Expedited Review of Financial Conflicts of Interest on IRB Applications: Type 1 & Type 2 Review Procedures

The Conflict Review Committee (CRC) has instituted procedures for expedited review of Conflict of Interest (COI) Significant Financial Interest-Disclosure and Management Plan (SFI-DMP) associated with IRB applications to facilitate prompt review. This procedure has been approved by the Vice Chancellor for Research (VCR). This document outlines two expedited review procedures:

- **Type 1** expedited review is the primary expedited review procedure, and is conducted by the COI Human Subjects Research Committee (COI-HSR committee). Type 1 expedited review is used for all new submissions, and all amendments/continuing reviews that do not qualify for Type 2 expedited review.

- **Type 2** expedited review procedures may be used for amendments/continuing review of protocols which have previously been reviewed and received a recommendation from the COI-HSR committee that the conflict be considered managed, and in which neither the COI nor the SFI-DMP has changed since the previous review.

These expedited review procedures are used to review SFI-DMPs and the relevant human subjects research protocol submissions to Institutional Review Boards (IRBs) instead of submitting SFI-DMPs for a full CRC review. If Type 1 or Type 2 expedited reviews lead to a recommendation that the COI be considered managed, the recommendation goes to the IRB for its review and final determination.

When OPRS sends a protocol submission to the COI office for review, a COI administrator conducts a pre-screening of the protocol to determine whether it is subject to Type 1 or Type 2 expedited procedures. Other members of the COI-HSR committee or the CRC may be consulted in reaching that determination. The criteria for each type of expedited review are presented below. Type 1 expedited review procedures will be used unless it is clear that the submission qualifies for Type 2 review procedures.

By inclusion on the next-available CRC meeting agenda, the CRC is informed of all recommendations made under Type 1 and Type 2 expedited review processes. The COI Office will maintain documents for the conflict management plan (SFI-DMP) and COI-HSR committee review. Documents provided by the Office for the Protection of Research Subjects (OPRS) will be maintained by OPRS according to their document management procedures.

- **Type 1 Expedited Review** –

*Type 1 expedited review procedures are appropriate for:*  
- Review of new COI disclosures on IRB protocols, and amendments/continuing reviews not meeting the criteria outlined below for Type 2 expedited review.
- Evaluation of whether a previously-reviewed and implemented SFI-DMP or a management mechanism contained therein is no longer needed.
- Evaluation of whether a previously-reviewed and implemented SFI-DMP should be changed to include other (non-required or non-standard) mechanisms.

*Type 1 expedited reviews are conducted by:*  
- Type 1 expedited review procedures are performed by the COI-HSR committee. The COI-HSR committee is an ad-hoc committee consisting of at least three reviewers, at least one of
which is a member of the CRC. Reviewers may include but are not limited to COI administrators, OPRS administrators, ORS administrators, OACIB administrators, research compliance administrators, Legal Counsel, and Associate Vice Chancellor for Research. The COI-HSR committee may consult with others as needed.

- The Vice Chancellor for Research is informed of and approves the reviewers included in this committee.
- Reviewers represent the CRC, supporting the CRC’s role as advisory to the Vice Chancellor for Research.

**Type 1 expedited review procedures:**

- The COI-HSR committee evaluates whether Financial Conflicts of Interest (FCOIs) disclosed on IRB applications are appropriately managed. In doing so, the committee reviews the COI-SFI-DMP and the IRB submission provided by OPRS. "Significance" is defined by relevant University policies. If revisions of the SFI-DMP are requested by the committee, COI office staff work with the investigator during the revision process.

- The COI-HSR committee provides protocol-specific recommendations to the IRB. The IRB has the final authority to approve the research protocol, including the COI management mechanisms, and may request that the SFI-DMP be changed.

- A recommendation for approval of the SFI-DMP by expedited procedures is complete by itself and does not require any further review or ratification by the full CRC.

- If the COI-HSR committee believes that there is sufficient reason for not considering the COI managed by the SFI-DMP (even if revised or augmented by a RNUA-MP), or that the nature of the COI requires review by the full CRC, the committee must refer the SFI-DMP and IRB submission to the CRC.

- If the committee believes that a formal Report of Non-University Activities - Management Plan (RNUA-MP) is needed, the SFI-DMP may be recommended for approval, but the final recommendation for approval will require the implementation of the RNUA-MP. Exceptions to this guideline may be requested by or on behalf of the investigator. Requests for exceptions are evaluated by the COI-HSR committee in consultation with the CRC Chair.

- The COI-HSR committee may make the following recommendations to the IRB:
  - The SFI-DMP as presented or revised is an acceptable mechanism for managing the potential financial conflict of interest.
  - After the development and approval by the Vice Chancellor for Research of a formal RNUA-MP, then the SFI-DMP (as presented or revised) is an acceptable mechanism for managing the potential financial conflict of interest.

- **Type 2 expedited review –**

**Type 2 expedited review procedures are appropriate for:**

- Review of continuing review/amendment submissions of IRB protocols meeting the following criteria:
  1. The COI-HSR committee has previously reviewed the protocol and the SFI-DMP, and has recommended to the IRB that the conflict be considered managed; and
  2. Neither the COI nor the SFI-DMP has changed since the previous COI review, or, any changes in the COI or the SFI-DMP are in accordance with standard required management mechanisms. The following are examples of changes that may qualify for Type 2 expedited review:
• Changes to the protocol are unrelated to, and do not affect, the COI or its management.
• Changes in the SFI-DMP reflect changed title of protocol or addition/removal of non-conflicted investigators.
• The COI has been eliminated (e.g., a conflicted investigator has been removed) but the management mechanisms outlined in SFI-DMP remain in place.
• Changes in the SFI-DMP reflect the inclusion of required standard management mechanisms not previously in the SFI-DMP, when the situation that presents the conflict of interest has not changed.

**Type 2 expedited reviews are conducted by:**

- Type 2 expedited review procedures are performed by a single member of the COI-HSR committee, who is also a member of the CRC. The reviewer represents the CRC, supporting the CRC’s role as advisory to the Vice Chancellor for Research.
- The reviewer may consult with others as needed, including members of the COI-HSR committee and the CRC.

**Type 2 expedited review procedures:**

- The reviewer evaluates whether Financial Conflicts of Interest (FCOIs) disclosed on IRB amendment /continuing review applications, having previously been approved, continue to be appropriately managed by an existing SFI-DMP. In doing so, the reviewer assesses the SFI-DMP and IRB submission provided by OPRS. "Significance" is defined by relevant University policies.
- The reviewer may request revisions of the SFI-DMP. The COI office works with the investigator during the revision process. If the revised SFI-DMP is changed beyond the qualifying conditions described above, the documents may not undergo Type 2 expedited review, and must be instead be reviewed using Type 1 expedited review.
- The reviewer only provides protocol-specific recommendations on the management of the conflict of interest to the IRB. The IRB has the final authority to approve the research protocol, including the COI management mechanisms, and may request that the SFI-DMP be changed.
- A recommendation for approval of the SFI-DMP by these expedited procedures is complete by itself and does not require any further review or ratification by the COI-HSR committee or the full CRC.
- If the reviewer believes that (a) there is sufficient reason for not considering the COI to be managed by the SFI-DMP (even if revised); (b) the nature of the COI requires full review by the CRC, or (c) the situation does not meet the qualifying conditions for Type 2 expedited review, the reviewer must refer the SFI-DMP and IRB submission for Type 1 review.
- If the reviewer believes that a formal RNUA-MP is needed but one is not yet in place, the protocol must be referred to the COI-HSR committee for Type 1 expedited review.
- The reviewer may make the following recommendations:
  - Recommend to the IRB that the SFI-DMP as presented or revised is an acceptable mechanism for managing the potential conflicts of interest.
  - Refer the SFI-DMP and the IRB submission to the full COI-HSR committee for Type 1 expedited review.

Contact the Conflict of Interest office at coi@uic.edu