PHS Employee Discovery or Invention Report
Instructions

The information provided on the attached sheets should be:

- as complete as possible;
- shown to the inventor's immediate supervisor; and
- given to the Agency's Technology Development Coordinator.

A report should be completed for each discovery or invention that has potential commercial value or represents a breakthrough in science.

Your Technology Development Coordinator will then forward this report to the Office of Technology Transfer's (OTT) Patent Branch for a patentability and licensing assessment. If your Agency, in consultation with the Office of Technology Transfer, decides not to file a patent application on your invention you will have an opportunity to request a waiver of rights to the invention. A waiver will allow your to file a patent application at your own expense.

The following form should take less than two hours to complete. Absent an emergency, the entire patent drafting process generally will take several months before a patent application can be filed. Questions regarding this Employee Invention Report should be referred to your Agency's Technology Development Coordinator, Beatrice A. Droke, on 301-443-6890.

The submission of this employee invention report is the first step in obtaining patent protection, but does not constitute the filing of a patent application. Additional information on patents and patent law is provided on Page 2 of these instructions. Whenever you think you have enough data to warrant public disclosure through a presentation, talk or publication, that is the time to fill out this form and send it along for consideration. At the very least, the submission of an employee invention report should coincide with the first submission of any manuscript or abstract to a journal or for public presentation (including posters). The simplest way to complete the descriptive portion of this report is to attach a draft copy of any manuscript you may be thinking of submitting to a journal. If the patenting process is begun in a timely manner, a patent application can always be filed on or before the date of a public disclosure.

Thank you for your cooperation.

Privacy Act Notice: The Public Health Service is collecting this information under authority of 45 CFR Parts 6, 7, and 8, E.O.9865, and E.O. 10096. The information will be maintained as a part of the System of Records: 09-25-0168, "Invention, Patent and Licensing Documents maintained by the National Institutes of Health HHS/NIH/OD," on behalf of the Food and Drug Administration. Provision of this information is mandatory; filing for patent protection is part of an employee's responsibility. Failure to provide complete information may adversely affect the Government's rights to future patent applications and licensing agreements. Provision of the Social Security Number is voluntary.

The OTT will use this employee invention report as the initial step toward pursuing patent protection of inventions submitted by PHS employees.

The information you provide on this form will not be disclosed outside the Department without your written consent, except as indicated below.

•Scientific personnel, both in this agency and other Government agencies, and in non-Governmental organizations such as universities, who possess the expertise to understand the invention and evaluate its importance as a scientific advance.

•Contract patent counsel and their employees and foreign contract personnel retained by the PHS for patent searching and prosecution in both the United States and foreign patent offices.

•Government agencies contacted by patent advisors regarding possible use, interest in, or ownership rights of the inventions.

•Prospective licensees or technology finders who may further make the invention available to the public through sale, use or publication.

•Parties, such as supervisors of inventors, whom the OTT contacts to determine ownership rights, and those parties contacting OTT to determine the Government's ownership.

•The United States and foreign patent offices for filing of patent applications.

•A congressional office in response to an inquiry from the congressional office made at the request of the record subject.

•The Department of Justice, if needed, to enable PHS to obtain advice on legal issues raised by the invention report and to present an effective defense in the event that the Department becomes involved in litigation.

NOTE: FDA reimburses NIH/OTT under an Interagency Agreement for patent prosecution and licensing services.

Background

The purpose of the referenced form is to provide a description of your invention so that its patentability and commercial potential can be evaluated. Your thoroughness in completing this form will help us to do the best possible (and most cost effective) job in transferring technology from your laboratory to the public.

What is a Patent?

A patent is a legal document, analogous to a deed to land, that memorializes the ownership of a property right described in words. In a deed, that property right might be defined as "the old Smith farm, bounded on the north by the Potomac River…" or "FDA Hills, plat 1, block 10, lot 100." In either case, the public (and potential trespassers) can identify the deed holder's property. The patent similarly defines a property right, such as "a method of treating AIDS by administering dideoxyinose" or "a transgenic cow that expresses the gene for human insulin in its milk."

Patent applications will be submitted for examination to the U.S. Patent and Trademark Office (PTO) on inventions that are deemed to be patentable and of reasonable commercial interest to companies. Patentability and the scope of the property right to which your invention may be entitled are judged in the context of related research findings and other information that were available in the public domain such as relevant journal articles.Your knowledge of the state of the art in your field will save much time and money if we can rely on your expertise and files.

The patent application itself consists of two components, the first, known as the "specification," is essentially the text of a journal article, and the second, known as the "claims," provides the legal description of the inventive property right sought to be patented. Although the claims have greater legal significance and must be carefully crafted by patent professionals, the specification is much longer in length and detail and can be adapted from your manuscripts. Thus, copies (on diskette, if available) of submitted and draft manuscripts that describe your invention are requested by this form.

In order to be patentable, a "claimed" invention must be novel, useful and nonobvious. In plain English: novelty means that the exact invention was not previously known to exist in the public domain; utility means that the claimed invention has a real world inventiveness, i.e.. function, such as treating disease; and nonobviousness means that the gap between what pre-existed in the public domain (known as the "prior art") and your claimed invention would not have been bridged by the average skilled worker in your technological field with a reasonable expectation of success employing existing technology. The journal articles that you attach to this form should reflect the closest prior art to your invention. Inventors and their patent agents must disclose to the PTO the most relevant prior art known to them during the examination process to avoid forfeiture of patent rights.

Critical Aspects of Patent Law

•Public disclosure includes talks, lectures, presentations, all publications, or any other unrestricted disclosure of the invention, such as unrestricted deposits in gene banks or the ATCC or sequences in GenBank.

•Public disclosure of the invention before a patent application has been filed creates an absolute bar to pursuing a patent in foreign countries.

•Public disclosure of the invention more than a year before the filing date of a U.S. patent application precludes the ability to seek patent protection.

•Please remember that additional research or related work regarding the invention is extremely important to the continued processing of your case. The data generated can be useful in proving that your invention works as claimed for filing additional related patent applications, or may necessitate the filing of an additional patent application, etc. It is important that subsequent public disclosures relating to your invention be discussed "prior to" with your Technology Development Coordinator and Patent Advisor.

•When an invention is made by two or more persons jointly, they should apply for a patent jointly. Inventors may apply for a patent jointly even though: (1) they did not physically work together or at the same time; (2) each did not make the same type or amount of contribution; or (3) each did not make a contribution to the subject matter of every claim of the patent.

•Not all inventions or discoveries are patentable, and not all patentable inventions have commercial potential!

A more detailed but readable overview of patent law as it applies to biomedical research can be found in Science 224:357 (April 27, 1984). Further information about patent law, the patenting process, and technology transfer are available from the OFACS Technology Development Coordinator at 301-443-6890.

PHS Employee Invention Report/FDA

Use plain paper if more space is needed.

For Patent Branch Use
E-Number
U.S.P.A.#
U.S. Filing (date)

Part I: To Be Completed by the Inventor

First Inventor's Name:
Phone No.

1. Give a short descriptive title of your discovery or invention.

2. Please provide (in non-scientific terms if possible) a one paragraph description of the essence of your discovery or invention and identify the public health need it fills.

3. Who contributed to the invention or discovery? Please identify all colleagues who could merit co-authorship credit for the associated publication, whether or not you believe them to be "co-inventors."

4. Is anyone outside of the Public Health Service aware of your invention or discovery? If so, please identify them and describe the dates and circumstances.

5. Are you aware of any PHS patent applications that are related to your invention or discovery?

6. Please list the most pertinent previous articles, presentations or other public disclosures, made by you or by other researchers, that are related to your invention or discovery. Also, attach copies, please!

7. Please indicate any future dates on which you will publish articles or make *any* presentations related to your invention or discovery.

8. In one paragraph, please speculate (and be creative!) about possible commercial uses of your invention or discovery.

9. a. Is the subject matter of your invention related to a PHS Cooperative Research and Development Agreement (CRADA) involving your laboratory or Center?
   - ☐ No
   - ☐ Yes. If yes, please identify the collaborator:

   b. Is the subject matter based on research materials that you obtained from some other laboratory?
   - ☐ No
   - ☐ Yes. If yes, please attach any Material Transfer Agreements (MTA) under which you received the material.

10. What companies or academic research groups are conducting similar research (if you know)? Can you identify any companies that may be good licensing prospects?

11. What further research would be necessary for commercialization of your invention? Generally, what are your future research plans for the invention and/or for research in areas related to the invention?

12. Human Subject Certification: Does this invention rely upon data involving human subjects as defined in and regulated under 45 CFR Part 46?
    ☐ No ☐ Yes → If "yes," please provide the Institutional Review Board (IRB) protocol approval number and date: or explain fully below:

13. First Inventor Information: (Provide this information for each inventor who contributed to the essence of the

invention. If more than one, use Page 4, "Information on Additional Inventors.")

Name		Degree	Social Security No. (optional)
Position Title		Office address	
Office Phone No.	FAX No.	Citizenship ☐ U.S. ☐ Other:	

Home address

Affiliation ☐FDA (specify Center and applicable box below)

☐ GS	☐ CO	☐ Visiting Scientist	☐ Special Volunteer
☐ GM	☐ Visiting Fellow	☐ Howard Hughes Fellow	☐ Other *(specify):*
☐ SES	☐ Visiting Associate	☐ Guest Researcher	

☐ Non-FDA Affiliation (specify):

If more than one inventor, what specific contribution did you make to this work?

14. Inventors' Signatures

This report is submitted pursuant to Executive Order 10096 and 10930 and/or Department Regulations. PHS employees have an obligation to report inventions they make while employed by PHS. Under E.O. 10096 and 367 CFR 501 the Government shall obtain the entire right, title, and interest in inventions: (i) made during working hours; or (ii) with Government facilities, equipment, materials, funds or information; or (iii) which bear a direct relationship or are made in consequence of the official duties of the inventor. If you are employed by PHS to conduct or perform research it is presumed that the invention was made under the foregoing circumstances. If this is not the case you must contact your Technology Development Coordinator (TDC) and provide the TDC with the details pertaining to this particular discovery or invention so that a determination of rights can be made.

Inventors' Signatures	Dates	Witnesses' Signatures	Dates

Part II: To be completed by the Technology Development Coordinator.

15. Center and Agency sponsoring this invention:

16. Patent prosecution fees are to be charged to:

CAN:			
CTR:			

Authorizing Official (Typed)	Signature	Date

If necessary, send 3 copies of the following form when completed to the Technology Development Coordinator, HFA-500, 301-443-6890.

Information on Additional Inventors (copy this page as needed)

Name:		Degree	Social Security No. (optional)
Position Title		Office address	
Office Phone No.	FAX No.	Citizenship ☐ U.S. ☐ Other:	

Home address

Affiliation ☐ FDA (specify Center and applicable box below)

☐ GS	☐ CO	☐ Visiting Scientist	☐ Special Volunteer
☐ GM	☐ Visiting Fellow	☐ Howard Hughes Fellow	☐ Other (specify):
☐ SES	☐ Visiting Associate	☐ Guest Researcher	

☐ Non-FDA Affiliation (specify):

What specific personal contribution did she/he make to this work?

Name		Degree	Social Security No. (optional)
Position Title		Office address	
Office Phone No.	FAX No.	Citizenship ☐ U.S. ☐ Other:	

Home address

Affiliation ☐ FDA (specify Center and applicable box below)

☐ GS	☐ CO	☐ Visiting Scientist	☐ Special Volunteer
☐ GM	☐ Visiting Fellow	☐ Howard Hughes Fellow	☐ Other (specify):
☐ SES	☐ Visiting Associate	☐ Guest Researcher	

☐ Non-FDA Affiliation (specify):

What specific personal contribution did she/he make to this work?

Name		Degree	Social Security No. (optional)
Position Title		Office address	
Office Phone No.	FAX No.	Citizenship ☐ U.S. ☐ Other:	

Home address

Affiliation ☐ FDA (specify Center and applicable box below)

☐ GS	☐ CO	☐ Visiting Scientist	☐ Special Volunteer
☐ GM	☐ Visiting Fellow	☐ Howard Hughes Fellow	☐ Other (specify):
☐ SES	☐ Visiting Associate	☐ Guest Researcher	

☐ Non-FDA Affiliation (specify):

What specific personal contribution did she/he make to this work?