

**NATIONAL INSTITUTES OF HEALTH
NIH Ethics Program**

**Procedure for Reviewing the
HHS-520 Request for Approval of Outside Activity**

INTRODUCTION	2
DESCRIPTION OF THE FORMS AND REQUIRED INFORMATION	2
1. HHS-520, Request for Approval of Outside Activity (1/06)	2
2. NIH-2657, Supplement to the HHS-520 (6/06)	2
3. Potential Additional Information Required	3
REVIEWERS' RESPONSIBILITIES	3
Getting Started	4
Conducting the Technical and Conflicts Reviews	5
Immediate Supervisor	5
IC Ethics Office Staff/IC Deputy Ethics Counselor (DEC)	6
NIH Ethics Office Staff/NIH DEC	7

NIH Ethics Office (TM/FP); 5/2/2007; 8:11pm
File Name: 520-Reviewer-Procedure.wpd

INTRODUCTION

The purpose of this procedure is to provide detailed instructions for supervisors and other reviewers to complete the form HHS-520, Request for Approval of Outside Activity. Use of the HHS-520 Request for Approval of Outside Activity is governed by NIH policy, Manual Chapter 2400-07.

Employees are to submit their HHS-520 package to their immediate supervisor as soon as possible after their decision to engage in the activity, or at least 8 weeks prior to the proposed start date.

Help: For assistance, contact your IC's Ethics Office. Names and addresses of [ethics staff](#) are available on the NIH Ethics Program web site. ([Http://ethics.od.nih.gov/coord.pdf](http://ethics.od.nih.gov/coord.pdf))

Incomplete packages may be returned without action. It is the employee's responsibility to ensure that all required information is provided and that the request form is complete.

Note: Internal IC procedures are mentioned but not detailed here. Contact your IC Ethics Office.

DESCRIPTION OF THE FORMS AND REQUIRED INFORMATION

All forms are available on the NIH Ethics Program web site, on the Ethics Forms page:
<http://ethics.od.nih.gov/forms.htm#hhs520>

1. **The HHS-520, Request for Approval of Outside Activity (1/06)**, is divided into 8 sections, plus the Privacy Act Statement, a page for listing attachments, and space for additional information. Only the latest version is acceptable. The employee will complete and read the following sections:

Section I.	Employee Information (page 1)
Section II.	Outside Activity Information (pages 2-5)
Section III.	Official Duty Information (page 6)
Section VIII.	Notices: Employee responsibilities; Excerpts from the governing regulations; Privacy Act Statement (pages 11-13)
Attachment List	(page 14)
Additional Space	(page 15, if needed)

The supervisor and other reviewers complete the remaining Sections IV-VII of the form HHS-520.

2. **The NIH-2657, Supplement to the HHS-520 (Rev 4/07)**, is used in addition to the HHS-520 only when the activity involves consulting, legal consulting/testimony/practice, or outside professional health care practice. The employee will complete the sections as follows:

Section A	All employees with any of the following activity requests.
Section B	Read the conditions and sign, only for consulting activities, including consultative services on a scientific advisory board. Before submitting the request package, the employee must obtain a signature from the outside entity indicating that the outside entity agrees with the terms outlined in this section.
Section C	Read the conditions and sign, only for legal practice, legal consulting, or testimony.
Section D	Read the conditions and sign, only for health care practice (e.g, physicians, nurses, respiratory therapists, laboratory technicians and technologists, and other allied health care providers).

3. **Potential Additional Information Required:** For any of the following conditions, employees may need to provide additional information.

- a. **Is the outside entity a foreign organization?** The Emoluments Clause of the US Constitution says that, without the consent of Congress, Federal Government employees may not accept employment, gifts, or compensation from any foreign government, including any entity which is owned or operated by the foreign government, unless Congress gives its consent. Congress gave consent for some activities in the Foreign Gifts and Decorations Act (FGDA). If the proposed activity is with a foreign entity, ethics officials will make a determination on whether the Emoluments Clause is applicable to the activity.
- b. **Is the outside entity a private foundation?** Certain employees are subject to a provision in the Internal Revenue Service law which restricts “acts of self dealing” with private foundations. “Acts of self dealing” means accepting payment other than travel expenses for something you do, e.g., give a speech or serve on a board or committee. If the proposed activity is with a private foundation, ethics officials will make a determination on whether this IRS provision applies to the activity.
- c. **Is the outside entity a Supported Research Institutions (SRI)?** If yes, you will need to consider whether the proposed activity is prohibited by the HHS Supplemental Standards of Ethical Conduct (5 CFR 5501.109), or permitted under the exceptions. In addition, questions 8d and 8e in Section II of the HHS-520 deal with whether the activity is funded by or related to anything funded by or intended for submission to HHS, and whether the outside entity intends to seek HHS support, even for other projects. SRI determination may be made using information obtained from two NIH databases (IMPAC II and QVR).

Note: Any information added to an Outside Activity request must be listed on Page 14 of the HHS-520 and clearly labeled.

REVIEWERS' RESPONSIBILITIES

This section provides detailed instructions for reviewers of an Outside Activity request. It describes who completes which sections, followed by specific review instructions for each review level.

Note: Contact your [IC Ethics Office staff](#) to determine if your IC has internal IC procedures and request a copy.

Due: Employees are expected to submit a complete Outside Activity request package to the supervisor at least 8 weeks prior to the proposed start date to permit adequate time for a thorough review at all levels. **Supervisors and Managers will review the package and forward to the next level of review within 5 working days of receipt.** The package must arrive in the IC Ethics Office (ICEO) as soon as possible.

ICEOs will submit an Outside Activity request package under NIH Ethics Advisory Committee (NEAC) jurisdiction to the NIH Ethics Office (NEO) as quickly as possible, or at least 6 weeks prior to the proposed start date. Because of the extra time needed for NEAC review, employees are expected to submit these requests earlier. See Deadlines for Submission to NEO on the NIH Ethics Program web site Forms Page:

<http://ethics.od.nih.gov/forms.htm>

Help: Reviewers seeking assistance should contact their ICEO staff. Names and addresses of [Ethics Coordinators](#) are available on the NIH Ethics Program web site.

ICEO Specialists and IC DEC's may contact the NEO Specialist who handles their IC for assistance.

Incomplete packages forwarded to the next level of review may be returned without action. It is the responsibility of the employee and each reviewer to ensure that all required information is provided and the technical and conflict reviews are complete prior to forwarding the package to the next reviewer. All reviewers are required to sign the form HHS-520. The signature and/or initials verify that the review is complete and accurate.

GETTING STARTED

The following table shows the names of each section of the form HHS-520 and identifies who will sign in that section based on the status of the employee and whether the activity is under the jurisdiction of the NEAC and NIH DEC.

Employee submission noted below; signed by reviewers as indicated in the row.	NEAC Review	Section IV Supervisor Review	Section V Management / Committee / Other Review	Section VI Agency Ethics Official Review	Section VII Agency Designee (Approving Official) Determination)
Employee completes Sections I, II, III, and the attachment list, and reads the notices in Section VIII.					
IC Staff	N	Supervisor and 2 nd level reviewer	Leave Blank	IC Ethics Specialist*	IC DEC or delegated official
IC Staff	Y	Supervisor and 2 nd level reviewer	IC Specialist* and IC DEC	NEO (documents NEAC advice)	NIH DEC
Senior** (other than IC Directors and DEC's)	Y	Supervisor	IC Specialist* and IC DEC	NEO (documents NEAC advice)	NIH DEC
IC Directors	Y	Leave Blank	IC Specialist* and IC DEC	NEO (documents NEAC advice)	NIH DEC
DEC's (Senior**, not IC Director)	Y	Supervisor	NEO Specialist	NEO (documents NEAC advice)	NIH DEC
DEC's, Not Senior	N	Supervisor	Leave Blank	NEO	NIH DEC
DEC's, Not Senior	Y	Supervisor	NEO Specialist	NEO (documents NEAC advice)	NIH DEC

* If this responsibility has been delegated by the IC DEC.

** "Senior" based on the NIH definition from the regulation.

All reviewers, from the supervisor through the agency designee who makes the final determination, must be familiar with the following documents. All are available on the NIH Ethics Program web site, on the [Forms Page](#), or on the [Regulations and Policies page](#): <http://ethics.od.nih.gov>

1. HHS-520 and NIH-2657
2. NIH DEC Memorandum Regarding Supervisory Review of Outside Activities
3. Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR 2635)
4. HHS Supplemental Standards of Ethical Conduct (5 CFR 5501)
5. HHS Supplemental Financial Disclosure Reporting Requirements (5 CFR 5502)
6. NIH Ethics Manual: Outside Activities (Outside Work) (Chapter 2400-07)

CONDUCTING THE TECHNICAL AND CONFLICTS REVIEWS

In summary, each reviewer conducts a technical and conflicts review. The technical review confirms that all questions are answered and all appropriate information is attached and labeled. The conflicts review compares the proposed Outside Activity request to the employee's official duties to confirm that no conflict exists and that there is no overlap of topic or content. Each reviewer then signs the appropriate box on the HHS-520 as indicated in the table above before forwarding the package to the next individual or office. Each reviewer will follow the instructions in the relevant section below.

Immediate and Second Level Supervisor

(Skip this section for IC Directors)

Time Frame: The immediate supervisor must complete his/her review and forward the package within 5 working days of receipt.

1. Enter the date you received the HHS-520 from the employee in the "Date Filed" box at the top of page 1.
2. Review and confirm accuracy of employee information on page 1 (Section I) of the HHS-520.
3. Thoroughly read the description of proposed Outside Activity on pages 2-5 (Section II) of the HHS-520, and the description of current official duties on page 6 (Section III).
4. Compare the two descriptions, paying particular attention to how the proposed Outside Activity is described in relation to current official work. Obtain clarification from the employee if needed.
5. If the proposed activity involves general consulting, or legal consulting/testimony, or health care practice, confirm that the NIH-2657 is attached and completed correctly.
6. Read the **Summary of Applicable** Law on page 7 of the HHS-520.
7. In Section IV, Supervisor Review, Box 2, **at the top of that box**, write a justification for why the proposed activity can be permitted, e.g.,:
Agree that there is no overlap between this proposed activity and employee's current official work because this is a general talk for undergraduate students. Topic is general science rather than research, and audience is not researchers. No current research results will be discussed. Recommend approval.
8. Check the box either recommending approval or disapproval in Box 3, and sign. You **MUST** conclude that there is **no overlap** between the proposed Outside Activity and current official work in order to recommend approval.
9. Confirm that the employee kept a copy of the entire package and forward the original package to the second level reviewer if one is required in your IC. Any second level reviewer must sign at the very bottom of page 7, underneath the supervisor's signature.

If no second level reviewer is required in your IC, the package is submitted to the IC Ethics Office.

If there is a second level supervisor, that individual follows these same instructions and also signs on the Supervisor section, page 7.

IC Ethics Office Staff/IC DEC

IC Ethics Specialists will perform the following steps on behalf of the DEC when authority to do so has been appropriately delegated.

1. On page 1 of the HHS-520, in the box labeled “Agency Use Only”, enter the date the request was received in the IC Ethics Office.
2. Enter the data about the proposed activity into the Ethics Management Information System (EMIS). Change DEC Action to “Pending.” Save the record. Open the record, scroll to the bottom of the screen, and click on the “Review Report ” button to produce the summary and review sheet. Use this printed report to double check data entry. For requests being forwarded to the NEO, include this completed page in the package.
3. Thoroughly read the description of proposed Outside Activity on pages 2-5 (Section II) of the HHS-520, and the description of current official duties on page 6 (Section III).
4. Compare the two descriptions, paying particular attention to how the proposed Outside Activity is described in relation to current official work. Obtain clarification from the employee if needed. You **MUST** conclude that there is **no overlap** between the proposed Outside Activity and current official work in order to recommend approval.
5. If the proposed activity involves general consulting, or legal consulting/testimony, or health care practice, confirm that the NIH-2657 is attached and completed correctly.
6. Document the review, using the appropriate section as outlined in the table above on page 4.
7. The IC Ethics Office staff will update information in EMIS, either completing the record for those activities under the IC DEC jurisdiction, or adding the date sent to the NIH Ethics Office for activities under the jurisdiction of the NIH DEC, including activities for NEAC review.
8. The next steps depend on whether the activity falls under the jurisdiction of the IC DEC or NIH DEC:
 - a. **IC DEC Jurisdiction:** Following the DEC decision, the IC Ethics Office staff will:
 - Make a copy of the entire package for the employee, and send the copy to the employee.
 - Finalize the record in EMIS by adding DEC signature date and action, and date copy sent to the employee. Correct any other information as needed.
 - File the original HHS-520 package in the employee’s ethics file.
 - b. **NIH DEC Jurisdiction:** Use this option for IC Directors, DECs, Senior employees, and all requests requiring NEAC review. Following IC DEC recommendation, the IC Ethics Office staff will:
 - Make a copy of the entire package for the IC Ethics Office file and forward the complete original package to the NIH Ethics Office.
 - Add relevant information to the EMIS record, i.e., date sent to NEO.

- For Senior Employees and DEC's: Original requests for Senior employees and DEC's are maintained by the NIH Ethics Office. Following NIH DEC decision, you will receive two signed copies from the NIH Ethics Office. Forward one to the employee; file the second copy in the employee's ethics file in the IC Ethics Office. Update EMIS with the final dates (received from NEO, copy to employee).
- For Other Employees: Following NIH DEC decision, you will receive the original request package back. Make a copy and forward it to the employee. Update EMIS with the last dates (received from NEO, copy to employee).

NIH Ethics Office (NEO) Staff/NIH DEC

1. Upon receipt of an Outside Activity request package from an IC Ethics Office, NEO staff will enter date received into EMIS.
2. Thoroughly read the description of the proposed Outside Activity on pages 2-5 (Section II) of the HHS-520, and the description of current official duties on page 6 (Section III).
3. Compare the two descriptions, paying particular attention to how the proposed Outside Activity is described in relation to current official work. Obtain clarification from the employee if needed. You **MUST** conclude that there is **no overlap** between the proposed Outside Activity and current official work in order to recommend approval.
4. If the proposed activity involves general consulting, or legal consulting/testimony, or health care practice, confirm that the NIH-2657 is attached and completed correctly.
5. Confirm whether the request is under the jurisdiction of the NIH Ethics Advisory Committee (NEAC) and the NIH DEC. If no, continue with step 5. If yes, continue with step 7.
6. Requests under the jurisdiction of the NIH DEC but not reviewed by NEAC (DECs and NIH senior where the request does not meet the criteria for NEAC review).
 - Confirm that the package is complete. Document review and recommendation. Forward to NEO Deputy Director.
 - NEO Deputy Director will confirm the specialists review and recommendation and forward to NIH DEC for final determination.
 - Upon receipt of the package back from the NIH DEC, continue with step 8.
7. Requests under NEAC and NIH DEC jurisdiction (all IC Director requests, and requests from all other employees which meet the criteria for NEAC review).
 - Confirm that the package is complete. Document review and recommendation. Forward the complete package to the NEO NEAC Coordinator.
 - NEAC Coordinator will process the request through NEAC. Following NEAC review, forward to NIH DEC for final determination.
 - Upon return from NIH DEC, NEAC Coordinator inform the employee of the decisions.

8. Final Steps: Copy, file, send to IC Ethics Office and Employee

The NIH Ethics Office maintains the original records for Senior NIH employees and DECAs. For these individuals, NEO staff will:

- Make 2 copies of the full request package with all signatures. Forward both copies to the IC Ethics Office with a note to forward one copy to the employee.
- Finish the record in EMIS by adding DEC action and date, and date copy sent to the employee. Add any other relevant information per the instructions for EMIS. Confirm that the EMIS record contains all information.
- File the original request package in the employee's ethics file in NEO.

For all other employees, NEO staff will:

- Make one copy for the employee's file in NEO.
- Enter relevant dates into EMIS, i.e., DEC action and date, forward to IC date.
- Return the original signed package to the IC Ethics Office (who will send a copy to the employee and finalize the record in EMIS).