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NIH announces final rules on ethics

On 25 August 2005, the National Institutes of Health (NIH) announced final rules on mandatory reporting by NIH employees of certain financial interests, stock divestiture, outside activities, and awards[1]. These regulations were developed by the Department of Health and Human Services and NIH in an attempt to minimize conflicts of interest related to research decisions without placing undue limitations on the interactions of NIH employees with the greater scientific community.

The final conflict-of-interest rules include the following elements:

• "The basic prohibition on outside consulting by NIH staff with substantially affected organizations, such as pharmaceutical, biotechnology or medical device manufacturing companies, health care providers or insurers, and supported research institutions remains unchanged.

• "Divestiture of all holdings in substantially affected organizations in excess of $15,000 per company will be required for all senior NIH employees and their spouses and minor children. As defined by the final regulations, these senior employees include the NIH Director and Deputy Director; all direct reports to the NIH Director; all Institute/Center (IC) Directors, Deputy Directors, Scientific Directors, and Clinical Directors in each IC; extramural program officials who report directly to an IC Director; and other employees designated as such because they possess equivalent levels of decision-making responsibility. All other employees may be required to divest if, after review, a potential conflict resulting from their holdings or those of their spouses and minor children would impede their ability to do their government job.

• "The receipt of monetary awards from outside sources will continue to be contingent upon prior approval and be limited to awards that have been determined through a pre-screening process to be bona fide. The final regulations will bar senior employees from receiving the cash component of pre-screened awards offered by donors who have matters pending under their official responsibility.

• "Employees who file either a public (SF 278) or a confidential (OGE 450) financial disclosure report, and those non-filers who serve as clinical investigators identified on an NIH clinical study, are required to report their interests in substantially affected organizations, as well as those of their spouse and minor children, and to indicate the amount held in such investments.

• "To facilitate academic and scientific interactions, the final regulations will allow, subject to prior approval and review by ethics officials, outside activities with professional or scientific organizations, service on data and safety monitoring boards, Grand Rounds lectures, and scientific grant review.

• "The regulations maintain current provisions that permit NIH scientists, to the extent allowed under existing government-wide rules and with prior approval, to engage in compensated academic outside activities such as teaching courses at universities, writing general textbooks, performing scientific journal reviews or editing, and providing general lectures to physicians and scientists as part of a continuing professional education program. NIH scientists can also engage in the practice of medicine and other health professions with prior approval and in accordance with existing rules. Outside activities that involve hobbies, sports, civic organizations or interests unrelated to the NIH mission are permissible, generally without prior approval."

1. NIH. NIH announces final ethics rules: ban on outside consulting with industry remains in force. NIH News. (25 August 2005). http://www.nih.gov/news/pr/aug2005/od-25.htm.

APHIS requests extension on information collection related to handling, care, treatment, and transportation of certain animals

On 18 August 2005, the US Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS) announced its "intention to request an extension of approval [for a period of three years from the Office of Management and Budget] of an information collection in support of regulations issued under the Animal Welfare Act for the humane handling, care, treatment, and transportation of certain animals by dealers, research institutions, exhibitors, carriers, and intermediate handlers[1]."

The Animal Welfare Regulations in 9 CFR Part 2 require facilities that use animals for regulated purposes (dealers, research institutions, exhibitors, carriers, and intermediate handlers) to obtain a license or register with the USDA, and document specific information, which APHIS uses to ensure compliance with the Animal Welfare Regulations.

Regulated facilities must keep records that include official identification for all dogs and cats and certification of those animals received from pounds, shelters, and private individuals (to ensure that