

# UNIVERSITY OF MIAMI

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## UDisclose System Triggering Events Quick Guide

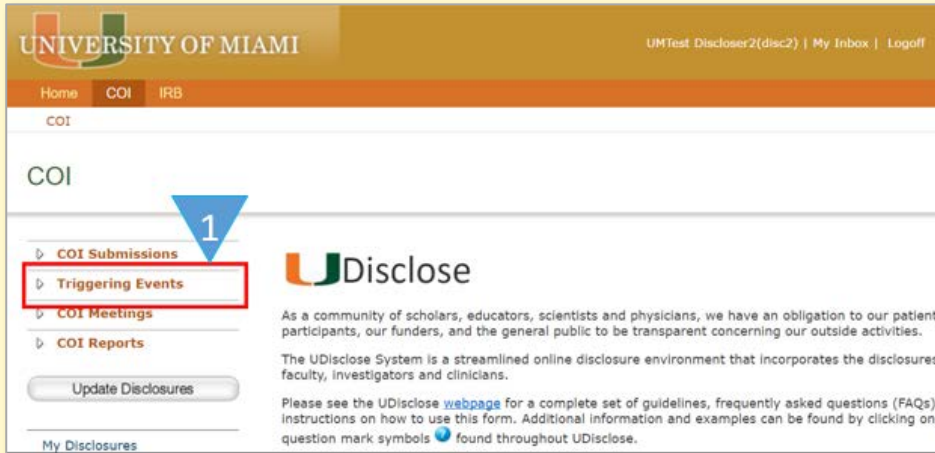
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<https://UDisclose.miami.edu>

## PD/PI/Proxy Process for Adding or Removing Project Team Members

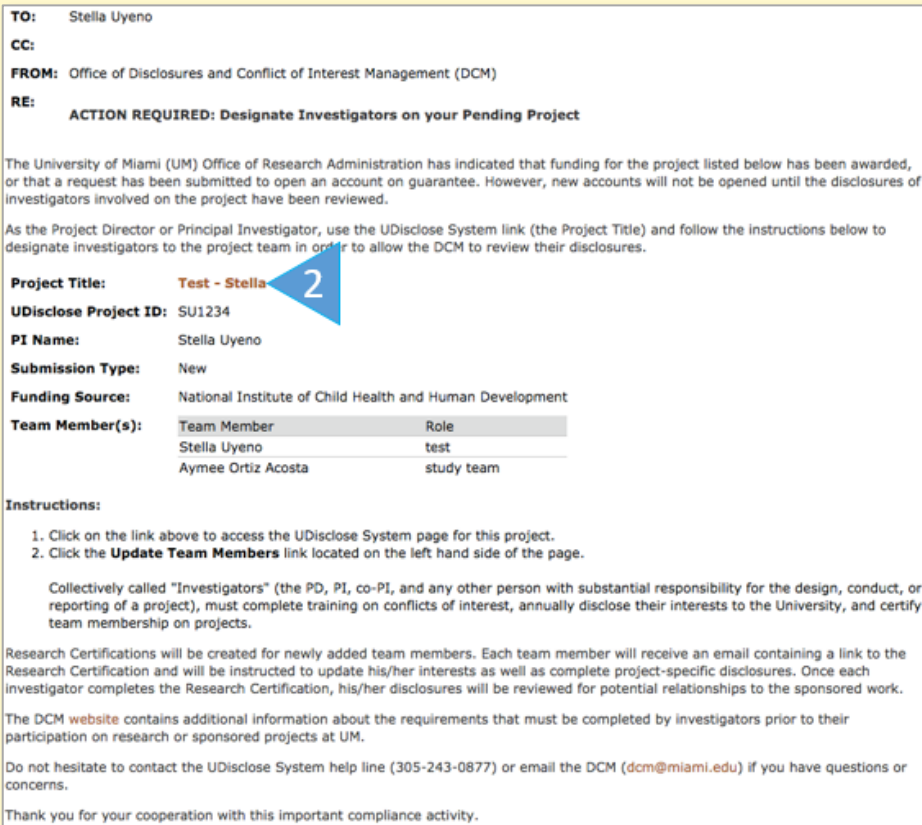
This process must be completed by the Project Director/Principal Investigator (PD/PI) or his/her Proxy when there is a New or Competing Renewal generated in UDisclose. When there is a Supplement or Non-Competing Renewal, the PD/PI will be reminded to update the team members on the project.

- For Human Subject Research (HSR) studies, team members are designated in the eProst (IRB7) system. Please contact the HSR Office Help Desk at [eproost@med.miami.edu](mailto:eproost@med.miami.edu) or 305-243-2314 for assistance.



### What do I do?

1. A PD/PI (or Proxy) can access their projects using the **Triggering Event** link found in the upper left tool bar in the UDisclose System.
2. In addition, every time a new project is created in the UDisclose System, the PD/PI (and Proxy) will receive an email. By clicking on the "Project title" link, the PD/PI will be redirected to the correct Triggering Event workspace in the UDisclose System.



## Update Team Members

3. Once directed to the Triggering Event workspace, the PD/PI (or Proxy) will click the **Update Team Members** link under My Current Actions.

4. The PD/PI will add or remove team members (only investigators with substantial responsibility for the design, conduct or reporting) using the **Add** and **Delete** (4.1) buttons.

4.1 Check the box at the bottom of the page (4.2) only if the PD/PI is the sole investigator working on the project.

4.2 The principal investigator should not add himself or herself as a team member on the project.

5. The PD/PI may search for their team members by entering the first few letters of each person's last name, and then selecting the appropriate investigator by department or division to ensure selection of the correct investigator.

➤ A PD/PI does not need to know a team member's C-Number to add him/her to a project.

6. A Research Certification will be created for each newly added team member, and the system will send an email notification to each person with a link to his/her Research Certification for the project.

**Update Team Members**

Directors/Principal Investigators (PD/PIs) use this screen to designate the "investigators" who will perform the work on this project. "Investigator" means the PD, PI, and any other person with substantial responsibility for the design, conduct, or reporting of the project.

Use the "Update Team Members" link to designate investigators, or to remove them from the project team.

A "Research Based Certification" is created for each investigator. UM will review each investigator's disclosures to determine relatedness to the proposed project.

- Use the "View Triggering Event" button to see additional information about this project.

C-Number	Name	Role	Certification Status	Certification Status	Date Submitted	Certified in last 11 months?	CITI Training Current?	Certification Cleared?
C1111111	UMTest Discloser 100 (disc100)	Principal Investigator	OK0000247	reviewed	3/29/2017	Yes	Yes	Yes
	UMTest Discloser 100 (disc100)	Principal Investigator	DC00000247	reviewed	3/29/2017	Yes	Yes	Yes

This is a list of all investigators currently designated to the project.

- Use the "Add" button to add new investigators to the project team.
- Use the "Delete" button next to an investigator's name to remove him/her from the project team.

**Update Research Team Members:**

Team Member	Role	Delete
UMTest Discloser 100 (disc100)	Principal Investigator	Delete
Test PI	TM	Delete
UMTest Discloser2(disc2)	Data Collection	Delete

Check this box if there are no investigators (team members with substantial responsibility for the design, conduct, or reporting of this project) other than the Project Director/Principal Investigator

OK Cancel

**Add Research Team Member**

1. Person: [disc] Select...

Name	First	Organization
Discloser 1(disc1)		UMTest School of Communication
Discloser 100 (disc100)		UMTest Medicine, Department of
Discloser10 (disc10) - DO NOT USE (FOR UAT)		UMTest Facial, Plastic and Reconstructive Surgery, Division of
Discloser2(disc2)		UMTest School of Communication
Discloser3 (disc3) - DO NOT USE (FOR UAT)		UMTest Anesthesiology, Department of
Discloser4(disc4) - DO NOT USE (FOR UAT)		UMTest Behavioral, Clinical, Diagnostic and Pediatric Services

OK OK and Add Another Cancel

**TO:** UMTest StudyStaff1 (ss1)

**CC:**

**FROM:** Office of Disclosures and Conflict of Interest Management (DCM)

**RE:** Research Initiated Certification for UMTest StudyStaff1 (ss1): 81881

Dear UMTest StudyStaff1 (ss1):

You have been designated as an investigator on the project below. "Investigators," (the PD, PI, co-PI and any other persons with substantial responsibility for the design, conduct, or reporting of a project) must:

- complete training on conflicts of interest prior to engaging in research,
- annually disclose their interests to the University, and
- certify team membership on projects.

Remember that you are required to update your disclosures within thirty (30) days of acquiring a new interest (e.g. through activity, purchase, marriage or inheritance).

Please click on the link below to complete a research-based certification for this project in the UDisclose system.

**UDisclose Project ID #: 81881**

**Project Title:** 205543 - A Phase III, randomised, double-blind, multicentre, parallelgroup, non-inferiority study evaluating the efficacy, safety, and tolerability of dolutegravir plus lamivudine compared to dolutegravir plus tenofovir/emtricitabine in HIV-1-infected tre

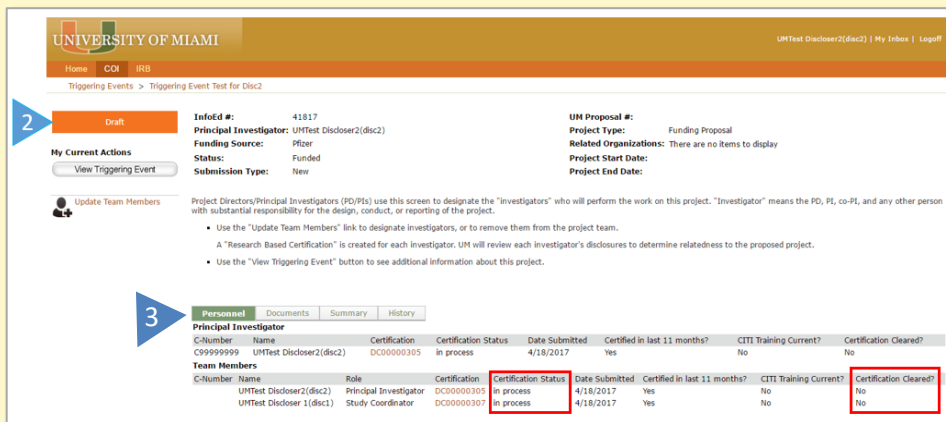
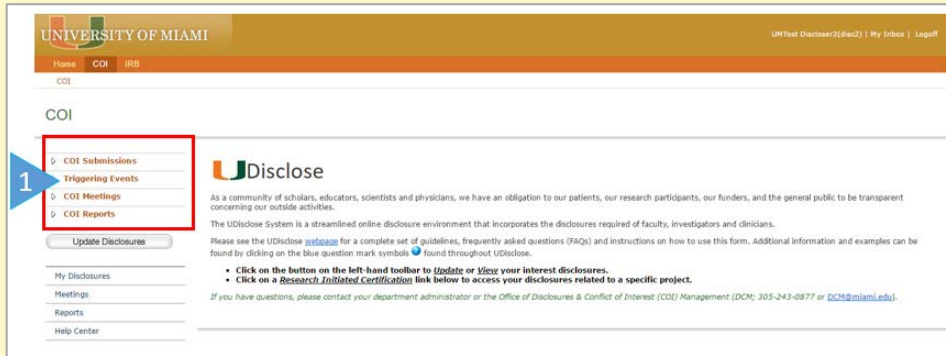
**Your Research Certification:** Research Initiated Certification for UMTest StudyStaff1 (ss1): 81881

# Checking the Status of Team Members on a Project

The PD/PI (or proxy) can check the status of a project from the “Triggering Events” list.

## What do I do?

1. From the COI workspace click on **Triggering Events** to view and select your desired triggering event.
2. The status bar of the triggering event page will always display a “draft” status, regardless of the state of team member certifications.
3. You can check the certification status of your team members in the **Personnel** section of the triggering events page.



Certification Status	
Draft	Individual needs to complete the certification
In Process	Certification under review
	Under management plan
Reviewed	Review complete
	Management plan satisfied

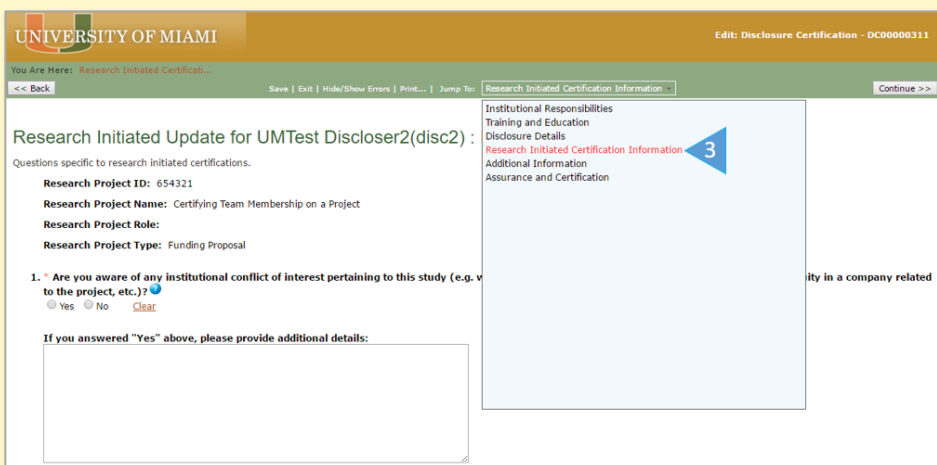
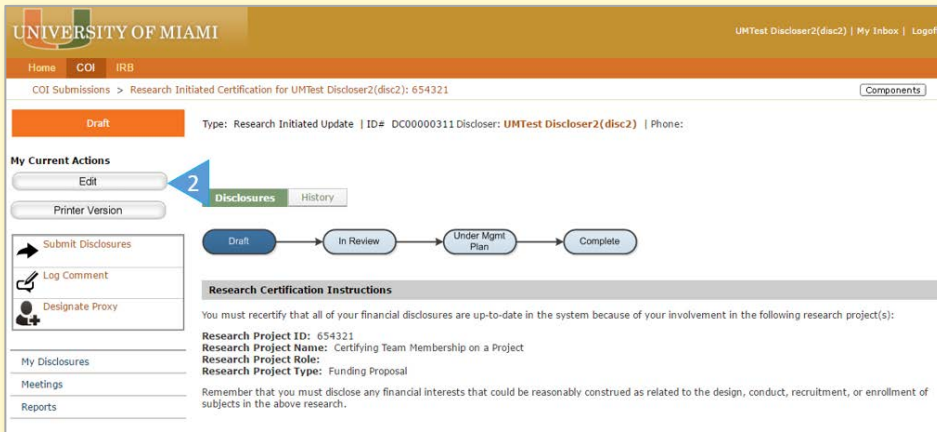
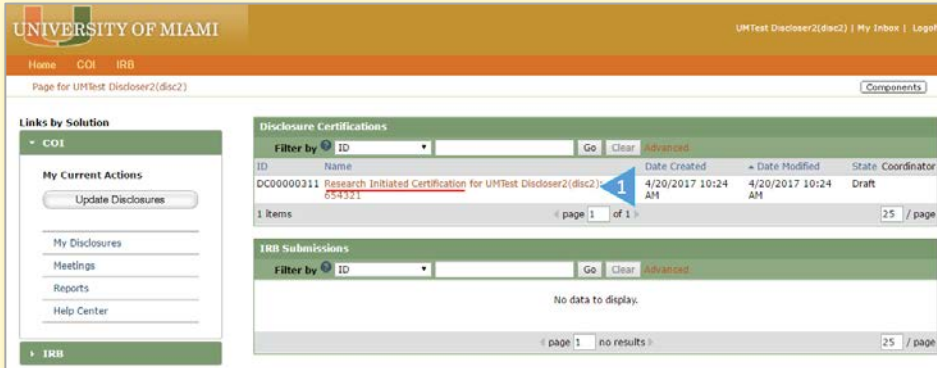
## Investigator Process for Certifying Team Membership on a Project

The Research Certification smartform includes the same pages required for annual disclosures, with the addition of a page containing a few questions specifically related to the research project. The investigator will have the ability to add new interests or update/delete any previously disclosed interests at this time.

### Certifying Team Membership

1. From your **My Inbox** page, select the Research Initiated Certification that you wish to update.
2. Under **My Current Actions**, click **Edit**.
3. Proceed through the smartform to update disclosures, or open the drop down menu to jump to **Research Initiated Certification Information** in order to answer the questions specifically related to the research project.

On the last page, select the check box to submit the certification. Click **Finish**. You can log off the system.



## **PI Process for Requesting the Creation of a Trigger Event**

There may be times when a PI wishes to begin the project certification early, but the project has not yet been entered into UDisclose. Should this occur, the PI can contact the Office of Disclosures & COI Management (DCM) for assistance. Once requested, a Triggering Event will be manually created, the PI assigned, and a notification sent via email. Following this, the PI can then log into UDisclose, and designate project team members.

DCM can be contacted at [DCM@miami.edu](mailto:DCM@miami.edu) or 305-243-0877.