



INTELLECTUAL PROPERTY

ALERT

NEW REGULATIONS FOR CONFLICT OF INTEREST POLICIES: ARE YOU COMPLIANT?

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On August 24, 2011, the Department of Health and Human Services (HHS) issued new regulations governing Conflict of Interest Policies for institutions that seek Public Health Service (PHS) funding for research. The purpose of these regulations was to promote objectivity in the research design and protocol. It was also to maintain public trust that the results of publically funded medical studies were properly performed and accurately reported. The new regulations became effective on September 26, 2011. **All applicable institutions must be compliant with them by August 24, 2012.**

Below, we explain some of the major changes in the new regulations and provide a general roadmap of steps that should be taken to ensure compliance. We urge institutions to review the regulations carefully and/or consult with an attorney or official familiar with the regulations to ensure that each of the specific requirements are met prior to the August 24 deadline.

Among its changes, the new regulations (1) expanded the definition of what is considered a significant financial interest, and (2) expanded reporting and public disclosure requirements for institutions. Turning to the former, under the new regulations the *de minimis* threshold for when remuneration from an entity to an investigator qualifies as a significant financial interest has been reduced from \$10,000 to \$5,000. That is, if an investigator receives a sum from a third-party entity that is in excess of this amount, then it qualifies as a significant financial interest and must be evaluated as a potential Financial Conflict of Interest (FCOI).

Remuneration is not limited to salary received, but also includes payment for other services, equity or ownership that is received by the Investigator, the Investigator's spouse or dependents.

Under the new regulations, the reporting and public disclosure requirements of an institution have also changed. Institutions must still determine if a FCOI exists for each investigator before PHS-funding is received, as well as on an on-going basis. Under the new regulations, it must also report to the PHS Awarding Component the value of the FCOI, the reason the FCOI presents a conflict and the institution's plan for managing the conflict. To improve transparency in the process, each institution must make its Conflict of Interest Policy publically available (such as through its website). Institutions are also required to make publically available certain conflicts, such as any FCOI of senior or key personnel.

To ensure compliance by the August 24 deadline, institutions should begin (or should have already begun) performing at least the following steps:

1. Each institution should prepare a new Conflict of Interest Policy reflecting the changes to the new regulations. This policy must be finalized and posted to the institution's publically accessible website (if available) before the August 24 deadline.
2. Each institution should train all investigators on its new Conflict of Interest Policy. (We recommend that the training include an overview of the changes, the relevant

definitions of the new regulations and the duty of each investigator to disclose a significant financial interest both prior to applying for any PHS funding and on a regular basis).

3. Each institution should establish an enforcement mechanism for investigator non-compliance with the Conflict of Interest Policy. (We recommend that Investigators be informed of such mechanisms during the training).
4. Each institution should develop a program for continuing or refresher FCOI training over at least a four year cycle. (We recommend that the initial training and all subsequent trainings for each investigator be documented with proof of investigator attendance).
5. Each institution should establish a system for

evaluating potential conflicts of interest and for reporting those FCOIs to the PHS Awarding Component in accordance with the regulations. Along these lines, an institution official and/or committee should be appointed to oversee this system.

We caution that these steps are provided merely as an overview. Again, we urge careful consideration of the regulations (link provided below) and that each institution verify that all requirements are met prior to the August 24 deadline. To read the new regulations in their entirety, [please click here](#).

If you have questions about this Alert, please contact J. Eric Sumner at 610.458.6712 or esummer@foxrothschild.com or any member of Fox Rothschild's [Intellectual Property Department](#).



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