FAQ on the Conflict of Interest Policies of the NIH Intramural Research Program for SMART IRB

This document is provided to answer some of the frequent questions that have been raised by the SMART community on how the NIH Intramural Research Program addresses financial conflicts of interest. The COI revisions of the SMART IRB Master Reliance Agreement apply to all federal agencies who join the SMART platform, however the information provided in this document pertains only to the NIH Intramural Research Program. Other federal agencies apply the same COI rules but may follow different internal policies or procedures.

1. What information about conflicts of interest (COI) will the NIH Intramural Research Program provide to the reviewing IRB?

The NIH will provide the reviewing IRB a written assurance that it has completed the conflicts of interest analyses required under NIH procedures (based on federal law and policy) and that the participation of each NIH investigator in the research is permissible.

2. Will the NIH tell the reviewing IRB whether any NIH investigators have a financial conflict of interest related to the research under review, and whether there is a management plan in place for any identified conflicts?

The NIH will not identify or inform the reviewing IRB if any individual investigator has or does not have a financial conflict of interest. Nor will it disclose if there is a management plan. NIH has internal procedures that address all legal and NIH COI policy requirements. All NIH investigators will have gone through this process and it will have been determined that their participation in the research is permissible. As discussed above, the NIH will provide to the reviewing IRB a written assurance that all NIH COI requirements have been met.

3. Why won't the NIH disclose this information to us? Extramural institutions routinely disclose this information to a reviewing IRB.

As an agency of the US Government the NIH is subject to several laws that do not apply to non-federal institutions. These laws restrict the disclosure of this information.

4. If the reviewing IRB is not informed about any investigator COI, how can it be certain that appropriate human subjects protections are in place?

The laws and policies that govern financial COI for NIH investigators are very stringent and are designed to prevent or minimize any actual or apparent financial conflict of interest. Citations to applicable laws and regulations can be found in NIH policies (see below). Except in very rare cases, the investigator is required to eliminate the conflict or is not permitted to participate in the research. The assurance that is provided to the reviewing IRB certifies that these requirements are met.

5. What is the NIH financial COI policy?

The NIH policies are publicly available and can be reviewed *here*. A summary of the process and policies that NIH investigators follow is outlined below.

NIH Principal Investigators must provide a detailed disclosure of their financial holdings to the Ethics Office of their Institute or Center within the NIH. The Ethics Office will review the financial interests and determine whether there is any conflict of interest related to the research under review. This analysis

includes all entities that might directly or indirectly be affected by the research. If a disqualifying financial interest is identified, the investigator must either recuse themselves from any participation in the research, or divest below the de minimis thresholds, thus eliminating the conflict of interest.

On rare occasion, if the conflict cannot be eliminated by recusal or divestiture, the NIH Director may grant a waiver to the COI policy requirements. This is an extremely rare situation and is typically a temporary measure in place while steps are taken to eliminate the conflict of interest.

6. What is a disqualifying financial interest and what are the de minimis thresholds according to NIH policy?

NIH employees cannot participate in research if they have a disqualifying financial interest, as defined in federal law. By way of relevant example, these include:

1. Ownership and other financial interests in publicly-traded Substantially Affected Organizations (SAO) involved in or that will be affected by the research unless the values are within regulatory de minimis levels (see 5 CFR Part 2640). At present, the de minimis exemptions provide there is no conflict where:
    a. The aggregate value of the interest of an investigator and his/her spouse and minor child(ren) in the SAO(s) whose products are being/may be evaluated in the research does not exceed $15,000;
    b. The aggregate value of the interests of an investigator and his/her spouse and minor child(ren) in all SAOs that may be directly or indirectly affected by the research (including those whose products are being/may be evaluated) does not exceed $25,000;
    c. The aggregate value of the interest of an investigator and his/her spouse and minor child(ren) in health-related sector funds does not exceed $50,000; and/or
    d. The otherwise disqualifying financial interest arises from ownership of shares in a widely-diversified mutual fund.
2. Ownership and other financial interests, regardless of value, in privately-held companies whose products are/may be evaluated by the research and/or that might be indirectly affected by the research.
3. Proprietary interests and royalty sharing rights derived from work done outside NIH that are related to or may be affected by research performed at the NIH including, but not limited to, a patent, trademark, copyright or licensing agreement. (Note: under federal law, neither royalty payments received nor the right to receive such payments from the Federal Government based on work done as a federal employee constitutes a disqualifying financial interest.)
4. A Board or other fiduciary relationship to a commercial sponsor of the research, regardless of compensation. (Note: NIH employees are subject to legal and policy limitations on such activities and need prior approval consistent with NIH and IC procedure(s); such activities with commercial entities are prohibited.) NOTE: Compensation for performance of clinical research is prohibited by Federal law, e.g. pharmaceutical sponsors cannot compensate the NIH or NIH researchers for enrolling subjects in research, as occurs in the private sector. Federal law prohibits NIH employees from receiving payments or other things of value from any payer other than the US Government for work done as part of official duties.

7. What is a Substantially Affected Organization (SAO)?

A Substantially Affected Organization (SAO) is defined as follows: A biotechnology or pharmaceutical company, a medical device manufacturer; or a corporation, partnership, or other enterprise or entity significantly involved, directly or through subsidiaries, in the research, development, or manufacture of biotechnological, biostatistical, pharmaceutical, or medical devices, equipment, preparations, treatments, or products (5 CFR § 5501.109(b)(10)).

8. The disqualifying financial interests does not mention honoraria or speakers' fees. Do NIH investigators receive these?

No. NIH investigators, as employees of the Federal Government, are not permitted to receive honoraria or speakers' fees from any third-party for work or activities undertaken as part of their government job.

9. Will the NIH inform the reviewing IRB if the NIH Director grants a waiver from the COI requirements?

The reviewing IRB may request this information of the NIH if it wishes to know if a waiver has been granted.

10. Do all investigators at the NIH provide a financial disclosure to the Ethics Office?

NIH staff who are federal employees that are engaged in human subjects research, or involved in the statistical analysis of primary endpoint data and whose role has the potential to bias the research results even if they are not otherwise engaged in human subjects research, file a financial disclosure to the Ethics Office. These individuals are personnel who have independent, decisional roles in conducting a specific covered research protocol and are influential in the design, direction, or conduct of a covered research protocol, or are engaged in the analysis or interpretation of data. This includes the Principal Investigator, personnel whose resume or CV is provided to a sponsor, personnel listed on a FDA 1572 Form, and personnel engaged in human subjects research, including but not limited to individuals who obtain informed consent or who make decisions about research eligibility. Others who have decisional responsibilities that meet the policy requirements, e.g. as coinvestigator, research nurse, associate investigators, or an individual who interprets or analyzes research data, are also required to disclose. Individuals who participate only through isolated tasks that are incidental to the research (for example, scheduling patient tests), and those individuals who support research in many protocols through the performance of routine patient care tasks are not required to file a disclosure.

11. Do individuals who are not federal employees provide a financial disclosure to the Ethics Office?

Individuals who are not federal employees (for example, contractors) are not subject to federal COI or other federal ethics laws and regulations. Therefore, these individuals do not provide a financial disclosure to NIH, and NIH does not review information regarding their financial interests. These individuals are required to provide to NIH a Conflict of Interest Certification for Non-Federal Employees, in which they certify that they will abide by NIH guidelines for avoiding a COI or perceived COI in clinical research at NIH. The Ethics Office will not provide clearance for the research protocol until all required Certifications are submitted.

12. Can NIH investigators receive royalty payments for inventions based upon work performed at NIH?

Intellectual property that is created by NIH investigators becomes the property of the Federal

Government. Under Federal Law, royalty payments or licensing fees generated must be shared with the investigator. Currently, the maximum amount per year that any NIH investigator can receive is $150,000. This cap applies regardless of the number of inventions, meaning that if an investigator is entitled to payments from several inventions, the total amount received in a year cannot exceed $150,000.

13. Are NIH investigators permitted to work on research protocols using the intellectual property for which they are receiving federal royalty payments?

Yes, NIH investigators may work on research protocols that study their federal intellectual property. In this case, the reviewing IRB is informed that an investigator is receiving payments, and this fact is required that this be disclosed in the informed consent document.

14. Will the NIH tell the reviewing IRB if the involved NIH investigator is receiving royalty payments?

Yes, the NIH is permitted to disclose to the reviewing IRB that an NIH investigator is receiving royalty payments.