

UDisclose System
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General background

1. Why does UM require the disclosure process?

Entrepreneurial and consulting partnerships with outside entities are important to the research and educational missions of the University of Miami (UM). Importantly, these relationships must be undertaken with a clear understanding of potential conflicts of interest that might endanger patient safety, data integrity, the integrity of our educational/training programs, and/or our reputation.

Although UM has been among the nation's leaders in promoting transparency in our external relationships and sponsored activities, academic institutions are being asked to comply with an increasing number of regulations in this regard, including the Public Health Service (PHS) regulations (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>). Since we receive PHS funds, UM (and other universities) is required to collect and review Investigator disclosures and report conflicts of interest. The regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

Importantly, the responsibility for determining if an Investigator's relationships could represent a COI with his/her sponsored work will now rest with the University. As a result, UM must garner from Investigators (**anyone involved in research/sponsored activities, including faculty, trainees, staff and subcontractors**) disclosures of interests related to their institutional responsibilities.

The UDisclose System streamlines the disclosure processes at UM. Most users will disclose interests on an annual basis, and some Investigators will use the UDisclose System to disclose interests in a timelier manner. Further, Project Directors/Principle Investigators will use the system to designate team members to their sponsored project to allow a review of their team members' interests that may be deemed to be COIs.

2. Who needs to disclose their outside professional activities (OPAs)?

All full-time faculty, University of Miami Medical Group (UMMG) members, and Miller School faculty members who may provide clinical or teaching services for UHealth must disclose their OPAs to UM by the end of each calendar year.

In addition, all Investigators (**anyone deemed by a PD/PI to be substantially involved in the design, conduct or reporting of research/sponsored activities, including faculty, trainees, staff and subcontractors**) are required to disclose his/her OPAs and Financial and Obligatory Interests (FOIs) that relate to their Institutional Responsibilities (IRs) prior to submission of a proposal/contract on which they will be a team member, or at least once a year using the UDisclose System. Further, if currently funded by the PHS, all Investigators must complete travel disclosures that related to their IRs.

3. I did not engage in any OPAs. Do I need still need to disclose?

Yes. Each Investigator is responsible for submitting his/her own disclosures (or certifying to a lack thereof) through UDisclose.

4. How often do I have to update my UDisclose certification?

You can update your disclosures an infinite number of times throughout the year, and any information you enter is saved and will be available for editing the next time you access the UDisclose System. However, if you receive funding for sponsored activities or are paid by sponsored accounts, you are required to enter your disclosures within 30 days of acquisition (not when you are compensated for them). Even if you do not receive funding for sponsored activities or are paid by sponsored accounts, we strongly recommend that enter your disclosures within 30 days.

PHS-funded Investigators must also disclose the occurrence of any reimbursed travel or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities (IRs). This disclosure requirement does not apply to travel that is reimbursed or sponsored by 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.

5. What happens if a disclosure is not made in a timely fashion?

For faculty not involved in sponsored activities, failure to comply with the required annual disclosure of OPAs as stated in the Faculty Manual may lead to disciplinary action by the Provost, Dean and/or Chair.

For Investigators involved in sponsored activities:

Failure by an Investigator to disclose within thirty (30) days an OPA, FOI or a travel event (if PHS-funded) that relates to sponsored activities could lead to disciplinary action by the Provost, Vice Provost for Research, Dean and/or Chair, including but not limited to withdrawal of pending proposals and/or placing a hold on, or terminating, an active award, contract or cooperative agreement.

Non-compliance related to PHS-funded activities requires the University to conduct a retrospective review of the Investigator's activities in order to determine whether the research or scholarly activity, or any portion thereof, conducted during the time period of noncompliance was biased in design, conduct, or reporting.

Additional information related to the retrospective review can be located in the [UM COI Policy](#).

6. What do staff members need to complete?

Anyone (including staff) who is deemed to be substantially involved in the design, conduct or reporting of research or externally sponsored scholarly activities must complete the disclosure process.

Staff members who are involved with sponsored activities ("Investigators") are required to disclose their outside professional activities (OPAs), Institutional Responsibilities (IRs) and Financial and Obligatory Interest (FOIs) and possibly their sponsored travel in the UDisclose System.

7. Where is the disclosure data stored? Who has access to it?

Data captured in your certifications are housed and monitored on internal UM servers by UM personnel with permission explicitly granted to select individuals and compliance groups. A limited

group of University officials including (as appropriate) the Provost, Vice Provost for Research, Vice Provost for Faculty Affairs, Conflict of Interest Committee, Research Administration, Deans, and Department Chairs will have access to view disclosure information.

8. Do voluntary or part time faculty members need to disclose?
If involved in research, sponsored scholarly activities or are a member of the University of Miami Medical Group (UMMG) that may provide clinical or teaching services, then you are required to complete the disclosure process in the UDisclose System.
9. Why does UM review all research projects and related outside interests as though they were PHS-funded projects?
As a community of scholars, scientists and physicians, we have an obligation to our colleagues, patients, research participants, research sponsors, and the general public to be transparent about the external relationships that relate to our institutional responsibilities. The importance of this transparency has been underscored by federal regulations. As a matter of ethical principle, however, we are obliged to hold all research performed under the auspices of UM, regardless of funding source, to the same high standards of excellence and integrity.
10. Why does UM have a financial disclosure threshold that is more stringent than required by Federal regulations?
The University recognizes that the need for transparency must be balanced with the desire to reduce unnecessarily burdensome tasks for UM investigators. UM's threshold for financial disclosure is \$600 – the threshold for reporting income to the Internal Revenue Service on the 1099 tax form.
11. Do members of UM's leadership have to make disclosures?
As one of the nation's leading private research universities, UM is committed to maintaining objectivity in research and upholding the highest scientific and ethical standards. When a member of UM's leadership team also has a role as investigator, he/she is required to comply with the same policies/procedures as all other members of the UM community.

UM is governed by a Board of Trustees that includes many of South Florida's most prominent business and community leaders. Under the direction of the UM Office of the General Counsel, the Office of the Secretary coordinates all activities of the UM Board of Trustees, including disclosures related to outside interests held by board members.
12. Why should I disclose private information about my outside interests to UM?
Disclosure of interests related to institutional responsibilities not only ensures an investigator's compliance with federal regulations and UM policies, but also allows identification and management of conflicts of interest. Outside interests, including those that cause conflicts, are not inherently negative, as long as they are disclosed and appropriately managed in order to reduce the introduction of bias into the results of a project. In the end, disclosure serves to protect the reputations of the investigators and of the institution.

UDisclose System access

13. How do I get access to the UDisclose System?

UDisclose users must have a CaneID and password, and an eProst account prior to accessing the system.

- A valid C Number is required in order to request an eProst account. See the Cane ID webpage for additional information: caneidhelp.miami.edu.
- Request a new eProst account using the form at the bottom of the webpage: eprostat.med.miami.edu. It is important that users avoid having duplicate accounts. For assistance, contact the eProst Help Desk at eprostat@med.miami.edu or 305-243-2314. Your request will be forwarded to the Human Subjects Research Office (HSRO) for verification. Once verified, you will receive an email from the eProst Help Desk confirming creation of your account. New account requests will normally be processed within one business day.
- The UDisclose System is available on the web at www.UDisclose.miami.edu.

Proxy designation in the UDisclose System

14. I have been designated as a “Proxy” for someone else. What does that mean?

Within the UDisclose System, a “proxy” is a person who can add/update interest disclosures on behalf of an investigator. A proxy can also add/update membership of a study team if designated by the Project Director/Principal Investigator of the project.

However, only the investigator who designated the proxy can officially submit certifications into the system. The proxy must alert the investigator when the certification is ready for submission.

15. Is the UDisclose Proxy the same as an IRB7/eProst Proxy?

No. the Proxy designation in the UDisclose is separate and distinct from that in the IRB7/eProst system.

16. Are there any limitations to a Proxy’s role?

A Proxy will not be able to submit a certification on behalf of another User. Once the Proxy enters all pertinent information into the system, the User will need to review information and submit the certification.

17. How do I designate or change a Proxy in the UDisclose System?

From your “My Inbox” page, open one of your disclosure certifications. On the left hand tool bar, click the “Designate Proxy” button. Enter the name of the user you wish to designate as your Proxy. From the same screen, you have the option to replace or remove your current proxy.

Note: the person who you designate as your UDisclose Proxy will have FULL ACCESS to details of your disclosed interests.

18. How many UDisclose Proxies can I have at once?

The UDisclose System only allows one Proxy per user at a time.

19. Does the Proxy need to be a team member on a project or can I designate anyone?

The Proxy does not need to be a team member on a project, anyone with a UM C-number can be designated as a Proxy.

20. Will my UDisclose Proxy be able to view all of my disclosures, research studies, etc.?
Yes. The Proxy will be able to view all of the information for their designated PI (including disclosures, research studies, etc.).
21. Does the Proxy receive email reminders to enter or update information in the system, or does the PI receive such notifications?
Once designated, both the User and the Proxy will receive notifications.
22. Who should the Proxy contact with questions regarding the UDisclose system?
- All questions about the content of the UDisclose System should be directed to Disclosures & Relationship Management (DRM) help line (305) 243-0877.
 - Technical questions on system performance should be directed to the office of Research Information Technology (RIT) at 305-243-2314.
23. Does the UDisclose System work on ALL browsers (i.e. Google Chrome, Internet Explorer, and Firefox)?
Yes. Questions about technical issues should be directed to RIT at 305-243-2314.

Outside interests to be disclosed to the University

24. Why is the disclosure process more convenient in the UDisclose System?
In the Disclosure Profile System (DPS) outside interests were categorized by the type of activity performed (OPAs were submitted into a different tab than FOIs or Travel). The UDisclose System streamlines the process wherein the User identifies the outside entity, and then simply lists all activities performed for that entity on one smartform.

Outside Professional Activities (OPAs)

25. What is an OPA?
All non-University professional activities performed for remuneration, including lecturing, delivering professional advice, expert witness testimony, arbitration, government services, corporate board activities, royalties, and private practice (which is only allowed for services that do not violate University of Miami Medical Group (UMMG) by-laws or compete with services that are or could be offered by the University). Only OPAs performed for \$600 or more must be disclosed to the University.

Examples of OPAs include paid consulting, artistic performances, or board membership for, or royalties received from, an external entity.

26. Is there anything improper about performing OPAs?
No. In fact, the University encourages the creation and maintenance of mutually beneficial relationships between the faculty and non-academic entities (i.e., industry, other private sector organizations). These entrepreneurial and consulting partnerships facilitate the flow of knowledge between the corporate world and academia, expedite research applications, and promote the educational and clinical missions of the University.

27. Are there entities/payors that are excluded from the regulations?
Yes. Compensation received for OPAs from the following entities do not need to be disclosed: Federal, state, or local government agencies, institutions of higher education as defined at 20 U.S.C. 1001(a), academic teaching hospitals, medical centers, or research institutes that are affiliated with an institution of higher education.
28. How do I disclose to UM that I have a relationship with an outside entity?
Access the UDisclose System at UDisclose.miami.edu. From My Inbox, click **Update Disclosures** on the left. Answer the questions to the best of your ability, complete the pages and click **Continue** to move to the next page.
29. What if I have multiple types of interests with the same entity, for instance consulting and teaching? Do I need to create a separate entry for each?
No. Your UDisclose certification should be a comprehensive summary of your relationship with an entity, as it exists on the day you disclose, with all activities included in one disclosure. Compensation is cumulative for the relationship, not for each activity.
30. What if I don't know the exact amount of compensation for an OPA at the time that I disclose?
What do I enter?
Enter information to the best of your ability at the time of entry. You can update your certification an infinite number of times, and any information you enter is saved. Keep in mind that if you perform research, are receive funding for sponsored activities or are paid by sponsored accounts, you are required to enter your disclosures within **30 days** of acquiring the OPA (not when you are compensated for them). Even if you do not perform research or receive sponsored funding, we strongly recommend that enter your disclosures within 30 days.
31. Do I disclose the OPA when performed or when I am compensated?
You should enter the OPA at the earliest possible time. You can update your disclosure profile an infinite number of times, and any information you enter is saved and will be available for editing.
32. How long do I have to disclose a newly acquired OPA or FOI?
You must disclose a new OPA or FOI within 30 days of performing the new activity, acquiring the new interest, or discovering one that was not disclosed in a timely fashion. Also, if any of your disclosures change, you must update the change within 30 days. If you are involved in research or sponsored activities and your disclosures are not made in a timely manner, your activity/interest and work must undergo a comprehensive retrospective review to determine if bias has occurred.
33. Am I required to disclose an OPA when the payment is made to the University?
No. Since the payment for services is paid to the University, your disclosure is not required. However, if payment for services is paid directly to you, the remuneration must be disclosed, no matter if the Investigator turns the money over to the Institution or if the money will be used to support the Investigator's future sponsored activities.
34. I have an appointment at the VAMC. Is that considered an OPA?
No. A dual appointment at the Veteran's Affairs Medical Center (VAMC) is not considered an OPA.

35. If I have a 9-month appointment at UM. Do I disclose OPAs done in the summer?

Yes. UM is committed to maintaining the integrity of our community of scholars and to re-enforcing the public trust in the academy. With that in mind, full-time faculty, University of Miami Medical Group members, and Miller School faculty members that could provide clinical or teaching services for UHealth, must disclose their outside professional activities (OPAs) to UM by the end of each calendar year. This includes those faculty members with 9-month and 12-month appointments.

36. I am on sabbatical or on leave. Do I need to disclose?

Yes. Full-time faculty, University of Miami Medical Group members, and Miller School faculty members that could provide clinical or teaching services for UHealth, must disclose their outside professional activities (OPAs) to UM by the end of each calendar year. This includes those on sabbatical or leave.

37. Why do I have to disclose unexercised stock options?

Unexercised stock options are classified as compensation due to their potential/future value.

38. When do I need to enter compensation/reimbursement for travel?

Sponsored or reimbursed travel is considered to be compensation, and as such, must be disclosed to the Institution. If the travel is paid for by an award through UM's sponsored programs, it does not need to be reported as an Outside Professional Activity.

Regardless of source of funding, PHS-funded Investigators must disclose the occurrence of any reimbursed travel or sponsored travel related to their institutional responsibilities. The estimated cost of anticipated travel can be disclosed ahead of a travel event (e.g. beginning of the year) but must be updated within 30 days of the end of the travel.

This disclosure requirement does not apply to travel that is reimbursed or sponsored by 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.

Institutional Responsibilities (IRs)

39. What is an Institutional Responsibility (IR)?

“Institutional responsibilities” means an Investigator’s professional responsibilities on behalf of UM or his/her Institution. Examples include teaching, conducting research, or performing clinical duties for UM.

40. How do I know if an interest is related to my IRs?

An interest is related to Institutional Responsibilities if both are associated with a common idea, practice, or are in the same field of expertise for which a person is employed.

For instance,

- voluntary membership on the board of an art foundation is associated with a UM artist's IRs;
- royalties received for a clinical device patented through a prior employer are associated with a UM physician's IRs; or
- stock ownership in an engineering company is associated with a UM engineer's IRs;

- while no one in the examples above would have Institutional Responsibilities associated to their spouse's employment as a certified public accountant.

Financial and Obligatory Interest (FOI)

41. What is a FOI?

A Financial Interest is:

1. Ownership (valued at \$600 or more) in a public company;
2. Any ownership in a privately held company; or
3. Protected Intellectual Property (IP), whether or not income is received from the IP.

An Obligatory Interest is a relationship (regardless of compensation) that involves a responsibility or commitment to an external entity.

Your FOIs should include:

1. Your financial interests (as defined above) related to your institutional responsibilities.
2. Your obligatory interests related to your institutional responsibilities.
3. Your spouse's and dependent children's financial or obligatory interests related to your institutional responsibilities, regardless of amount of compensation or value.

42. Is there anything improper about having a financial or obligatory interest (FOI)?

No. The University needs to be able to identify interests and relationships that may pose a conflict of interest that could endanger patient safety, data integrity, the integrity of our education and training programs, or our reputation.

43. What is the difference between disclosure of an OPA and disclosure of a FOI?

Faculty members disclose OPAs, while investigators also disclose FOIs and sometimes Travel. An OPA disclosure is required if you are compensated more than \$600 for performing an activity that is related to your profession. Disclosures for FOIs include interests or relationships held or performed by your spouse and dependent children. A FOI disclosure is required if you (or your spouse or dependent children) have either a financial or obligatory interest.

A financial interest means anything of monetary value, whether or not the quantitative value is readily ascertainable, that is related to your institutional responsibilities. You do not need to perform any activity to have a financial interest.

An obligatory interest means a relationship (regardless of compensation) that involves a responsibility or commitment to an external entity, including but not limited to being a founding member of that entity, or holding scientific advisory or governing board membership.

- A. With regard to any publicly traded entity, a financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure or the value of any equity interest in the entity as of the date of disclosure exceeds \$600. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

- B. With regard to any non-publicly traded entity, a financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure exceeds \$600, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock options (vested or unvested), or other ownership interest); or
- C. With regard to Intellectual property (IP) rights and interests (e.g., patents, copyrights), a financial interest is considered to be present as soon as protection is sought (e.g., filing an invention disclosure, patent application, etc.).

The term *financial interest* does not include the following types of interests: salary, royalties, or other remuneration paid by the University of Miami to the Investigator if the Investigator is currently employed or otherwise appointed by the University of Miami, including intellectual property rights assigned to the University of Miami and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, teaching engagements, service on advisory committees or review panels for, or sponsored by a United States 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.

44. Do I need to separate entries for my spouse and/or dependent children if more than one of us has an FOI with the same entity?

No. Your certification is capturing your and your spouse's and dependent children's relationship with the entity. If your spouse owns equity in a company, for PHS regulation and University policy purposes, then so do you. Therefore, you should be making only one disclosure and including all activities for that entity therein.

For example, if you are an uncompensated consultant for a private company and your spouse own 10% of that same company, you should make one disclosure capturing both of these relationships.

45. Do I need to report changes in value of stock or other similar interests?

No. Generally, the requirement to update your disclosures annually will be sufficient to provide updated information regarding any previously disclosed FOI (e.g., the updated value of a previously disclosed equity interest).

Travel

46. In the DPS, there was a travel section. Where do I enter travel in the UDisclose System?

In the UDisclose System, the certification process first asks you to identify the outside entity on the Disclosure Details page, and then a smartform is created on which you indicate the types of interest you have with that entity. "Sponsored or Reimbursed Travel" is one type of interest you can have with the external organization.

47. Who needs to disclose travel?

Only those investigators who are involved with Public Health Service (PHS)-funded projects need to disclose sponsored or reimbursed trips they have taken and only if the travel was related to their institutional responsibilities.

48. When do I need to enter compensation/reimbursement for travel?

PHS-funded Investigators must disclose the occurrence of any reimbursed travel or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities within 30 days of travel.

This disclosure requirement does not apply to travel that is reimbursed or sponsored by 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.

49. Do I have to disclose travel that does not relate to an IR?

No. Travel is considered to be compensation, and as such, travel associated with your work at UM should be disclosed. All of your travel disclosures should be related to your IRs.

50. Can I have reimbursed or sponsored travel not related to an IR?

Yes. If you have a travel event that does not relate to the IRs you perform for the Institution, you do not have to disclose the trip.

51. My award includes money to attend a meeting. Where do I disclose it?

Even if received from an award or contract, travel paid for or reimbursed by a private or not-for-profit organization (neither a US government entity nor a US institution of higher education) must be reported if you are sponsored by the Public Health Service (PHS) including the:

- National Institutes of Health (NIH),
- Food and Drug Administration (FDA),
- Substance Abuse and Mental Health Services Administration (SAMHSA),
- Agency for Healthcare Research and Quality (AHRQ),
- Agency for Toxic Substances and Disease Registry (ATSDR),
- Centers for Disease Control and Prevention (CDC),
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS).

If the travel is paid by an award through UM's sponsored programs, it does not need to be reported as an Outside Professional Activity.

Projects that will require research certifications

Triggering Events

52. What is a “Triggering Event”?

A triggering event in UDisclose corresponds to either a New or Competing Renewal of a funded award. One Triggering Event is created each time a new or competing renewal of a project/award/contract is received by UM.

53. What is the purpose of Triggering Events?

PDs/PIs use Triggering Events to designate team members (including subcontractors and subawardees) who are substantially involved in the design, conduct or reporting of the proposed work, and to determine the compliance status of the team members (TMs) on that project. If an

Investigator is not deemed to be substantively involved, then he/she does not need to be listed on the Triggering Event team.

Remember that under the federal regulations, the University must be aware and review each team member's disclosures that are related to that person's research or sponsored activities. Therefore, **no new UM accounts will be opened until each TM's disclosures have been reviewed.** It is the responsibility of the PD/PI to designate project teams in the UDisclose System in order to ensure that TM disclosures are reviewed in a timely manner.

54. How is it determined whether a person is substantively involved in the design, conduct, or reporting of research/sponsored educational activities, and thus qualifies as an "investigator"?
- At UM, it is the responsibility of the Principal Investigator/Program Director to determine which members of a study team are substantively contributing to the design, conduct or reporting of sponsored research, other human subject research, or sponsored scholarly activities. Depending on academic discipline, an investigator could be responsible for "substantive contributions" to one or more of the following: writing/editing proposals for funding, designing protocols, conducting experiments, educating students, collecting or analyzing data, interpreting results, or conveying results in publications and/or presentations.
55. What is a UDisclose Project ID?
- The UDisclose Project ID corresponds to the IBIS Research number of the New or Competing Renewal for the project.
56. What is the source for the pre-populated information?
- IBIS Research. As team members are designated once for each project (triggering event) at the time of award, research administration must have already uploaded all Project/Award/Contract information into IBIS.
57. As a PD/PI, how do I add (or delete) people to my team?
- 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. Locate the project and click the link to move to the Triggering Event workspace. Click the Update Team Members link under My Current Actions. Add (or remove) team members (only investigators with substantial responsibility for the design, conduct or reporting of the project) using the Add (and Delete) buttons.
58. As PD/PI, how do I determine the compliance status of investigators that I want to add to my project?
- Call Disclosures & Relationship Management (DRM) at 305-243-0877.
59. Why does the UDisclose System not list all of the awards or contracts on which I work?
- Triggering events in the UDisclose System are pre-populated by information in the IBIS Research System, Research Administration's proposal tracking system. As such, the triggering events list in the UDisclose System lists only externally funded projects/awards/contracts.

Once per project, when external funding is imminent, the PD/PI designates team members for that award or contract in the UDisclose System. Once the team is designated, team members will receive an email indicating that he/she was added to the team, and requesting that the team member

complete a certification for that project in the UDisclose System. Each Team Member's disclosures will be reviewed for potential relationships to the sponsored work.

For a team member, a project will not be listed as a triggering event in the investigator's UDisclose System until the PD/PI designates him/her as a Team Member on project.

Human Subject Research (HSR) Studies

60. How are HSR studies listed in the UDisclose System?

The UDisclose and IRB systems are integrated, streamlining the disclosure processes at UM.

Prior to study approval, each Team Member on a human subject research (HSR) protocol must disclose to UM their interests in the UDisclose System by completing a research certification specific for that protocol.

61. Which HSR studies require research certifications from the team members?

Research certifications by team members will only be required for new HSR studies or modifications that were initiated to add team members in the IRB7 system.

62. Who is included on the study team; who must make disclosures?

Study team members will appear in the UDisclose System only if included in the Study Team list in the IRB system.

63. What must be done to complete a research certification for HSR studies?

Every HSR Team Member must disclose non-UM relationships (including "Outside Professional Activities" (OPA), "Financial and Obligatory Interests" (FOI) and sometimes "Travel") in the UDisclose System. He/she will then answer three questions directly related to the HSR protocol.

64. Why are my ongoing studies not listed in the UDisclose System?

Only studies and modifications that are newly initiated after the launch of the system will appear in the UDisclose System.

65. What is an Institutional COI?

Institutional Conflicts of Interest (COI) are those that may not be directly related to the Principal Investigator (PI) or other Team Members but are related to the University or affiliated institutions. An institutional conflict of interest can arise when the financial interests of an institution, or an institutional official who is acting within his or her authority on behalf of the institution, may influence or appear to influence the research, education, operations, business transactions, or other activities of the institution. Such financial interests might exist as intellectual property, royalties, stockholdings, stock options, gifts, equity, or direct payment for Board service or consulting.

Examples of interests that must be disclosed by the PI or Team Members are

- The research involves a drug, device or other invention created at the University or affiliated institution, or by an employee currently or formerly at the University or affiliated institution.
- The research involves a drug, device or other invention created by someone other than the PI or Team Members for which the University or affiliated institution holds a financial interest.

66. How do I get additional information?

Questions about the IRB software or a specific clinical study should be directed to the Human Subject Research Office (HSRO) at 305-243-3195; HSRO webpage at <http://hsro.med.miami.edu> , or Kenia Viamonte at kviamonte@med.miami.edu