



Date: October 21, 2014

To: Scientific Directors  
Clinical Directors  
IRB Chairs  
All NIH Intramural Clinical Investigators

CC: AAHRPP Contacts  
IRB Professional Administrators Committee (IPAC)

From: Deputy Director for Intramural Research, NIH  
Principal Deputy Director, NIH

Re: NIH HRPP SOP 21, Revisions to NIH Intramural Requirements for Managing Conflict of Interest Issues

We are happy to announce and distribute a new streamlined Intramural Conflict of Interest Policy that will be effective on October 27, 2014. The policy is delineated in the attached documents: "A Guide to Avoiding Financial and Non-financial Conflicts or Perceived Conflicts of Interest in Clinical Research at NIH" (The Guide) and "SOP 21: Conflict of Interest Requirements for Researchers and Research Staff." Both documents are available on the NIH Ethics Office website (<http://ethics.od.nih.gov/procedures.htm#protocol>) and the NIH Human Research Protection Program website (<https://federation.nih.gov/oHSR/nih/formtmp.php>). You will get another email from The Office of Human Subjects Research Protections (OHSRP) explaining how to submit forms so that the NIH can review possible conflicts of interest in the performance of research. The changes are as follows:

1. We will no longer require Deputy Ethics Counselor (DEC) clearance for every research protocol. Instead, assessment of financial conflict of interest is required ONLY for "covered" protocols – those that may lead to the financial benefit or loss of any individual or entity. This includes studies of investigational drugs and devices, studies whose research question involves a commercially available drug or device, studies involving a CRADA or Clinical Trials Agreement, studies involving collaboration with a substantially affected organization<sup>1</sup>, or studies involving intellectual property. NIH research protocols

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<sup>1</sup> **Substantially Affected Organization (SAO):** 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)).

2. that are categorized as Teaching and Training, or Natural History studies are not covered research protocols, unless they meet the criteria listed above. Most interventional protocols will be covered protocols unless the intervention does not involve the criteria listed above (e.g. a behavioral intervention might not meet the criteria for a covered research protocol).
  
3. We have clearly defined which researchers are covered by NIH conflict of interest requirements. Covered Individuals are personnel who have independent decisional roles in conducting a specific covered research protocol. These individuals are influential in the design, direction, or conduct of a covered research protocol, or engaged in the analysis or interpretation of data. Individuals who participate only through isolated tasks that are incidental to the research (for example, scheduling patient tests), and those individuals who support research of many protocols through the performance of routine patient care tasks are not covered individuals. Covered Individuals include the principal investigator, personnel whose resume or CV is provided to a sponsor, personnel listed on a FDA 1572 Form, and personnel who obtain informed consent or who make decisions about research eligibility. Others who have decisional responsibilities that meet the definition of a covered individual, e.g. as co-investigator, research nurse, associate investigators, or an individual who interprets or analyzes research data, are also covered individuals.
  
4. The DEC clearance process for managing possible conflicts of interest is similar to the current process, but the PFH form will have different fields and we will now require certification forms from two groups of "covered individuals" as explained below:
  - a. If a "covered individual," is an NIH employee who does not file either a form 717-1, form 450 or form 278, that individual must complete a form in which he/she certifies that he/she has read the Guide, that the individual has no conflict of interest (as defined in the Guide) with the protocol and that he/she will contact his/her ethics office if he/she becomes aware of a conflict in the future.
  
  - b. If a "covered individual" is not an NIH employee, the individual must complete a form in which he/she will certify that he/she has read the Guide and will comply with it. The individual must also certify that if his/her home institution has a conflict of interest policy that he/she is in compliance with it. Such an individual will attest only to compliance with the home institution policy if the NIH policy would cause a

violation of the home institution policy. The individual will also agree to inform the NIH PI if circumstances change and he/she is no longer compliant with his/her institution's conflict of interest policy.



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