

FDA

Procedure for Submitting the  
HHS-520 Request for Approval of Outside Activity

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## INTRODUCTION

The purpose of this procedure is to provide detailed instructions to employees to request approval of an Outside Activity.

**Due:** Submit through your Supervisor to your Center DEC-POC as soon as possible after your decision to engage in the activity, or at least 8 weeks prior to the proposed start date.

**Help:** For assistance, contact DEI Ethics Office staff, whose [names and addresses](#) are available on the FDA Ethics Program web site.

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. Detailed instructions are provided in the sections below.

**Note:** Internal Center procedures/deadlines are not detailed here. Contact your Center DEC-POC to determine if there are additional requirements.

## DESCRIPTION OF THE FORMS

HHS-520 is available on the FDA Ethics Program web site, on the Ethics Forms page: <http://inside.fda.gov:9003/downloads/EmployeeResources/Ethics/FDAEthicsProgram/UCM234747.pdf>

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. Employees must complete or 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. Reviewer instructions are available in a separate document, Reviewer Procedure for Form HHS-520 Request for Approval of an Outside Activity.

## EMPLOYEE RESPONSIBILITY

This section provides details for the employee to identify needed forms, obtain the forms, complete each required form appropriately, and assemble the request package for submission.

### GETTING STARTED

1. Obtain the HHS-520. Located here: <http://inside.fda.gov:9003/downloads/EmployeeResources/Ethics/FDAEthicsProgram/UCM234747.pdf>
2. Gather the information about the proposed Outside Activity, including any documents that must be submitted, i.e., invitation letter; copyright statement; syllabus; agenda; or outline.

3. Gather information about your current official duties, e.g., position description or equivalent (e.g., appointment letter for Title 42 appointees), description of your office functions, or other material to help you respond to the questions in Section III.

When you have gathered the necessary information and forms, complete the forms using the instructions in the following sections. There is a separate section for each form.

#### FORM HHS-520, REQUEST FOR APPROVAL OF OUTSIDE ACTIVITY

1. On the HHS-520 form, indicate whether this is the Initial Request, Revised Request, or a Renewal by checking the appropriate block.

Note: Renewals should be submitted 8 weeks prior to the expiration of the period authorized or within the time frame designated by your IC. Consult your IC's internal procedures.

2. Date Filed will be completed by the Supervisor.

#### Section I. Employee Information ( Page 1)

1. Name: Self explanatory
2. Agency (Op/Staff Div): FDA  
Agency (Subcomponent): Enter your Center's acronym and your Division or other office acronym
3. Title of Position: Enter your official job title.
4. Grade/Step: Enter your Grade and Step if you are GS or WG. If you are in a non-graded pay system, enter N/A.
5. Federal Salary: Enter your total annual federal salary amount, including locality pay.
6. Appointment Type: Check the relevant box to indicate your appointment type:
  - PAS/PA: Presidential Appointee Senate Confirmed / Presidential Appointee
  - Non-Career SES
  - Career SES: applies to SES appointees at the FDA
  - Schedule C
  - Commissioned Corps
  - GS: General Schedule: GS, GM, and WG employees
  - Title 42
  - Other: indicate the appointment type if none of the above fit
7. Financial Disclosure Filing Status: Indicate which form you file; OGE 278e Public or OGE 450 Confidential Financial Disclosure Report, or None if you are not required to file either report.
8. Office Address: Self-explanatory, give complete information.
9. Office Contact Information: Self-explanatory, give complete information.
10. Name of Immediate Supervisor: Self-explanatory.
11. Title of Supervisor: Self-explanatory.
12. Supervisor Contact Information: Self-explanatory, give complete information.

## Section II. Outside Activity Information ( Pages 2-5)

Provide the information requested about the proposed Outside Activity.

1. Nature of Outside Activity. Mark the block which best describes the type of activity you are requesting.

Describe. Thoroughly describe the activity, using non-scientific terms when possible.

Example: "Teaching": The proposed activity involves teaching a basic biology course at the University of Maryland, University College. The course, entitled Basic Biology (BIO 101), is an introductory, undergraduate level course covering basic biological terminology, basic biological functions, and basic laboratory experiments. No specific research information from my current or unpublished government research is expected to be part of the class. The syllabus is attached. The course is regularly scheduled during the fall and spring semesters, and occasionally during a summer session.

**Self-Employed Activity.** If you plan to be self-employed as described on the form, mark this box. Describe your service or product and your intended clients; i.e., specify the type of business, industry, or economic section.

Example: The self-employment activity involves providing individual and group psychological consultation and therapy in a private office. Clients will be individuals in the communities, or family groups who wish consultation and psychological counseling.

**Subject Matter of Activity.** For activities involving teaching, speaking, or writing, mark this block to indicate that you attached a syllabus or other description of the subject matter; e.g., a copy of the proposed speech, outline, agenda. List the attachment on page 14.

**Text of Disclaimer.** If your activity requires a disclaimer, mark the box to indicate that you have attached the disclaimer. For example, when you publish an article in a scientific or professional journal, you may be able to use your FDA title/affiliation with a disclaimer. Provide the text of the disclaimer in the space to the right of the box, on the Additional Space page (page 15) or as an attachment, and list the attachment on page 14.

Example Disclaimer Text: "This commentary was written by Dr. John Doe in his private capacity. The views expressed in this article/speech do not represent the views of or endorsement by the United States Government or the FDA."

2. Outside Employer or Other Entity: Provide the full name of the outside entity with which you propose to engage in an Outside Activity. Also provide the full name and title of your contact person at that organization. If you also have a logistical contact and that person is with a different organization (e.g., a PR/Marketing/Travel Agency, etc.), you should provide his/her name, organization, and other contact information on page 15 of the form under Additional Space. If you are requesting approval of self-employment, indicate "self-employment" and continue to question #3.
3. Outside Entity Address: Provide the full address of the outside entity, as indicated. If you are requesting approval of self-employment, enter the address of your proposed outside office. City and State are acceptable for self-employment.
4. Contact Information: Provide the required information for the contact person listed in #2. If you have a logistical contact person who is with a different organization, you should also provide that person's name, organization, and other contact information on page 15 of the form under Additional Space. If you are requesting approval of self-employment, indicate "self" in this block.

5. Location: Indicate the location where the activity or services will be performed. For example, if you wish to provide patient care, indicate the name of the clinic or hospital where you plan to work. If you are self-employed, indicate “home office” or the location of your office.
6. Travel: Indicate whether travel is involved by checking yes or no. If yes, indicate whether travel-related expenses will be at your own (personal) expense, or if the outside entity will provide in kind expenses (ticket, hotels, and/or meals paid directly by the entity), or will reimburse you. Include the estimated amount and describe what that entails. Do not report the honorarium, fee, or other payment for services here.

Example: Round trip coach class airfare (approximately \$700); 7 days lodging (approximately \$1200); per diem (approximately \$600); incidental expenses (approximately \$500).

7. Time: Indicate fully the time frame involved.
  - a. Period covered: Indicate the proposed start date and end date, using the format indicated, including travel time. Approval may be granted for one year only. Activities which are expected to last longer than one year must be renewed before the end of the approved time frame for the current request.
  - b. Estimated Total Time Devoted to the Proposed Activity: Indicate the total number of hours per day, the number of days per week, and the number of weeks in the year during which you plan to engage in the proposed activity. For partial hours/days/weeks, round up to the nearest hour/day/week.
  - c. Will work be performed entirely outside of usual working hours? Check either yes or no. If your answer is no, indicate the anticipated amount and type of leave you will use (i.e., approved annual leave or approved leave without pay).
8. Compensation: Indicate whether the activity is compensated, and if yes, answer the remainder of the question. Exclude travel expenses reported above, in #6.
  - a. Method or Basis of Compensation. Check each type of compensation that applies. If any non-travel related expenses will be reimbursed, describe that here. For example, indicate if you will receive reimbursement for expenses incurred in preparing for the activity, such as copying handouts.
  - b. Compensation Amount: Indicate the total amount of compensation, excluding the travel-related expenses already included in Part II, question #6.
  - c. Payor: If the entity which pays you is someone other than the entity to which you are providing services under this request (e.g., different than the entity listed in Part II, #2), provide the full name of the entity who will pay you and explain why; e.g., check issued by logistics or marketing firm hired by the outside entity to organize the meeting.
  - d. Funding Source: If your answer is “Yes” that funds will come from HHS, explain fully.

Example 1: You are a self-employed psychologist providing consultative and therapist services to individuals and groups, and you are a designated Medicare provider. You could receive HHS money when your accountant bills Medicare for your services. Even though Medicare and Medicaid are HHS programs, and therefore HHS funds, these programs are not considered ‘funding mechanisms’ under the HHS Supplemental Standards of Ethical Conduct (5 CFR 5501.106).

Note: You personally may not bill Medicare for your services (prohibited by statute regarding representation, 18 USC § 205). You must use the services of an accountant, billing service, or similar situation where that entity represents the client to obtain payment for services you rendered.

Example 2: You are presenting a talk at a conference which is receiving partial support from the HHS. Your compensation must be paid from the portion of funds derived from other than HHS funds. You may need to explain that in writing to the entity which invites you, and the entity must certify that no HHS funds are being used to compensate you. Annotate the HHS-520 to reflect this.

Note: Your compensation must be derived from other than HHS funds.

- e. Grantee, Contractor, or Other Status. Complete this section only for consultative or other professional services. Indicate whether the outside entity is a current grantee, contractor, or in another way will receive or intends to seek HHS funds, separate from your proposed Outside Activity. If your answer is "Yes", explain fully. Seek information from the proposed outside employer, if necessary, to adequately respond.
- f. Record of Prior Compensation from Same Source: This section requires you to list all previous compensation and activities with the same outside entity for the past six calendar years plus the current year. It may be previous payments associated with the current request for renewal, or it may be previous Outside Activities with the same entity, even though they ended in the past. You may use approximate dates for payments received in the distant past. Use one or both lines for each numbered activity. See the example below.

### Section III. Official Duty Information (Page 6)

This section requests information about your current official duties and responsibilities to permit an adequate conflicts analysis between the proposed activity and your current official work.

1. Nature of Official Duties: Either attach a Position Description that accurately describes your current duties or describe your main duties and responsibilities here. Include the topic and substance of your research; the specifics about your administrative duties; the types of outside entities with which you routinely interact; and what that interaction involves. You may use official descriptions of your office, but you must also include a description of the substance of what you do officially, e.g., research in what specific areas; or manage grants in what program area.
2. Relationship of Official Duties to Outside Activity: Describe any of your official duties which relate in any way to the proposed activity. If there is no relatedness, explain why there is none.

Example 1: You are an extramural program administrator and you wish to teach a class at a local university. Your response to this question may be:

Official duties do not relate to this proposed activity. Official duties involve administering grants in the specific area of obesity in children, whereas the substance of the outside activity is research processes, how to design and carry out a good research project. I must know how to design and conduct a valid research project to function as a program administrator, but that knowledge is general and not specific to FDA nor specific to my official position.

Example 2: You are an intramural research scientist and you wish to give a Continuing Medical Education (CME) talks at a local medical center. Your response to this question may be:

My official duties involve conducting research on adolescent brain function and interacting with

researchers, e.g., publishing in research and other scientific journals. The substance of the outside activity is to teach on the general topic of neurology, which is considerably broader than my research area, and relies on my education and expertise, much of which was gained prior to my position at the FDA. The audience will be mainly practitioners rather than researchers.

3. **Effect of Official Duties on Outside Employer:** In performing your official duties, are there any matters which would affect the interests of the proposed outside employer? Explain why or why not. For example, are you a Health Scientist Administrator with a certain university in your grant portfolio and you wish to teach at the university? Explain the details. It is permissible to indicate that your official duties have no effect on the outside entity; provide a justification for why that is true.
4. **Assignments Involving Outside Employer:** Describe any official interactions or matters involving the outside entity in which you were involved during the past year, for example, grant applications you reviewed, pending decisions, or any other particular matters involving the proposed outside organization. Include all facts about the situation to permit a full and complete analysis. The following examples are illustrative only, and are not meant to imply that such activities would always be approved.

Example 1: Approximately 3 months ago, I reviewed a grant application from this university. The application was not funded and there has been no further interaction with the university.

Example 2: I am working on a Cooperative Research and Development Agreement (CRADA) involving the outside organization, but I have no decision making responsibilities and have no contact with the CRADA partner in my official capacity. My official work is purely technical assistance behind the scenes, a function I may do for any number of CRADAs and other projects being undertaken in the lab.

5. **Certification:** Sign and date, certifying that the responses are true and complete to the best of your knowledge. Note that you need to read the notices in Section VIII (pages 11-13) of the form prior to signing. Your signature certifies that you have read the notices and will abide by the requirements therein. Employees are encouraged to sign electronically using their FDA-issued PIV card so that the signature is authenticated.

#### List of Attachments (Page 14)

Remember to list all attachments where indicated on page 14 of the form. For example, you must list and attach any of the applicable items, e.g., invitation letter, syllabus, agenda, outline, and organization documentation. Label each attachment to clearly identify it; e.g.,

1. Invitation Letter
2. Position Description

#### ADDITIONAL INFORMATION REQUIRED

Review the following questions. If any apply to you, submit the required information. You may seek assistance from your [ethics office staff](#) at any time, including prior to submission of your request package.

1. Is the outside entity a foreign organization? The Emoluments Clause of the US Constitution prohibits Federal Government employees from accepting 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 needed, submit proof whether it is (or is not) a foreign government entity. You may work with the FDA Ethics Office staff to identify needed information and who will obtain it. Foreign entity determinations are confirmed by the FDA Ethics Office and the

Office of the General Counsel, Ethics Division, before you may be permitted to engage in the activity. This applies only to those organizations which are not clearly outside of the government. Private sector businesses do not need this review. Ethics staff needs the following information to confirm whether the entity is, or is not, foreign government.

- A. What is the funding source – government or private sector? If it is a private sector company or organization, the Emoluments Clause does not apply and there are no restrictions. If the funding source is the foreign government, then proceed to Step B.
- B. Is the foreign entity an educational institution? If yes, continue with Step C. If no, the employee may engage in the activity only as permitted by Congress in the FGDA, i.e., no payment over the minimal gift amount (currently the amount is \$375), and travel expenses only for travel which originates and ends outside of the US and its territories. So the employee may not accept travel expenses from a local airport; the employee must get himself or herself to a foreign departure point at his/her own expense. The foreign government can then pay for round trip travel from that point, and all expenses for lodging, meals, and incidentals in a foreign area.
- C. For an educational institution, you can use the analysis provided by the Office of Legal Counsel (OLC) in the DOJ in their decision regarding the University of Victoria (1998). That opinion indicated that when an educational institution operates autonomously, for purposes of the Emoluments Clause, it will be considered “non-government.” Operating autonomously means that the institution establishes its own rules, appoints board members, and makes all hiring decisions, all without intervention or approval by the government. In addition, its employees are NOT considered Government employees.

You may be asked by your ethics staff to obtain the following information to determine whether the foreign entity is (or is not) considered government.

- Does the educational institution establish its own constitution, bylaws, and operating rules without a government official reviewing and approving them? If the government official must approve them, then the government runs the university.
  - Who appoints the Board? If the government appoints any board members, what percentage are appointed by the government? If the government appoints the majority of the board members, that means the government runs the university.
  - Are the employees of the educational institution considered government workers? If yes, then it is an entity of the foreign government.
  - Does a government official or agency oversee the institution and approve or disapprove the decisions? This means operational decisions, not the general government oversight of all universities to ensure they are compliant with the laws of the nation.
2. 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. This web site contains a list of foundations with private status confirmed. If a foundation is not listed, you may need to contact the organization’s Counsel and ask for a copy of the IRS determination letter, or you may check IRS Publication 78, which provides the status of the foundations registered with IRS. Help for searching and understanding the codes is provided on the IRS web site.  
<http://www.irs.gov/charities/article/0,,id=96136,00.html>

You may contact your [FDA Ethics Office staff](#) at any time for assistance in obtaining the correct information. If the organization is not listed in the web site, it must be reviewed by the FDA Ethics Office and Office of the General Counsel staff for a definitive determination. Your proposed Outside Activity cannot be approved until after that determination is made.



Note: Any information added to your Outside Activity request as a result of this review must be listed on Page 14 of the HHS-520 and clearly labeled.

3. Is the outside entity a Significantly Regulated Organization (SRO)? If yes, you will need to consider whether the proposed activity is prohibited by the HHS Supplemental Standards of Ethical Conduct (5 CFR 5501.106c3), 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. SRO determination may be made using information obtained from two separate databases (Public & Private) located here:  
<http://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/ucm079670.htm>

Note: Any information added to your Outside Activity request as a result of this review must be listed on Page 14 of the HHS-520 and clearly labeled.

#### ASSEMBLE YOUR OUTSIDE ACTIVITY REQUEST PACKAGE ELECTRONICALLY

Double check your package to ensure that you have responded to all questions, completed the list of attachments, and labeled the attachments. Assemble your electronic request package in the following order:

- Form HHS-520 (PDF)
- Invitation letter or electronic mail
- Other information – syllabus,  
etc.

#### SAVE A COPY FOR YOUR RECORDS

The complete HHS 520 package needs to be routed to the following individuals for review/approval::

1. employee's supervisor;
2. Center DEC-POC to obtain designated reviewing official approval (Centers – the Director or Deputy Center Director; OC – the Office Director; ORA – the Associate Commissioner for Regulatory Affairs for employees at Headquarters or your District Director for employees in the Field);
3. Division of Ethics and Integrity Staff for an ethics review via the Advice Team inbox at [FDAethics\\_Advice@fda.hhs.gov](mailto:FDAethics_Advice@fda.hhs.gov); and
4. Agency designee for final approval/disapproval.

Once approved, the HHS 520 package will be returned to the employee, his/her supervisor, and the Center DEC POC.