

**NATIONAL INSTITUTES OF HEALTH
NIH Ethics Office**

**Minutes – DEC/EC Meeting – March 9, 2004
1:30 pm, 31/Conference Room 6**

1. Discussion of Blue Ribbon Panel on Conflict of Interest Policies Holli Beckerman Jaffe

Ms. Jaffe gave her portion of the presentation that she and Dr. Raynard Kington, NIH Deputy Director and DEC, gave to the NIH Blue Ribbon Panel on Conflict of Interest Policies on March 1, 2004. The Blue Ribbon Panel is a working group to the Advisory Committee to the Director, NIH, and will report its findings to the ACD and Dr. Zerhouni on May 6, 2004. Copies of the slides were distributed at the meeting and can be obtained by contacting the NIH Ethics Office.

She discussed the **history of the changes in NIH policies from 1985 to 1995**, including a review of the changes in the NIH manual chapter 2300-735-4 during that time. The goals of the analysis were:

- Review NIH policies related to management of conflict of interest through the last major change in 1995
- Review definitions of activities and differences in policies across different categories of employees.

Currently, NIH is abiding by the Standards of Ethical Conduct, but now the NIH Ethics Advisory Committee is reviewing more employee requests to enhance consistency cross NIH. As more requests are reviewed, NEAC will be able to more clearly define issues. At this point, it is better to send more background information so that NEAC members will not have to defer a decision pending receipt of additional data.

ACTION: As NEAC clarifies issues, Ms. Jaffe will forward those to the ethics community.

Stock option vs. income: Exercising or holding stock options causes a different kind of relationship with the outside organization than does receiving direct payment. Owning stock or options is a relationship under 18 UCS 208, the conflict of financial interest law. Stock or options add to one's financial interests for as long as that stock is owned, or those options remain available for exercising. Under 208, you cannot participate in an official particular matter which affects this specific financial holding, nor can you work on a particular matter which affects a competitor. Receiving payment is a single event, causes an appearance of conflict under 5 CFR 2635.502, and your recusal ends at the end of the cooling off period.

2. Use of Review Sheet to Monitor 520 Corrections Steve Hausman

To enhance his review of the HHS 520, Request for Approval of Outside Activity, Dr. Hausman developed a review sheet to track questions and responses.

ACTION: Dr Hausman will distribute his review sheet electronically.

3. Employee Participation in External Advisory Committees Elaine Ayres

The question arose whether an intramural employee may serve on an external advisory committee for a grant or Data and Safety Monitoring Board (DSMB) funded by NIH funds. The NIH Scientific Directors meeting of January 15, 2004, indicates that NIH intramural employees may not participate in this manner (minutes not available electronically). In addition, the HHS Supplemental Standards of

Ethical Conduct prohibit compensated consultative services for HHS funded grants, and applications intended for submission to an HHS agency. Therefore, NCI does not permit their employees engage in an outside activity to participate in an external advisory committee or DSMB if it is funded by NIH.

4. **EMIS Hand-On Training: April 19-23, 2004, EPS 100, Room 6**

The NIH Ethics Management Information System (EMIS) is ready for the ICs to start using it. Data on their employees have been loaded into the system. Ms. Fran Plyler will provide hands on training during the week of April 19-23 at the training center at Executive Plaza South. Two 3-hour classes will be held each day: 9am to noon and 1pm to 4 pm each day. **Register by contacting Ms. Plyler at her personal email: feplyler@juno.com.**

You will need to bring some employee information to enter, preferably an employee with several types of activities. No one else will see your information. In addition, the EMIS manual is being corrected and will be available for printing prior to the class. Students need to print the manual and bring it with them. For questions or to obtain a login and password, contact Ms. Plyler, via email or phone (623-907-5978).

5. **New Confidential Financial Disclosure Forms**

OGE has revised the OGE 450A, Statement of No New Interests. The old form is obsolete and should not be used. The new form is available on the NIH Ethics Program forms page:
<http://ethics.od.nih.gov/Forms/forms450.htm>

OGE is also in the process of revising the full OGE 450, Confidential Financial Disclosure Report. It was discussed and copies distributed at the recent OGE conference. The new form will be added to the web site as soon as it is finalized and distributed by OGE.

6. **OGE Annual Conference:** The recent OGE conference was held in New York City. All handouts will be on the OGE website within 4 to 6 weeks.

7. **Ethics Questions Raised:**

a. An intramural employee asked to be a visiting professor at a university. Would this be done as an official duty activity or outside activity?

Analysis:

- Review employee's job description or requirements, does it include teaching?
- Is the university domestic or foreign? If foreign, determine if the Emoluments Clause applies.
- Is the topic close to current official duties? If so, does the exception for teaching related to official duties apply? (5 CFR 2635.807(a)(3)).

b. An employee wants to serve on an editorial board; is it official or outside activity?

Analysis:

- Is the employee extramural or intramural? Normally done as official duty by intramural scientists because they routinely publish and its part of the professional activities to review manuscripts for journals. Extramural and administrative employees could do so as an outside activity.
- What is the level of involvement – scientific review / editor / editor-in-chief? Intramural scientists may participate officially to review manuscripts, and in some instances serve as a section editor, as long as the workload associated with the section editor does not preclude the scientist from accomplishing his/her regular official duties. Editor-in-chief positions, which carry decision-making and sometimes business decision authority, should normally be done as an

outside activity. During an outside activity, the employee is recused from reviewing manuscripts from IC colleagues, or NIH colleagues, depending on the level of recusal required by the DEC.

- c. Can peer review of grant applications be done as official duty or outside activity? Analysis:
- Is the application going to be submitted to HHS? If yes, employee cannot receive compensation for consultative services to help prepare or review the application.
 - Is it relevant to the employee's official duties? That is, does it benefit the NIH to have the employee serve as a reviewer on behalf of the NIH? If not, consider it an outside activity.
 - Is the employee assisting with funding decisions or just offering advice on the scientific aspects of the application? If assisting w/ decisions, must be done as outside activity.

Keep in mind there must be a real benefit to the NIH for an employee to participate in peer review of grant applications for other organizations as an official duty activity. Absent such a clear benefit, employees should submit an outside activity request, and decline compensation if the application will be submitted to an HHS agency.

- d. As part of the dissemination of information about NEAC and the requirement to resubmit outside activity requests, some employees have informed their EC that they have some ongoing outside activity for which they never received approval. What should the EC do?
- Request the HHS 520 package. Employee should use the original start date in block 8 and attach a cover memo explaining why he/she did not obtain advance approval. Provide information on 5 years worth of income in the block on the back for explanations for Item 17. This is especially important if the activity must be revised by NEAC.
 - In the review, indicate whether the employee was a filer, If yes, was the activity listed on the 278 or 450? If yes, the EC should have checked for approved 520s for any activities listed on the financial disclosure report. If no, there is no way the EC or DEC would have known about the activity.
 - If someone identifies a personal outside activity that they performed without permission, the EC needs to determine whether that employee engaged in an official activity from which the employee should have been recused because of the outside activity.
 - Determine whether any punitive actions are necessary, e.g., was the employee told in the past to submit 520 packages for all activities so this is another infraction?
 - Document your review, analysis, decision, and actions.

8. NIH Management Steering Committee apparently discussed limiting all lectureships as official duty. It is unclear who is on this committee or what the responsibility of the committee covers. Since such activities are covered by ethics rules and regulations, the NIH Ethics Officer, in consultation with the NIH DEC and ethics community, would be the appropriate to disseminate policies regarding ethics activities.

9. NEAC Processes: The NIH Ethics Office staff are setting up a tracking system for NEAC submissions. If an activity is fast approaching and you have not heard the decision, call Ms. Jaffe. Employees engaged in clinical practice may continue to do even though the new request may not be approved.

Next Meeting: Tuesday, April 13, 2004
1:30 pm, Bldg 31, Conference Room 6 (C wing, 6th floor)

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