

- Do individuals or institutions receive any compensation that may be affected by the study outcome?
- Do individuals or institutions involved in the research:
 - +have any proprietary interests in the product including patents, trademarks, copyrights, and licensing agreements?
 - +have an equity interest in the research sponsor and is it a publicly held company or non-publicly held company?
 - +receive significant payments of other sorts? (e.g. grants, compensation in the form of equipment, retainers for ongoing consultation, and honoraria)
 - +receive payment per participant or incentive payments, and are those payments within the norm?
 - Given the financial relationships involved, is the institution an appropriate site for the research?
 - How should financial relationships that potentially create a conflict of interest be managed?
- Would the rights and welfare of human subjects be better protected by any or a combination of the following:
 - +reduction of the financial interest?
 - +disclosure of the financial interest to prospective subjects?
 - +separation of responsibilities for financial decisions and research decisions?
 - +additional oversight or monitoring of the research?
 - +an independent data and safety monitoring committee or similar monitoring body?
 - +modification of role(s) of particular research staff or changes in location for certain research activities, e.g., a change of the person who seeks consent, or a change of investigator?
 - +elimination of the financial interest?

C. Specific Issues for Consideration Regarding

1. Institutions

The Department recommends that institutions engaged in federally conducted or supported human subjects research consider the following actions or other actions regarding financial conflicts of interest:

- Separate responsibilities for financial decisions and research decisions.
- Establish conflict of interest committees (COICs)⁷ or identify other bodies or persons to deal with

individuals' financial interests in research or verify their absence.

- Extend the responsibility of the COIC to address institutional financial interests in research or establish a separate COIC to address institutional financial interests in research.
- Establish criteria to determine what constitutes an institutional conflict of interest, including identifying leadership positions for which the individual's financial interests are such that they may need to be treated as institutional financial interests.
- Establish clear channels of communication between COICs and IRBs.
- Establish policies on providing information, recommendations, or findings from COIC deliberations to IRBs.
- Establish measures to foster the independence of IRBs and COICs.
- Include IRB members and staff and appropriate officials of the institution, along with investigators, among the individuals who report financial interests to COICs.
- Establish procedures for disclosure of institutional financial relationships to COICs.
- Provide training to appropriate individuals regarding financial interest requirements.
- Use independent organizations to hold or administer the institution's financial interest.
- Include individuals from outside the institution in the review and oversight of financial interests in research.
- Establish policies regarding the types of relationships that may be held by parties involved in the research and circumstances under which those financial relationships and interests may be held.

2. IRB Operations

The Department recommends that institutions engaged in human subjects research and IRBs that review HHS conducted or supported human subjects research or FDA regulated human subjects research consider establishing policies and procedures addressing IRB member potential and actual conflicts of interest as part of overall IRB policies and procedures. These might include:

- Reminding members of conflict of interest policies at the start of each meeting.
- Polling members to verify that no conflicts of interest exist regarding any protocols to be considered during the meeting.
- Recording the polling results in the meeting minutes.
- Recording in the meeting minutes verification for each protocol that any

conflicted members did not participate in discussion or vote on protocols involving their conflict of interest, except to provide information as requested by the IRB (45 CFR 46.107(e), 21 CFR 56.107(e)).

- Developing educational materials about the regulations' requirements for IRE members.

3. IRB Review

The Department recommends that IRBs reviewing HHS conducted or supported human subjects research or FDA regulated human subjects research consider the following actions, or other actions related to conduct or oversight of research, based on particular situations:

- Determine whether methods being considered or used for management of financial interests of parties involved in the research adequately protect the rights and welfare of human subjects.
- Determine when an IRB needs additional information to decide whether the financial interests of parties involved in research could affect the rights and welfare of subjects as well as mechanisms for obtaining the additional information.
- Determine what actions are necessary to minimize risks to subjects.
- Determine the kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.

4. Investigators

The Department recommends that investigators consider the potential effect that a financial relationship of any kind might have on a clinical trial, including interactions with research subjects, and whether to take any of the following actions:

- Including information in the consent document, such as
 - the source of funding and funding arrangements for the conduct and review of research, or
 - information about a financial arrangement of an institution or an investigator and how it is being managed.
- Using special measures to modify the consent process when a potential or actual financial conflict exists, such as
 - having a non-biased third party obtain consent, especially when a potential or actual conflict of interest could influence the tone, presentation, or type of information presented during the consent process.

⁷ The acronym COIC will be used to represent the body or person(s) designated to review financial interests.