

(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]

#### PARTS 5503–5599 [RESERVED]