RETROSPECTIVE REVIEW

1. Whenever (i) an FCOI is not identified or managed in a timely manner (including failure by the Investigator to disclose an SFI that is determined by the Institution to constitute an FCOI; (2) failure by the Institution to review or manage such a financial conflict of interest; or (iii) failure by the Investigator to comply with an FCOI management plan, the designated official shall, within 120 days of the Institution’s determination of noncompliance, complete a retrospective review to determine whether any research, or portion thereof, conducted prior to the identification and management of the Financial Conflict of Interest was biased in the design, conduct, or reporting of such research.

2. The Institution must document the retrospective review. Such documentation shall include, but not necessarily be limited to, all of the following key elements:

   (a) Project number;
   (b) Project title;
   (c) Name of the Principal Investigator;
   (d) Name of the Investigator with the FCOI;
   (e) Name of the entity with which the Investigator has a financial conflict of interest;
   (f) Reason(s) for the retrospective review;
   (g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
   (h) Findings of the review; and
   (i) Conclusions of the review.

3. Based on the results of the retrospective review, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. The mitigation report must include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution’s plan of action or actions taken to eliminate or mitigate the effect of the bias. Thereafter, the Institution will continue to submit FCOI reports annually. Depending on the nature of the FCOI, an Institution may determine that additional interim measures are necessary with regard to the Investigator’s participation in the research project between the date that the FCOI or the Investigator’s noncompliance is determined and the completion of the Institution’s retrospective review.

4. When an FCOI report involves an SFI that was not disclosed timely by an Investigator or, for whatever reason was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to complete a retrospective review to determine whether any research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of research.