NIH Intramural Research Program
Our Research Changes Lives

Information sheet for PROTECT question on Investigator inventions

OHSRP's study application asks investigators about intellectual property related to the research. This information sheet is intended to provide information on the purpose of this question and assist investigators in answering it.

Rationale:

Research conducted at the NIH sometimes leads to the development of intellectual property that is then commercially developed, which can make the technology available for continued research and ultimately to the entire community. Development of such products is an important goal of the NIH.

The process of commercial development is initiated when the inventor files an invention statement with the technology transfer office. The invention may then be patented and/or licensed to outside entities, which may then pay licensing fees or royalties to the NIH. The NIH is then obligated to share those monies with the inventors.

When inventors are conducting research on their own inventions, the outcome of that research may impact the value of the invention and alter the payments to the NIH and therefore to the investigator themselves. Although this is not legally considered a financial conflict of interest, it does create an apparent conflict of interest for the inventor/investigator.

The revised Policy 102-Investigator Conflict of Interest and Government Royalties addresses this apparent conflict of interest when the research involves human subjects. The policy states the following:

- Section C.4: The NIH requires that the potential for actual or apparent conflict of interest must be considered for all investigators and individuals engaged in activities described in B.1. above, in relation to a Covered Research Protocol. (Note: B1 refers to being engaged in human subjects research, or conducting the statistical analysis of primary endpoint data from human subjects research)
- Section E.4.g: If the NIH IRB is informed that an NIH investigator has or may receive royalty payments or licensing fees or has received a waiver from the NIH Director from the conflict of interest requirements related to the research under review, the NIH IRB will consider whether additional measures are required to protect human subjects.
    - Such measures may include, but are not limited to: 1) disclosure of government royalty rights related to this research in the informed consent document, or if other circumstances exist in which there may be a financial conflict of interest, a statement that an actual or apparent conflict of interest may exist without identifying any individual(s) or specifying the nature of that conflict, 2) restrictions on performing specific study activities such as obtaining informed consent from subjects, or 3)

establishment of an independent data monitoring committee, as appropriate, and consistent with applicable federal law, regulation and policy, including NIH policy.

The questions in the study application (and listed below) are intended to inform the IRB if there is an apparent conflict of interest, so that it may determine if additional management strategies are necessary to protect human subjects. The OHSRP Protocol Royalties Analysis Committee (PRAC) will review the invention disclosure and make recommendations to the NIH IRB and/or relevant study team after completing the steps below.

Questions in PROTECT

Question 10: Is any investigator engaged in this research listed as an inventor for any intellectual property (for example a drug, device, assay) that is the object of this investigation? Options: Yes/No

If Yes:

Question 11: Indicate the name of the person(s) identified above.

Question 12: Please identify the IP being studied.

Question 10 should be answered yes if any individual that is listed as an investigator or associate investigator is an inventor of intellectual property that is being studied in this research. Some examples are provided below

- The PI has invented a drug to treat lung cancer and filed an invention report with NIH Technology Transfer. The PI is conducting a clinical trial to test the safety and effectiveness of that drug. This question should be answered **YES** and the name of the drug being studied entered.
- An Investigator invented a novel assay to diagnose COVID 19 disease and filed an invention report with NIH Technology Transfer. The investigator is conducting a study directly comparing the sensitivity and specificity of this new assay compared to standard PCR testing. This question should be answered **YES** and the assay listed in the submission.
- An investigator has invented a widely used assay to measure blood glucose levels. The investigator is conducting a study on metabolic syndrome and the aim of the study is to characterize insulin resistance in obese type 2 diabetics. The subjects must undergo frequent blood glucose measurements during one part of the study. The study uses the investigator's assay to measure blood glucose. As the assay is not the object of the investigation, this question should be answered **NO**.

When an invention is the object of the study, and the inventor is an investigator engaged in the research, OHSRP will reach out to the inventor's Technology Transfer office to ascertain whether the protocol will utilize commercially licensed NIH-owned or co-owned intellectual property or materials of which the Investigator is an inventor.

When the answer to that question is yes, the PRAC Chair or designee, and PRAC support staff, will meet with Tech Transfer and/or the inventor and/or the PI of the study to further discuss the study and the invention. Questions to be explored at that time:

1. *Is the investigator receiving royalty payments or licensing fees from this intellectual property.*

We recognize that when NIH pays royalties or licensing fees to investigators, the source of the monies and the IP it is related to are not disclosed. Nonetheless, investigators may be aware of the source of the monies if, for instance, they are listed only on a single invention. If the investigator is aware that they are receiving royalties or licensing fees from the IP that was disclosed in the first question, this should be answered **YES**. If the investigator is confident they are not receiving monies related to this, answer No. If the investigator does not know, answer "**UNSURE**".

2. *Does the outcome of this research have the potential to influence the value of the royalty payment or licensing fee?*

This question is to determine if the results of the research could increase (or decrease) the potential monetary value of the IP being studied. Examples are provided below

The PI has invented a drug to treat lung cancer and is conducting a clinical trial to assess the safety and effectiveness of the drug. The trial is being supported by a CRADA with a pharmaceutical company, which will use the results of this trial to support a marketing application to the FDA for the drug. In this case, the results clearly could impact the value of the IP, therefore the investigator should answer **YES.**

What happens if I am an inventor and am receiving/will receive royalty payments or licensing fees?

OHSRP has instituted a process to determine whether the receipt of royalty payments or licensing fees constitute an apparent conflict of interest that requires management to protect human subjects. That process is as follows:

1. If an investigator is identified as an inventor and is receiving royalty payments or licensing fees, OHSRP will confidentially contact NIH Technology Transfer office to determine whether the IP is licensed and associated with payment of royalties to the inventor, such as via a CRADA.
2. If the value of the payments for the prior 12 months is less than $5000, then inclusion of the standard COI language in the consent may be sufficient, unless the study is assessed to be particularly high risk to subjects, or the research may have a large impact on the financial value of the IP.
3. If the value of the payments for the prior 12 months exceeds $5000 per annum, or in some cases if the study is deemed to be particularly high risk to subjects, the study may be referred to OHSRP's PRAC for evaluation. That committee will determine if any additional measures are necessary to protect human subjects. Possible measures could include, for example, disclosure in the consent, restricting the investigator that is receiving payments from independently obtaining the informed consent of subjects, requiring independent adjudication of AEs and SAEs,

or other measures as deemed appropriate and necessary to protect human subjects. When the research does not influence the royalty stream, disclosure in the informed consent document may be sufficient management.

4. The inventor, PI, and Tech Transfer will be informed of the outcome of the review, and the recommendation for additional measures will be provided to the IRB as well. In most cases, any recommended study changes can be added to the next planned protocol amendment or modification. PRAC support staff will monitor studies regularly to ensure recommendations that involve IRB submissions (e.g., an amendment to update consent language) are submitted to the IRB.
5. If the investigator disagrees with the measures, they may appeal to either the Director of OHSRP or the Deputy Director for Intramural Research and request reconsideration.

OHSRP PRAC staff will conduct an annual re-review of open studies with invention disclosures to ascertain whether changes have occurred that may warrant additional review by the PRAC.

Additional information on this process can be found in the OHSRP Management of Investigator Royalties document available on the OHSRP Policy page.