

Acronyms & Glossary

Acronyms

- CITI: [Collaborative Institutional Training Initiative](#)
- COI: [Conflict of Interest](#)
- COIC: [Conflict of Interest Committee](#)
- DCM: [Office of Disclosures & COI Management](#)
- FCOI: [Financial Conflict of Interest](#)
- FI: [Financial Interest](#)
- HHS: [Department of Health and Human Services](#)
- IR: [Institutional Responsibilities](#)
- IP: [Intellectual Property](#)
- NIH: [National Institutes of Health](#)
- OCOI: [Obligatory Conflict of Interest](#)
- OI: [Obligatory Interest](#)
- OPA: [Outside Professional Activities](#)
- ORA: [Office of Research Administration](#)
- PD: [Project Director](#)
- PHS: [Public Health Service](#)
- PI: [Principal Investigator](#)
- SFI: [Significant Financial Interest](#)
- TM: [Team Member](#)
- VPR: [Vice Provost of Research](#)

Glossary

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[Contractor](#)

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- **Administrative Review**- The process of a disclosure certification being reviewed for any conflicts of interest
- **Conflict of Interest (COI)** – An actual or potential interest that could directly and substantially (as determined by the Vice Provost for Research and/or his/her designee, acting on behalf of the Provost), affect the design, conduct, or reporting of funded research, or of scholarly and/or educational activities funded under external grants, contracts or cooperative agreements. COIs can be financial (FCOI) or obligatory (OCOI) in nature.
- **Conflict of Interest Committee (COIC)**-Committee that meets to review disclosures and determine if there is a Conflict of Interest. The COIC also determines Management Plans for COIs
- **Contractor** – An entity providing property or services under contract for the direct benefit or use of an awarding component.
- **COI Management Plan Response**- Investigator’s response to Management Plan.
There are two options:
 - 1. Accept
 - 2. Request Clarification
- **Disclosure Certifications** - A submission in the UDisclose System that confirms a set of a discloser’s interests and other information at a certain point in time. Certifications can be “**annual**” or “**research**” based.
 - **Annual Certification** - A Disclosure Certification that is required to be submitted once each year. A **Disclosure Update** is created/submitted any time a discloser’s interests change during the year.
 - **Research Certification** - A Disclosure Certification that is required to be submitted for each funded project and IRB study in which the discloser is involved. Research Certifications incorporate additional pages that relate to a specific funded project/IRB study.
- **Disclosure Certification Status**- A “real time” account of the review of a disclosure certification.
 - **Draft**-Certification process has begun but has not been submitted
 - **In Review**-Certification has been submitted and is being reviewed for a possible COI
 - **Under Management Plan**- An agreed upon plan put in place to manage a conflict of interest.
***If there are no conflict of interests found in a review, the status will go from “In Review” to “Complete”
 - **Complete**- Certification process is complete and the project released from the DCM office.
- **Disclosure of Financial Interests** – An Investigator’s (collectively, an educator, researcher, etc; see below) disclosure of financial interests to the University.

- **Financial Interest** – Anything of monetary value, whether or not the quantitative value is readily ascertainable.
 - 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;
 - 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
 - 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.

- **Financial Conflict of Interest (FCOI)** – A financial interest that could directly and substantially affect the design, conduct, or reporting of funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.
- **FCOI Report** – The University’s report of a financial conflict of interest to a funding component.
- **Governmental Agency** – Any governmental agency that has promulgated regulations or policies requiring investigator financial disclosure or requiring institutional conflict of interest policies relating to award of grants or contracts.

- **Imminent** – Funding is imminent when, for instance, a PD/PI
 - Is informed that his/her funding proposal review received what appears to be a fundable score
 - Wants to open a new account under guarantee of anticipated funding
 - Receives a notice of grant award (NoGA)
 - Is prepared to execute a contract with an outside entity

- **Institutional Responsibilities (IRs)** – An Investigator’s professional responsibilities on behalf of the Institution. These may include for example: activities such as research, research consultation, consulting, lecturing, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards, Data and Safety Monitoring Boards, or external advisory boards. Income from, or obligations arising from any outside activity that is related to the Investigator’s institutional responsibilities must be disclosed to the University.

- **Institutional COI-** Financial interests of an institution (e.g. University) that may affect the research, education, clinical care, or business transactions

- **Intellectual Property** – The filing of a thought or idea that could be protected. Intellectual property rights and interests (e.g., patents, copyrights) become SFIs when an individual receives an aggregated income of \$5,000 or more from one entity for said rights and interests.

- **Investigator** – The project director (PD), principal investigator (PI), co-principal investigators, and any other person who could be responsible for the design, conduct, or reporting of:
 - Research irrespective of funding source
 - Scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

“Investigator” is used to collectively indicate individuals whose role could be described as an educator, researcher or investigator. This includes sub-awardees, sub-contractor(s), consultants and “to be appointed” positions as well as any individual whose biographical sketch is included in the proposal or whose name appears in the budget (including subcontract budgets). The Investigator also includes the investigator’s spouse and dependent children. The phrase “team member” is used interchangeably with Investigator.

- **Key (Senior) Personnel** – The PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the funding agency by the University.

- **Management of a COI** – Taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- **Obligatory Interest** – 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.
- **Obligatory Conflict of Interest (OCOI)** – A responsibility or commitment that could directly and substantially affect the design, conduct, or reporting of funded research, or of scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.
- **Outside Professional Activities (OPAs)** – 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 UMMG by-laws or compete with services that are or could be offered by the University).
- **Public Health Service (PHS)** – One of the following federal government agencies:
 - 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)
- **PHS Funded Investigator** – Any Investigator who is paid from a University sponsored account funded by a PHS agency listed below:
 - 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)

- **Proxy** – Any discloser can designate a proxy who will be able to create and update that individual’s disclosures. However, a proxy cannot submit disclosure certifications on behalf of someone else; these must be submitted by the actual discloser.

- **Research** – A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic “bench”, “clinical” or applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term also includes any scholarly or educational activity for which external funding is available through a contract, grant or cooperative agreement.

- **Significant Financial Interest** - A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related (associated with a common idea or practice) to the Investigator’s institutional responsibilities:
 - With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. 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;
 - With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - Intellectual property rights and interests (e.g., patents, copyrights) become SFIs when an individual receives an aggregated income of \$5,000 or more from one entity for said rights and interests.

The term significant financial interest does not include the following types of interests: salary, travel, 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.

For PHS funded Investigators this also includes any reimbursed 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 an Investigator's institutional responsibilities that the Vice Provost for Research and/or his/her designee determines constitutes an FCOI with the Investigator's funded research.

- **Sponsored Activities** – Externally-funded research or educational activities.
- **State of a certification** - A State represents one step in the workflow process. As users execute activities in the system, a disclosure certification moves from one state to another.
- **Team Member** – Used interchangeably with 'Investigator'. Any other person who could be responsible for the design, conduct, or reporting of
 - Research (irrespective of funding source) and/or
 - Scholarly or educational activities funded under external grants, contracts or cooperative agreements.
- **Triggering Event** – A Triggering Event is created when a new funding proposal (new and competing renewals) is ready for COI disclosure review. The Triggering Event includes basic information about the funded project, such as PD/PI, sponsor/funding source, ID (InfoEd #), and involved personnel/team members.

When a Triggering Event is created, a Research Certification will be created for the PI, and the PI will then be able to add his/her team members to the project, which in turn generates Research Certifications for each team member.

Triggering Events will generally be created automatically, but can also be generated by DCM or Research IT, if needed.

- **UDisclose History**-Record of correspondence throughout the review process between the Investigator and COI (e.g. dates a disclosure was submitted, emails, etc.)
- **UDisclose Project ID** – In the DPS, team members were required to complete disclosure certifications for every year of awarded funding, designated by separate InfoEd numbers. Within the UDisclose System, certifications are completed once (and updated when necessary) for a research project. The Project ID corresponds to the InfoEd number assigned to a funded research project at the time it was entered into the UDisclose System.
- **UDisclose System SmartForm** – A series of pages (such as Institutional Responsibilities, Disclosure Details) in a form with built-in logic that determines which pages need to be completed. By clicking the Continue button in a SmartForm, the discloser will be guided through the process of submitting his/her disclosures.