

Participating in research is a choice

Joining a research study is an important personal decision. Before you decide whether to join, researchers will talk with you about the goals of the study and possible risks and benefits. They will also explain the rules they follow to protect your safety and privacy. Ask for help if you don't understand something or if you have questions.

You should never feel rushed or pressured to make a decision. Being part of a research study is completely voluntary – it's your choice.

After you understand the study, if you decide to take part you will be asked to sign a document called an “informed consent form”. You can change your mind at any time, for any reason, even after you sign.

Where can I find out more about COI?

Many institutions have developed a variety of procedures for managing COI, such as:

- > Adopting COI policies and procedures to best manage any COIs
- > Obtaining disclosure forms from all research staff members, and updating them periodically
- > Requiring any research staff member with a potential conflict to disclose it to their institution before the research study begins, so that the institution can decide how best to manage the potential COI

Questions to ask

You have a right to ask questions about a COI before you decide whether to take part in a research study. You may want to ask the following questions before making your decision about participating:

- > How can I find out if there is a COI in this research?
- > What are the laws, regulations, or rules about COI specific to this study?
- > Where can I find more information about COI for this study?
- > If there are COIs, how are they being managed?
- > What will the specific COI affect? Will it affect the research study? If so, how?
- > If I discover a potential COI in this research, who should I discuss it with/report to?

CONFLICT OF INTEREST IN RESEARCH



Participating in research is your choice.
Be informed. Ask questions. Get answers.

A conflict of interest, or “COI,” may exist when professional judgment or actions could be influenced by a private or personal interest, resulting in personal, financial, or professional gain. Participant safety may be influenced by a tendency on the part of the investigator to want a favorable outcome.



What is a conflict of interest?

A conflict of interest, or “COI,” may exist when professional judgment or actions could be influenced by a private or personal interest, resulting in personal, financial, or professional gain. COI can affect the design, conduct, or reporting of research data and possibly impact research participants.

Why should you consider COI?

When deciding to participate in a research study, you should be aware of the risks and benefits of participating in the study, including whether or not the research staff has other interests that may play a role in the outcome of the study. The investigator can have an effect on participant safety if he/she desires a favorable study outcome.

How does COI affect research studies?

COI can impact research studies in many ways, such as the research study design, how the study is managed, review of the data, and how the data is interpreted. Although not every COI would affect the research, it is possible that COI might affect you or the quality of the research.

COI is generally thought about in terms of financial interest, but any circumstance that could influence the research is considered a potential COI.

How will the research team inform you if there is a COI?

The research team is required to indicate whether there is a COI, and how the conflict is being handled. During the informed consent process, you will be informed of any potential COI and the ways it might affect the research.

Types of COIs in research:

Financial interests:

Financial interests include opportunities where an individual uses his/her professional judgment for personal financial gain or to benefit a company in which the individual has a financial interest such as a patent, trademark, copyright, licensing agreement, ownership interest, or stock options. Or, a research team member could be influenced by substantial payments that may be upcoming. This might include, for example, a grant to fund similar research or one that competes with the investigator’s respective study.

Non-financial interests:

- > *Personal:* When an individual’s other interests may impact the research study’s results, staff, or participants
- > *Professional:* When an individual has the opportunity for professional growth based on his/her involvement in the research study
- > *Institutional:* When the benefits and/or financial interests of an institution may affect or appear to affect the research or other activities of the institution
- > *Perceived:* When the appearance of a conflict is known to others and may bring about questions regarding the appropriateness of that individual’s involvement in the study

What are the examples of COI in a research study?

- > Accepting gifts such as meals, drug samples, etc. from a company which could be interpreted as willingness to impact research data
- > Receiving consulting fees from the research study company while performing clinical research funded by the company
- > Owning stock in a company while performing clinical research sponsored by the company
- > Receiving milestone incentives such as payments, stock options, gifts, etc.

How does the research team handle COI?

COIs are not always unethical or unacceptable; they are sometimes unavoidable and in many cases can be appropriately managed or the impact can be reduced to an acceptable level.

Disclosure is the most common strategy for dealing with COI. It is important to disclose COI to the investigator’s institution, the Institutional Review Board (a group of people who review studies to consider the rights and welfare of people participating in research), and those to whom the results are reported (e.g., journals, sponsors, FDA, etc.).

Managing COI may include a decision to not allow the individual with a conflict to participate in the study to reduce the perception of a conflict.