

At. 20

Public reporting burden for this collection of information is estimated to average 80 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0417). Do not return the completed form to this address.

### **Disclosure for Institutions**

#### **42 CFR § 50.605 Management and reporting of financial conflicts of interest.**

(a) Management of financial conflicts of interest.

(3) Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

(ii)

(A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period

of the noncompliance, was biased in the design, conduct, or reporting of such research.

(B) The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has a financial conflict of interest;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.

#### **45 CFR § 94.5 Management and reporting of financial conflicts of interest.**

(a) Management of financial conflicts of interest.

(3) Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

(ii)

(A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of

interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

(B) The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has a financial conflict of interest;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.