Significant Financial Interests (SFIs)

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Significant Financial Interest (SFI)

1) ...is a financial interest

Which is: anything of monetary value, whether or not the value is readily ascertainable of the Investigator (and those of the Investigator’s spouse and dependent children)

that reasonably appears to be related to the Investigator’s institutional responsibilities

Key Points:
1. Aggregated Financial Interests: Investigator + Spouse + Dependent Child(ren), as applicable
2. Related to Institutional Responsibilities: teaching, research, service, etc
Disclosing SFIs

The UofA Procedure (and NIH 2011 FCOI Regulation) requires Investigators to disclose the monetary value of, and the frequency and/or duration of, and/or range of types of interactions with, an identified entity.

Key Point:
The intent is to be able to identify relationships (between the Investigator and the entity) that reasonably appear to have the potential to lead to, or constitute, FCOIs.
Example 1:

Stock held (a financial interest) in Google Inc., unrelated to the Investigator’s “Institutional Responsibilities” (teaching, research, service), would NOT represent a SFI if the Investigator’s Institutional Responsibilities are not, say, in the area of Information Technology, and even more specifically, search engines.
Example 2:

Stock held in Roche by an Investigator (or, say, the spouse’s salary from Roche) *would represent a SFI* if the Investigator’s Institutional Responsibilities involve the study of, or prescription of, drugs that could reasonably be viewed to have the potential to impact the returns Roche would have in those specific drugs.
Example 3:

Stock/interest held by the dependent child in a non-publicly traded spin-off company would represent a SFI; this would be particularly true if it were the Investigator’s spin-off company.
• Example 4:

A $7,000 royalty payment for licensed intellectual property would represent an SFI if the Investigator has retained the rights to that IP.

(Please note the exclusion for the case where the Investigator assigns the IP to the Institution [UAlberta])
• Example 5:

Travel worth $4,000 which was reimbursed by the Dalhousie University would NOT represent a SFI (& would not need to be disclosed)
Example 6:

Travel for a thesis defense sponsored by Colorado State University would **NOT** represent a SFI (& does not need to be disclosed regardless of its monetary value).
• Example 7:

Pfizer Canada Inc. pays expenses for an Investigator traveling to a conference which total $2,300, along with an honorarium of $1,500. None of these payments, individually, would have to be disclosed. However, because the total of $6,100 from one entity within the previous 12 months exceeds $5,000, each of these interests must be disclosed and would represent an SFI.
Example 8:

Teva Canada Inc. pays expenses for participation on an Advisory board totalling $4,700, along with an honorarium of $1,500 for a talk done at a conference 5 months later. None of the payments, individually, would have to be disclosed. However, because the total of $6,200 from one entity within the previous 12 months exceeds $5,000, each of the interests must be disclosed, and would represent a SFI.
• Example 9:

Remuneration for travel when paid from a CIHR grant held by UAlberta on behalf of the Investigator, would **NOT** need to be disclosed (& does not need to be disclosed as the payment will be from the Institution, UAlberta)
Example 10:

A UAlberta PI has an individual NIH grant for her research and she also has a major financial interest in a spin-off company which itself has acquired separate NIH funding.

- This situation would represent an SFI: The PI would disclose the nature and value of her financial interest in the spin-off company for compliance with the Regulation for her NIH grant awarded through UAlberta.

- The PI would not need to disclose those interests when the spin-off company requires disclosures in order for it to comply with the funding contract/Regulation (in this case the spin-off company would be the Institution).
Example 11

McGill University pays an honorarium for a seminar/teaching where the payments total $4,600. This would NOT represent a SFI and would not need to be disclosed.
• Example 12:

Payment received from a the same Canadian health sciences centres for service on three review panels total $5,200. These three review panels would represent an SFI and needs to be disclosed.

Had the total been $4,800, the disclosure would not be necessary.
If in doubt about a financial interest, disclose it to the Institution

• The UAlberta’s Designated Official conducts a routine consultation with all Investigators with respect to the content of their disclosures.
SFI – Publicly traded entities

With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

Key Points:
1. $5,000 aggregate (Investigator + spouse + dependent child[ren]) threshold (previous 12 months for remuneration) for disclosure
2. Remuneration &/or equity (value at the time of disclosure) included in these financial interests
**SFI – Non-publicly traded entities**

With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest)

Key Points:
1. Same $5,000 aggregate threshold as above for disclosure of remuneration (previous 12 months)
2. Any equity interest (regardless of monetary value) must be disclosed (e.g., spin-off company equity/interest)
Intellectual property rights and interests (e.g., patents [regardless of filing status], copyrights), upon receipt of income related to such rights and interests, in excess of $5,000 per year per entity (source/payor).

Key Points:
1. When Investigator retains rights (does not assign them [e.g., to UAlberta])
2. Disclose only upon receipt of income greater than $5,000 from the payor in the previous 12 months
SFI – Reimbursed or Sponsored travel

Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities when the annual aggregated amount paid to the specific Investigator exceeds $5,000 per entity. Disclosure is for the previous 12 months.

However, this does not apply to travel paid for by a U.S. federal, state or local government agency, a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. Institution of higher education.

Key Points:
1. The $5,000 threshold applies
2. These U.S. sources of funds for reimbursed/sponsored travel provide important exclusions from disclosure especially if the monetary value were to exceed $5,000 per entity in the previous 12 months.
**Significant Financial Interest (SFI)**

SFIs to which the minimum $5,000 threshold does **NOT** apply (therefore, SFIs must be disclosed):

1. Any equity in a non-publicly traded entity (e.g., spin-off company)

2. Receipt of **more than $5,000 per year from one entity** in total payments for multiple SFIs (as defined above); the details of each such SFI must be disclosed

   (e.g., $3,000 for travel + $1,500 honorarium for a seminar + $2,500 consulting fee to spouse, all from one entity [sum = $7,000]: need disclosures for all three SFIs)

**Key Point:**

Disclosures of some less-than-$5,000 SFIs are required
SFI Exclusions

Salary, royalties, or other remuneration paid by the Investigator’s current Institution to the Investigator;

Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights;

Key Points:
1. Remuneration from UAlberta, regardless of its previous origin, is excluded from disclosure
2. IP Rights assigned to the UAlberta are excluded from disclosure
SFI Exclusions

Any ownership interest in the Institution (when the “Institution” is a commercial or for-profit organization such as a spin-off company) held by the Investigator must be disclosed.

Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;

Key Points:

1. Spin-off companies could hold NIH funding and be “Institutions” by the NIH definition for such (not a common situation; such a commercial organization would be required to have a FCOI Policy compliant with the NIH 2011 FCOI Regulation)

2. Mutual funds are commonly held and are excluded if the Investigator is not directing the investments
SFI Exclusions

Income from seminars, lectures, or teaching engagements or for service on advisory committees or review panels sponsored by a U.S. federal, state or local government agency, or a U.S. Institution of higher education is excluded (regardless of dollar amount).

Similar income from non-US equivalents of these entities where the annual aggregated amount paid to the specific Investigator does not exceed $5,000 per entity is also excluded.

Key Points:
1. The same U.S. entities are listed in these exclusions as is the case for reimbursed or sponsored travel
2. The UAlberta Procedure provides exclusions for the non-US equivalent entities (when the annual $5,000 threshold is not exceeded)