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otherwise prohibited by this section under the following conditions:

(1) There is a determination by the NIH Director (or the Secretary, with respect to awards tendered to the NIH Director) that acceptance of the gift will further an agency interest because it confers an exceptionally high honor in the fields of medicine or scientific research. The following criteria will be considered in making such a determination:

- (i) The identity of the awarding organization;
- (ii) The longevity of the awards program;
- (iii) The source of award funds;
- (iv) The size of the monetary component of the award recognition;
- (v) The identity and credentials of past award recipients;
- (vi) The degree of publicity attendant to receipt of the award; and
- (vii) The impact of the substantive contribution being recognized;

(2) Absent the prohibition in paragraph (c)(1) of this section, the gift would be permitted under part 2635 of this title; and

(3) The designated agency ethics official shall have determined that the application of the prohibition in paragraph (c)(1) of this section is not necessary to ensure public confidence in the impartiality or objectivity with which NIH programs are administered or to avoid a violation of part 2635 of this title.

(e) *Disposition of improperly accepted awards*—(1) *Failure to obtain prior approval.* If an employee accepts an award for which approval is required under paragraph (c)(2) of this section without obtaining such approval, the employee may be required, in addition to any penalty provided by law and applicable regulations, to forfeit the award by returning it to the donor.

(2) *Receipt of prohibited award.* If an employee accepts an award prohibited by paragraph (c)(1) of this section, the employee shall be required, in addition to any penalty provided by law and applicable regulations, to:

- (i) Reject the award and instruct the donor to strike the honoree's name from any list of award recipients;

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(ii) Remove the recognition from the employee's résumé or curriculum vitae;

(iii) Return any tangible indicia of the recognition to the donor; and

(iv) Forfeit the award by returning it to the donor.

[70 FR 5563, Feb. 3, 2005, as amended at 70 FR 51572, Aug. 31, 2005]

§ 5501.112 One-year disqualification of employees of the National Institutes of Health from certain matters involving an award donor.

An employee, other than a special Government employee, of the National Institutes of Health who has, within the last year, accepted an award permitted under 5 CFR 2635.204(d) or § 5501.111 shall not participate in any particular matter involving specific parties in which the donor is or represents a party unless authorized to do so under 5 CFR 2635.502(d).

[70 FR 5564, Feb. 3, 2005]

PART 5502—SUPPLEMENTAL FINANCIAL DISCLOSURE REQUIREMENTS FOR EMPLOYEES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Sec.

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5502.107 Supplemental disclosure of financial interests in substantially affected organizations applicable to employees of the National Institutes of Health.

AUTHORITY: 5 U.S.C. 301, 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2634.103.

SOURCE: 70 FR 5564, Feb. 3, 2005, unless otherwise noted.

§ 5502.101 General.

The regulations in this part apply to employees of the Department of Health and Human Services and supplement

the Executive Branch Financial Disclosure Regulations in 5 CFR part 2634. Any regulation in this part made applicable only to the employees of an HHS component designated as a separate agency under § 5501.102(a) of this chapter shall apply to the employees of that component as defined in § 5501.102(b)(1) of this chapter.

§ 5502.102 Annual supplemental report of outside employment or activities.

Any employee, other than a special Government employee, for whom an outside employment or activity has been approved, or who has participated in any outside employment or activity for which prior approval is required, under part 5501 of this chapter shall file on or before February 28 of each year a report concerning all such activities that were approved or undertaken in the previous calendar year. The annual report shall be filed with the employee's supervisor who shall review the form, in consultation with an agency ethics official, and determine whether the employee has complied with applicable laws and regulations and whether approval of any ongoing outside activity should be cancelled because the activity does not meet the standard in § 5501.106(d)(5) of this chapter.

[70 FR 5564, Feb. 3, 2005, as amended at 70 FR 51573, Aug. 31, 2005]

§ 5502.103 Content of annual supplemental reports.

The annual supplemental report of outside employment or activities required by § 5502.102 shall include the following information:

(a) The employee's name, contact information, organizational location, occupational title, grade, step, salary, appointment type, and financial disclosure filing status;

(b) A list of all outside activities for which prior approval is required under part 5501 of this chapter that were approved pursuant to 5 CFR 5501.106(d) or undertaken within the reporting period. The report must identify the person or organization for whom or with which the employee was to perform the activity and the approval date;

(c) A statement as to whether the anticipated work described in a previously approved outside activity was

actually performed for the person or organization named in the request for approval;

(d) For each outside activity actually performed, the beginning date of the relationship with the outside entity, the date(s) personal services were provided, the total number of hours spent and leave used on the activity within the reporting period, and the ending date;

(e) For each outside activity that remains ongoing at the time of filing the report, a statement as to how long the activity is anticipated to continue, the date on which prior approval expires, and whether a request for renewal of approval is anticipated;

(f) For each outside activity actually performed, the type and amount of any income and/or reimbursements actually received during the reporting period and the date paid;

(g) For each outside activity actually performed, the type and amount of any income and/or reimbursements earned during or attributable to the reporting period that were not in fact received during the reporting period and remain due;

(h) A statement as to whether any change has occurred or is anticipated with respect to information supplied in the original outside activity approval request;

(i) A description of any change in the nature, scope, or subject matter of any approved activity; and

(j) A description of any change in jobs or in the duties and responsibilities of the employee's position that occurred after the outside activity was approved.

§ 5502.104 Confidentiality of reports.

Each report filed under this part is confidential and shall not be disclosed to the public, except as provided under § 2634.604(b) of this title.

§ 5502.105 Agency procedures.

(a) The designated agency ethics official or, with the concurrence of the designated agency ethics official, each of the separate agency components of HHS listed in § 5501.102(a) of this chapter may prescribe forms for the collection of information under this part and establish procedures for the submission

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and review of each report filed. These procedures may provide for filing extensions, for good cause shown, totaling not more than 90 days.

(b) For good cause, the designated agency ethics official may extend the reporting deadlines for reports required under this part during the initial implementation phase for any reporting requirement, without regard to the 90 day maximum specified in paragraph (a) of this section.

[70 FR 37009, June 28, 2005, as amended at 70 FR 51573, Aug. 31, 2005]

§ 5502.106 Supplemental disclosure of prohibited financial interests applicable to employees of the Food and Drug Administration.

(a) *Applicability.* This section does not apply to special Government employees.

(b) *Definitions.* For purposes of this section:

(1) *Confidential filer* means an employee who meets the criteria in 5 CFR 2634.904 and who has not been excluded from the requirement of filing a confidential financial disclosure report under the procedures in 5 CFR 2634.905.

(2) *Prohibited financial interest* means a financial interest prohibited by § 5501.104(a), including those financial interests that are excepted under § 5501.104(b) of this chapter.

(3) *Public filer* means an employee who meets the criteria in 5 CFR 2634.202 and who has not been excluded from the requirement of filing a public financial disclosure report under the procedures in 5 CFR 2634.203.

(4) *Remainder of HHS* has the meaning set forth in § 5501.102(b)(2) of this chapter.

(5) *Separate agency component* has the meaning set forth in § 5501.102(a) of this chapter.

(c) *Report of prohibited financial interests*—(1) *New entrant employees.* A new entrant employee shall report in writing within 30 days after entering on duty with the FDA any prohibited financial interest and the value thereof held upon commencement of employment with the agency.

(2) *Reassigned employees.* An employee of a separate agency component other than the FDA or of the remainder of HHS who is reassigned to a position at

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the FDA shall report in writing within 30 days of entering on duty with the FDA any prohibited financial interest and the value thereof held on the effective date of the reassignment to the agency.

(3) *Incumbent employees.* An incumbent employee of the FDA who acquires any prohibited financial interest shall report such interest and the value thereof in writing within 30 days after acquiring the financial interest.

[70 FR 5564, Feb. 3, 2005, as amended at 70 FR 51573, Aug. 31, 2005; 70 FR 61713, Oct. 26, 2005]

§ 5502.107 Supplemental disclosure of financial interests in substantially affected organizations applicable to employees of the National Institutes of Health.

(a) *Applicability.* This section does not apply to special Government employees.

(b) *Definitions.* For purposes of this section:

(1) *Clinical investigator* means an employee identified as a principal investigator, accountable investigator, lead associate investigator, medical advisory investigator, associate investigator, or other subinvestigator in an NIH clinical study involving human subjects under a clinical research protocol approved by an institutional review board.

(2) *Clinical research* has the meaning set forth in 42 U.S.C. 284d(b).

(3) *Institutional review board* (IRB) means any board, committee, or other group formally designated by an institution to review a clinical research protocol and approve the initiation of biomedical research involving human subjects and to assess periodically the progress of the investigation to protect the rights and welfare of the trial participants.

(4) *Confidential filer* means an employee who meets the criteria in 5 CFR 2634.904 and who has not been excluded from the requirement of filing a confidential financial disclosure report under the procedures in 5 CFR 2634.905.

(5) *Public filer* means an employee who meets the criteria in 5 CFR 2634.202 and who has not been excluded from the requirement of filing a public financial disclosure report under the procedures in 5 CFR 2634.203.

(6) *Remainder of HHS* has the meaning set forth in § 5501.102(b)(2) of this chapter.

(7) *Separate agency component* has the meaning set forth in § 5501.102(a) of this chapter.

(8) *Substantially affected organization* has the meaning set forth in § 5501.109(b)(10) of this chapter.

(c) *Report of financial interests in substantially affected organizations*—(1) *New entrant employees*. A new entrant employee who is a public filer or a confidential filer or who is designated to serve as a clinical investigator shall report in writing within 30 days after entering on duty with the NIH any financial interest in a substantially affected organization and the value thereof held upon commencement of employment with the agency.

(2) *Reassigned employees*. An employee of a separate agency component, other than the NIH, or of the remainder of HHS who is either a public filer, a confidential filer, or a clinical investigator who is reassigned to a position at the NIH shall report in writing within 30 days of entering on duty with the NIH any financial interest in a substantially affected organization and the value thereof held on the effective date of the reassignment to the agency.

(3) *Incumbent employees*. An incumbent employee of the NIH who is either a public filer, a confidential filer, or a clinical investigator who acquires any financial interest in a substantially affected organization shall report such interest and the value thereof in writing within 30 days after acquiring the financial interest. Any incumbent employee, irrespective of financial disclosure filing status, who is designated a clinical investigator shall report in writing within 30 days of the approval of the clinical research protocol by the relevant institutional review board any financial interest in a substantially affected organization and the value thereof held on the date of the IRB approval.

(4) *Initial report by on duty employees*. An employee on duty at the NIH on August 31, 2005, who is either a public filer, a confidential filer, or a clinical investigator shall report in writing on or before October 31, 2005, any financial interest in a substantially affected organization and the value thereof held on the date the report is filed.

[70 FR 51573, Aug. 31, 2005, as amended at 70 FR 61713, Oct. 26, 2005]

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