



Understanding Conflicts of Interest in Research

Description:

The following slides provide information on federal regulation that is in place to promote objectivity in research, Aurora Health Care's policy for Conflicts of Interest in Research and your responsibility, as an investigator or someone who is involved in the design, conduct, reporting or review/approval of research, to disclose significant interests.

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Why Disclosure and Management is Important



Federal regulation, accreditation standards and institutional policy are in place to help ensure that conflicting interests do not inappropriately influence the outcome of the research. To protect research subjects and maintain public trust, it is essential that certain interests (i.e., those determined to have a higher likelihood of creating a conflict of interest) be identified and, where necessary, managed.

Certainly not all interests you will be asked to disclose will create a conflict, but the disclosure process allows an independent party to make an assessment and develop management strategies where necessary.

While the process is in place primarily to protect subjects of the research, it also offers protections for the individual holding the interest and the institution. Should something go wrong that is outside of the control of the investigator or the institution, appropriate management strategies will help to demonstrate that conflicted individuals did not have the ability to influence the design, approval, conduct, or reporting of research.

External Sources Drive Aurora Policy Requirements



In addition to institutional policy, regulations at 42 CFR 50 and 45 CFR 94 require disclosure and management of interests that have the potential to inappropriately influence the design, conduct or reporting of research. These regulations are applicable to Aurora as an institution that applies for or receives Public Health Service (PHS) funding and to many Aurora investigators who are responsible for designing, conducting or reporting PHS-funded research. In addition, many non-PHS funding agencies require that award recipients follow the PHS regulations.

Human subject protection accreditation standards broaden the applicability of the regulatory requirements to anyone involved in the design, conduct, or reporting of research.

Aurora policy reiterates the requirements of the regulations and accreditation standards and further extends the applicability to those involved in the review and approval of research. The policy also details how regulatory and accreditation requirements will be implemented.

Aurora's COI Policies



Let's talk policy.

Aurora Health Care has three policies addressing conflicts of interest:

- System Policy #80 – Conflicts of Interest
- [System Policy #269 – Conflicts of Interest in Research-Individual](#)
- System Policy #270 – Conflicts of Interest in Research-Institutional

The following slides highlight requirements of policy #269—the policy that you, as someone involved in the design, approval, conduct or reporting of research, need to be familiar with. You may click on the policy title above to review the entire policy.

Aurora's COI in Research Policy



The [COI in Research-Individual](#) policy outlines requirements and processes for:

- Disclosure of Significant Interests
- Review of those interests
- Management of any interest that creates a conflict
- Monitoring of management plans
- PHS funded research and non-PHS agencies that follow PHS regulations

A description of what constitutes a Significant Interest and summary of each of these areas follows.

What is a Significant Interest?



In general, Significant Interests are items or relationships of value that, depending on specific circumstances, have the potential to influence the design, review/approval, conduct or reporting of research. Aurora's policy provides very specific parameters for the interests that are considered significant and therefore must be disclosed. It is not necessary to go through them in detail because they will be listed in the disclosure questionnaire that you will complete, but be aware that they fall within the follow categories:

- Equity in publicly traded & non-publicly traded entities
- Remuneration from publicly traded & non-publicly traded entities
- Intellectual property interests or rights
- Reimbursed or sponsored travel
- Formal and informal relationships with sponsors of research

A detailed list of Significant Interests is also available in the [COI in Research-Individual](#) policy for your reference.

Disclosure of Significant Interests

If you are an investigator or someone involved in the design, conduct or reporting of research, you are responsible for:

- Disclosing Significant Interests annually
 - This disclosure will occur as part of the annual disclosure process required for certain Aurora caregivers, and must occur no later than the time of Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) review or application for funding, if applicable
 - If you are a Principal Investigator on an IRB or IACUC submission or considered Key Personnel on a PHS application, you must also certify with each new submission/application that your disclosure is up to date, and either: (1) you do not believe any disclosed interests are related; or (2) identify any related interests. Others have a general obligation to disclose relatedness but will not be asked with each submission/application.
- Updating your disclosure within 30 days of discovering/acquiring a new Significant Interest

Disclosure of Significant Interests



If you are involved in the review and approval of research, you are responsible for:

- Completing a Significant Interest disclosure prior to review of research involving human or animal subjects, and annually thereafter.
- Recusing yourself from the review, discussion and vote of proposed or ongoing research that is related to any Significant Interests you hold, except to provide information requested by the IRB or IACUC.

Review of Significant Interests



A Significant Interest is not the same as a Conflict of Interest. If you are an investigator or someone involved in the design, conduct or reporting of research, Significant Interests that you disclose are reviewed to first determine whether the Interest is related to any ongoing or proposed research. If not, there is no potential for that interest to create a Conflict of Interest and the review process is complete.

Regulation and accreditation standards require that someone other than the individual holding the interest determine whether an interest is related to ongoing or proposed research and also whether the interests creates a Conflict of Interest, thus the need to disclose Significant Interests, even when you don't believe they are related or create a Conflict of Interest.

If a Significant Interest is determined to be related, then an evaluation takes place to determine whether the interest and specific factors surrounding the related research create a Conflict of Interest.

Review of Significant Interests



If you are an investigator or someone involved in the design, conduct or reporting of research, a Conflict of Interest is defined as a Significant Interest that could directly and *significantly* affect the design, conduct or reporting of ongoing or proposed research. *Significantly* means to a degree that could potentially alter the outcome of the research.

For investigators and research staff, an initial assessment of whether a related Significant Interest creates a Conflict of Interest is made by the Compliance Department and confirmed or refuted by the Research Conflict of Interest Committee. Individuals holding Significant Interests are kept apprised of the initial determination and given an opportunity to provide input during the review process.

If you are involved in approving research, you must recuse yourself from the review of any project in which you hold a Significant Interest. Due to the logistical challenges of reviewing and making a timely Conflict of Interest determination for each member of the IRB and IACUC each time a study is reviewed, no Conflict of Interest determination is actually made.

Management of Conflicts of Interest



For investigators and research staff, Significant Interests that are determined to create a Conflict of Interest may be managed in a variety of ways. Examples include:

- Disclosure of the interest to study participants
- Limitations on the conflicted individual's involvement in the research (e.g., having non-conflicted caregivers conduct the final informed consent discussion and/or confirm eligibility determinations)
- Appointment of an independent monitor

In all cases, a written management plan is tailored to the specific research project and Conflict of Interest. Input is requested from the conflicted individual and final approval of the management plan is granted by the Research Conflict of Interest Committee. The conflicted individual is asked to sign the management plan indicating their agreement to implement and abide by the various provisions of the plan.

Monitoring Management Plans

Once a management plan is in place, monitoring of the plan occurs on an at least annual basis. Monitoring includes:

- Confirmation by the conflicted individual that the management plan has been implemented and is being complied with
- Research Conflict of Interest Committee reassessment that the management plan remains adequate to address the conflict.

The need for additional monitoring is determined by the Research Conflict of Interest Committee and may include auditing of study records, interviewing or requesting reports from department leaders/caregivers, reviewing publications, requiring reports from the conflicted individual, etc.

Research Subject to PHS Regulations



If you are an investigator or research staff and your disclosed interest is related to research funded by PHS or another agency that follows PHS regulations, additional requirements apply including:

- Reporting of Conflicts of Interest to funding agencies
- Specific timeframes for reviewing and management of Conflicts of Interest
- A retrospective review process for interests that are not disclosed, reviewed or managed in a timely manner
- Disclosing to the public, upon request, Conflicts of Interest held by researchers
- Ensuring sub-recipients of funds meet regulatory requirements

The details of these requirements can be found in [Appendix A of the Conflicts of Interest in Research-Individual policy](#).

In Summary

- Conflict of Interest requirements are in place to protect subjects, the integrity of research, you and the institution.
- If you are an investigator or research staff, you must:
 - disclose Significant Interests annually and within 30 days of discovering/acquiring a new Interest; and
 - if your Interest is determined to be a Conflict of Interest, abide by the management plan and submit any requested monitoring reports.
- If you are an IRB or IACUC member or staff, you must:
 - disclose Significant Interests annually; and
 - recuse yourself from the review of any project in which your Interest is related.
- If you are named as Key Personnel on an application or award from an agency that follows PHS regulation, be aware that there are more restrictive timeframes and requirements for review, management and disclosure of Interests that create a Conflict.