



# Novelution Financial Conflict of Interest Guidebook

# Financial Conflict of Interest Introduction

Novelution's robust Financial Conflict of Interest (FCOI) module provides seamless electronic disclosure and management for both annual "Significant Financial Interest" (SFI) and "Project-Specific Disclosures". All disclosures will now be submitted, reviewed, managed, and approved electronically and will be centrally housed within Novelution. Given the robust features of the FCOI module, this guide will assist users in becoming familiar and understanding the purpose of each function and how to submit and manage disclosures.

#### "Significant Financial Interest" (SFI)

The "Significant Financial Interest" (SFI) submission replaces what is currently Section 1 of the Significant Financial Interest disclosure form. This is where researchers will generally answer whether they have any financial interests in the form of activities in an external company, equity interest, intellectual property, or travel. This is also the place where researchers will provide detailed descriptions about their outside companies. This can be thought of as your FCOI user profile and will only need to be submitted once and updated annually or when a researcher becomes involved in a new external activity.

#### "Project-Specific Disclosures"

The Project-Specific Disclosure submission replaces what is currently Section 2 of the Significant Financial Interest disclosure form. Researchers will complete this section for each new research project that has been awarded to answer questions about how the current project specifically relates or does not relate to the researcher's external financial activities which were previously disclosed.

#### Key Benefits

The FCOI module was created with the intent to provide seamless disclosures, management, and transparency while reducing unnecessary burden for Researchers, Administrators, Approvers, and the FCOI Committee Members. Since all disclosures will be submitted and managed electronically, it eliminates the traditional "paper" or "PDF" disclosure form, meaning the paper or PDF disclosure form will no longer have to be downloaded, completed, physically signed by researcher and any other approver(s), emailed, or uploaded into each proposal file. Additionally, the annual SFI is now only completed <u>once</u> and shall be valid for twelve (12) calendar months, unless there has been a change regarding the annual SFI. This now eliminates the need to have to complete the annual SFI for each and every proposal as in the past. A Researcher can complete or update/renew the annual SFI at any time and the annual SFI shall cover all proposals submitted within the twelve (12) calendar month when the Annual SFI was completed or updated/renewed. When an Annual SFI is updated/renewed, the validation period starts over (extended for another twelve calendar months) from the updated/renewed date.

For "Project-Specific" disclosure, Novelution will automatically notify and create a task for the researcher at "Award" stage if there is project-specific disclosure to be completed and managed. The researcher will

then complete the requirements for the project-specific disclosure and then route for signatures/FCOI Committee review/approval/management plan.

# **Key Benefits Summary**

- Eliminates the "paper" or "PDF" disclosure form
- Annual SFI is completed once and is valid for twelve (12) calendar months
- If an Annual SFI is current, the researcher does not have to submit an Annual SFI disclosure for each proposal, unless there has been a change to the Annual SFI
- The Annual SFI can be completed or updated/renewed at any time. Upon updating/renewing, the twelve (12) calendar month validation period is extended and starts over
- System generated notification/tasks for "Project-Specific" disclosures
- Electronic routing and approval for "Project-Specific" disclosures, including review, approval, and management plans

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# **Definitions**

#### Annual Disclosures

Annual, significant financial interest (SFI) disclosure(s) shall be completed electronically via Novelution.

#### Project-Specific Disclosures

Only occurs if there is a financial conflict of interest disclosure in the Annual SFI in Novelution and the proposal has been awarded.

#### Ad Hoc Disclosures

Within thirty (30) days of joining a research project already in progress or within 30 days of acquiring a new Annual SFI. The Annual SFI in Noveltuion should be updated/renewed and then submitted.

#### **Travel Disclosures**

Within Thirty (30) days of any reimbursed or sponsored travel undertaken by the Researcher rated to their Institutional Responsibilities (over \$5,000).

#### Login to Novelution

- Sign in at <u>fau.novelution.com</u>
- Click "Continue" to use your FAU Single Sign-On (SSO) username and password.

Part of Florida Atlantic University?
Click "Continue" button to use your FAU username and password to login.
Continue
Try to log me in automatically when possible
Not part of Florida Atlantic University?

• You will be taken to your institutional log-in page.

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# Novelution Home Page (All My Tasks)

Upon successfully signing in Novelution, the landing/home page automatically defaults to the user's "All My Tasks" view under the "Profile & Settings" tab. In order to access the FCOI module, the user must move their mouse cursor and hover over the "FCOI" tab.

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When the cursor is hovering the FCOI tab, additional sub-sections will appear, including:

- 1. My FCOI Disclosure
- 2. Search FCOI Disclosures
- 3. Search Project-specific Disclosures
- 4. Search Management Plans
- 5. Ad-hoc Reports

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#### Annual Significant Financial Interest (Defining Each Sub-section)

1. My FCOI Disclosure – The "My FCOI Disclosure" panel allows users to disclose their "annual" significant financial interest (SFI) through a series of four (4) defined questions. This is a unique section with its own "Panel shortcuts" menu on the upper left-hand side for ease of navigation. A user can click on the specific section of interest or scroll down on the page to reach the intended section. When answering the four (4) defined questions, the user will select "Yes or No" utilizing radio buttons. If the selection is "No", the user can proceed to the next question.

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lapse all   expand all	Edit - Disclosure for Tracy Vuong
Review Comments	
Financial	Florida Atlantic University Division of Research/Sponsored Programs FINANCIAL INTEREST DISCLOSURE FORM
Financial Equity Interest	Preface: Federal and state regulations require that a university manage, reduce or eliminate any actual, potential or perceived financial conflicts of interest that may arise as a result of compensated financial interests of persons involved in sponsored research projects. A conflict of interest is best described as a situation in which a person serves or represents two distinct entities or persons involved in sponsored research projects. A conflict of interest is best described as a situation in which a person serves or represents two distinct entities or persons involved in sponsored research projects. A conflict of interest is best described as a situation in which a person serves or represents two distinct entities or persons involved in sponsored research projects.
Intellectual Property	and must choose between two conflicting loyatiles or interests. A researcher has a conflict when their interest/activity or financial interest could potentially interfere with the employee's research obligations. Inis form must be submitted to the office of Sponsored Programs, Division of Research upon initial submission of a proposal; annually on projects funded for more than one year; and updated if a person's significant financial interest changes during the course of a funded research project.
Travel	
Additional Information	A researcher has a contact when their interesvactivity, or inflatioal contact of interest, could potentially interere with the employee's research obligations, it is in timind, please answer the following questions as it relates to your research bligations, [E.g., you should disclose the entity if your research is in the area of immunology and you have received income from a clinic. You should not disclose entities related to video game development if your research is in immunology.
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Requirements	La request amenoment
	collapse all   expand all
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	O Add Comment
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	<ul> <li>▼To-Do</li> <li>▲ Financial Interest/Activity</li> </ul>
	<ul> <li>To-DO</li> <li>Financial Interest/Activity</li> <li>In the past twelve (12) months have you, your spouse, or dependent children engaged in an activity with any entity resulting/involving financial interests which could reasonably appear to affect or be affected by your areas of Research in which you or they:</li> <li>have any ownership or supervisory role, including, but not limited to, managerial responsibilities</li> <li>received any payments over 55.000 (apart from any payments through Florida Atlantic University), including salary, consulting fees, honoraria, fees, paid authorship, or other forms of comeensation or anything of value, *0</li> </ul>
	<ul> <li>▼To-DO</li> <li>Financial Interest/Activity</li> <li>In the past twelve (12) months have you, your spouse, or dependent children engaged in an activity with any entity resulting/involving financial interests which could reasonably appear to affect or be affected by your areas of Research in which you or they:         <ul> <li>have any ownership or supervisory role, including, but not limited to: managerial responsibilities</li> <li>received any payments over \$5,000 (apart from any payments through Florida Atlantic University), including salary, consulting fees, honoraria, fees, paid authorship, or other forms of compensation or anything of value. * ●</li> <li>Yes ® No</li> </ul> </li> </ul>
	To-Do     In the past twelve (12) months have you, your spouse, or dependent children engaged in an activity with any entity resulting/involving financial interests which could reasonably appear to affect or be affected by your areas of Research in which you or they: <ul> <li>have any ownership or supervisory role, including, but not limited to, managerial responsibilities</li> <li>received any payments over \$5,000 (apart from any payments through Florida Atlantic University), including salary, consulting fees, honoraria, fees, paid authorship, or other forms of compensation or anything of value. * ●</li> <li>Ves ® No</li> </ul>
	To-Do    Financial Interest/Activity In the past twelve (12) months have you, your spouse, or dependent children engaged in an activity with any entity resulting/involving financial interests which could reasonably appear to affect or be affected by your areas of Research in which you or they: <ul> <li> have any ownership or supervisory role. Including, but not limited to, managerial responsibilities <ul> <li> received any payments over \$5,000 (payt from any payments through Florida Atlantic University), including salary, consulting fees, honoraria, fees, paid authorship, or other forms of compensation or anything of value. * • </li> <li> O yes • No </li> </ul> </li> <li> Do you, your spouse, or dependent children have an Equity Interest valued over \$5,000 in a publicly-traded or any equity in a non-publicly traded entity involving financial interests which could reasonably appear to affect or be affected by your areas of research, including but not limited to shares of stock or stock options within the prior 12 months? </li> </ul>
	To-Do    Financial Interest/Activity In the past twelve (12) months have you, your spouse, or dependent children engaged in an activity with any entity resulting/involving financial interests which could reasonably appear to affect or be affected by your areas of Research in which you or they: <ul> <li>a have any ownership or supervisory role, including, but not limited to, managerial responsibilities</li> <li>received any payments over \$5,000 (payt from any payments through Florida Atlantic University), including salary, consulting fees, honoraria, fees, paid authorship, or other forms of compensation or anything of value. * • </li> <li>O ves • No</li> </ul> A Financial Equity Interest Do you, your spouse, or dependent children have an Equity interest valued over \$5,000 in a publicly-traded or any equily in a non-publicly traded entity involving financial interests which could reasonably appear to affect or be affected by your areas of research, including but not limited to shares of stock or stock options within the prior 12 months? Do NOT include equity held in a mutual, pension, or investment fund over which you have no control with regard to investment decisions.* O ves • No

2. If the selection is "Yes" - Additional action is required and an "Add" button will appear either to add activity, add financial Equity Interest, add intellectual property, and/or add travel. Depending on which question(s) were answered "Yes", once the "Add" button is clicked, a pop-up will appear with additional questions pertaining to that specific disclosure. The four (4) defined questions pertain to the following areas:

# Financial Interest/Activity

Activity		×
Reporting for	⊖ self ⊖Spouse ⊖ Dependent Child	
Entity's Name	Start typing	
Type of Activity	Select one	
Start date of your involvement with this entity	<b>#</b>	
What is the current status of this involvement?	Ongoing Completed	
Describe your, your spouse's, or dependent child's relationship/role/dutie or responsibilities in this company or entity		
Will the entity involve the use of the university's or school's facilities o resources?	O Yes O No	
Are any other university personnel involved with this entity?	○ Yes ○ No	
Was this Activity compensated?	O Yes O No	
Provide any other information relevant for it to be determined whethe your financial interests/activities create an actual, potential or perceived sinancial Conflict of interest. Note: The more details you provide the more expeditious the process will be as additional follow up is less likely tr		
occur		
	Cancel Save Save Save and Add Another for the same Outside Organization	

# **Financial Equity Interest**

Equity Interest		×
Reporting for*	O Self O Spouse O Dependent Child	
Entity's Name*	Start typing 🔻	- 82
Type of Equity Interest. Select all that apply.*	Stock/Shares Units Options	
Provide any other information relevant for it to be determined whether your financial equity interests/activities create an actual, potential or perceived Financial Conflict of Interest. Note: The more details you provide the more expeditious the process will be as additional follow up is less likely to occur.		
×	Cancel Save Save and Add Another for the same Outside Organization	

# Intellectual Property

Reporting for*       Oseif         Spouse       Operadent Child         Entity's Name (licensee or optionee)*       Start typing         Describe the IP Interest*       Image: Comparison of the imag	ntellectual Property		×
Entity's Name (licensee or optionee)*          Describe the IP Interest* <ul> <li>Describe the IP Interest*</li> <li>Inventor</li> <li>Owner</li> <li>Ulcensee</li> <li>Assignee</li> </ul>	Reporting for*	⊖ Self ⊖ Spouse ⊖ Dependent Child	
Describe the IP Interest*	Entity's Name (licensee or optionee)*	Start typing •	
What is their role in the Intellectual Property interest?* O Inventor O Owner O Licensee O Assignee	Describe the IP Interest*		
O Other	What is their role in the Intellectual Property Interest?*	O Inventor O Owner O Licensee O Assignee O Other	
X Cancel     Save     Save and Add Another for outside organization		x Cancel Save Save and Add Another for outside organization	

#### <u>Travel</u>

Travel		×
Travel Sponsor*	Start typing 🔻	- 1
Reporting for*	O Self O Spouse O Dependent Child	- 1
Year in which trip(s) took place?*	<b></b>	_
Travel Destination*		_
Travel Purpose*		_
Total Number of Days*		_
	u Caned	_
		-

3. Additional Information – This section allows users to provide additional details regarding their or their family member's financial interest disclosure(s) to assist the review process. If there is no disclosure or if there are no additional details to be added, the user can select "No" using the radio buttons and move to the "Attestation" section. If additional details are to be provided, the user will select "Yes" where a "Please Explain" text box will appear for further details.

Additional Information		<ul> <li></li> <li></li></ul>
Are there any additional details about you or your Family Member's Finar $\odot$ Yes $\bigcirc$ No	icial Interests that may assist in the review of this Financial Interests Disclosure?*	
Please explain.*		

4. Attestation – This section allows users to attest and certify that they have completed the Financial Conflict of Interest in Research Investigation Training Course, have read and understand Florida Atlantic University's policy on Conflict of Interest Related to Research, and to certify that the disclosure is complete and true to best of their knowledge and that they will comply with any conditions or restrictions imposed by Florida Atlantic University. The user must click the "Certification" checkbox to complete this section.

<b>~</b>	Certification
	I have completed the Financial Conflicts of Interest in Research Investigator Training Course.
	I have read and understand the Florida Atlantic University Policy on Conflicts of Interest Related to Research.
	By submitting this information I certify that the disclosure is complete and true to the best of my knowledge. I acknowledge that should my financial interests, or those of my Family Members, change in a way that results in different answers to any of the questions asked in this disclosure, I will submit updated information. If required, I will comply with any conditions or restrictions imposed by Florida Atlantic University.*

5. Workflow and Requirements – This section allows users to view the status of their annual SFI disclosure. Since the annual SFI does not require additional approvals, there is only one "Status" and "Requirement". When the annual SFI section has been complete in full and submitted, the "Completion State" will indicate "Completed" along with who it was completed by and the date of completion.

Stage - Revision #		Created		Current Status			Status Date		Notes
Disclosure - revision #1.1 (05-14-2021) Viewing		02/08/2021 1:33 PM		Disclosure Completed	۲		05/14/2021 3:52 PM	И	
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isclosure Submission Pending	Employee must submit disc	osure	✓Completed	ł	#1.1	Vuong, T	racy	05/14/2021 3:52 P	M
isclosure Completed									

6. Save, Submit and Check Validations – At any time, the user can utilize the save and check validation button at the bottom of the page. The check validation button will alert the users if there are any warning or errors due to incomplete sections or unanswered mandatory questions as designated by a red asterisk. The "Submit" button should only be utilized once all required sections and questions are complete. Once submitted, no additional action is required for the annual SFI until a notification or task is generated by the system.

Should a proposal submitted by the researcher become funded, then additional actions will be required for the "Project-Specific" or relatedness/project disclosure.

<ul> <li>Certification</li> </ul>						
I have completed th	ne Financial Conflicts of Interest in Research	Investigator Training Course.				
I have read and un	derstand the Florida Atlantic University Policy	y on Conflicts of Interest Related to Research.				
By submitting this i Members, change i conditions or restri	nformation I certify that the disclosure is cor n a way that results in different answers to a ctions imposed by Florida Atlantic University	mplete and true to the best of my knowledge. I ac ny of the questions asked in this disclosure. I will .*	knowledge that should submit updated inform	my financial interests, or those of my Fa nation. If required, I will comply with any	imily	
Workflow and Requirement	S					8
Stage - Revision #	Created	Current Status		Status Date	Notes	
Disclosure - revision #1.1 Viewing	06/08/2021 4:42 PM	Disclosure Submission Pending 🥏		06/08/2021 4:42 PM		
Status	Requirement	Completion State	Revision	Completed by Comple	ted Date	
Disclosure Submission Pending	Employee must submit disclosure	Ready				
isclosure Completed						
		Check Validations				_
	SAVE SUDIVILI					*

#### Project-Specific Disclosures

The "Project-Specific" or relatedness/project question is only triggered under two (2) conditions. First, there must be a disclosure within the Annual SFI. Second, the proposal/project must be awarded. If all questions within the Annual SFI were checked "No", there is no additional FCOI action required the by researcher once the proposal status has been updated to award in Novelution. However, if any of the Annual SFI questions were checked "Yes" and an activity was added, upon updating the status to "Award" by the Office of Sponsored Programs, a system generated task will be created and viewable in the researcher's "All My Tasks" home/landing page when they first log in.

Novelution Research	Management System									Tracy Vuon
le & Settings Si	ite Admin IRB Module	IACUC Module	Grants & Contracts	Radiation Safety	FCOI					
ome > 🛔 Profile &	Settings > All My Tasks									
ll My Tasks										
ilter Search by	y Task meta-data									
Type:				Keyword:			(	Completed Status:		
Filter by Task Typ	pe						h	ncomplete		v
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The number of assigned FCOI tasks will be based on the number of proposals the researcher has submitted and were awarded. In the example above, there are 4 total "Project-Specific" disclosure actions that are required to be completed since the Researcher has 4 pending awards. To access the project-specific task, simply click on the "blue" text in the "Message" column which will direct the researcher to that specific project to complete the project-specific disclosure.

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pse un l'expand un	collapse all   expand all						
Project-specific Questions	▲ Project-specific Quest	ions					<ul> <li>Image: Comparison of the second second</li></ul>
Related Outside Interests	Describe this specific spons	ored research project (in lay language	)*				
Attestation							
Admin Review						li	
Workflow and Requirements	(include any supervision o	role in this sponsored research proje ver students involved in the research)	ct :*				
	▲ Related Outside Intere	ests					<ul> <li>Image: Comparison of the second second</li></ul>
	Microsoft (Public)						
	collapse rows 🛢   expand row	s 🖸					
	Activities						
	Date Added 🗸	Entity	Туре	Who	Compensation	View Details	
	06/23/2021	Microsoft	Consulting	Self	\$5,000.00		

When the "Project-Specific" disclosure module is open, there are a new set of disclosure questions that are required to be completed, including "Project-Specific Questions", "Related Outside Interest", and Attestations". Please note, the number of questions or action required will be based on the number of disclosures and types of disclosures on the Annual SFI. The Researcher must complete all required sections and submit for "Chair Review" and then "FCOI Admin Pre-review". The FCOI Committee will ultimately review once the FCOI Admin has completed their requirements. Depending on the nature of the disclosure, the FCOI Committee will recommend if or how the conflict will be managed. FCOI related documents by the FCOI Admin and FCOI Committee will be uploaded within Novelution upon its completion.

Edit Stage/Status 🕜 Upda	te all incomplete req	uirements							
Stage - Revision # Created		Created		Current Status			Status Date	Notes	
Initial PRF - revision #1.1 06/23/2021 1:31 PM		06/23/2021 1:31 PM		Departmental Review 💿			06/23/2021 1:31 PM		
		C	Completion State Revision			Completed by Completed Date		te	
isclosure Submission Pending Employee must submit disclosure		st submit disclosure	~	✓Completed #1.1		Vuong, Tracy 06/23/2021		06/23/2021 1:31 PM	•••
partmental Review Chair Review		R	eady					•••	
OI Admin Pre-review FCOI Admin Pre-review		N	Not ready						
01 Review									
closure Completed									

Upon resolution by the FCOI Committee, if there are no additional "holds" on the awarded proposal, the Office of Sponsored Programs will be notified to proceed with the Post-Award process.