NIH ETHICS OFFICE
PROGRAM REVIEW GUIDELINES

July 31, 2007

PURPOSE OF A REVIEW

The purpose of an ethics program review is to measure compliance with the ethics requirements found in the various statutes, regulations, and policies. A review also measures the efficiency and effectiveness of the program in terms of the systems, processes, and procedures that an institute has established to prevent ethics violations from occurring. The review is meant to discover deficiencies and provide solutions to correct them.

The review is also an opportunity for the institute deputy ethics counselor (DEC) to identify issues he or she has with the program and discuss them with the program review team. You will have many discussions with the DEC about various aspects of the program. Use the documents in the program to verify what the DEC or other ethics specialists or coordinators are telling you actually occurred, and to spot issues that he may not have related to you.

Members of the review team, at all times, shall have the professional demeanor of a consultant, objectively analyzing the ethics program, and always acting in a positive manner with the deputy ethics officials and all other institute officials. Your job is not to assess blame, but to find problems and solve them. Give an institute credit in the report for those things they have done well. You may want to make suggestions which, while not technically required by law or regulation, would greatly improve the ethics program in a given area (best practices).

Each review will be different, as each DEC has different procedures, and each institute may have different type filing systems. For example, one institute may have all of an employee's ethics forms in the file with the financial disclosure form, while another institute may have a separate filing system for awards, outside activities, etc. This will require decisions by the team leader as to the best way to collect and record the information.

These guidelines are intended to serve as a basic road map for conducting a program review from start to finish. **These guidelines should change over time as reviewers become more attuned to issues that occur in NIH ethics programs, as regulations change, or as you want to focus on other elements of the program.** In certain years, or certain institutes, you may want to spend more time on one element of the program that has been a problem.

STAFFING

The head of the program review section and the staff must be dedicated solely to performing program reviews, drafting and referencing reports, and scheduling and conducting pre-review work for future reviews. They cannot be pulled on and off as office crises occur, or be assigned other work, especially work with tight deadlines. Sometimes, other work can be done if there is a scheduling problem between program

reviews, after the report is developed, or while waiting to get into the next institute. But once the program review function is operational, there will be little time to do other work. As staff experience grows, so will the quality and depth of their analysis. But they must have the time to do it, the time to be inquisitive and look into various issues.

A review team usually consists of two staff members, the more experienced of which should be the team leader. One review team of two experienced staff members should be able to perform 4 or 5 reviews a year, with a mixture of small and large institutes. Determine how frequently you want each institute reviewed and set your staffing accordingly. One team performing 5 reviews a year would mean each institute would be reviewed approximately every six years. Four staff members split into two teams would result in each institute being reviewed at least once every three years, which is probably optimal.

These guidelines assume that staff members assigned to conduct program reviews are experienced, with knowledge of the laws, regulations, policies, and procedures affecting NIH's ethics program. No guidelines such as these can list every nuance of what you should be looking for when you review financial disclosure reports, advice and counseling, or NIH approval forms. Team members should be able to discern problem areas from their knowledge and past ethics experience.

Each team should have an experienced team leader who is responsible for the review, from the pre-review to the issuance of the report. The team leader supervises other staff assigned to the review. The team leader is responsible for ensuring the accuracy and completeness of the review and the report. If both team members are equally experienced, they should take turns as the team leader.

Follow-up reviews at an institute can be performed by the same team who did the review, or by another team or even one person. If the review and recommendations were extremely complicated, send the same team to conduct the follow-up. The person or team conducting the follow-up should consult with the team that performed the review, if necessary.

SCHEDULING OF REVIEWS

Once the program review team is staffed and functioning, a schedule of institutes to be reviewed in the next 6 months or year should be assembled and made available to the deputy ethics officials. This will force those institutes which are on the list to focus on their program and correct deficiencies, which is the goal of program review.

The schedule of institutes to be reviewed should be coordinated with the NIH Ethics Office Financial Disclosure Team. Ideally, after the first few reviews, the Program Review Team should follow 6 months to one year after the Financial Disclosure Team has visited an institute. This will allow the Program Review Team to determine whether the institute has implemented the advice of the Financial Disclosure Team and should make the review easier to conduct.

REVIEW AUTHORITY

Under 5 C.F.R. § 2638.202(b) (6) one of the responsibilities of the agency head is to select a Designated Agency Ethics Official who has the ability to administer a system for periodic evaluation of the ethics program. Under 5 C.F.R. 2638.203 (b)(10), the Designated Agency Ethics Official shall ensure that the agency's standards of conduct regulations, financial disclosure systems, and post-employment enforcement systems are evaluated periodically to determine their adequacy and effectiveness in relation to current agency responsibilities.

TIME PERIOD COVERED BY THE REVIEW

Generally, a review will cover the most recent filing cycles for public and confidential financial disclosure reports. Make sure the reports have been certified. We do not want to review reports that have not yet been certified, as we want to get a good read of the adequacy of the ethics official's review. Most reports should have been certified 60 days after the filing date, save for those who were granted extensions, or for reports where the DEC is trying to obtain more data.

ELEMENTS OF PROGRAM REVIEW

1. Thirty-day notice memo to the institute
2. Pre-review work by NEO staff
3. Entrance conference with the institute
4 The actual review of:
    - -Ethics program administration
    - -Public financial disclosure system
    - -Confidential financial disclosure system
    - -Substantially affected organizations (HHS Form 717-1)
    - -NIH approvals of outside activities, awards, WAGs, etc
    - -Enforcement of ethics laws and regulations
    - -Advice and counseling system
    - -Education and training program
    - -Travel reimbursements (Form 348 Travel)
    - -Special government employees
    - -Staffing and structure of the ethics program
5. Exit conference conveying results to the institute
6. Drafting the report, including conclusions and recommendations
7. Referencing the report
8. Internal review and approval of the report
9. Thirty-day letter back from institute
10. Three month follow-up report
11. Maintaining master report files
12. Best practices

THIRTY DAY NOTICE MEMO TO THE INSTITUTE (See attached memo)

Thirty days prior to the initiation of a review, send a memo to the DEC of the institute to be reviewed informing him of the date the review will commence. Notify the ethics official that you will have an entrance conference with him at his office the first morning to discuss the details of the review and the overall ethics program. In the memo set forth the ethics systems and records that you will need to examine so he will have them available. You may want to notify him that you will need working space for your team. Inform the ethics official of the name of the team leader performing the review and his or her telephone number.

PRE-REVIEW BY AUDIT STAFF

The basic purpose of the pre-review is to learn as much as possible about the institute's ethics program to prepare for the review. This will involve a review of all available information currently available about the institute's ethics program. Download any available data from the EMIS/NEES system. Personnel throughout NEO should be informed of the review by email so that any relevant information or concern they have about the program can be given to the review team. The staff member in NEO responsible for the institute should be consulted for relevant information

During the pre-review the team will:

1. From the EMIS/NEES system, download a listing of all public and confidential disclosure report filers and pertinent information about their reports, **for the most recent SF 278 and OGE 450 filing cycle.** If it is too soon for the reports to have been certified by the institute, go back to the prior filing period. Make sure all equal classification positions have been included in the system. From the system, determine the following statistics for inclusion in the final report:

    - how many filers still have not filed their reports as yet;
    - how many were filed more than 30 days late;
    - how many reports are not yet certified;
    - how many reports were not initially reviewed within 60 days; and
    - how many employees did not receive initial or annual training..

2. From the EMIS/NEES system, determine your sample size, usually all public filers and a sampling of confidential filers. In most institutes, unless very large, limit the total number of public and confidential reports we review no more than 150 reports. Sampling will be based on selecting those in the most critical positions that are vulnerable to ethics issues. Always review the reports of those filers who are most at risk for ethics issues, such as top institute officials, procurement officials, and others from your experience with the institute. **We will only look at outside activities, awards, and WAGs, etc. for the filers whose**

financial disclosure reports we pick for our review sample, unless there are good reasons to look at others.

3. For those in our sample, note all actions and approvals they may have, such as outside activities, WAG approvals, awards, waivers, ethics agreements, contained in EMIS/NEES, so we can review the actual documents during the course of the review.

4. Review the institute's mission and organizational structure.

5. Review the institute's portion of the most recent annual agency questionnaire completed by the NIH Ethics Office for the annual questionnaire to be sent to OGE by HHS. Examine their numbers for the prior year, of:

    -disciplinary actions;
    -18 U.S.C. § 208(b) (1) and (b) (3) waivers;
    -amount of written advice/counseling available for review;
    -public and confidential financial disclosure reports required to be filed;
    -covered employees who received annual ethics training;
    -special government employees employed by the institute; and
    -outside employment approval requests submitted.

    Do the numbers in the questionnaire match the numbers currently in EMIS? This should make you more aware of the type of activity in the institute and help focus your review.

6. Perform an internet search of past news stories about the institute to refresh your memory on ethics issues that may have occurred in the institute over the last year.

7. Determine whether other groups such as the HHS Inspector General, HHS General Counsel, OGE, GAO, etc. have done any reviews or investigations at the institute in the last five years. Obtain copies of their reports if available. In future years, review the NEO reports of prior reviews conducted at the institute.

ENTRANCE CONFERENCE WITH THE INSTITUTE (See questions attached**)**

The purpose of the entrance conference is to meet with the institute DEC, counselors, specialists and other relevant ethics staff to explain the process and content of the review, obtain access to necessary reports and documents to review, obtain working space, and answer any questions about the review. During this conference ask questions to get a good overview of the program, how it is managed, and program areas with which they have difficulty.

The ethics official may invite other institute officials if he so chooses. If high level institute officials, like the institute director, are to be there, you may want the Director of the NIH Ethics Office to attend. Discuss general questions you may have at

this time, but it is not necessary to do a thorough interview with the ethics official of all elements. You will start your review right after the entrance conference, so let him know what documents you will need right away, such as the public or confidential financial disclosure reports.

Prepare a list of questions to ask beforehand. The team leader will be in charge of the review and should prepare the questions for the entrance conference. Other team members should take notes and ask questions as needed, but not "take over" leading the entrance interview.

ETHICS PROGRAM ADMINISTRATION

In this section of the review you will determine and describe how the ethics program is administered in the institute. Determine the staffing and structure, and who is responsible for which systems. At the end of the review make a determination whether there is adequate staffing, and whether the structure is efficient and effective for the institute.

The focus of your report will be on describing how the program is administered. Identify the key ethics officials and how much time they spend on the program, what other non-ethics duties they have, and whether the staffing is adequate for the workload.

Review Steps

1. From the DEC, obtain a good overview of how the system works, the identity of all the ethics officials, and how much time they spend on the program (as a percentage of all their duties). If ethics officials have non-ethics duties, find out what they are.

2. Determine who is responsible for managing each element of the ethics program. and the institute's system for filing all ethics forms and reports.

3. Determine how long each ethics official has been working in the ethics program – what is their experience level? What ethics training have they received from OGE, HHS, NIH, or other sources?

4. Ask questions: What are the most troubling ethics issues they are facing? What is the most difficult part of their work? What is the most time consuming part of their work? Do they need assistance from Sandie Dunham's financial disclosure team?

5. Does the DEC believe he has the support of institute management?

REVIEW OF THE PUBLIC FINANCIAL DISCLOSURE SYSTEM

During the review, examine all public financial disclosure reports filed by institute officials for the filing cycle selected, unless there are a large volume of such reports and you wish to pick a sample of them. Your sample size of SF 278s should be large, at least 75-100, depending on the number of reports filed. These reports should be from the last filing cycle where the reports were filed at least 60 to 90 days prior, so that, with few exceptions, they should already be certified by the DEC. When looking at the public financial disclosure system, determine whether all public financial disclosure reports:

- were listed in the EMIS/NEES system;
- were filed, and filed on time (paid late filing fees if applicable);
- were reviewed within 60 days of the date filed, and certified;
- were adequately reviewed to determine (1) whether the reports were technically complete and (2) whether the reports disclosed any conflicts of interest or other violations of ethics laws or regulations; and
- were acted upon timely if problems were noted.

Ensure that all positions and grades designated as being required to file have done so. Make sure that all equal classification positions have been included.

The focus of your report should be describing how the financial disclosure system works, the adequacy of the collection process, and the adequacy of the review process. Document the strengths and weaknesses of the public financial disclosure system and the impact on the institute's ability to prevent and detect ethics violations through the use of the reports. Assess whether the reviewers have been adequately trained, or have enough experience to do their duties.

Obtain numbers at all times so your report can also be informative, as numbers will help tell the story, and prove the points you are trying to make. For instance you will want to state:

> "In XXXX Institute, 19 officials were required to file public financial disclosure reports. Of these 19, two reports had not been filed, and three others were filed more than 30 days late. For those filed late the ethics official collected the mandatory $200 late filing fee for two of the reports. The third official had not as yet paid his fee."

Always keep numbers in mind. You will need them in the final report, and you always need to be accurate. All numbers in the report must be referenced back to the workpapers.

Always be looking for better procedures to manage the system. If something doesn't make sense, or is inefficient, find a better way to do it and make it a recommendation.

When you have examined about 25 reports and you find all or the majority of the reports have problems and the system is a mess, you may stop at this time and give a cursory look at another 25 reports to see if they are in the same condition. If they are, you may stop your review of the reports. You will then report what you found, and tell the institute they have to clean up the reports.

Review Steps

1. From the DEC, get a good description of how the public financial disclosure system is managed so you can describe it in the report. Do they have written collection and review procedures? If so, obtain a copy.

2. From EMIS/NEES obtain a master list of institute employees required to file public reports (SF 278's) for the most recent filing cycle.. These reports should be from the last filing cycle where the reports were filed at least 60 to 90 days prior, so that, with few exceptions, they should already be certified by the DEC. If you have questions, you may want to independently verify its completeness and accuracy with the personnel office in terms of Presidential appointee (PA), career Senior Executive Service (SES), non-career SES, Schedule C employees and Special Government Employees (SGE's). Determine whether there are any discrepancies between the lists. Make sure all equal classification positions have been included in the master list.

   -Does the ethics official keep EMIS/NEES current to monitor the filing and review of the new entrant, annual and termination reports?

3. Obtain all the public financial disclosure reports for the last filing cycles. You will also want to obtain all the financial disclosure reports from the year prior to the year you are reviewing so you can compare reports. Determine the status of any public reports that could not be obtained.

4. Review the **new entrant, annual and termination** public reports, to ensure that:

   -they have been filed in a timely manner;

   -they have been date-stamped (or hand-dated) upon receipt;

   -they have been reviewed by the ethics official no later than 60 days after being filed (although a report is not specifically required to be certified within 60 days, it should be certified immediately following the completion of the review unless the reviewer is awaiting requested additional information);

. If any public reports have been filed more than 30 days late, ensure that the institute has assessed the $200 late filing fee. Has the institute applied to NEO for a waiver of any fees? Have assessed fees been paid?

5. Determine what materials the ethics official uses to review the reports, such as lists of substantially affected organizations, contractors, grantees, prohibited interests, etc? Obtain these lists and use them in your review. Does the reviewing official compare the report to the prior year's report?

6. Review all, or a sample, of the reports to determine whether they have been filed and reviewed on time, adequately completed by the employee and adequately reviewed by the ethics official. **Compare the reports to the reports filed in the prior year.** For all reports reviewed, at a minimum, you will examine the following information:

   a. name of official, position, type of report, and date report was filed.
   b. type of report (new entrant, annual, termination or combination).
   c. date of initial review.
   d. date report was certified by the ethics official.
   e. whether late filing fees were collected, if applicable.
   f. whether the report was technically complete.
   g. whether there were substantive problems with what was reported.
   h. whether the ethics official's review of the report was adequate both to find technical problems as well as substantive problems.
   i. all current actions, activities, approvals and ethics agreements the employee has in the file and whether they were done correctly.
   j. information pertinent to each activity if you find problems (obtain a copy of the activity report for your workpapers).
   k. a judgment as to whether the activity was approved or denied according to policies and procedures, and whether you agree with the decision that was made.
   l. whether the 520 activity was documented in the reports comment section.
   m. whether all appropriate entries were included on the disclosure report for each activity.
   n. whether required SAO forms (HHS Form 717-1) were filed and approved and any necessary actions such as divestiture or disqualification were taken.
   o. a judgment as to whether the ethics official keeps EMIS/NEES current with actions in the report files.

   For each filer, list any issues or problems you have with the financial disclosure report or any of the activities, on the data collection sheets developed for the review. If you do a sample of reports, always review the reports of critical positions, such as institute directors, deputy directors, procurement officials, and others.

   Determine whether any of the reports reveal any actual or potential conflicts-of-interests or violations of NIH policies or other ethics regulations. Make note of any issues or questionable items so you can ask the ethics official

about them. Review the current year's report against the prior year's report. This is not a complete listing, but be mindful of all NIH policies when reviewing the public and confidential financial disclosure reports, and make note of any deficiencies.

7. Ensure that each file contains a listing of any ethics agreements made by the filer, and ensure that such ethics agreements were complied with, and the date the agreement was completed. For divestitures and resignations, is there written proof in the file of the date they were completed. For recusals (disqualifications), are there written disqualifications in the file? NIH policy states that all recusals must be in writing.

8. Determine whether the reports have been reviewed by the institute by no later than 60 days after being filed, and are certified (a report which has not been certified by the 61st day pending the receipt of requested additional information generally will be considered to have been reviewed within 60 days).

9. If the employee reports any outside employment or activities, make sure that the employee requested prior written approval for each. Also, make sure the employee has filed an annual HHS 521 report. Compare all these reports to spot any inconsistencies.

10. If the employee reports awards, make sure the Form 348 was approved. Determine whether the DEC has problems getting information to approve awards.

11. Describe the system for pre-screening all new entrant public filers' reports. Review all new entrant reports to ensure that pre-screening was done.

12. Ensure that all reports are kept on file for six years, and are then destroyed. Does the institute have a system for doing this?

<u>Best Practices</u>

A. Does the ethics official send cautionary letters to filers that an interest they list could be an issue in the future?

REVIEW OF THE CONFIDENTIAL FINANCIAL DISCLOSURE SYSTEM

Many steps for the review of the confidential financial disclosure system are the same as the public disclosure system. When looking at the confidential financial disclosure system, determine whether all confidential financial disclosure reports required to be filed:

- were filed, and filed on time;
- were completely filled out;

- were initially reviewed within 60 days from the date filed;
- show evidence of the ethics official's review, such as issues noted, questions to be asked or incomplete parts;
- were adequately reviewed to disclose any conflicts of interest or other violations of ethics laws or regulations; and
- received adequate and timely action if problems were noted.

Determine whether the institute has effectively designated filing positions by applying the coverage criteria at 5 C.F.R. § 2634.904 and NIH criteria in conjunction with the exclusion criteria at § 2634.905. Many organizations under-designate or, much more frequently, over-designate positions. Over-designation often occurs because of fear of OGE, GAO, or IG criticism. OGE has asked agencies to periodically review their position designations to make sure they continue to meet the designation criteria.

When you have examined about 25 reports, and you find all or the majority of the reports have problems and the system is a mess, you may stop at this time. Eyeball another 25 reports to see if they are in the same condition. If they are, at this point you may stop your review of the reports at this point. You will then report what you found, and tell the institute they have to clean up the reports.

The focus of your report should be the strengths and weaknesses of the confidential financial disclosure system and its impact on the institute's ability to prevent and detect ethics violations through the use of the reports. Obtain numbers at all times so your report can also be informative. Determine, from your experience, if there are better procedures to manage the system. If something doesn't make sense, or is inefficient, find a better way to do it and make it a recommendation.

<u>Review Steps</u>

1. From the DEC, get a description of the system and how it operates. From EMIS/NEES obtain a master list of institute employees required to file confidential reports (OGE 450's) for the current year. Determine whether the institute has effectively designated filing positions by applying the coverage criteria at 5 C.F.R. § 2634.904 and NIH criteria, in conjunction with the exclusion criteria at § 2634.905.

2. Determine, from looking at an institute organizational chart, whether there are there other positions which you believe should be required to file because they meet the criteria. Examine the position description for these positions to see if they meet the criteria. Are there positions filing which you believe do not meet the criteria for filing or the position receives adequate supervision and therefore should not file? If in doubt ask for and review the position description

   -How often does the DEC review the positions designated to determine whether other positions need to be added, or whether employees' duties have changed and they no longer meet the criteria for filing?

3. Does the ethics official keep EMIS/NEES current to monitor the filing and review of the annual and new entrant reports?

4. Obtain all the confidential financial disclosure reports for the current year that you want to review as part of your sample. Check to determine whether they have been date stamped. Determine the status of any confidential reports that could not be obtained. In many years, employees whose interests or position have not changed from last year are allowed to file an OGE form 450-A, "Confidential Certificate of No New Interests." Every third year, the employee must file a complete financial disclosure report. Make sure the last complete report is in the file and review it.

5. Review the new entrant and annual reports to ensure that they have been filed in a timely manner, and that they have been reviewed by the institute by no later than 60 days after being filed.

6. Determine what materials the ethics official uses to review the reports, such as lists of substantially affected organizations, contractors, grantees, prohibited interests, etc? Obtain these lists and use them in your review.

7. Review all, or a sample, of the reports to determine whether they have been adequately completed by the employee and adequately reviewed by the ethics official. For Form 450-A, go back to the last complete Form 450 filed to review it. For all reports reviewed, at a minimum, examine the following information:

   a. name of official, position, and date report was filed.
   b. type of report (new entrant, annual, termination or combination).
   c. date of initial review.
   d. date report was certified by ethics official.
   e. whether the report was technically complete.
   f. whether there were substantive problems with what was reported.
   g. whether the ethics official's review of the report was adequate both to find technical problems as well as substantive problems.
   h. all actions, activities, approvals and ethics agreements the employee has in the file and whether they were done correctly.
   i. information pertinent to each activity if you find problems (obtain a copy of the activity report for your workpapers).
   j. a judgment as to whether the activity was approved or denied according to policies and procedures, and whether you agree with the decision that was made.
   k. whether the 520 activity was documented in the reports comment section.
   l. whether all appropriate entries were included on the disclosure report for each activity.

m. whether required SAO forms (HHS Form 717-1) were filed and approved and any necessary actions such as divestiture or disqualification were taken.

n. a judgment whether the ethics official keeps EMIS/NEES current with actions in the report files. .

Always review the reports of the most critical positions. Review at least 50 to 100 reports (depending on the volume of reports in an institute) to get a clear picture of how well the system is operating. Determine whether any of the reports reveal actual or potential conflicts-of-interests or violations of NIH policies or other ethics regulations.

For each report you review, fill out the data collection sheet developed for the review and make note of all data required for the disclosure reports and the employees' activities. Make note of any issues or questionable items on the data collection sheets. Again, make sure you consider all NIH policies as you review the financial interests on the reports, and the activities approved.

8. Determine whether the reports have been reviewed by the institute within 60 days of being filed (a report that has not been certified by the 61st day pending the receipt of requested additional information generally will be considered to have been reviewed within 60 days) and that they have been certified.

9. If the employee reports any outside employment or activities, ensure that the employee requested prior written approval for each. Also make sure the employee has filed an HHS 521 annual report. Compare all these reports to spot any inconsistencies.

10. Determine whether the confidential reports are retained for six years after receipt, after which they are destroyed.

SUBSTANTIALLY AFFECTED ORGANIZATIONS (SAOs)

For each public and confidential financial disclosure report we review, we should look to determine whether the employee holds an interest in any SAOs, whether the requisite HHS Form 717-1 has been completed and approved, and updated if necessary, and whether all regulations and policies have been enforced. Ensure that a conflicts-of-interests determination was made, and that needed actions such as disqualification or divestiture have taken place.

For Clinical Investigators not required to file a financial disclosure report, review the institute's files of any HHS Forms 717-1 they have filed to determine that they have been properly completed, reviewed and approved, and that a thorough conflicts-of-interests analysis occurred, with requisite actions taken.

REVIEW OF OUTSIDE ACTIVITIES

The purpose of this section of the report is to determine whether the review and approval of the Form HHS-520, Form 348, and Form 2803 are being done properly, and that each request is thoroughly reviewed to insure the activity, employment, award, or widely attended gathering is allowed under applicable regulations. Review all such forms for employees in our review sample to determine whether they have been have been submitted and approved, and whether you agree with the decision that was rendered.

The focus of your report should be a description of the system and how well it is operating in the institute.

Review Steps

1. Determine the institute's system for reviewing and approving Form HHS-520 Request for Approval of Outside Activity. Determine whether the ethics official is prompt at entering such reports into EMIS. Does the ethics official notify employees when a continuing activity approval will expire? How does the ethics official ensure that employees disqualify themselves from any organizations with which they have outside activities or employment? Is a written disqualification on file?

2. From the DEC obtain the Forms HHS-520 – Request for Approval of Outside Activity. Review these forms in compliance with all NIH policies concerning outside employment to ensure that the forms were properly reviewed, and that you agree with the decision that was made to approve or deny the request.

3. Make sure that all outside activities approved are reported on the employee's public or confidential financial disclosure report, and that all pertinent information, such as compensation, travel reimbursements, etc. are included on t he report per policy.

4. Make a listing in the workpapers of all Form HHS-520's received for each individual whose financial disclosure report we review, whether they were approved, and whether you agree approval should have been granted. For those approvals with which you disagree, schedule pertinent information and reasons why you disagree, and place a copy of the Form HHS-520 in the workpapers.

5. Have all employees with approved outside activities filed an annual HHS-521 report by the due date?

Awards

1. Describe the institute's system for reviewing and approving awards from the Forms 348. What problems does the DEC have in getting information from the organization that is giving the award?

2. Review the Form 348s to determine that they have been properly completed, and that based on the form content, you agree with the approval. Ensure that awards for senior NIH staff, and gifts valued at $2500 or more have been forwarded for NEAC review prior to the DEC decision.

3. If a cash award (or equivalent) or travel reimbursements were received by the employee, are they listed on the financial disclosure form for the appropriate year?

Widely attended gatherings (WAGs)

1. Determine the institute's system for approving employee attendance at widely attended gatherings. What issues come up in approving WAGs?

2. Review the Forms 2809 to determine whether they were properly completed, and that based on the form content, whether you agree with the approval.

3. Ensure that all WAGs are listed on there employee's applicable financial disclosure report.

ENFORCEMENT

The purpose of this section is to ensure that ethics officials are enforcing ethics laws and regulations when they do find non-compliance with ethics requirements or violations of ethics laws and regulations. Determine whether Form 2850 was used in any instances this year for the supervisor to take action where there was non-compliance with ethics requirements. Ensure that any potential violations of criminal statutes are referred to the Inspector General for investigation.

The focus of the report should be to describe the system for enforcement, and report on the number of cases the institute has found, and how they dealt with them. Also, report on the system for waivers and how it is working.

Review Steps

1. Through discussions with the DEC determine whether the institute has used the Form 2850 - Non-compliance Referral for Ethics Violations. Determine whether any cases were referred to the Inspector General to investigate violations of ethics laws or regulations. If the institute has used the Form 2850 or referred cases to the Inspector General, review the case files to determine whether they were handled properly.

2. Determine the system for granting 18 U.S.C. § 208(b) (1) waivers and who is the approving official? Is there a written delegation for the approving official if not the Director?

3. Obtain from the institute copies of all of the 18 U.S.C. § 208(b) (1) waivers that were granted to current employees. Ensure that waivers comply with NIH policy and were reviewed by the NIH Ethics Counsel. Through an examination of the waivers and, as appropriate, discussions with the DEC, ensure that the waivers comply with subpart C of 5 C.F.R. part 2640, including that:

   -each waiver describes the disqualifying financial interest, the particular matter or matters to which it applies, the employee's role in the matter or matters, and any limitations on the employees ability to act in such matters (5 C.F.R. § 2640.301(a)(3));

   -each waiver is based on a determination that the disqualifying financial interest is not so substantial as to be deemed likely to affect the integrity of the employee's services to the Government (§ 2640.301(a) (4));

   -each waiver is issued prior to the employee taking action in the matter (§ 2640.301(a) (5)) or, if not, the employee disqualified him- or herself before being granted the waiver; and

   -the institute has consulted with the NIH Ethics Counsel prior to granting each waiver and, if not, why not.

REVIEW OF THE ADVICE AND COUNSELING PROGRAM

The purpose of this section is to determine whether the advice rendered to employees is in accordance with OGE and HHS regulations. Good knowledge of the standards of conduct, ethics laws and regulations, and HHS and NIH policies is essential to performing this part of the review. You may need the standards of conduct regulations with you while examining certain pieces of advice. If you have problems with the advice given, have them reviewed by the NIH Ethics Office. Most questions asked and advice given probably is done by email.

The focus of the report in this area should be on whether the advice and counsel rendered was accurate, timely, and in enough detail that the employee can understand the basis for the answer. If you find advice that is wrong, document this to determine whether you want to use it as an example in the final report, and to document your numbers.

<u>Review Steps</u>

1. Obtain copies of all of the written advice and counseling provided to current employees addressing various ethics matters (e.g., gifts, invitations, conflicts of interest, outside employment, seeking employment, post-employment, etc.) to make an assessment whether the advice is complete and accurate and in accordance with OGE, HHS, and NIH regulations, policies and procedures. Make

sure the advice considers all relevant regulations and explains why the decision was made.

2. Ensure that written records have been kept, where appropriate, on advice rendered (5 C.F.R. § 2638.203(b) (8)). Was the advice rendered entered into the EMIS/NEES system?

3. Keep copies of any advice you review in your workpapers. Make note of any advice you think is erroneous and document your reasons. Document discussions you have had with the ethics official, the NIH Ethics Office, or others about such advice. When in doubt about a piece of advice, have another team member review it, or seek advice from other staff in the NEO.

4. If there is a large volume of advice, you may wish to separate it by category of question asked and take a sample of each.

5. Interview the ethics official to determine what type of questions are frequently asked, what issues seem to pose the most difficulty for employees, and also for the ethics official to answer. How many questions are asked in a typical month?

6. Obtain copies of any more formal advice (memoranda rather than email) given in writing to employees. This happens in cases where the case is complex or sensitive, and requires the writing of a formal memo or letter. Review such advice for accuracy and completeness. If this mechanism is not in use determine why.

7. Determine how and where the DEC files the ethics advice rendered. Is it in a location and form that the ethics official can use it to research future ethics questions?

Best Practices

A. Does the institute provide post-employment advice to all departing professional employees?

REVIEW OF THE EDUCATION AND TRAINING PROGRAM

The purpose of this section of the review is to determine whether all covered employees are receiving at ethics training annually, and that all new entrants are receiving ethics training after beginning employment with NIH. If the opportunity arises, attend any live ethics training sessions. On-line training developed by the institute should also be evaluated to determine its accuracy. Assess whether employees are being trained on those areas where they are most vulnerable. What are the types of ethics issues they are likely to face in this institute?

The focus of your report should be on the adequacy of the training program in terms of ensuring that all new entrants and employees annually receive the required

training. Assess the training materials to determine whether they are accurate**. (Note: If all ethics training materials used at the institute were prepared by the NIH Ethics Office, there is no need to evaluate the training materials, only whether all employees received training.)**

Review Steps

Initial Ethics Orientation

1. Through discussions with the DEC or other ethics official, a review of any pertinent documents, and, as appropriate, monitoring one or more sessions, ensure that initial ethics orientation is provided to each new entrant and consists of:

   -the standards of conduct, HHS regulations, and NIH policies;

   -the names, titles, office addresses, and telephone numbers of the institute officials available to advise the employees on ethics issues; and

   -one hour to review the matters described above.

2. Determine whether the ethics official adequately tracks, through EMIS, new employees coming to the institute, and ensures they attend ethics training or are given written ethics materials.

3. Review any available documentation to determine how soon after entry on duty at NIH that new employees have received training.

Annual training

1. Describe the institute's system for conducting annual training for covered employees.

2. Through discussions with ethics officials, a review of any pertinent documents, and, as appropriate, monitoring one or more sessions, ensure that verbal annual ethics training is provided to public filers each calendar year. Ensure that the training includes information on the Standards, HHS regulations, NIH policies, or the conflict-of-interest statutes, and the names, titles, office addresses, and telephone numbers of the DAEO and other institute ethics officials available to advise employees on ethics issues

3. Ensure that the training consists of at least one hour of official duty time for verbal annual ethics training given to each public filer, and is either presented by a qualified instructor or prepared by a qualified instructor and presented by telecommunications, computer, audiotape, or videotape.

4. Ensure that a qualified instructor was available during and immediately after verbal annual ethics training.

5. Through discussions with ethics officials, a review of any pertinent documents, and, as appropriate, monitoring one or more sessions, ensure that annual ethics training is provided to all other covered employees each calendar year.

6. Ensure that one hour of official duty time is given for verbal annual ethics training to other covered employees at least once every three years, either presented or prepared by a qualified instructor.

7. Ensure that an amount of official duty time the institute determines is sufficient is given for written annual ethics training, prepared by a qualified instructor, to other covered employees in the years in which the employees do not receive verbal training.

8. Review all training materials, if developed by the institute, to determine their accuracy and appropriateness.

9. Determine how the institute tracks employees to make sure they attend annual ethics training. If possible, review the documentation to determine whether all covered employees completed the training. Are training dates entered into the EMIS/NEES system?

Best Practices

A. Determine whether there is a written plan for annual ethics training for the current calendar year. While not required by each institute, it may be a good idea for the institute DEC to develop a plan annually, and then record details of the training actually given during the year. This will help immensely for the next review. It also allows the institute ethics official to determine quickly whether all employees have been trained.

B. Determine whether the DEC has ever considered giving ethics training periodically for employees not required to receive ethics training.

C. Determine whether high level officials ever participate in live training, or meet with new employees, to show the seriousness of the institute about creating an ethical culture.

D. Determine whether the ethics official ever provides a live presentation or briefing to new employees?

REVIEW OF TRAVEL REIMBURSEMENTS FROM NON-GOVERNMENT SOURCES UNDER 31 U.S.C. § 1353 (Form 348 Travel)

The purpose of this section is to determine whether the travel payments accepted under 31 U.S.C. § 1353 (Form 348) are being properly authorized, and include a conflict-of-interest analyses, to enable the institute to carry out functions (not required by statute or regulation) that are important but, perhaps because of budget constraints, would not be accomplished otherwise.

The report focus should discuss the strengths and weakness of the institute's system of accepting Form 348 travel payments. Evaluate whether such payments meet the requirements of the regulations, that they were for a meeting or similar function.

Review Steps

1. Obtain, from the central travel office, the institute's part of the last three NIH Semi-annual Reports of Payments Accepted from a Non-Federal Source that are filed through HHS with OGE.

2. Discuss with the DEC how this system operates in the institute:

   -who is responsible for approving such reimbursements?
   -who is responsible for preparing the semi-annual report of reimbursements received?
   -if the ethics staff does not prepare the semi-annual report, does he DEC review it before it is sent out?

3. Review a sample of the payments identified on the semiannual report(s). Obtain the approval documents (Form 348s) and any other documentation supporting acceptance of the payments (all forms or a sample size).

4. Review the Form 348s and any other accompanying documentation to ensure that each payment was:

   -authorized by officials at as high an administrative level as practical and, as appropriate, coordinated with ethics officials;

   -for a meeting or similar function which the employee has been authorized to attend in an official capacity on behalf of the institute;

   -for travel and related expenses which have been accepted from a non-Federal source which is not disqualified on the basis of a conflict-of-interest analysis;

   -payment in-kind or by check or similar instrument; and

-whether approval was granted for an accompanying spouse to attend.

5. Make an assessment as to whether the travel reimbursement authority is being used for the purposes for which it is intended.

SPECIAL GOVERNMENT EMPLOYEES (SGE's)

The purpose of this section of the review is to determine whether the institute has an effective ethics program for SGE's in terms of financial disclosure, education and training, advice and counseling, and waivers. It is also to determine whether individuals who serve as members of committees that advise institutes are properly designated as SGEs, since certain requirements and restrictions related to financial disclosure, the conflict of interest statutes, the standards, and training apply to SGEs that do not apply to non-SGEs.

Your report focus should be on the strengths and weaknesses of the institute's ethics program for SGEs, especially its ability to properly designate members of committees as SGEs, and the institute's effectiveness in collecting and reviewing financial disclosure reports to determine conflicts of interest. You will also want to examine the integrity of the waiver process, and whether proper 18 U.S.C. § 208(b) (3) waivers, examined by NIH Ethics Counsel, were executed prior to committee meetings.

<u>Review Steps</u>

1. Determine whether there are individuals assigned to the institute who serve for 130 days or less during any period of 365 days (i.e., temporarily on either a full-time, intermittent, or part-time basis) and are assigned to committees, councils, boards, commissions, etc., that advise the institute.

2. Determine whether there are any other individuals who serve for 130 days or less during any period of 365 days, such as experts/consultants.

3. For advisory committees, etc., determine whether the ethics office or a committee management office manages the advisory committees.

4. If a committee management council or office manages the advisory committees, determine whether ethics officials have any involvement at all, including:

   -establishing appropriate, or improving existing, lines of communication with committee management officials or others who have a role in managing or running advisory committees within their agencies;

   -helping ensure that the institute has a systematic approach or process for making status determinations for ethics purposes of the advisory committee

members and that the determinations of a member's status is made prospectively at the time of an individual's appointment or retention by a committee;

-being a part of the final clearance process for appointing members who are to serve on advisory committees, especially those committees that are newly created or are being renewed or reestablished by the institute;

-periodically reviewing the status determinations that are made by the institute to ensure that they are being properly made by committee management officials, especially for those advisory committees from which the enabling authority may have been amended or the mission or purpose may have changed in recent years, or which are standing committees with indefinite charters;

-ensuring that relevant committee management officials are aware of OGE's, HHS and NIH's guidance and procedures on SGE and representative status determinations, and are made aware of appropriate ethics points of contact to discuss issues involving status determinations and other ethics matters;

-providing advice and legal counsel to committee management officials, as appropriate, on matters concerning the status determinations of advisory committee members for ethics purposes;

-ensuring, as appropriate, that appointment letters or other committee documentation of appointments state clearly whether members are serving as SGEs or representatives and that committee members are properly informed of their member status, the application of Government ethics rules if they serve as SGEs, and the "recognizable group of persons" they represent if they serve as representatives; and

-recommending to committee management officials, in cases where members are serving as representatives, that committee members are informed about the group of persons that each respective member is expected to represent on the committee.

5. If there are individuals who serve for 130 days or less during any period of 365 days, ensure that the institute has properly determined whether or not they are SGEs. Review all such committee members to ensure they have been properly designated.

6. If the institute has advisory committees whose members are SGEs, determine whether the SGEs filed an OGE Form 450 prior to each committee meeting.

7. Obtain and review all OGE Form 450's for SGE's to determine that they have been adequately reviewed for conflicts of interests, and that necessary waivers were done prior to the meeting.

8. Obtain from the institute copies of all of the 18 U.S.C. § 208(b) (3) waivers that were granted to current SGE's. Ensure that the waivers comply with subpart C of 5 C.F.R. part 2640, including that:

-the advisory committee upon which the individual is serving or will serve is an advisory committee within the meaning of the Federal Advisory Committee Act (FACA);

-each waiver describes the facts upon which the waiver is based, including the nature of the financial interest, the particular matters to which the waiver applies, and any limitations on the ability of the individual to:

-each waiver includes a certification that the need for the individual's services on the advisory committee outweighs the potential for a conflict of interest;

-each waiver is issued prior to the employee taking action in the matter or, if not, the employee disqualified himself before being granted the waiver; and

-the DEC is aware that waivers are to be maintained by the institute for public inspection.

9. Ensure that where an SGE has agreed to obtain an 18 U.S.C. § 208(b) (3) waiver, and disqualification is required prior to the granting of the waiver, all terms of the agreement have been honored.

10. Ensure that all SGE's have received ethics training.

STRUCTURE AND STAFFING

Now that you have finished most of your review, consider your findings, and more specifically, what caused the deficiencies. Look at what you have found and determine whether you believe the structure of the institute's ethics program is efficient and effective. Would a different structure make the program more efficient and effective?

Determine whether there is adequate competent staff to manage the program effectively. In many cases lack of staff, or lack of competent staff, causes problems. Is the attitude of the DEC a problem? Consider making stronger recommendations when there is a lackadaisical attitude, rather than when the ethics staff are trying hard and care about the ethics program, but are overwhelmed with other work, are understaffed, or recently had a crisis occur that prevented some ethics work from being done.

In some instances you may want to recommend to the Institute Director that more staff be assigned to the program, or that a different structure be put in place. In very sensitive and rare cases, you may want the NEO Director to discuss with the Institute Director, the DEC's inability to manage the program competently if this is causing major problems.

OTHER ISSUES

Are there other ethics issues unique to the institute that the ethics official brought up or that you discovered in doing your work? Explore these issues to determine whether any additional review or information are needed for these issues.

As you discover new issues you wish to examine in each institute, you should add review steps for these issues to these review guidelines. These guidelines should be kept current, and added to, as the depth of staff experience conducting program reviews increases.

EXIT CONFERENCE WITH THE INSTITUTE

Once all work at the institute is completed, allow time to analyze your work to determine the main issues to be reported, and to develop your conclusions and recommendations. When you are fairly comfortable with these, schedule an exit conference with the DEC.

The purpose of the exit conference is to convey your findings to the DEC. While he should be aware, generally, of what you found due to the discussion during the review, this is where he learns all your findings, and potential recommendations. This is also the time for the DEC to bring up any facts to respond to your findings. Warn the DEC that the recommendations may change due to higher level review or other facts being considered. If your recommendations change greatly after the exit conference, notify the DEC before you issue the report.

DRAFTING THE REPORT (See Report Outline attached.)

Use a letter report format in transmitting your findings, unless the report is unusually long or complex, in which case you may want to attach the report to a transmittal letter. Address the report to the Director of the Institute, with copies to the NIH DEC, the NEO Director, and the Institute DEC. When starting to draft the report, first outline the various sections, and determine their order in the report.

Open the report stating that a review of the institute was performed from (date) to (date). Cite your legal authority to perform such a review. State your purpose for doing the review, such as “to make sure the program is in compliance with applicable ethics laws and regulations and HHS and NIH policies.” Your next paragraph will be a very brief overall summary of your findings to let readers know what is coming in the report.

Consider the most important findings of your review and prioritize them, with the most important issue first. Include a section in the report on each element you reviewed. Order your sections as in the attached report outline, or in order of your most significant findings. If you found deficiencies, briefly summarize the regulation or policy that is at

issue. Set forth the deficiency you found and the reasons you believe this deficiency occurred.

If possible, use examples in your report to illustrate problems. It is one thing to say "During her review the DEC did not find that 7 filers owned interests in 13 SAOs." Go on to state that

"For example:

- One contracts officer owned $43,000 worth of stock in Geddis Inc. which manufactures medical instruments. The contracts officer had signed contracts for the institute to purchase over $ 2 million worth of instruments from Geddis Inc. during 2006. We are referring this case to the HHS Inspector General.

- One Senior Investigator reported interests in 7 SAO's worth more than $300,000 for several years and had never filed an SAO report. The DEC had never questioned these interests."

Examples will help sell your recommendations, and make your report more interesting.

Because of Privacy Act considerations and other reasons, you should not use employee names in the report when talking about examples of issues you found that cast a bad light on an individual employee. In future years, these reports may be requested by congressional committees or the news media. You may refer to an employee's position, if there are many of these positions, such as a "Health Program Specialist." But you would not use "Deputy Director" if there are only one or two Deputy Directors, because then it may be easy to discern the person. You may, however, when talking about the ethics program, say that "John Smith is the DEC responsible for managing the ethics program." It will also be clear from the report that the DEC is responsible for the deficiencies you find, this cannot be avoided.

Drafting conclusions and recommendations

The conclusions and recommendations are the most important part of the report. Consider them carefully, and word them very specifically. **There should be nothing new in these two parts that has not been discussed earlier in the report.**

Conclusions are basically a general restatement of your major findings, both the institute's strengths and weaknesses. State the reasons why any deficiencies occurred, and pinpoint the exact causes. Was it lack of staff, poor procedures, lack of training, not enough time, etc? Recommendations should tell the institute what the problem is, what

caused it, and what they must do to correct it. Be specific in telling them how to correct it so there is no misunderstanding of what you expect them to do.

At the end of the recommendations, tell the institute to advise you in writing within 30 days of receipt of the report, of the actions they have taken or plan to take on the recommendations. Inform the institute that you will perform a follow-up review 3 months from the date of the report to make sure they have implemented the recommendations and corrected the deficiencies.

REFERENCING THE REPORT

Every report needs to be referenced. This means you take a final draft of the report and mark it up on the border with references back to the workpapers showing the sources from which obtained certain numbers, facts, deficiencies, etc. When this is completed, it is best to have someone who did not participate in the review be the "Referencer." This person will go through the draft report and check that what you said in the report is supported by what you have in the workpapers.

All audit organizations include this quality control step. While it is time consuming when you want to get your report out, it will save you much headache and embarrassment if your facts are wrong. It is an excellent quality control check on your report, and it prevents sloppy mistakes. The referencer may even challenge your findings, stating that you did not prove your point. After the referencer has finished, the team leader and the referencer should go over the report and reach agreement on all points.

INTERNAL REVIEW AND APPROVAL OF THE REPORT

While the report is being referenced, or after referencing, send the report through your internal review process, if any. Determine who, above the audit team, is going to review the report, and who will render final approval and sign the report. The report should not be signed until referencing is completed, to see if any part of the report changes.

There should be a routing sheet on the report as it goes for signature. This report routing sheet must be signed off and dated by each member of the review team, the referencer, the staff assistant making sure the report is in the proper format and contains no spelling errors, and the person giving final approval and signing the report. This routing sheet should be made part of the Master report Folder.

THIRTY DAY LETTER BACK FROM THE INSTITUTE

When you receive the 30 day letter back from the institute, review it to make sure the actions they have taken or plan to take comport with your recommendations. If they disagree with the report, or do not appear to be taking action which will resolve the deficiencies you found, call them to discuss these issues.

THREE MONTH FOLLOW-UP

Three months from the date of the report meet with the Institute DEC to perform a mini-review of what the institute has done to remedy the deficiencies you found. It is not enough just to discuss this with the ethics official. You need evidence. For example, if you questioned financial interests on five confidential financial disclosure reports, you need to look at the files and see evidence that these issues have been resolved properly to your satisfaction.

Once the follow-up review is complete, prepare a short internal report listing each recommendation, and what the institute has done to resolve the issue, and then make a statement as to whether you consider the recommendation closed, as it has been resolved. If you believe an issue still exists with a recommendation, note that and keep the recommendation open. Inform the DEC which recommendations remain open and schedule a further follow-up. If after several attempts to close all recommendations, you still are not satisfied, consider writing a letter to the Institute Director.

You will need to set up a tracking system to monitor all the recommendations you have made in each institute to record whether they have been implemented or not.

MASTER REPORT FILES

After the review, including follow-up, is done, set up a Master Report Folder for the review. This report folder should contain:

- the notification letter to the institute
- a copy of the final report
- a copy of the referenced report and referencer's comments
- 30-day response from the institute
- all follow-up reports
- report routing slip
- any other correspondence or materials that were sensitive to the review

All workpapers should be kept in a separate storage area and maintained according to Government record-keeping regulations. Retain the workpapers here until the next review at that institute is completed.

Each report should have a report number such as "2007-01-NINDS", which is the same number you put on the Master Report Folder and use in your follow-up reports to refer back to the original report.

BEST PRACTICES

After each review the team should determine whether the institute they reviewed had any "best practices" that NEO should share with other institutes. The institute should be given credit for any best practices in the report. NEO should share these best practices

in a section of the NIH ethics program web site. As the review teams find institutes that could benefit from these best practices, they should recommend them in the report.

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