MANAGING FINANCIAL CONFLICTS OF INTEREST IN HUMAN SUBJECT RESEARCH

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&

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LEARNING OBJECTIVES

- Defining Significant Financial Interest (SFI) within the scope of a research protocol
- Required FCOI training
- When to disclose SFIs to UVM
- How to disclose and update SFIs
- Managing conflicts

- ➢ It is not wrong to have an outside financial interest:
  as long as it is disclosed and properly managed

- ➢ We are here to help!

Our goals:

- ✓ *to help you meet investigators' obligations under the UVM Financial Conflict of Interest in Research policy,*

- ✓ *to protect human subjects participating in clinical trials*

- ✓ *to protect the trust placed in the outcome of research*

- ✓ *to protect investigators' reputation and ultimately, that of UVM.*

Differences with other UVM conflict policies:

There is **1 primary policy** that addresses conflicts of interest and conflicts of commitment. This policy applies to all faculty and staff. Investigators engaged in sponsored research must follow this policy.

The **Financial Conflict of Interest in Research Policy** is an **additional** conflict of interest policy specific investigators engaged in research.

	Conflict of Interest	Conflict of Commitment	Financial Conflict of Interest in Research Policy
Purpose	Academic, research and business integrity	Effectiveness of employees carrying out their UVM responsibilities	Research objectivity
Risk being addressed	Impairment of the public trust Bias in decision making	Over commitment	Impairment of the public trust in Research
Nature	Financial, legal, ethical	Time commitment	Financial
Applicability	UVM employees		UVM investigators engaged in research
Conflicts	Any existing or potential personal, financial or other interest that (a) impairs or may reasonably appear to impair his/her independence of judgment in the discharge of responsibilities to the University; or (b) may result in personal gain or advancement at the expense of UVM.	External activities undertaken by a UVM employee which will or reasonably can be expected to significantly interfere with his or her ability to perform obligations to UVM duties fully or effectively.	Any significant financial interest that could affect directly and significantly the **design, conduct, or reporting** of research.
Disclosure Requirements	Disclose under UVM CLICK		
Links to Policy	Conflict of Interest and Conflict of Commitment Policy		Financial Conflict of Interest in Research policy

Neuropsychopharmacology editor resigns after failure to disclose conflict of interest

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Charles Nemeroff has decided to resign as editor of the journal Neuropsychopharmacology after he co-authored a favorable article on a chest implant that treats depression and did not disclose his financial ties to Cyberonics, which manufactures the device, the Wall Street Journal reports.

The article, published last month in Neuropsychopharmacology, said that the device - which delivers mild electrical pulses to the vagus nerve in the neck - is "a promising and well-tolerated intervention that is effective in a subset of patients with treatment-resistant depression."

Nemeroff, chair of the Department of Psychiatry and Behavioral Sciences at Emory University, and seven of the eight other authors of the article serve as consultants for Cyberonics, and one of the authors was an employee of the company.

In an e-mail, the owner of Neuropsychopharmacology said that Nemeroff decided to resign, "in part, based on the recent adverse publicity to the journal."

Neuropsychopharmacology has published a correction that disclosed the financial ties of the authors of the article to Cyberonics (Armstrong, Wall Street Journal, 8/26).

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The Disclosure Rule

Investigators participating in research

will report *all significant financial interests*
held by themselves, their spouses, and their dependent children

related to their institutional responsibilities

when [for clinical trials]:

- [...] At the time of submission of a research project involving human subjects to the Institutional Review Board (IRB);
- At least annually thereafter during the period of research activity;
- During the research within thirty (30) days of acquiring or discovering a new significant financial interest.

Who needs to disclose?

Investigators participating in research

Investigator means

the project director (PD) or principal investigator (PI),

AND

any person, regardless of title or position,
who has independent responsibility
for the

design,
conduct, or
reporting

of the research

What do you need to disclose?

You need to disclose.

Whether or not you have a significant financial interest.

Significant Financial Interest
General Rule

- Any remuneration > $5,000 received in the course of the past twelve months from a single external source, for services or products
- Any IP rights or and/or technology that has been disclosed to UVM Innovations
- Any equity held in a company
- For PHS funded research only: any travel expenses received by an entity other than UVM

if they reasonably appear to be related to your institutional responsibilities.

Significant Financial Interest

What constitutes an SFI (if related to your institutional responsibilities and held by you, your spouse or dependent children) – within the past 12 months:

<table>
<tr><th colspan="2">Nature of SFI</th><th>Threshold</th><th>Excluded (Do Not Disclose)</th></tr>
<tr><td colspan="2">Compensation and/or other payments for service</td><td>Exceeds $5,000*</td><td>any compensation received for lectures, seminars, teaching engagements, relating to:
federal, state, or local government agencies,
a domestic institution of higher education,
an academic teaching hospital,
a medical center, or
a research institute that is affiliated with an institution of higher education,
(the “Excluded Entities”),
service on advisory committees or review panels relating to one of the Excluded Entities, or
compensation received from UVM (or UVM Health funds for faculty with double-employment)</td></tr>
<tr><td rowspan="2">Equity interests</td><td>in a publicly-traded entity</td><td>Value at time of disclosure exceeds $5,000:

when aggregated with any other financial interest in that company, e.g. if your equity in Company A is valued at $2,000, and you receive $3,000 in compensation from that Company A, you need to disclose.</td><td>Interests in any entity through personal retirement accounts and mutual funds</td></tr>
<tr><td>in a non-publicly-traded entity</td><td>0</td><td>Interests in any entity through personal retirement accounts and mutual funds</td></tr>
</table>

Intellectual property rights and interests upon receipt of income related to such rights and interests / any technology submitted to UVM Innovations	0	
Sponsored or reimbursed travel *Applies only to research submitted to* *PHS funding or any funding from agencies following PHS COI regulations*	0	Travel administered through UVM funds, and travel reimbursed or sponsored by one of the Excluded Entities (see definition above).
Venture or other capital financing *Applies only to research submitted to NSF funding.* *Disclose who or what the entity has invested in and who the other investors are*	0	*If a venture capital firm does not provide investment information, investigators must obtain a letter from the venture capital firm stating that the firm does not disclose who or what they have invested in,or who the other investors are.*

The case of Start-Ups

Start-ups

The rule:

Equity interests	In a publicly-traded entity	Value at time of disclosure exceeds $5,000*	Interests in any entity through personal retirement accounts and mutual funds
	In a non-publicly-traded entity	0	Interests in any entity through personal retirement accounts and mutual funds

What does it mean:

From the point where an investigator is founding a start-up,
i.e. the start-up is incorporated (registered with the local state company registry),
such investigator needs to include it in the FCOI disclosure.

Why? From that point onwards, the Investigator starts having a personal interest in the successful completion of the business purpose of the start-up.

Significant Financial Interest

Remember:

"Held by

you,

your spouse, or

your dependent children"

When do you need to disclose?

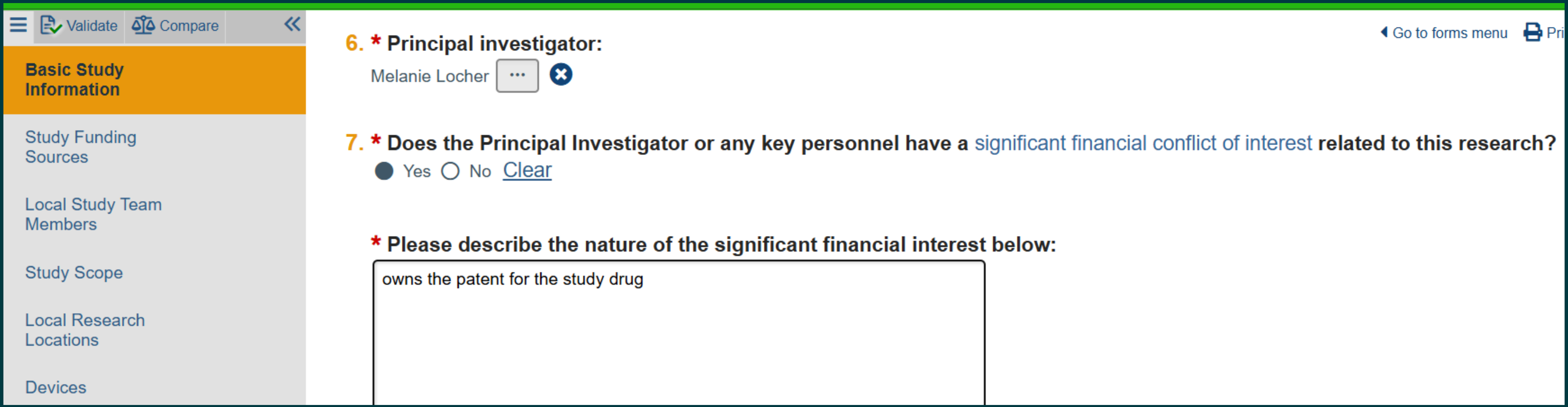
When do you need to disclose?

- [...] At the time of submission of a research project involving human subjects to the Institutional Review Board (IRB);

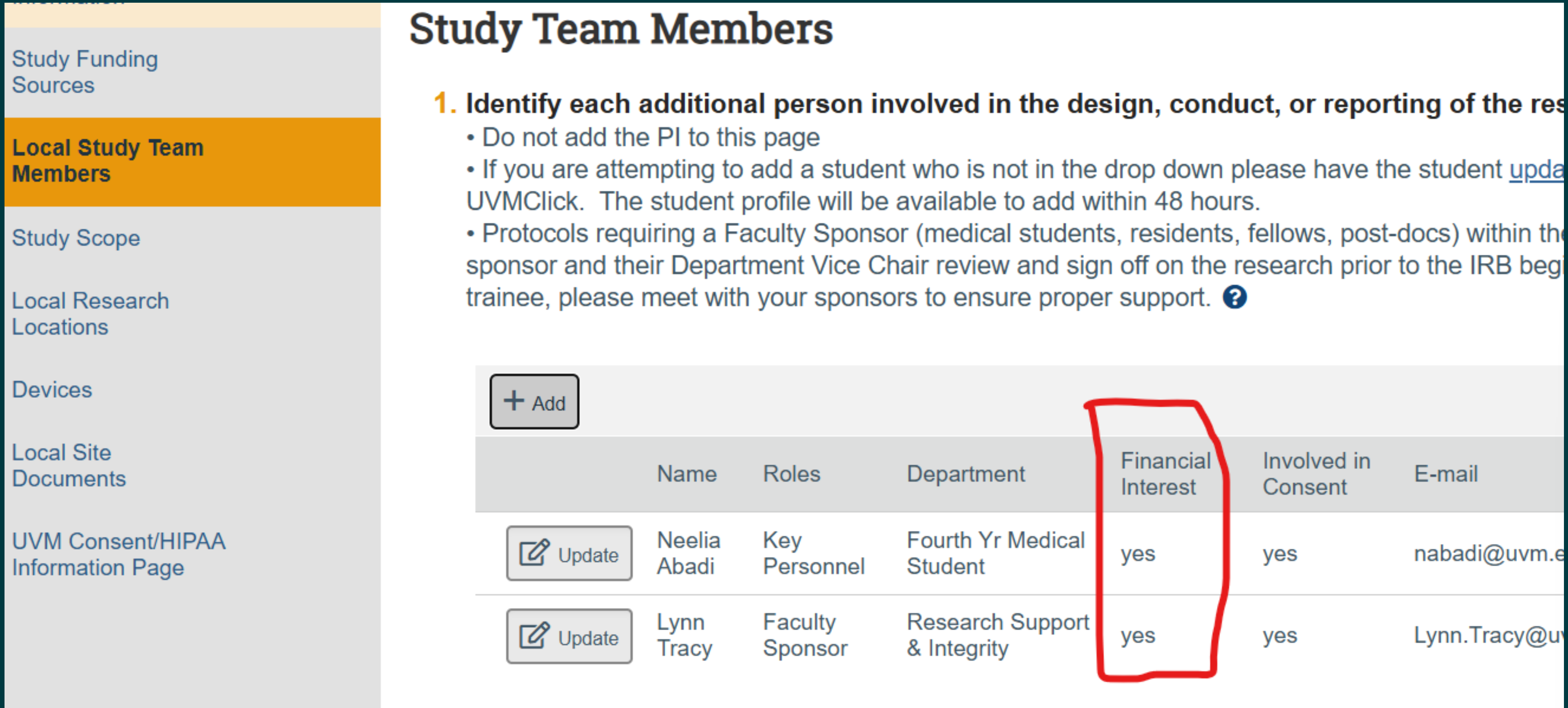
- At least annually thereafter during the period of research activity;

- During the research within thirty (30) days of acquiring or discovering a new significant financial interest;

DISCLOSE THE PI’S POTENTIAL FCOI ON THE BASIC INFORMATION PAGE AND DESCRIBE THE NATURE OF THE CONFLICT



INDICATE ALL STUDY TEAM MEMBERS POTENTIAL FCOI WHEN ADDING THEM TO THE ROSTER WHEN SUBMITTING TO THE IRB



New Significant Financial Interest

A New Significant Financial Interest is an SFI:

-of different type than the SFI previously disclosed (ownership vs consulting fee); or
-from a different source (company A vs company B).

How do you need to disclose?

Go to:

[UVM CLICK Log In]

If you fail to disclose…

Alleged violations of this policy should be reported to the Designated Institutional Official who will inform the appropriate department chair, dean and Chief Compliance Officer.

If this review finds there was a deliberate breach of the policy, including

- failure to file;
- knowingly filing incomplete, erroneous or misleading disclosure forms; or
- failure to comply with procedures prescribed in fulfillment of this policy,

the Dean will consult with the Vice President for Research on appropriate sanction, if any, to be imposed.

If you fail to properly disclose…

Possible sanctions include:

- letter to the investigator's personnel file;
- suspension of privileges to apply for external funds or seek IRB approval or supervise graduate students;
- non-renewal of appointment; or
- dismissal.

What happens after my disclosure?
The Financial Conflict of Interest Review

The Financial Conflict of Interest Review

Step 1: The Investigator and their research administration team make an assessment as to whether there is a conflict and discloses it to the Institutional Review Board. If there is any suspicion of a conflict, the Associate Director for Research is contacted and sets up a committee review.

Step 2: Review by the committee, if needed. The committee is faculty led across section of academic disciplines.
At this stage, the scope of the review is the determination of whether there is indeed a financial conflict of interest, and how it should be managed.

Financial Conflict of Interest means:

a Significant Financial Interest that could

directly and significantly affect the

design,
conduct, or
reporting

of research.

If there is a Conflict of Interest:
The Management Plan

The Management Plan

Management plan conditions may include:

- **Public disclosure** of financial conflicts of interest (e.g., when presenting or publishing the research);
- **Disclosure** of financial conflicts of interest directly **to research participants**;
- Appointment of an **independent monitor**;
- **Modification of the research plan (what an investigator is allowed to participate into, or is prevented from engaging in);**
- Entering into a **data use agreement**;
- **Change of personnel or personnel responsibilities**, or disqualification of personnel from participation in all or a portion of the research;
- **Reduction or elimination of the financial interest** (e.g., sale of an equity interest); or
- Severance of relationships that creates financial conflicts.

Training

Each Investigator should take our training module

- before making their first disclosure of a significant financial interest, and
- every four years thereafter.

CASE STUDIES

Company/Product	Challenge	Outcome
ABCD System partially owned by Discloser	**Study:** The study was testing the efficiency of a surgical intervention using the ABCD System in patients **Role of the discloser:** The Principal Investigator wishes to be involved in the recruitment of patients, but not performing the surgical intervention.	• the condition to disclose the conflict in publications, • the condition to disclose the conflict to the research team, as well as • the condition to disclose the conflict to the research participants.

CASE STUDIES

Company/Product	Challenge	Outcome
Patent application pending for a communication technology for patients.	**Study:** the purpose of the study was to test the use of the non-invasive communication technology with patients. **Role of the disclosers:** The inventors have designed the project and developed the technology. They hoped to be involved in data analysis, eligibility determination and possibly recruitment.	• disclosures to research participants, • disclosure to collaborators on the study, and • disclosures in publications and presentations, • disclosures in the consent form • The disclosers may consent the research participants and perform the data analysis. • If not automated, measurements of timing for using the software, proprietary efficiency, should not be performed by the disclosers.

CASE STUDIES

Company/Product	Challenge	Outcome
Consulting fee from pharmaceutical company, FGHI, for serving on an advisory board.	***Study:*** *A randomized, open-label, active-controlled, parallel-group, multicenter study of a drug manufactured by FGHI.* ***Role of the discloser:*** *-initial eligibility review* *-potential consenting volunteers* *-potential delivery of the investigational agent* *-no role in data analytics*	• An alternative PI was named on the study • all eligible participants are reviewed through a dedicated process prior to enrollment which the discloser has no role; • Disclosure to research participants in a consent form; and • Disclosure to study team (which may be satisfied by simply indicating the conflict under UVM CLICK to which all key personnel have access)

CASE STUDIES

Examples for informed consent language:

“You should know that one of the physicians involved in your treatment, Dr. Soandso, chairs a committee that advises FGHI on the therapies they are developing, and receives payment for those services. He does not receive any direct payment for this clinical study and does not own stock in FGHI or the drug being tested in this study. The UVM Clinical Research Conflict of Interest committee determined any potential conflicts are being appropriately managed and are being disclosed to you for full transparency. If you have further questions about this, please direct them to Dr. Soandso at 802.XXX.XXX.”

“You should also know that Dr. Soandso has a significant financial interest with KLMN: he was paid for services as a consultant. KLMN is the sponsor of this research study. Dr. Soandso has disclosed his personal financial interests to the Clinical Research Conflict of Interest committee (CRCOI committee) at the University of Vermont. The CRCOI is responsible for determining that any potential conflicts are being appropriately managed. However, negative impacts on subjects participating in this study are always possible and therefore the potential conflict is being disclosed to you. Please discuss this with the study doctor/staff any questions you may have about this.”

QUESTIONS?

Apply your knowledge

Scenario 1

In January you reported that you received consulting compensation of $8,000 from a private engineering firm, which relates to your institutional responsibilities. In September of that year you became an equity holder in that company. What actions should you take?

a. No action is required because you have already indicated that you have a financial interest in the company.

b. Update your disclosure because you now have a Financial Conflict of Interest.

c. No action is required because the company is not profitable so the equity has no value.

d. Update your disclosure within 30 days of becoming an equity holder.

Result

Answer d.

If the status of your outside interest changes, you must update your disclosure within thirty days. A significant financial interest, and therefore a disclosable interest, includes any equity in a privately owned company, regardless of value.

This new interest may or may not constitute a Financial Conflict of Interest, depending on its potential to directly and significantly affect the design, conduct, or reporting of funded research.

Scenario 2

 You are a faculty member in the Department of Animal Science with a nine-month appointment, and receive $6,000 in consulting over the summer months. The consulting is only peripherally related to your research. What should you do?

a. No action is required because this outside work would not directly and significantly affect the design, conduct, or reporting of your funded research.

b. You should disclose this income because it constitutes a Significant Financial Interest.

c. No action is required because you do not need to disclose income earned outside the appointment period.

d. You should disclose this income because consulting income must be disclosed.

Result

Answer b.

You should disclose this income because remuneration exceeding $5,000 in value is considered a Significant Financial Interest, and, therefore, must be disclosed if related to your University duties, even in a general way. Remuneration that exceeds this $5,000 threshold over a twelve-month period must be disclosed, whether or not it is earned outside the appointment period. If the remuneration is less than $5,000 it need not be disclosed.

This new interest may or may not constitute a Financial Conflict of Interest, depending on its potential to directly and significantly affect the design, conduct, or reporting of funded research.

Scenario 3

You are a professor and investigator on an NIH grant (a component of the PHS) in the Department of Medicine. Because of your expertise in cardiology you also serve on an advisory board for the American Heart Association (AHA). The Association's annual board meeting is scheduled for next month in Pittsburgh and the Association has paid your plane fare for the trip. What should you do?

a. No action is required because you are volunteering your time to AHA.

b. Disclose the purpose, sponsor, duration and destination of the travel prior to or within 30 days following the trip.

c. No action is required because the travel expense is less than $5,000.

d. Seek permission for the travel prior to the trip.

Result

Answer b.

PHS regulations specifically require disclosure of supported travel, regardless of amount, unless funded by a federal, state, or local government agency, an institution of higher education (or affiliated research institute), an academic teaching hospital or a medical center. In other words, PHS considers all such travel a Significant Financial Interest that must be disclosed.

Unless anticipated and reported previously in your annual disclosure, this new Significant Financial Interest, must be disclosed prior to or within thirty days of the trip.

Remember, if you are not funded by a PHS agency, such as the National Institutes of Health (NIH), the Center for Disease Control (CDC), or the Substance Abuse and Mental Health Services Administration (SAMHSA), or by a sponsor that follows the PHS regulations, then travel support need not be disclosed.

This new interest may or may not constitute a financial conflict of interest, depending on its potential to directly and significantly affect the design, conduct, or reporting of funded research.

Scenario 4

You are a post-doctoral researcher applying for a research fellowship from the American Chemical Society. Over the last year you have worked evenings and week-ends for the Alternative Energy Association, a non-governmental, non-profit agency, developing an on-line course entitled Technologies for Utilization of Renewable Energy Source. You have been reimbursed $5,200 from the Association for the time spent on the course's development, and you personally spent about $1,000 for software and images that you needed for the course development. Should you disclose this reimbursement?

a. You don't need to disclose the reimbursement because the amount you were paid, less the amount you spent, is less than $5,000.

b. You should make a disclosure because all payment for outside teaching requires disclosure.

c. You should disclose the reimbursement because you received more than $5,000 in remuneration in the twelve months preceding the proposal.

d. You don't need to disclose the reimbursement because the Alternative Energy Association is a non-profit organization.

Result

Answer C.

You should disclose this income because remuneration exceeding $5,000 in value over a twelve-month period is considered a Significant Financial Interest, and, therefore, must be disclosed if related to your University duties. This includes payments from non-profit organizations. The only exceptions to this requirement are payments from a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

This new interest may or may not constitute a financial conflict of interest, depending on its potential to directly and significantly affect the design, conduct, or reporting of funded research.