

Expedited Review of Financial Conflict of Interest Disclosures (PAF)

The conflict review committee (CRC) has instituted procedures for expedited review of SEAMs associated with PAFs to facilitate prompt review of proposals. This procedure has been approved by the Vice Chancellor for Research (VCR). This document describes the expedited review procedures.

When a financial conflict of interest (COI) is disclosed on a Proposal Approval Form (PAF) Office of Research Services (ORS) institutes a "COI hold." The COI hold functions to prevent the contract/grant from being executed until the conflict of interest disclosed is managed, reduced, or eliminated. The COI hold does not preclude submission of the grant application or proposal.

A COI disclosure typically requires that a Statement of Explanation and Management (SEAM) be submitted with the PAF. SEAMs will be processed by the COI Office according to the funding source (competitive review will follow the Just-In-Time Model described below; all other will be processed upon receipt).

JUST-IN-TIME MODEL. The COI office uses a just-in-time model for reviewing SEAMs submitted with proposals undergoing competitive review. The principal investigator on the grant should contact us when he/she has an indication that the proposal might be funded. Upon notification from the investigator(s) that the proposal is likely to be funded, the COI office will work with investigator(s) to provide feedback and make revisions.

Expedited review procedures are used as an initial screening tool to review the SEAM and the pertinent ORS documents. If the expedited review leads to a recommendation that the COI be considered managed, the COI Office notifies ORS that an approved SEAM is on file and the COI hold may be released. If the expedited review does not lead to a recommendation that the COI be considered managed, the SEAM is referred to the full CRC for review and recommendation.

The COI Office will maintain documents regarding the conflict management plan (SEAM) and its review. Documents provided by ORS will be maintained by ORS according to their document management procedures.

- Under the expedited review, person(s) who are members of the UIC CRC is/are assigned as reviewer/s to the SEAM on the PAF submission when a conflict of interest is disclosed by an investigator on the PAF COI Certification.
- Reviewer/s act on behalf of the CRC, supporting the CRC's role as advisory to the VCR.
- The reviewer/s evaluate whether significant financial COIs disclosed on PAFs are appropriately managed. In doing so, the reviewer/s evaluate the SEAM. "Significance" is defined by relevant University policies.
- A recommendation for the approval of a SEAM for a PAF by expedited procedures is complete by itself and does not require any further review or ratification by the full CRC.

However, the CRC may ask questions about any COI disclosures on PAFs previously approved under expedited procedures, and choose to re-review those COI disclosures on PAFs.

- The reviewer/s may consult with others as needed, such as the COI Coordinator, ORS staff, OPRS staff, the Associate Director for Research Compliance, Legal Counsel, Assistant Vice Chancellor, Associate Vice Chancellor, etc. If revisions of the SEAM are requested by the reviewer/s, COI office staff work with the investigator during the revision process.
- If the reviewer/s assess that there is sufficient reason for not considering the COI to be managed by the SEAM (even if revised), or the nature of the COI is not suitable for expedited review, then the reviewer/s must refer the SEAM and PAF to the full CRC for its review.
- If the reviewer/s assess that a formal Report of Non-University Activities - Management Plan (RNUA-MP) is needed, the SEAM may be recommended for approval, but final approval will require the implementation of the RNUA-MP.
- If the investigator appeals the decision of the reviewer/s, the matter will be referred to the full CRC.
- Under expedited review procedures, the reviewer/s may make the following recommendations to ORS on behalf of the CRC and the VCR:
 - The SEAM as presented or revised is an acceptable mechanism for managing the potential conflicts of interest.
 - After the development and approval by the VCR of a formal RNUA-MP, then the SEAM (as presented or revised) is an acceptable mechanism for managing the potential conflicts of interest.
 - Refer the SEAM and PAF to the full CRC for review.
- The CRC is informed of all recommendations to ORS on behalf of the Vice Chancellor made under this expedited review process.
- The VCR is informed of, and approves, all recommendations to ORS made under this expedited review process.