Disclosures and Certifications

Contents

Who Must Submit an Annual Certification?

- See Applicability

When are Annual Certifications Required?

During the initial roll out period the following groups will be required to complete Annual Certifications. These groups are:

- Faculty members that participate in research;
- Staff that meet the definition of Investigator and are named on a current funded project or proposal submitted within the last year; and
- Staff named as study personnel on IRB submissions that have current or pending funding.

After this initial certification, it is highly recommended that faculty and staff, new to research or the University, submit an Annual Certification prior to the submission of any proposals or IRB protocols.

Subsequent Annual Certifications are required between May 1st and May 31st of each year.

How are Certifications Made?

- Certifications are made in the myResearch Conflict of Interest module.

What External Interests Must be Reported?

- Obligations
- Financial Interests, where when aggregated for any one entity is greater than $5,000
- Equity interests
- Intellectual Property Rights and Interests, where royalty and other forms of payment are in excess of $5,000
- Travel (for PHS/NIH only)

Note: The above include obligations and financial interest for both you and any Immediate Family Members.

When Is It Required to Report a Change in External Interests?

- Within thirty (30) days of discovering or acquiring a new FI or Obligation.
- At the time of establishing a faculty owned company.
- At the request of the DIO, where new FIs have come to the attention of the DIO.
- For PHS/NIH funded investigators, applicable travel must be disclosed within thirty (30) days of said travel. Alternatively, travel that is anticipated can be disclosed anytime in advance and would satisfy the thirty (30) day requirement.

When May Research Certifications be Required?

- Prior to the establishment of any new award or University endorsement on any non-funded research agreement.
- Prior to the IRB Committee review of any non-funded IRB application.
- Prior to the final institutional endorsement of a Technology Transfer Agreement.

How are Annual Certifications Reviewed?

Annual Certifications that indicate that the Investigator holds no interests and/or obligations receive no further action and are stored in the myResearch module.

Annual Certifications that indicate that the investigator holds interests and/or obligations are reviewed by the DIO.

- If there have been any changes in the disclosures, the DIO will conduct a review of the Investigator's awards to determine if any of the changes created a new FCOI or SO.
- Once the review is complete and any necessary actions are taken on existing awards, the Annual Certifications are kept on file in the myResearch COI module.

How are New Projects, Changes in PI, Addition of Faculty, and Agreements Identified for Review?

Sponsored Projects

The Office of Sponsored Programs (OSP) will refer proposed projects (as referenced in Applicability) to the DIO through a Triggering Event Notification.   OSP will also refer changes in PI and the addition of any faculty to the DIO through a Triggering Event Notification.

Note: In any such case where human subjects research is involved, the DIO will work with the Office of Research Compliance to ensure that the Institutional Review Boards (IRBs) are aware of the case being reviewed. The fully convened IRB will conduct independent review of the potential conflict in compliance with its own conflict of interest policy to ensure the protection of human subjects.

IRB Applications

Conflict of Interest review of IRB applications that have no outside sponsorship or support and do not include a benefit for an outside entity are under the authority of the IRBs. If an IRB requires a review of an Investigator's Certification, the Office of Research Compliance (ORC) will refer the application to the DIO through a Triggering Event Notification.

Technology Transfer Agreements

The Office of Technology Licensing and Industry Relations (OTLIR) will refer proposed Technology Transfer Agreements involving a potential COI or CO to the DIO through a Triggering Event Notification.

How are Certifications Reviewed?

Administrative Review

Where the DIO has received a Triggering Event Notification, the DIO will review each Investigator's record. If no Disclosures are on file or if it is evident that the Disclosures are not Related to the Investigator's Research Project and/or Related to the Investigator's Institutional Responsibilities, the Administrative Review is complete and the file will be notated. If there are Disclosures on file that may be Related to the Investigator's Research Project and/or Related to the Investigator's Institutional Responsibilities one, or more, of the following three reviews may be completed. The DIO may send a Research Certification to the Investigator for additional information.

If:

a) it is evident that the Disclosures are not Related to the Investigator's Research Project and/or Related to the Investigator's Institutional Responsibilities, the Administrative Review is complete and the file will be notated.
b) It is evident that the Disclosures are Related to the Investigator's Research Project and/or Related to the Investigator's Institutional Responsibilities, the DIO may issue a Management Plan or forward for a Reviewer Review or COI Committee Review.

c) It is not evident that the Disclosures are Related to the Investigator's Research Project and/or Related to the Investigator's Institutional Responsibilities, the DIO will forward for either a Reviewer Review or a COI Committee Review.

Reviewer Review

If the DIO forwards a Research Certification to the Reviewer, the Reviewer will conduct a review of the Disclosures and the Research Certification in coordination with the project. The Reviewer will recommend – no FCOI or CO exists, FCOI or CO exists and Management Plan is required or forward for COI Committee Review.

COI Committee Review

For cases placed on the COI Committee meeting agenda, the convened COI Committee reviews the Disclosures and Research Certification in coordination with the project to recommend if an FCOI or CO exists. The COI Committee will recommend – no FCOI or CO exists, FCOI or CO exists and Management Plan is required, FCOI or CO exists and cannot be managed.

Subawards

PHS / NIH Only: Where the proposal involves sub-recipient's institution will apply to the sub-recipient's Investigators.

1. If the sub-recipient's institutional FCOI policy will apply to the sub-recipient investigators, the agreement will include a requirement that the sub-recipient's institution must:
    1. Provide certification that its FCOI policy complies with PHS regulation.
    2. Report to the University identified FCOI's for its Investigators in a time frame that allows the University to report said FCOI's to the NIH as detailed below (Reporting to External Sponsors, 'for PHS / NIH only').
2. If the University's FCOI policy will apply to sub-recipient investigators, the agreement will include a requirement that said investigators will submit disclosures to the University for review, identification, and handling of FCOI's as required by this policy (including those required only for PHS / NIH activities).