

## Factors for Assessing FCOI

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## Proposed Changes to Yale's COI Policy

### Highlights

- Individuals must submit disclosure forms with screening questions; however, only those activities that yield a Significant Financial Interest (SFI) need to be reported to the University;
- Branched Policy, SFI definitions and thresholds for disclosing SFIs
  - Yale - Main Policy
    - 1) SFI threshold: >\$10K past 12 months; >5% equity in publicly held corp.
    - 2) **Board of Dir or Officer of a for-profit entity (paid or unpaid) (with respect to the Discloser only);**
    - 3) Exclusions for travel expenses, book royalties, journal editorships/authorship activities for publishing companies, and speaking/service income from professional societies and public and non-profit entities;

### Highlights

#### - PHS / Appendix A

- 1) SFI threshold: >\$5K of income or equity in publicly held corp. for past 12 months; reimbursed travel in any amount for any institutional related travel;
- 2) IP income only upon receipt of income and not attributable to Yale;
- 3) Board of Dir or Officer of a for-profit entity (paid or unpaid) (with respect to the Investigator only);
- 4) Exclusions for government and US higher education, and organizations affiliated with higher education, but no exclusions for journal editorships/ authorship activities for publishing companies or service to professional societies.

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### Highlights (continued)

#### - NSF / Appendix B

- 1) SFI threshold: >\$10K past 12 months and **next 12 months**
  - 2) Exclusions for travel expenses, book royalties, journal editorships/authorship activities for publishing companies, and service to professional societies, non-profits and public entities;
  - 3) Board of Dir or Officer of a for-profit entity (paid or unpaid) (with respect to the Investigator only).
- All branches contain Yale guidelines for determining FCOIs on research awards;
  - Incorporated many of Yale's principles on startup companies into the main body of the COI Policy as factors in determining FCOI (remaining start-up guidelines appear in Appendix C of the Policy).

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### Highlights (continued)

- **Large Significant Financial Interests**
  - The Policy calls out for special attention by the COI Committee and senior academic leadership SFI's >\$100K.
- **Human Subjects Research**
  - The Policy does not have a single disclosure threshold for human subjects research; H/S research funded by NIH would be subject to the \$5K threshold for significance while H/S research funded by NSF or a corporate entity would have a \$10K threshold for significance.

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### Factors for Determining the Existence of FCOI

- The COI Committee will take into consideration whether the Discloser's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.
- Other factors that may be taken into consideration in the determination of an FCOI include:
  - the role of the Discloser and the opportunity to bias the results;
  - the nature of the research being proposed;
  - whether the work is funded by an entity in which the Discloser holds a SFI;
  - consideration of the value of the SFI in relation to the size and value of the entity.

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**Factors for Determining the Existence of FCOI (continued)**

- Other factors that should be considered include:
  - Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
  - Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
  - Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
  - Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or

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**Highlights (continued)**

- Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook.
- The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
- Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the Discloser from that technology, both retrospective and prospective; or
- The number and nature of relationships a Discloser has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or

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**Factors for Determining the Existence of FCOI (continued)**

- Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
- Whether other scientific groups are independently pursuing similar questions; or
- Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
- Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI.