1. Why did the disclosure process change?

Department of Health and Human Service (HHS) regulations governing financial conflicts of interest (COI) in sponsored research went into effect August 24, 2012. The University of Miami responded to these new regulations by changing its COI disclosure process in several ways.

The regulations place a greater burden on institutions that receive federal funding for sponsored activities to monitor and manage their financial COIs. This required the University to upgrade its systems and processes to comply with the regulations.
2. **Who needs to disclose his/her outside professional activities (OPAs)?**

   All full- and part-time faculty, University of Miami Medical Group members, and Miller School faculty members who could provide clinical or teaching services for UHealth must disclose their OPAs to UM by the end of each calendar year. Questions about the disclosure requirement for UM faculty members should be directed to UM Faculty Affairs at 305-284-3386.

   In addition, all UM community members involved in research or sponsored activities are required to disclose their OPAs and financial/obligatory interests (FOIs) related to Institutional Responsibilities (IRs), prior to submission of a proposal/contract on which they will be team members, or at least annually, using the UDisclose System. Further, if currently funded by the Department of Health and Human Service (HHS), all Investigators must complete travel disclosures that related to the IRs. Questions about the disclosure requirement for UM faculty members involved in research or sponsored activities should be directed to the Office of Disclosures & COI Management via the UDisclose System help line at 305-243-0877.

3. **If I did not engage in any outside professional activities (OPAs) do I need to complete the disclosure process?**

   Yes. If you are subject to reporting requirements as referenced in FAQ (b) above, you must complete the disclosure process in the UDisclose System, even if you have not engaged in any outside professional activities (OPAs).

4. **Do faculty members still need to complete their Faculty Disclosure Form (FDF) or update the Disclosure Profile System (DPS)?**

   No. The new UDisclose System replaces the FDF and the DPS. Full- and part-time faculty, University of Miami Medical Group members, and Miller School faculty members who could provide clinical or teaching services for UHealth, must disclose their outside professional activities (OPAs) to UM in the UDisclose System by the end of each calendar year.

   You can update your UDisclose certification at any time throughout the year. If you receive funding for sponsored activities or are paid by sponsored accounts, you are required to enter your disclosures in the UDisclose System within 30 days (rather than waiting until you are compensated for them). Even if you do not receive funding for sponsored activities or receive payments from sponsored accounts, we strongly recommend that you enter your disclosures within 30 days.

   In accordance with HHS regulations, faculty members (and all Investigators, regardless of rank) involved in sponsored activities will also be required to disclose their OPAs and Financial and Obligatory Interests (FOIs) in the UDisclose System. FOIs that must be disclosed are those related to your IRs.

   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 IRs.

   This disclosure requirement does not apply to travel that is reimbursed or sponsored by a U.S. federal, state, or local government agency, an institution of higher education as defined in 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 outside professional activities (OPAs) are not entered in a timely fashion?**
   If related to sponsored research, OPAs that were not disclosed within 30 days could require UM to conduct a retrospective review to determine whether bias had been introduced into the Investigator’s work since the time the interest should have been disclosed.

6. **Where are the disclosure data stored and who has access to view the information in the UDisclose System?**
   Data captured in your UDisclose System 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, the President, Provost, Vice Provost for Research, Vice Provost for Faculty Affairs, Conflict of Interest Committee, Deans, and Department Chairs will have access to view disclosure information as appropriate for their responsibilities.

7. **Do voluntary faculty members need to complete the disclosure process?**
   Yes; if you are involved in sponsored work, or you are part of the UMMG and could provide clinical or teaching services, you are required to complete the disclosure process.

8. **Are there entities/payors that are excluded from the UM disclosure requirements?**
   Yes. Compensation received for OPAs from the following entities do not need to be disclosed: U.S. federal, state, or local government agencies, U.S. 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.

9. **Does UM regard performance of OPAs as somehow improper?**
   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.

10. **What if I have multiple OPAs with the same entity? Do I need to create a separate entry for each? What if the dates of activity differ, how would that be shown?**
    Your certification is capturing your relationship with the entity, so you should be making only one disclosure. For ease of recordkeeping, you may want to disclose compensation earned on an annual basis. Otherwise, compensation is cumulative for the relationship (not for each activity), entered based on the amount received in the 12 months prior to the time of disclosure.
11. What if I don’t know the exact amount of compensation or duration of OPA at the time of the OPA? What do I enter?
   Enter information to the best of your ability at the time of entry. You can update your certification as many times as you wish; any information you enter is saved and will be available for editing. Keep in mind that if you receive funding for sponsored activities or are paid by sponsored accounts, you are required to enter your disclosures within 30 days. Even if you do not receive funding for sponsored activities or are paid by sponsored accounts, we strongly recommend that you enter your disclosures within 30 days.

12. I performed an OPA in the reporting period but have not received compensation for it yet. Do I disclose it now or wait until I am compensated?
   You should enter the OPA at the earliest possible time. You can always update your certification at a later time; the information you enter will be available for editing.

13. Am I required to disclose remuneration received from an outside entity for services performed (e.g., data analysis) when the payment is made directly to the University?
   No. Since the payment for services is paid to the Institution, your disclosure is not required. However, if payment for services is paid directly to you, the remuneration must be disclosed, regardless of whether you turn the money over to the Institution or if the money will be used to support your future sponsored activities.

14. I have an appointment at the Veterans Affairs Hospital. Is that considered an OPA?
   No. A dual appointment at the Veterans Affairs Medical Center (VAMC) is not considered an OPA.

15. If I have a 9-month faculty appointment at UM, do I need to disclose any OPAs conducted over the summer months?
   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- and part-time faculty, University of Miami Medical Group members, and Miller School faculty members who 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 both faculty members with 9-month appointments and those with 12-month appointments.

16. If I am on sabbatical or on leave from the University, do I need to complete the disclosure process?
   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- and part-time faculty, University of Miami Medical Group members, and Miller School faculty members who 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.
17. Why do I have to disclose unexercised stock options?
Unexercised stock options are classified as compensation due to their potential/future value.

18. I perform research, or receive external funding for a scholarly activity at UM. What do I have to disclose?
Faculty members who are involved in research or externally-funded scholarly activities must also disclose to UM their Financial and Obligatory Interests (FOI) and Institutional Responsibilities (IRs). If involved in Public Health Service (PHS) funded projects, sponsored or reimbursed travel must also be disclosed to the University in the UDisclose System.

19. 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 acquiring a new OPA 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 not disclosed in a timely manner, your interest and work may have to undergo a comprehensive retrospective review to determine if bias has occurred.

20. When do I need to enter compensation/reimbursement for travel?
Reimbursement of travel expenses is considered to be compensation. Therefore, travel received as compensation for an OPA must be disclosed.

Further, Public Health Service (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.

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

The UDisclose System website contains directions and additional FAQs to help users maneuver through the system. For specific questions, users can contact the UDisclose System help line at 305-243-0877.