Financial Conflict of Interest Policy

Understanding an Investigator’s obligations

Victoria Jones
Research Compliance Officer
Research Administration & Integrity Office
2/28/2019
This module reviews:

- the obligations of the investigators (whether or not they feel they have a conflict) involved in sponsored research projects
- how to disclose through Click, the new online FCOI disclosure system
- the mechanisms in place to mitigate the risk of potential bias in extramurally funded research
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 are:

- to help you meet investigators’ obligations imposed by the funding agencies,
- protect the trust placed in the outcome of research,
- protect investigators’ reputation and ultimately, that of UVM.
Differences with other UVM conflict policies:

There are 2 primary policies that address conflicts of interest and conflicts of commitment. Investigators engaged in sponsored research must follow both policies.

The Financial Conflict of Interest in Sponsored Research Policy is an additional conflict of interest policy specific to research proposed to external funding.

<table>
<thead>
<tr>
<th>Conflict of Interest Policy</th>
<th>Conflict of Commitment Policy</th>
<th>Financial Conflict of Interest in Sponsored Research Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Academic, research and business integrity</td>
<td>Effectiveness of employees carrying out their UVM responsibilities</td>
</tr>
<tr>
<td><strong>Risk being addressed</strong></td>
<td>Impairment of the public trust</td>
<td>Over commitment</td>
</tr>
<tr>
<td><strong>Nature</strong></td>
<td>Financial, legal, ethical</td>
<td>Time commitment</td>
</tr>
<tr>
<td><strong>Applicability</strong></td>
<td>UVM employees</td>
<td>UVM employees</td>
</tr>
<tr>
<td><strong>Conflicts</strong></td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Disclosure Requirements</strong></td>
<td>Disclose to immediate supervisor</td>
<td>Disclose to immediate supervisor</td>
</tr>
<tr>
<td><strong>Links to Policy</strong></td>
<td><img src="conflictofinterestpolicy" alt="Conflict of Interest Policy" /></td>
<td><img src="conflictofcommitmentpolicy" alt="Conflict of Commitment Policy" /></td>
</tr>
</tbody>
</table>
Background

The origin of the UVM policy:

The department of Health and Human services issued a regulation 42 CFR Part 50 to promote objectivity in research applying to Investigators participating in proposals submitted to PHS research funding.
These rules are also enforced by funding agencies that follow the PHS Financial Conflict of Interest regulations:

These include PHS Agencies and Non-PHS Agencies, such as NIH, AHRQ, HRSA, and the CDC.

Some other agencies, such as NSF and PCORI have issued a distinct set of rules and/or guidelines.
Background

The **UVM Financial Conflict of Interest in Sponsored Research** was drafted after the federal set of regulations and complies with most agencies rules.
Investigators participating in externally funded research will report all significant financial interests held by themselves, their spouses, and their dependent children related to their institutional responsibilities when 1. funded research is proposed, 2. annually thereafter, and 3. when new significant financial interests arise.
Who needs to disclose?
The Rule

*Investigators* participating in *externally funded research*

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

when 1. funded research is proposed,  
   2. annually thereafter, and  
   3. when new significant financial interests arise.
Investigators

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 proposed for sponsored funding.
Investigators

An Investigator may be:

- a post-doctoral associate
- a graduate student
- a statistician
Select from the following list each person who may be considered an “investigator” when participating in externally funded research:

a. A co-investigator  

b. A senior/key personnel  

c. A post-doctoral associate  

d. A statistical analyst  

e. A clinical trial nurse  

f. A pharmacist  

g. None.
Anyone may be an investigator, regardless of their actual title.
What do you need to disclose?
You need to disclose whether or not you have an external 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
- 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 children) — within the past 12 months:

<table>
<thead>
<tr>
<th>Nature of SFI</th>
<th>Threshold</th>
<th>Excluded (Do Not Disclose)</th>
</tr>
</thead>
</table>
| Compensation and/or other payments for service | Exceeds $5,000 | - 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 “Special Entities”),  
- service on advisory committees or review panels relating to one of the Special Entities, or  
- compensation received from UVM (or UVMCC) funds for faculty with double-employment |
| 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 |
| Intellectual property rights and interests upon receipt of income related to such rights and interests | 0 | Royalties received from UVM funds, and unlicensed intellectual property that does not generate income |
| 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 Special Entities (see definition above). |

*when aggregated with any compensation received from that company, e.g. If the equity is valued at $2,000, and you receive $3,000 in compensation from that same company, you need to disclose.
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?

With our new online FCOI disclosure system, Click, the process has changed slightly:

- When your first externally sponsored research project as an Investigator is proposed. 
  
  N.B.: the Research Administrator will contact you before the point of submission for external funding.

- Annually thereafter, and

- Within 30 days after the discovery or acquisition of a New Significant Interest.

- Within 30 days after your travel if you are disclosing travel expenses.

- If you have disclosed an SFI, each time there is an award on which you are an Investigator.
New Significant Financial Interest

A New Significant Financial Interest is an SFI:

- of different type than the SFI previously disclosed (ownership vs consulting fee) that meets the threshold; or

- from a different source (company A vs company B).
How do you need to disclose?

Go to:
https://www.uvm.edu/ovpr/uvmclick-fcoi/
How do you need to disclose?

Log in, using your UVM Net ID
How do you need to disclose?

Your Inbox will appear on the first screen. Click on the item prompting you to disclose:
How do you need to disclose?

Notice how the status of your disclosure reads “Draft”:

This institution is committed to ensuring its faculty an open and productive environment in which to conduct teaching, patient care, and research. The institution's concern with conflict of interest reflects the ever-increasing complexity of our society, our various relations with each other and with outside institutions, along with the heightened national and governmental sensitivity to such matters.

All full or part-time tenure-track faculty, visiting faculty, research scientists/scholars, and volunteer researchers must complete an annual conflict of interest disclosure form whether or not they conduct research at this institution. Principal investigators should ensure that any staff, students, or other employees who participate in the design, conduct, or reporting of research, complete a CCI disclosure form. Additionally, anyone engaged in any sponsored program, whether or not involving research, must complete an annual disclosure form. Disclosures must also be updated during the year whenever interests change.

To prepare for completing this form, you may want to collect the following documents:

- any consulting agreements you have signed this year
- receipts from travel paid by outside companies
- any stock option agreements
- your stock portfolio summary
- your IRS 1040 and/or 1029 forms.

To get started: Click on the “Edit Disclosures” button to the left, under “Next Steps.”
How do you need to disclose?

Annual Certification for Victoria Jones: Institutional Responsibilities

1. * Do you hold a position of executive leadership at the University of Vermont?  
   - Yes  
   - No  

2. * Are you directly or indirectly involved in any research at the University of Vermont? This includes, but is not limited to, being listed on any sponsored funding proposal, awarded grant, IRB, or IACUC submission.  
   - Yes  
   - No  

Continue
How do you need to disclose?

On this screen, you will enter whether you have an SFI to disclose. If not, you are done. If yes, the following screens help you make your disclosure.

Annual Certification for Victoria Jones: What to Disclose

The following question relates to any outside entities with which you have financial relationships outside of this institution in the previous 12 months and that qualifies as a Significant Financial Interest.

1. * Are there any outside organizations or companies with which you have a significant financial interest – which includes interests held by you, your spouse or dependent children? 
   - Yes
   - No
   - Clear
How do you need to disclose?
How do you need to disclose?

1. Select the external organization this disclosure is for:

2. If you are unable to find the organization, please enter as text below:
Disclosure for Victoria Jones: General Information

1. External organization:

   Name: ____________________________

   or

   If you cannot find the organization in the above list, enter the name as text here:

   Name: ______

2. Relationship to discloser:

   □ Self

   □ Spouse

   □ Dependent Child
How do you need to disclose?

3. *What type of Significant Financial Interest do you have with the external organization?*

- [ ] Equity (shares / options) in external company
- [ ] Consulting, advisory, or speaking compensation
- [ ] Editorial compensation
- [ ] Intellectual Property Rights (License / Royalties paid directly to individual)
- [ ] Reimbursements (excluding sponsored travel)
- [ ] Sponsored Travel
- [ ] Board of directors compensation
How do you need to disclose?

Disclosure for Victoria Jones: Organization Information

The organization you are disclosing for does not already exist in the database. Please provide some information about the organization to the institution.

1. *Organization name:
   Bonjour

2. *Is the organization publicly traded?
   ○ Yes  ● No  Clear

3. *Describe the nature of your financial interest in this company:
How do you need to disclose?

Disclosure for Victoria Jones in Bonjour: Stock or Equity

Outside organizations in which you or any member of your immediate family individually hold a form of equity. This does not include investments in mutual funds held by you or your dependents.

1. * Do you own stock / partnership shares in this organization?
   - Yes  No  Clear

2. If Yes, what is the current value of the shares?
   0

3. * Do you own stock options or any other form of equity in this organization?
   - Yes  No  Clear

4. If Yes, what is the current value of the options or other form of equity?
   0
How do you need to disclose?

**Disclosure for Victoria Jones in Bonjour: Disclosure Summary**

<table>
<thead>
<tr>
<th>Compensation Type</th>
<th>Dollar Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stock Equity</td>
<td>$0.00</td>
</tr>
<tr>
<td>Options Equity</td>
<td></td>
</tr>
<tr>
<td>Consulting, Advising, and Speaking</td>
<td></td>
</tr>
<tr>
<td>Editorial</td>
<td></td>
</tr>
<tr>
<td>License and Royalty</td>
<td></td>
</tr>
<tr>
<td>Reimbursements</td>
<td></td>
</tr>
<tr>
<td>Sponsored Travel</td>
<td></td>
</tr>
<tr>
<td>Board of Directors</td>
<td></td>
</tr>
<tr>
<td><strong>Total Value</strong></td>
<td>$0.00</td>
</tr>
</tbody>
</table>

- Save
- Exit
- Hide/Show Errors
- Print
- Jump To
How do you need to disclose?

Annual Certification for Victoria Jones: Disclosure Details

On this page, you will be required to provide information on each company/external organization with which you hold such significant financial interest as per the UVM Financial Conflict of Interest in Sponsored Research policy.

If the relationship has not previously been disclosed, click on the “Add Disclosure” button.

If the relationship has been previously disclosed, click on the “Modify” link next to the disclosure to update.

If the relationship is no longer active (e.g., a consulting agreement that is no longer active), click on the “Remove” link to the right of the disclosure.

1. Disclosures under review:

<table>
<thead>
<tr>
<th>View/Edit</th>
<th>Organization</th>
<th>Is Public Company</th>
<th>Relationships Disclosure Types</th>
<th>Total Value</th>
<th>Is Significant</th>
<th>Last Updated</th>
<th>Remove</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edit</td>
<td>Bonjour</td>
<td>no</td>
<td>Self</td>
<td>$0.00</td>
<td>yes</td>
<td>2/27/2019 11:00 AM</td>
<td>X</td>
</tr>
</tbody>
</table>
How do you need to disclose?

Annual Certification for Victoria Jones: Additional Information

1. * Details regarding your disclosures and why they are being modified:

   

2. Related documents:

   + Add

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   There are no items to display
How do you need to disclose?

Annual Certification for Victoria Jones: Assurance and Certification

- I hereby acknowledge that I have read and understand the UVM Financial Conflict of Interest in Sponsored Research policy.
- I affirm that the information provided is to the best of my knowledge true and complete and does not misstate any facts.
- I will provide any additional information as requested by the UVM Office of Research Administration and Integrity.
- I agree to cooperate in the development of any needed management plan as required per the Federal Regulations or otherwise by the UVM Financial Conflict of Interest in Sponsored Research policy to manage, reduce, or eliminate existing conflicts of interest related to my research. I agree to comply with the terms and conditions contained in any management plan.

Disclosures under review:

<table>
<thead>
<tr>
<th>Organization</th>
<th>Disclosure Type(s)</th>
<th>Total Value</th>
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<tbody>
<tr>
<td>Bonjour</td>
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Reviewed disclosures:

<table>
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<tr>
<th>Organization</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

There are no items to display.

Date submitted:

Before you finish:

To save your disclosure certification for completion at a later time: DO NOT check the confirmation box and click "Finish".

To finalize and submit your disclosure certification for review: DO check the confirmation box and click "Finish".

☐ My disclosures are up-to-date and accurate and I confirm that I understand and agree with the above statements.
How do you need to disclose?

This institution is committed to ensuring its faculty an open and productive environment in which to conduct teaching, patient care, and research. The institution's concern with conflict of interest reflects the ever-increasing complexity of our society, our various relations with each other and with outside institutions, along with the heightened national and governmental sensitivity to such matters.

All full or part-time tenure-track faculty, visiting faculty, research scientists/scholars, and volunteer researchers must complete an annual conflict of interest disclosure form whether or not they conduct research at this institution. Principal Investigators should ensure that any staff, students, or other employees who participate in the design, conduct, or reporting of research, complete a COI disclosure form. Additionally, anyone engaged in any sponsored program, whether or not involving research, must complete an annual disclosure form. Disclosures must also be updated during the year whenever interests change.

To prepare for completing this form, you may want to collect the following documents:
- any consulting agreements you have signed this year
- receipts from travel paid by outside companies
- any stock option agreements
- your stock portfolio summary
- your IRS 1040 and/or 1099 forms.

To get started: Click on the “Submit Disclosures” button to the left under “Next Steps.”
How do you need to disclose?

Submit Disclosures

Discloser Assurance and Certification

- I hereby acknowledge that I have read and understood the Financial Conflict of Interest policy.
- I affirm that the information provided in this disclosure is to the best of my knowledge true and complete and does not misstate any facts.
- I agree to cooperate in the development of any needed management plan as required per the Federal Regulations to manage, reduce, or eliminate existing conflicts of interest related to my research. I agree to comply with the terms and conditions contained in any management plan.

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<td></td>
<td>There are no items to display</td>
<td></td>
</tr>
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</table>

*All disclosures are accurate and up-to-date and you agree with all of the above statements: ☐

OK  Cancel
If you fail to disclose...
If you fail to properly 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.
Possible sanctions include:
• formal admonition;
• 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
Financial Conflict of Interest means:

a Significant Financial Interest that could
directly and significantly affect the
design,
conduct, or
reporting
of funded research.
The Financial Conflict of Interest Review

Step 1: Review by the Designated Institutional Official and Research Compliance Officer in consultation with the investigator’s department chair, if appropriate

Step 2: if applicable, Review by the committee. The committee is faculty led across section of academic disciplines.
If there is a Conflict of Interest:
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;

and, very rarely:

- 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 create 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.
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.
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.
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 weekends for the Alternative Energy Association, a non-governmental, non-profit agency, developing an online 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.