

Financial Conflict of Interest Policy

Understanding an Investigator's obligations

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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.*

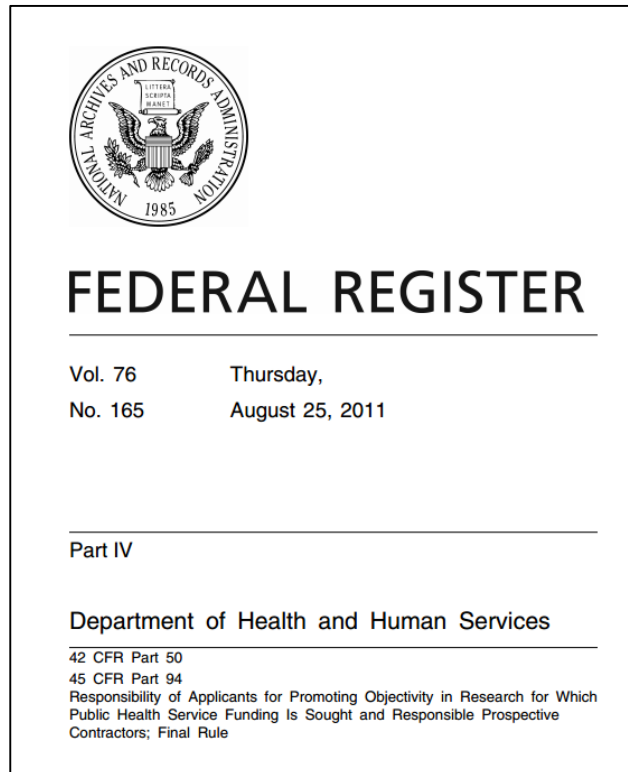
Differences with other UVM conflict policies:

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.

	Conflict of Interest Policy	Conflict of Commitment Policy	Financial Conflict of Interest in Sponsored 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	Over commitment	Impairment of the public trust
Nature	Financial, legal, ethical	Time commitment	Financial
Applicability	UVM employees	UVM employees	UVM investigators engaged in externally funded 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 externally funded research.
Disclosure Requirements	Disclose to immediate supervisor	Disclose to immediate supervisor	Disclose to designated institution official at conflict@uvm.edu
Links to Policy	Conflict of Interest Policy	Conflict of Commitment Policy	Financial Conflict of Interest

Background

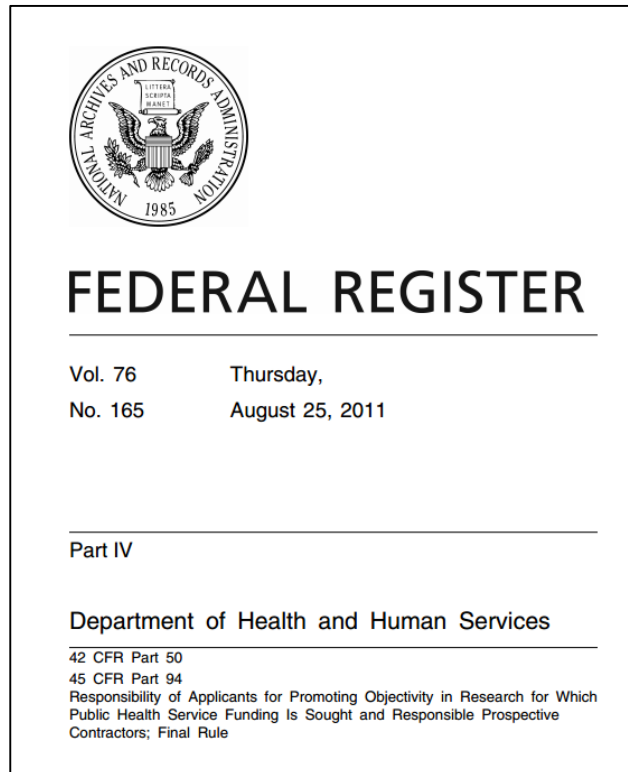


The origin of the UVM policy:

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

Background




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 University of Vermont

OFFICE OF AUDIT AND COMPLIANCE SERVICES
UVM.EDU/POLICIES

POLICY

Title: Financial Conflict of Interest in Sponsored Research

About This Policy

Responsible Official:	Vice President for Research	Approval Authority:	President
Policy Number:	V.6.3.5	Effective Date:	January 29, 2019
Revision History:	<ul style="list-style-type: none">V.6.3.4 Approved by the President on January 13, 2013V.6.3.3 Approved by the President on August 16, 2012V.6.3.2 Approved by the President on July 5, 2011V.6.3.1 Approved by the President on May 4, 2010		

Questions concerning the daily operational interpretation of this policy should be directed to the following (in accordance with the policy elaboration and procedures):

Title(s)/Department(s):	Contact Information:
Office of Research Administration & Integrity	oadi@uvm.edu (802) 656-7863

Policy Statement

The University of Vermont recognizes its obligation to identify and manage situations in which both real and perceived financial conflicts of interests could compromise objectivity or integrity relative to research. As such, investigators must disclose to the University whether or not they, their spouse, and/or their dependent children hold any Significant Financial Interest that reasonably relates to the investigator's institutional responsibilities.

Reason for the Policy

UVM recognizes the importance of allowing investigators the ability to collaborate with outside entities. These collaborations stimulate UVM's research programs and are vital when translating academic research into knowledge and discoveries that can have significant public benefit. However, some outside activities may have an appearance, or could have the potential, to compromise the objectivity of the research being conducted. The challenge is to balance and manage these outside interests without compromising the integrity of the research.

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University of Vermont Policies and Operating Procedures are subject to amendment. For the official, approved, and most recent version, please visit UVM's Institutional Policies Website (<http://www.uvm.edu/policies>).

The UVM Financial Conflict of Interest in Sponsored Research was drafted after the federal set of regulations and complies with most agencies rules.

The Disclosure 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.

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



Test your knowledge



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**:

Nature of SFI		Threshold	Excluded (Do Not Disclose)
Compensation and/or other payments for service		Exceeds \$5,000	<ul style="list-style-type: none"> any compensation received for lectures, seminars, teaching engagements, relating to: <ul style="list-style-type: none"> 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 UVMCMC 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 <i>Applies only to research submitted to PHS funding or any funding from agencies following PHS COI regulations</i>		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

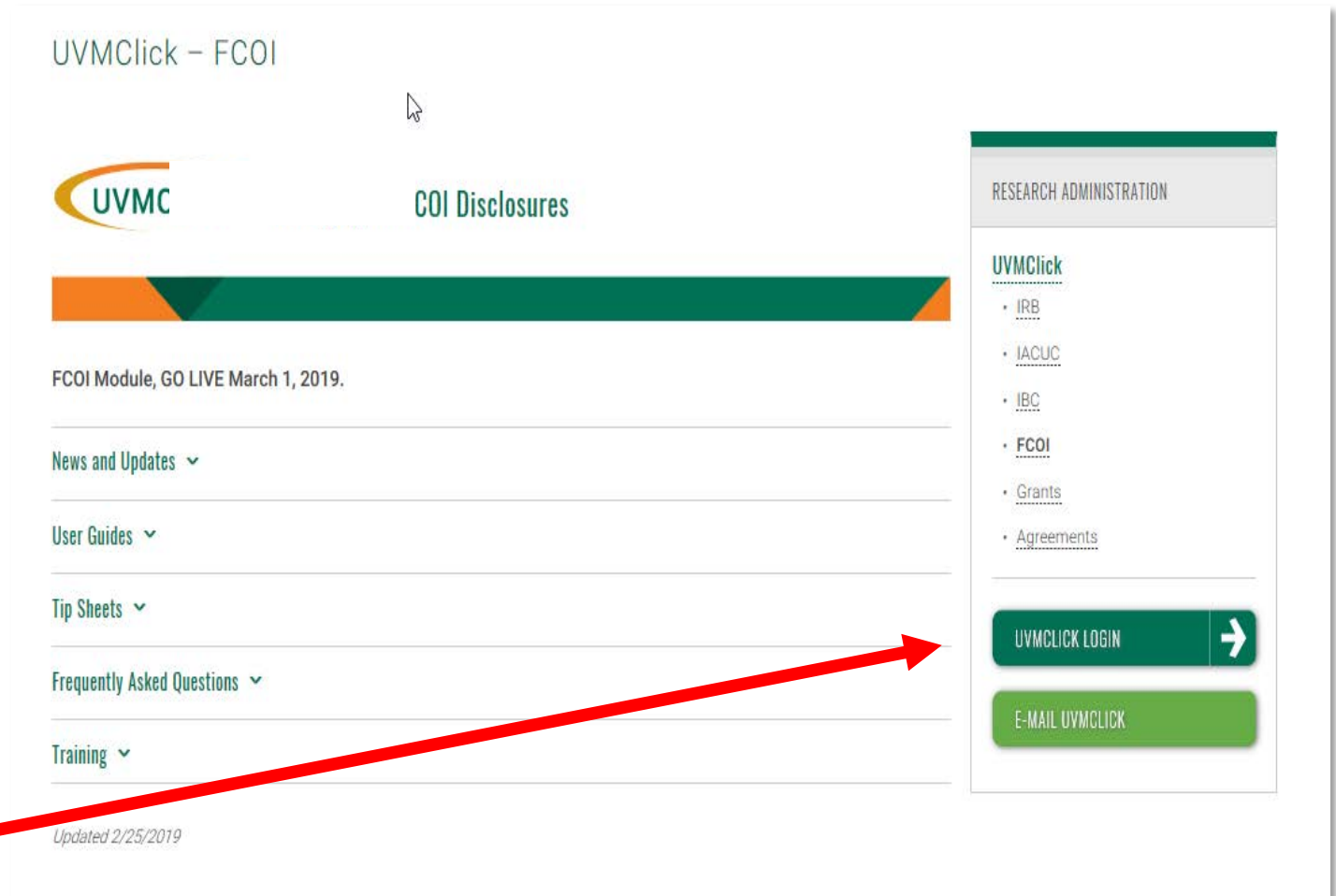
A New Significant Financial Interest is an SFI:

- 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/>



UVMClick – FCOI

UVM

COI Disclosures

FCOI Module, GO LIVE March 1, 2019.

News and Updates ▾

User Guides ▾

Tip Sheets ▾

Frequently Asked Questions ▾

Training ▾

Updated 2/25/2019

RESEARCH ADMINISTRATION

UVMClick

- IRB
- IACUC
- IBC
- **FCOI**
- Grants
- Agreements

UVMCLICK LOGIN →

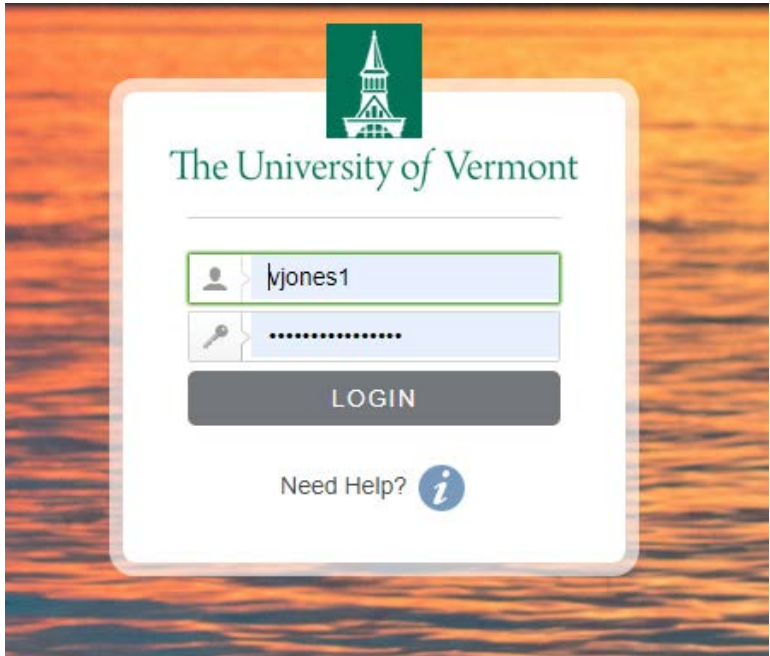
E-MAIL UVMCLICK

How do you need to disclose?

Log in, using your UVM Net ID




The image shows the UVMClick login page. At the top is the UVMClick logo, which consists of a stylized orange and green swoosh above the text "UVMClick". Below the logo, the text "IRB, IACUC, IBC, FCOI, Proposals, Awards, Agreements" is displayed. A large green button with the word "Login" in white is centered on the page. A red arrow points from the left towards this button. Below the button, the text "Having trouble? Email uvmclick@uvm.edu" is shown. The entire page is framed by a black border.



The image shows the University of Vermont login page. At the top is the University of Vermont logo, which consists of a green square with a white building icon. Below the logo, the text "The University of Vermont" is displayed. There are two input fields: the first is for the username, with "mjones1" entered, and the second is for the password, with "*****" entered. Below the input fields is a grey button with the word "LOGIN" in white. At the bottom, the text "Need Help?" is followed by a blue circular icon with a white "i" inside. The background of the page is a sunset over water.

How do you need to disclose?

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


Hello, [Victoria Jones](#) ▼

»
My Inbox
COI
Facilities
IRB
Safety

COI

IRB

My Inbox

Filter by ?


ID ▼

Enter text to search for

Q

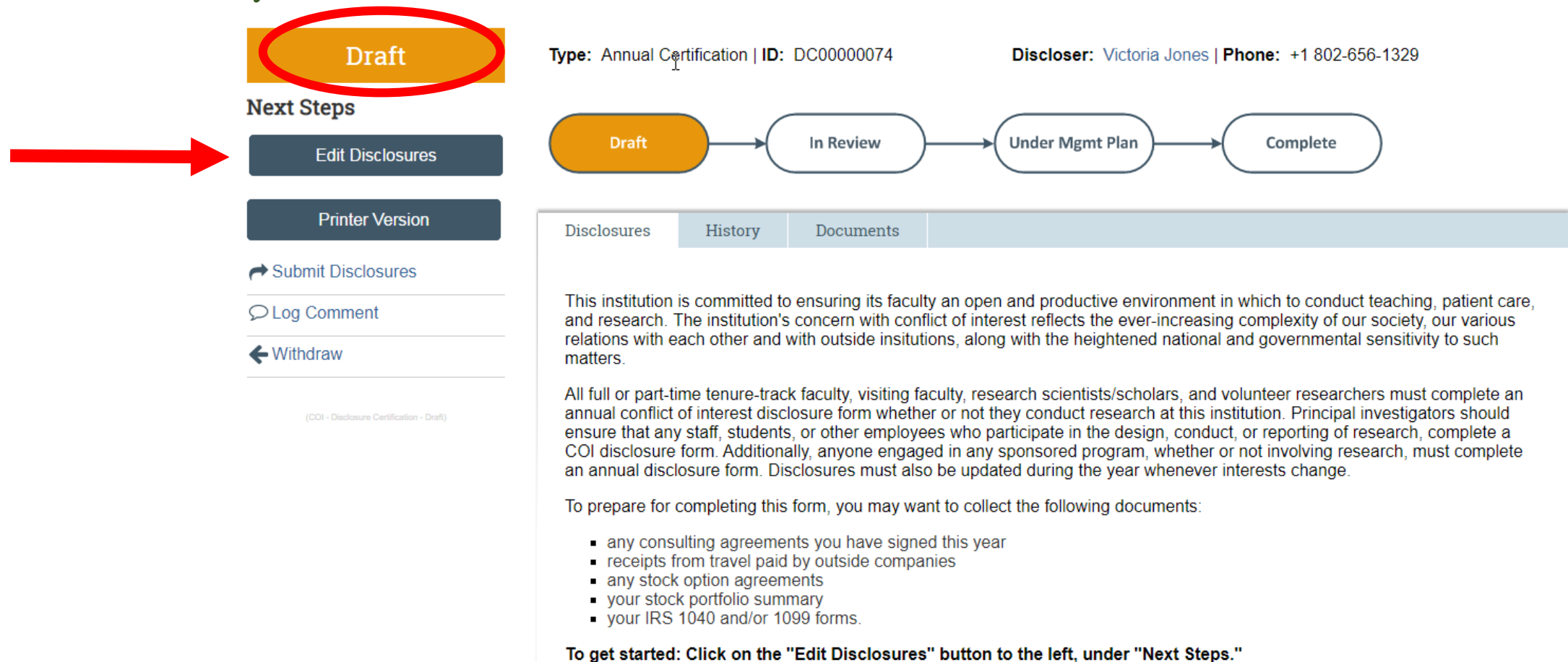
+ Add Filter

✕ Clear All

ID	Name	Date Created	▼ Date Modified	State	Coordinator
 DC00000074	Annual Disclosure Certification for Victoria Jones 2019	2/26/2019 1:50 PM	2/26/2019 1:50 PM	Draft	

How do you need to disclose?

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



Draft

Type: Annual Certification | ID: DC00000074 | Discloser: Victoria Jones | Phone: +1 802-656-1329

Next Steps

- Edit Disclosures
- Printer Version
- Submit Disclosures
- Log Comment
- Withdraw

(COI - Disclosure Certification - Draft)

Progress: Draft → In Review → Under Mgmt Plan → Complete

Disclosures | History | Documents

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 insitutions, 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 "Edit Disclosures" button to the left, under "Next Steps."


How do you need to disclose?

Edit: Disclosure Certification - DC00000074

You Are Here:  Annual Disclosure Certificatio...

[<< Back](#) [Save](#) [Exit](#) [Hide/Show Errors](#) [Print](#) [Jump To](#) [Continue >>](#)

Annual Certification for Victoria Jones : Institutional Responsibilities

1. * Do you hold a position of executive leadership at the University of Vermont? 

☒ Yes ☐ No [Clear](#)

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 [Clear](#)

[<< Back](#) [Save](#) [Exit](#) [Hide/Show Errors](#) [Print](#) [Jump To](#) [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?

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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.

[Add Disclosure](#)

1. Disclosures under review:

View/Edit	Organization	Is Public Company	Relationships	Disclosure Types	Total Value	Is Significant?	Last Updated	Remove
There are no items to display								

2. Previously reviewed disclosures: (click 'Modify' to enable editing)

Modify	View	Organization	Is Public Company	Relationships	Disclosure Types	Total Value	Is Significant?	Last Updated	Remove
There are no items to display									

[<< Back](#) [Save](#) [Exit](#) [Hide/Show Errors](#) [Print](#) [Jump To](#) [Continue >>](#)

How do you need to disclose?

Create New Disclosure

1. Select the external organization this disclosure is for:

 ...

2. If you are unable to find the organization, please enter as text below:

OK

Cancel

How do you need to disclose?



You Are Here:  Annual Disclosure Certificatio... >  Disclosure FI00000012 for Vict...

[<< Back](#) [Save](#) [Exit](#) [Hide/Show Errors](#) [Print](#) [Jump To ▾](#)

Disclosure for Victoria Jones : General Information

1. External organization:

or

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

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

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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:

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](#)

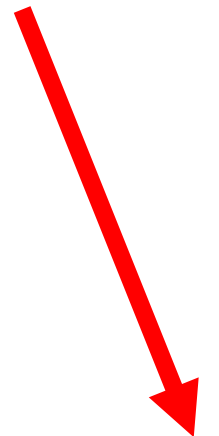
4. If Yes, what is the current value of the options or other form of equity?

|


How do you need to disclose?

Disclosure for Victoria Jones in Bonjour: Disclosure Summary


Compensation Type	Dollar Value
Stock Equity	\$0.00
Options Equity	
Consulting, Advising, and Speaking	
Editorial	
License and Royalty	
Reimbursements	
Sponsored Travel	
Board of Directors	
Total Value	\$0.00

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How do you need to disclose?



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Save

Exit

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Jump To ▾

Continue >>

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.

Add Disclosure


1. Disclosures under review:

View/Edit	Organization	Is Public Company	Relationships	Disclosure Types	Total Value	Is Significant?	Last Updated	Remove
Edit	Bonjour	no	Self	Equity (shares / options) in external company	\$0.00	yes	2/27/2019 11:00 AM	×

How do you need to disclose?



Edit: Disclosure Certification - DC00000074

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Annual Certification for Victoria Jones : Additional Information

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


2. Related documents:

[+ Add](#)

Name	Description
------	-------------

There are no items to display

How do you need to disclose?

Edit: Disclosure Certification - DC00000074

You Are Here: Annual Disclosure Certificatio...

[<< Back](#)[Save](#)[Exit](#)[Hide/Show Errors](#)[Print](#)[Jump To](#)[Finish](#)

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:

Organization	Disclosure Type(s)	Total Value
Bonjour	Equity (shares / options) in external company	\$0.00

Reviewed disclosures:

Organization	Disclosure Type(s)	Total Value
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.

[<< Back](#)[Save](#)[Exit](#)[Hide/Show Errors](#)[Print](#)[Jump To](#)[Finish](#)


How do you need to disclose?

Draft

Next Steps

Edit Disclosures

Printer Version

 [Submit Disclosures](#)

[Add Comment](#)

[Withdraw](#)

Type: Annual Certification | ID: DC00000074

Discloser: Victoria Jones | Phone: +1 802-656-1329



Disclosures

History

Documents

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 insitutions, 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 "Edit Disclosures" button to the left, under "Next Steps."

My Disclosures

Export

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 will provide any additional information as requested by the Office of Research Compliance.
- 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.

Disclosures under review:

Organization	Disclosure Type(s)	Total Value
Bonjour	Equity (shares / options) in external company	\$0.00

Reviewed disclosures:

Organization	Disclosure Type(s)	Total Value
There are no items to display		

*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.

If you fail to properly disclose...

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

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.

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.