential co-owners who are external to the NIH and FDA. The NIH OTT should keep the (Lead) IC/FDA TDC informed of such notices and communications with the external entities.

(3) Once NIH OTT has made a determination that a reported invention is a CRADA subject invention, regardless of whether or not the CRADA Collaborator is a potential co-owner of the patent rights, the NIH OTT has the responsibility for notifying the CRADA Collaborator of the CRADA subject invention. The NIH OTT should keep the (Lead) IC/FDA TDC informed of such notices.

2. Sending EIRs to NIH OTT – All Cases

a. All EIRs must be submitted to NIH OTT to the attention of the Director, Division of Technology Development and Transfer (DTDT). DO NOT ADDRESS EIRs TO ANY NIH OTT PERSONNEL OTHER THAN THE DIRECTOR, DTDT.

b. Any EIR submitted by IC/FDA staff directly to NIH OTT without the TDC’s signature will be forwarded to the TDC. It will be the responsibility of the TDCs to inform IC/FDA staff that each EIR must be submitted through the TDC to NIH OTT before it will be processed.

c. EIRs may be sent by hand delivery, by interoffice courier, through the US Postal Service, or by a commercial overnight courier. When hand delivering EIRs, place them in the designated in-box at NIH OTT. All documents and outside envelopes should be clearly marked as “Confidential” and “EIRs.”

   (1) The NIH interoffice mailing address is:
       Office of Technology Transfer
       Box OTT MSC 7660
       ATTN: Director, DTDT, OTT

   (2) The street address for delivery via the U.S. Postal Service is:
       Office of Technology Transfer National Institutes of Health
       6011 Executive Boulevard, Suite 325
       Rockville, Maryland 20852-3804
       ATTN: Director, DTDT, OTT
(3) The address for commercial overnight couriers is:
Office of Technology Transfer
6011 Executive Boulevard, Suite 325
Rockville, MD 20852-3804
(301) 496-7057

DTDT will confirm, through facsimile or email, receipt of all EIRs to the appropriate
TDC(s) within three (3) work days. This confirmation will include the NIH OTT
receipt date and the assigned identification number.

Electronic EIR submissions (e.g., via facsimile or email) are encouraged, but must be
followed by the paper original; the submission will not be considered “received” if
the submission is incomplete or contains illegible documents. NIH OTT will
maintain a central email inbox for such electronic submissions and will inform the
TDCs accordingly.

3. Sending EIRs to NIH OTT – “Rush” and “Emergency” Cases

For optimal processing, EIRs should be submitted to NIH OTT at least 90 days prior to
any planned public disclosure of the invention. It is encouraged that EIR submissions be
made as soon as the invention is realized. Any EIR submitted to NIH OTT less than 90
days and more than 30 days prior to a planned public disclosure will be considered as a
“rush” case. Any EIR submitted to NIH OTT 30 days or less prior to a planned public
disclosure will be considered as an “emergency” case.

In the event of a “rush” or “emergency” case, the following additional procedures must
be used:

a. The (Lead) TDC must notify (by phone conversation or personal visit) the individual
designated by the Director, DTDT, as the “EIR Coordinator” that an EIR is being
submitted as a “rush” or “emergency” case. (The Director, DTDT, will inform the
(Lead) TDCs of the current direct-contact information for the EIR Coordinator.)

b. If the EIR Coordinator is not immediately available, the (Lead) TDC may instead
personally notify, in the order indicated below, one of the following NIH OTT staff
that a “rush” or “emergency” EIR is being submitted:
   (1) Director, DTDT, NIH OTT
   (2) Director, NIH OTT

c. With prior notice to, and with the specific acknowledgment of, the EIR Coordinator,
the (Lead) TDC must either email a PDF version of the EIR to the EIR Coordinator,
or send the EIR by facsimile addressed to the attention of the EIR Coordinator. The
EIR Coordinator will alert the (Lead) TDC whether the entire submission was
received in legible form; the submission will not be considered “received” if the
submission is incomplete or contains illegible documents.
d. Given the time and circumstances of the individual case, NIH OTT may determine to perform only a preliminary patentability and marketability analysis or no patentability and marketability analysis prior to filing with the U.S. Patent and Trademark Office. In such cases, the NIH OTT may defer its complete patentability and marketability analysis including a formal Art Search until after the initial filing. Should such post-filing analyses reveal factors indicating patent filing is not warranted, such will be communicated to the (Lead) TDC, along with a recommendation to discontinue patent prosecution.

E. EFFECTIVE DATE

The procedures set forth in this Manual Chapter are effective June 17, 2010, and supersede in their entirety the procedures in PHS Technology Transfer Manual Chapter 201, which was first approved on September 30, 1994.

F. ADDITIONAL INFORMATION

For additional information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 496-7057 or http://www.ott.nih.gov/contact-us.