FLORIDA ATLANTIC UNIVERSITY

Novelution

Financial Conflict of Interest Module (FCOI)

PRESENTED BY: THE OFFICE OF SPONSORED PROGRAMS &

THE OFFICE OF RESEARCH INTEGRITY

Introducing the Novelution FCOI Module

What is the FCOI Module

- 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.

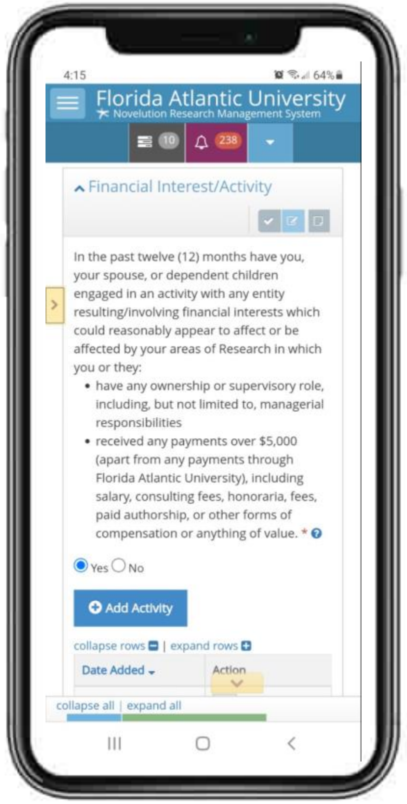
Key Benefits

- Seamless disclosures, management, and transparency that reduces investigator burden
- Replaces the traditional SFI "paper" or "PDF" disclosure form
- Eliminates having to print & scan/email/pass around the SFI disclosure form for signatures
- Eliminates the requirement of having to submit a SFI disclosure form for each proposal
- SFI disclosures are valid for 12 months with updates/renewal accessible any time

Novelution's Additional Benefits

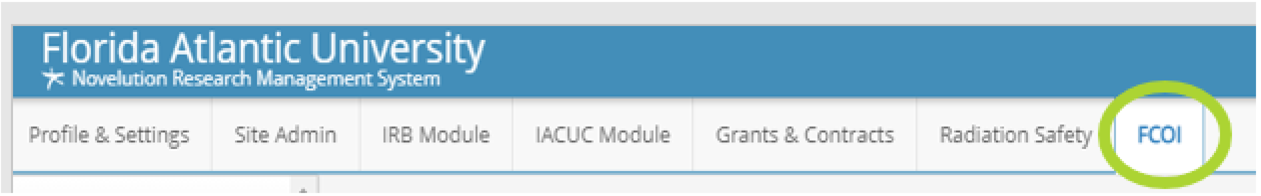
Additional Key Benefits

- Since Novelution is web-based, it can be accessed anywhere there is an internet connection and users can update their FCOI disclosures utilizing their FAU Single-Sign-On username and password
- In-system task reminders when a SFI or Project-Specific Disclosure is required
- The FCOI Module works directly with the Sponsored Research Module which makes FCOI routing requirement seamless
- Project-Specific Disclosures are only required if the project has been awarded and if there was a SFI disclosed
- Each SFI update/renewal automatically extends the disclosure to be active for an additional 12 months



August 2, 2021

“Soft Launch” Date



- **<u>Optional</u>** Novelution submission
- Not required at this point, paper submission is ok
- FCOI Tab will appear in the system for use of the module

September 1, 2021

Official Launch Date

- Novelution submission will be **<u>required</u>** at this point
- Paper disclosure will no longer be accepted for new submissions

FCOI Novelution Module Training Dates

~~Friday, August 6th at 3:00pm~~

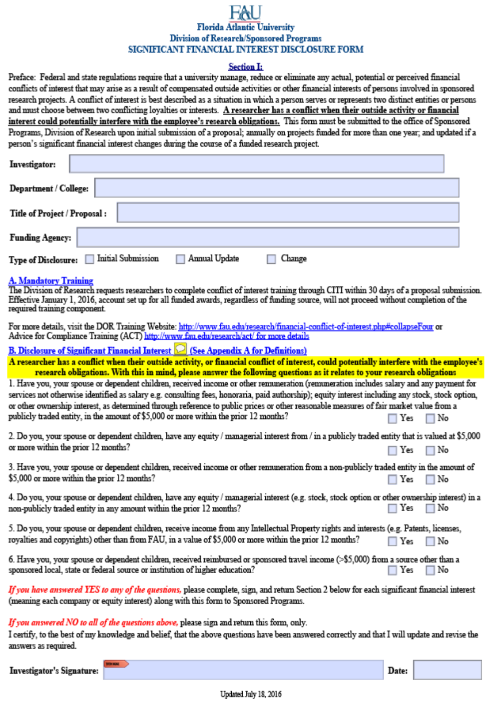
~~Thursday, August 19th at 3:00pm~~

Wednesday, September 1st at 3:00pm

Significant Financial Interest (SFI)

- Is now a two part process:
  - SFI disclosure (at the time of proposal submission)
  - Project-Specific disclosure (at the time of award)

The first two pages of the paper form are now the first part of the disclosure process in Novelution



FAU

Florida Atlantic University
Division of Research/Sponsored Programs
SIGNIFICANT FINANCIAL INTEREST DISCLOSURE FORM

Section I:

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 outside activities or other 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 and must choose between two conflicting loyalties or interests. **A researcher has a conflict when their outside activity or financial interest could potentially interfere with the employee's research obligations.** This 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.

Investigator:

Department / College:

Title of Project / Proposal :

Funding Agency:

Type of Disclosure: ☐ Initial Submission ☐ Annual Update ☐ Change

A. Mandatory Training

The Division of Research requests researchers to complete conflict of interest training through CITI within 30 days of a proposal submission. Effective January 1, 2016, account set up for all funded awards, regardless of funding source, will not proceed without completion of the required training component.

For more details, visit the DOR Training Website: http://www.fau.edu/research/financial-conflict-of-interest.php#collapseFour or Advice for Compliance Training (ACT) http://www.fau.edu/research/act/ for more details

B. Disclosure of Significant Financial Interest (See Appendix A for Definitions)

A researcher has a conflict when their outside activity, or financial conflict of interest, could potentially interfere with the employee's research obligations. With this in mind, please answer the following questions as it relates to your research obligations

1. Have you, your spouse or dependent children, received income or other remuneration (remuneration includes salary and any payment for services not otherwise identified as salary e.g. consulting fees, honoraria, paid authorship); equity interest including any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value from a publicly traded entity, in the amount of $5,000 or more within the prior 12 months? ☐ Yes ☐ No

2. Do you, your spouse or dependent children, have any equity / managerial interest from / in a publicly traded entity that is valued at $5,000 or more within the prior 12 months? ☐ Yes ☐ No

3. Have you, your spouse or dependent children, received income or other remuneration from a non-publicly traded entity in the amount of $5,000 or more within the prior 12 months? ☐ Yes ☐ No

4. Do you, your spouse or dependent children, have any equity / managerial interest (e.g. stock, stock option or other ownership interest) in a non-publicly traded entity in any amount within the prior 12 months? ☐ Yes ☐ No

5. Do you, your spouse or dependent children, receive income from any Intellectual Property rights and interests (e.g. Patents, licenses, royalties and copyrights) other than from FAU, in a value of $5,000 or more within the prior 12 months? ☐ Yes ☐ No

6. Have you, your spouse or dependent children, received reimbursed or sponsored travel income (>$5,000) from a source other than a sponsored local, state or federal source or institution of higher education? ☐ Yes ☐ No

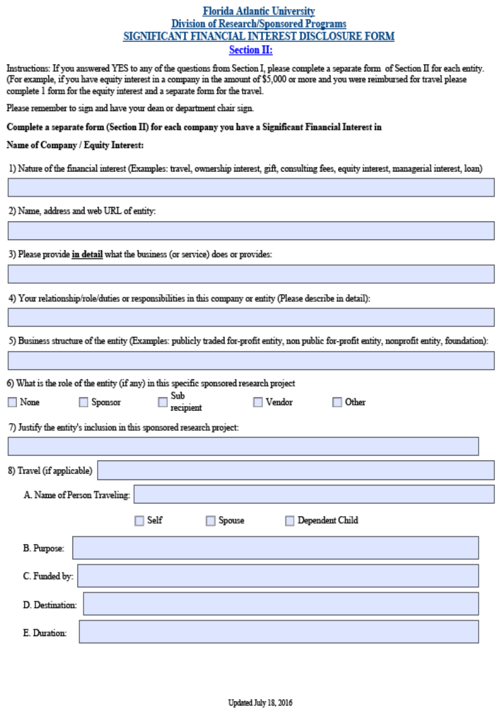
If you have answered YES to any of the questions, please complete, sign, and return Section 2 below for each significant financial interest (meaning each company or equity interest) along with this form to Sponsored Programs.

If you answered NO to all of the questions above, please sign and return this form, only.

I certify, to the best of my knowledge and belief, that the above questions have been answered correctly and that I will update and revise the answers as required.

Investigator's Signature: **Date:**

Updated July 18, 2016



Florida Atlantic University
Division of Research/Sponsored Programs
SIGNIFICANT FINANCIAL INTEREST DISCLOSURE FORM
Section II:

Instructions: If you answered YES to any of the questions from Section I, please complete a separate form of Section II for each entity. (For example, if you have equity interest in a company in the amount of $5,000 or more and you were reimbursed for travel please complete 1 form for the equity interest and a separate form for the travel.

Please remember to sign and have your dean or department chair sign.

Complete a separate form (Section II) for each company you have a Significant Financial Interest in

Name of Company / Equity Interest:

1) Nature of the financial interest (Examples: travel, ownership interest, gift, consulting fees, equity interest, managerial interest, loan)

2) Name, address and web URL of entity:

3) Please provide **in detail** what the business (or service) does or provides:

4) Your relationship/role/duties or responsibilities in this company or entity (Please describe in detail):

5) Business structure of the entity (Examples: publicly traded for-profit entity, non public for-profit entity, nonprofit entity, foundation):

6) What is the role of the entity (if any) in this specific sponsored research project

☐ None ☐ Sponsor ☐ Sub recipient ☐ Vendor ☐ Other

7) Justify the entity's inclusion in this sponsored research project:

8) Travel (if applicable)

A. Name of Person Traveling:

☐ Self ☐ Spouse ☐ Dependent Child

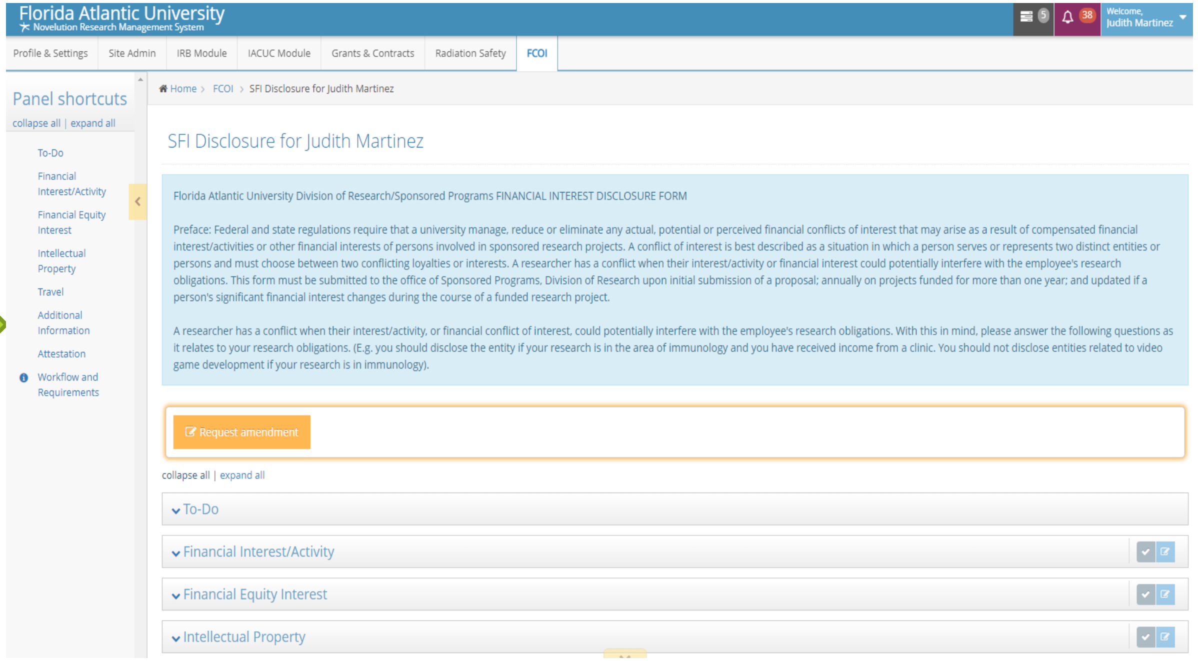
B. Purpose:

C. Funded by:

D. Destination:

E. Duration:

Updated July 18, 2016



[Expanded views on the next slides]

Florida Atlantic University
Novelution Research Management System

5 38 Welcome, Judith Martinez

Profile & Settings | Site Admin | IRB Module | IACUC Module | Grants & Contracts | Radiation Safety | FCOI

Home > FCOI > SFI Disclosure for Judith Martinez

Panel shortcuts

collapse all | expand all

- To-Do
- Financial Interest/Activity
- Financial Equity Interest
- Intellectual Property
- Travel
- Additional Information
- Attestation
- Workflow and Requirements

SFI Disclosure for Judith Martinez

Florida Atlantic University Division of Research/Sponsored Programs FINANCIAL INTEREST DISCLOSURE FORM

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 interest/activities or other 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 and must choose between two conflicting loyalties or interests. A researcher has a conflict when their interest/activity or financial interest could potentially interfere with the employee's research obligations. This 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.

A researcher has a conflict when their interest/activity, or financial conflict of interest, could potentially interfere with the employee's research obligations. With this in mind, please answer the following questions as it relates to your research obligations. (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).

Request amendment

collapse all | expand all

To-Do

Financial Interest/Activity

Financial Equity Interest

Intellectual Property

Part B of the SFI disclosure in paper form

B. Disclosure of Significant Financial Interest (See Appendix A for Definitions)

A researcher has a conflict when their outside activity, or financial conflict of interest, could potentially interfere with the employee's research obligations. With this in mind, please answer the following questions as it relates to your research obligations

1. Have you, your spouse or dependent children, received income or other remuneration (remuneration includes salary and any payment for services not otherwise identified as salary e.g. consulting fees, honoraria, paid authorship); equity interest including any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value from a publicly traded entity, in the amount of $5,000 or more within the prior 12 months? ☐ Yes ☐ No

2. Do you, your spouse or dependent children, have any equity / managerial interest from / in a publicly traded entity that is valued at $5,000 or more within the prior 12 months? ☐ Yes ☐ No

3. Have you, your spouse or dependent children, received income or other remuneration from a non-publicly traded entity in the amount of $5,000 or more within the prior 12 months? ☐ Yes ☐ No

4. Do you, your spouse or dependent children, have any equity / managerial interest (e.g. stock, stock option or other ownership interest) in a non-publicly traded entity in any amount within the prior 12 months? ☐ Yes ☐ No

5. Do you, your spouse or dependent children, receive income from any Intellectual Property rights and interests (e.g. Patents, licenses, royalties and copyrights) other than from FAU, in a value of $5,000 or more within the prior 12 months? ☐ Yes ☐ No

6. Have you, your spouse or dependent children, received reimbursed or sponsored travel income (>$5,000) from a source other than a sponsored local, state or federal source or institution of higher education? ☐ Yes ☐ No

Part B of the SFI disclosure in the Novelution form

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:

- have any ownership or supervisory role, including, but not limited to, managerial responsibilities
- 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. *

○ Yes ◉ No

Financial Equity Interest

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?

DO NOT include equity held in a mutual, pension, or investment fund over which you have no control with regard to investment decisions.*

○ Yes ◉ No

Intellectual Property

Do you, your spouse or dependent children, receive income from any Intellectual Property rights and interests (e.g. Patents, licenses, royalties and copyrights) other than from FAU, in a value of $5,000 or more within the prior 12 months?*

○ Yes ◉ No

Travel

Have you, your spouse or dependent children, received sponsored travel or reimbursed income (>$5,000) from a source other than a sponsored local, state or federal source or institution of higher education?

List reimbursed travel or travel that was paid on your behalf and not reimbursed to you for the past 12 months related to your professional responsibilities. Do not report travel that was paid or reimbursed by FAU, Federal, state, or local government agency, U.S. institutions of higher education, and affiliated teaching hospitals, medical centers, or research institutes.*

○ Yes ◉ No

Additional Information

Are there any additional details about you or your Family Member's Financial Interests that may assist in the review of this Financial Interests Disclosure?*

○ Yes ◉ No

Attestation

☑ 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.*

Florida Atlantic University
Division of Research/Sponsored Programs
SIGNIFICANT FINANCIAL INTEREST DISCLOSURE FORM
Section II:

Instructions: If you answered YES to any of the questions from Section I, please complete a separate form of Section II for each entity. (For example, if you have equity interest in a company in the amount of $5,000 or more and you were reimbursed for travel please complete 1 form for the equity interest and a separate form for the travel.

Please remember to sign and have your dean or department chair sign.

Complete a separate form (Section II) for each company you have a Significant Financial Interest in

Name of Company / Equity Interest:

1) Nature of the financial interest (Examples: travel, ownership interest, gift, consulting fees, equity interest, managerial interest, loan)

2) Name, address and web URL of entity:

3) Please provide **in detail** what the business (or service) does or provides:

4) Your relationship/role/duties or responsibilities in this company or entity (Please describe in detail):

5) Business structure of the entity (Examples: publicly traded for-profit entity, non public for-profit entity, nonprofit entity, foundation):

6) What is the role of the entity (if any) in this specific sponsored research project

☐ None ☐ Sponsor ☐ Sub recipient ☐ Vendor ☐ Other

7) Justify the entity's inclusion in this sponsored research project:

8) Travel (if applicable)

A. Name of Person Traveling:

☐ Self ☐ Spouse ☐ Dependent Child

B. Purpose:

C. Funded by:

D. Destination:

E. Duration:

Updated July 18, 2016

Section II (questions 1-8) of the paper form will now appear as a blue button option to add interests when there is a "yes" answer to any of the categories

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:

- have any ownership or supervisory role, including, but not limited to, managerial responsibilities
- 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. *

◉ Yes ○ No

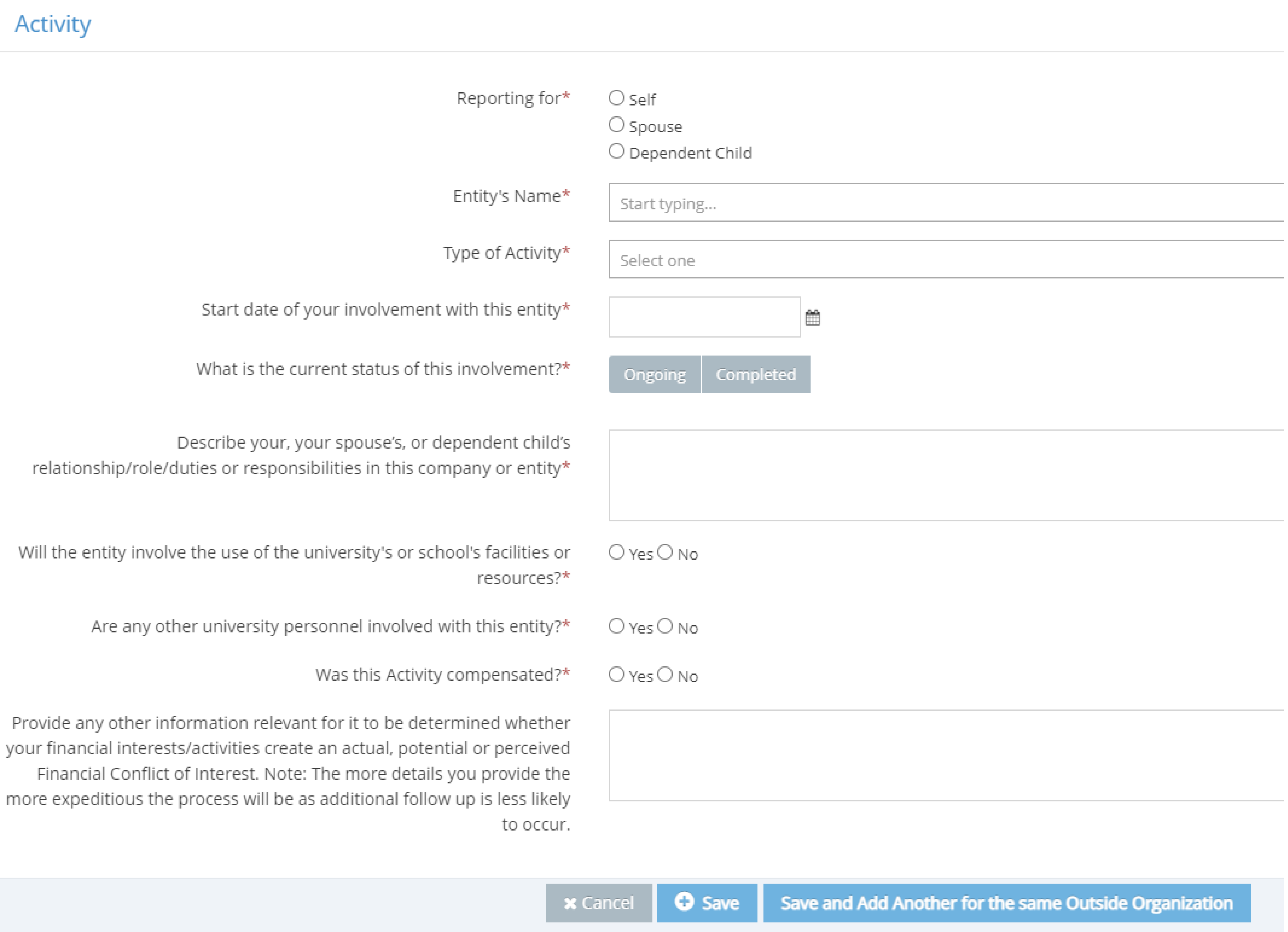
Add Activity

collapse rows | expand rows

Date Added	Entity	Type	Who	Compensation	Action
02/10/2021	Pfizer (Archived)	Consulting	Self	$7,000.00	...

Financial Equity Interest

Disclose an outside activity (consulting, organization, etc.). This information is completed **ONCE** and automatically links to the researcher's account. Think of it as a "User Profile". FCOI reviewers will be able to see these entities


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*

What is the current status of this involvement?* Ongoing | Completed

Describe your, your spouse's, or dependent child's relationship/role/duties or responsibilities in this company or entity*

Will the entity involve the use of the university's or school's facilities or resources?* ○ Yes ○ No

Are any other university personnel involved with this entity?* ○ Yes ○ No

Was this Activity compensated?* ○ Yes ○ No

Provide any other information relevant for it to be determined whether your financial 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

Disclose an equity interest (stocks/shares, etc.)

Financial Equity Interest

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?

DO NOT include equity held in a mutual, pension, or investment fund over which you have no control with regard to investment decisions.*

(•) Yes ( ) No

Add Financial Equity Interest

collapse rows | expand rows

Date Added	Entity	Type	Who	Value
05/12/2021	Deetex LLC	Stock/Shares	Self	Not Applicable

Equity Interest

Reporting for*

- ○ Self
- ○ Spouse
- ○ Dependent Child

Entity's Name*

Start typing...

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

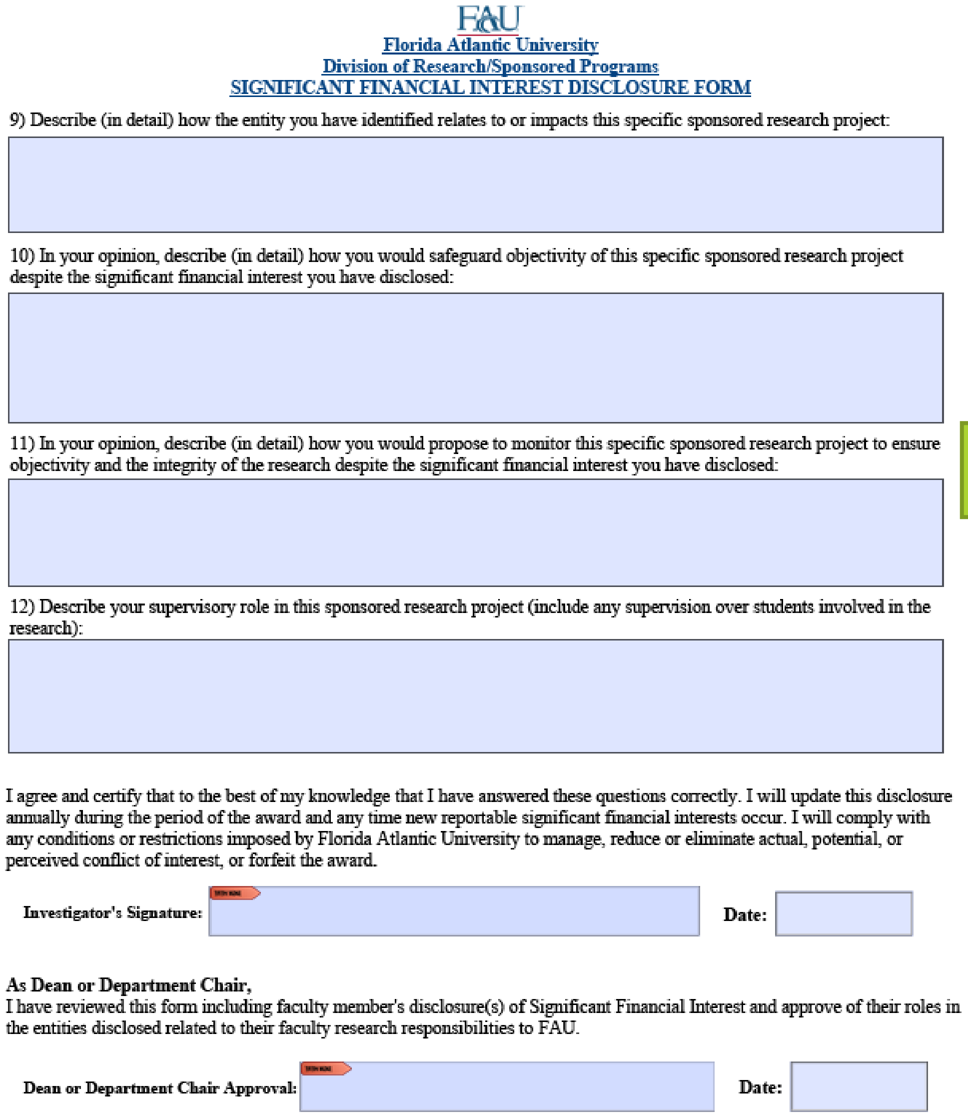
Disclose IP, Travel, and add any additional details in a text field as applicable

Outside interests will only need to be disclosed <u>**ONCE**</u>.

- RI will approve the submission after all information is complete and thorough
- Changes can be made to previously disclosed interests and new interests may be added at any time

“Project-Specific Disclosure” or “Relatedness”

This section in Novelution replaces Section II, questions 9-12 on the paper form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9) Describe (in detail) how the entity you have identified relates to or impacts this specific sponsored research project:

10) In your opinion, describe (in detail) how you would safeguard objectivity of this specific sponsored research project despite the significant financial interest you have disclosed:

11) In your opinion, describe (in detail) how you would propose to monitor this specific sponsored research project to ensure objectivity and the integrity of the research despite the significant financial interest you have disclosed:

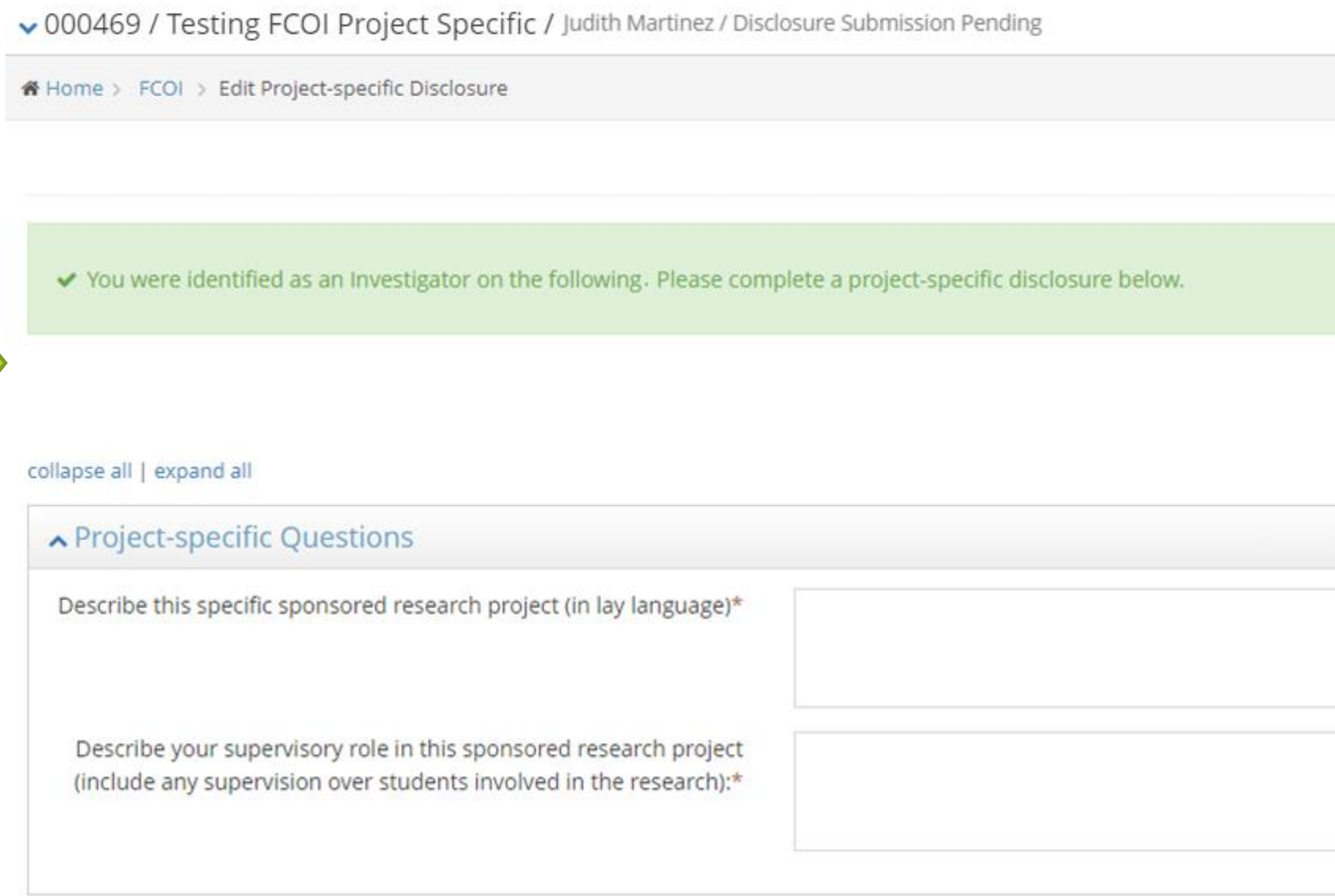
12) Describe your supervisory role in this sponsored research project (include any supervision over students involved in the research):

I agree and certify that to the best of my knowledge that I have answered these questions correctly. I will update this disclosure annually during the period of the award and any time new reportable significant financial interests occur. I will comply with any conditions or restrictions imposed by Florida Atlantic University to manage, reduce or eliminate actual, potential, or perceived conflict of interest, or forfeit the award.

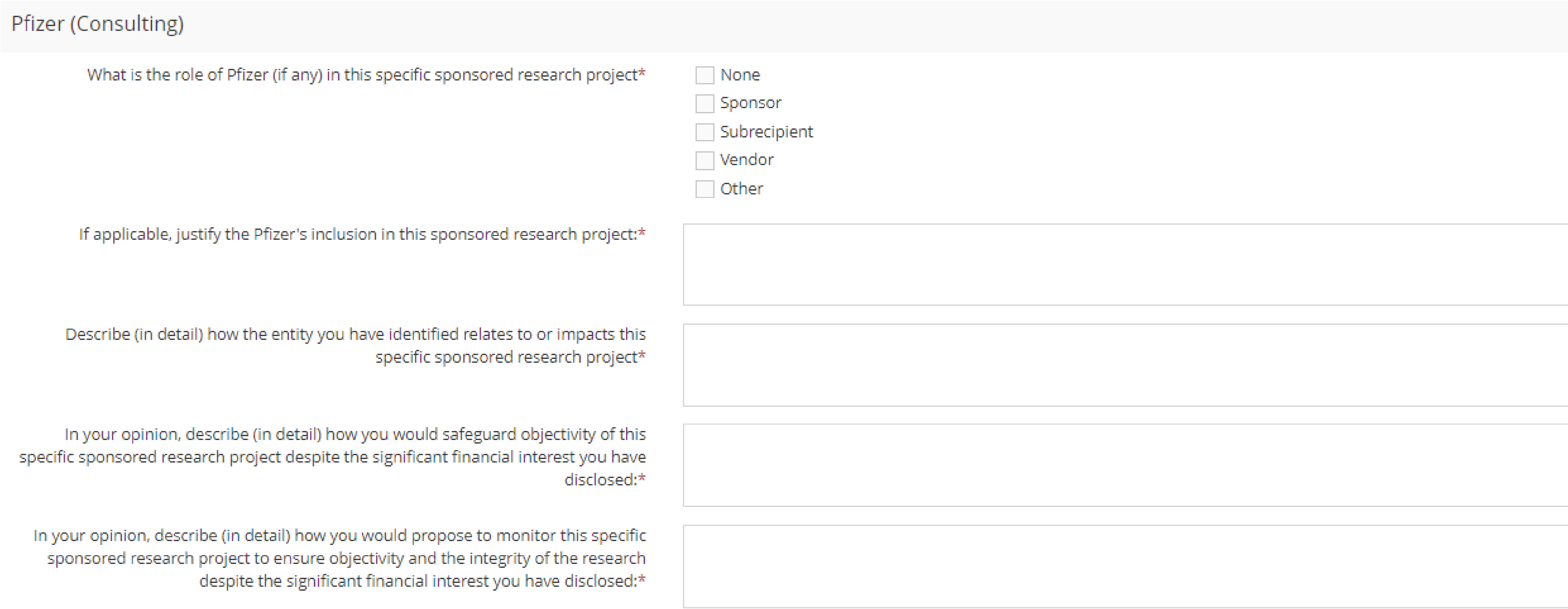
Investigator's Signature: **Date:**

As Dean or Department Chair,
I have reviewed this form including faculty member's disclosure(s) of Significant Financial Interest and approve of their roles in the entities disclosed related to their faculty research responsibilities to FAU.

Dean or Department Chair Approval: **Date:**



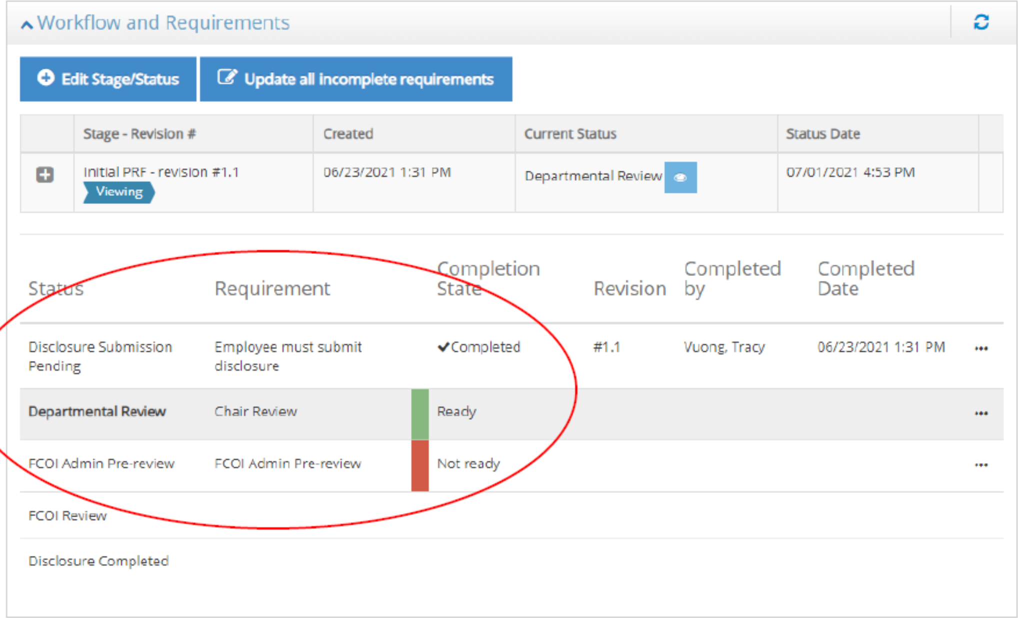
After answering the two general project-specific questions from the previous slide, researchers will have a panel for each entity that has been disclosed and will be asked to describe how the outside interest does or does not relate to the present project.



Project-Specific Disclosures will be required for ***each*** new project **<u>ONCE.</u>**

- Annual updates: 60-days prior to the annual update due date, researchers will receive a notification to confirm if no changes were made or to make changes as needed
- The form does not need to be re-completed from scratch

Project-Specific Disclosures



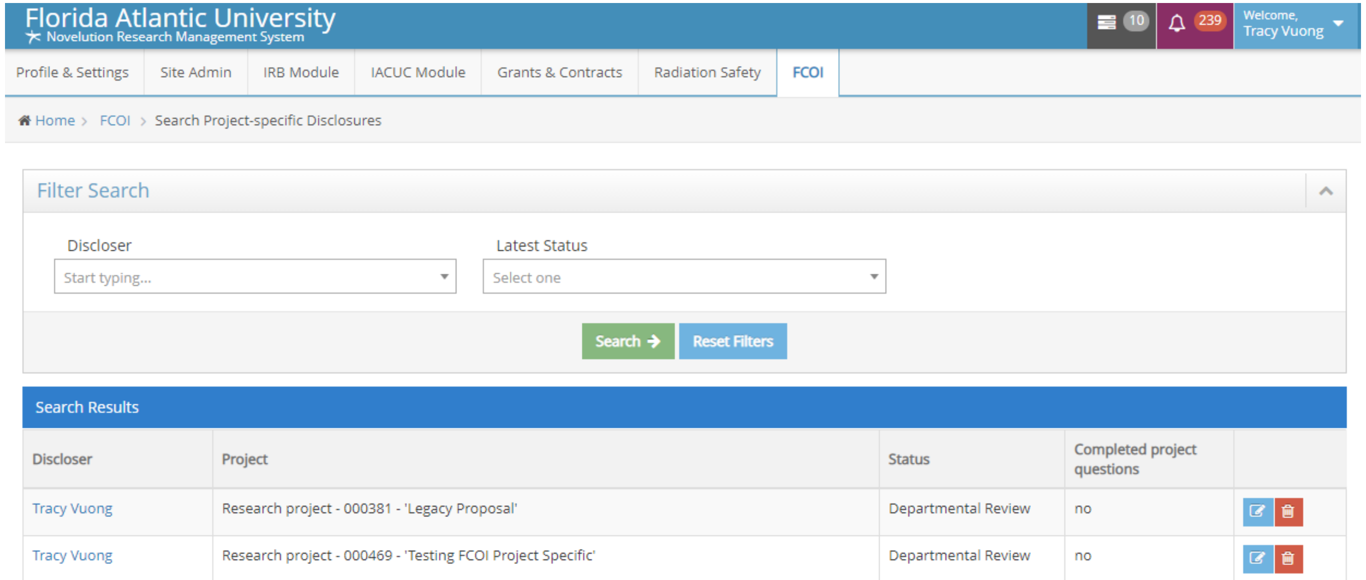
Project-Specific Disclosures

- Are only required if, there was a SFI disclosure **<u>and</u>** the project has been awarded
- Novelution will auto-generate notification(s) and task(s) for the investigator to complete the project-specific disclosure
- Review, management, and approval from the department Chair, FCOI Committee, or others will be seamless and transparent through the workflow history

Users are in Control of their own Disclosure

Managing and Tracking Disclosures

- Users can manage or review past disclosures
- All submitted disclosures remain in the user's FCOI module profile
- Users can search past disclosures including project-specific disclosures
- Approval documents or management plans will also be uploaded in the users' FCOI module profile



FCOI Novelution Module Training Dates

Friday, August 6th at 3:00pm

Thursday, August 19th at 3:00pm

Wednesday, September 1st at 3:00pm

Contact Judith Martinez at martinezj2012@fau.edu or at researchintegrity@fau.edu for questions or comments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