Title: DCP Guidance Regarding Reporting Financial Conflict of Interest

Version: 1.1

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REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
1.1	MAY-06-2025	Updated the URL for the FCOI Submission Instructions.
1.0	SEP-29-2023	Original version of document.

1. INTRODUCTION AND PURPOSE

The Division of Cancer Prevention (DCP) guidance regarding reporting Financial Conflict of Interest (FCOI) clarifies expectations and shares resources regarding the National Institutes of Health (NIH) FCOI policy and the DCP process related to early phase cancer prevention studies conducted in the Cancer Prevention Clinical Trials Network (CP-CTNet).

2. DEFINITIONS

Term	Definition
AE	Adverse Event
CIRB	Central Institutional Review Board
CP-CTNet	Cancer Prevention Clinical Trials Network
CPC	Cancer Prevention and Control
DCP	Division of Cancer Prevention
eRA	Electronic Research Administration
FCOI	Financial Conflict of Interest
LAO	Lead Academic Organization
NIH	National Institutes of Health
SAE	Serious Adverse Event
SO	Signing Official

3. KNOWN FCOI FOR A STUDY TEAM MEMBER

This section highlights important information that CP-CTNet members must consider when there is a known FCOI regarding a member of the study team. When an Investigator has multiple FCOIs with different entities, the grantee is required to submit one FCOI report per entity. If there are multiple members of the study team with a known FCOI, this guidance should be followed for each study team member.

1. Proper submission of the conflict should first occur at the conflicted team member's institution.

    1.1. An FCOI management plan should be available, formally noted (usually in a letter), and shared with the LAO overseeing the protocol where the FCOI is relevant.

    1.2. The LAO should review the management plan for their information and in readiness to communicate the conflict as needed (e.g., to the CIRB and DCP).

2. Per the NCI CIRB SOP: The management plan needs to describe the plans to avoid bias in data collection and analysis.

3. Since CP-CTNet is managed under the NIH cooperative agreement mechanism, the LAO should collaborate closely with their Office of Sponsored Research or Clinical Trials Office to properly address any FCOI as per NIH rules for grants and cooperative agreements. Please see the NIH FCOI Policy and NOT-OD-22-210 for more information.

    3.1. The FCOI from the conflicted team member's institution needs to be reported by the CP-CTNet cooperative agreement grant recipient (i.e., the LAO) through the eRA Commons *FCOI Module* by the LAO's Signing Official (SO) with an FCOI role and then reviewed by NIH program and grants management staff. Please see the FCOI Submission Instructions for additional guidance.

3.2. In addition to the required FCOI reporting, the LAO should notify via encrypted email the DCP Program Official, Study Team (Scientific Lead, Medical Monitor, and Nurse Consultant), and CPC CIRB immediately of any changes to the initial FCOIs, and of any new FCOIs.

3.3. Initial, annual or modified FCOIs should follow the NIH FCOI reporting rules noted above and also consider any CPC CIRB-specific reporting requirements (See CIRB SOP "Study Leader Financial Conflict of Interest" Section 8.1.2). Generally, the more stringent reporting requirements will apply if there are discrepancies between reporting thresholds in the institutional requirements/FCOI management plans and the CPC CIRB's financial conflict of interest reporting requirements.

4. As per the *CP-CTNet Concept Submission Form*, an FCOI should be noted by the submitting LAO team with the concept submission.

5. During protocol development:

   The institutional letter regarding the FCOI management may have specific requirements or guidance on the informed consent and/or protocol language.

   5.1. Consider language regarding the conflicted study team member's role/responsibilities in the study conduct, especially if they are a PI, which may need to be inserted into the protocol. Some examples to consider are limitations regarding consenting a participant, reviewing AEs or SAEs, and who will be appointed to assume these responsibilities for the conflicted study team member.

   5.2. Consider language regarding the conflicted study team member that may need to be inserted into the informed consent for the study. Some examples include notifying participants of a study team member's conflict and its potential impact on the study and inserting the name of an alternate study team practitioner for participants to direct their questions regarding the research.

   5.3. The protocol application to the CPC CIRB should identify the FCOI.

   5.4. In rare situations where relevant FCOI documents have been submitted for CPC CIRB review, but these documents have not yet been entered into the eRA Commons FCOI module, the LAO should send the relevant documents submitted for the CPC CIRB review to the DCP Study Team (Scientific Lead, Medical Monitor, and Nurse Consultant) via encrypted email.

   5.5. The protocol will not be approved until the FCOI has been formally reported to NIH via the eRA Commons FCOI module and reviewed by NIH and the CP CTNet Program Official.

4. REFERENCES

Document	ID	Location
CIRB SOPs	SOP	ncicirb.org
CP-CTNet Concept Submission Form	Form	Program Resources
DCP CP-CTNet Informed Consent Template	Template	Program Resources
eRA Commons	Website	era.nih.gov
FCOI Submission Instructions	Reference	grants.nih.gov
NIH FCOI Policy	Reference	grants.nih.gov
NOT-OD-22-210	Reference	grants.nih.gov

5. APPENDICES

None