



Conflict of Interest FAQs for Clinical Researchers

1) What is a financial interest?

Financial Interest is a broad term meaning ownership in, intellectual property rights to, remuneration from, or a fiduciary responsibility (even if uncompensated), or receipt of gifts, gratuities or to her business courtesies (e.g. meals, entertainment) greater than \$150 from an Outside Source.

2) What is a conflict of interest (COI)?

Conflict of Interest means a situation in which financial or other outside interests may compromise, or appear to compromise, the judgment regarding patient care, educational activities, research activities, business decisions, or relationships with vendors, loyalty to UH or ability to perform his or her responsibilities to a UH entity.

Per UH Policy CE-20, a financial interest greater than \$4,999 is considered a conflict of interest and must be managed.

3) Who must disclose?

UH policy CE-20 requires all UH employed physicians and advance practice providers (i.e., "Licensed Practitioners") disclose outside activities that involve a financial interest greater than \$150. Licensed Practitioners must also disclose family member financial interests. These disclosure should be made in COI Smart (<https://uhhs.coi-smart.com>).

In addition, all individuals involved in the design, conduct, or reporting of research at UH are required to disclose financial interests in their IRB submission. These disclosure are made in the SpartaIRB system (<https://spartaarb.case.edu>) on the study personnel table. Note that individuals should only indicate "Yes" if the financial interest/COI is related to that specific study. Information regarding financial interest among the study team should be shared with all personnel involved in the IRB submission (e.g., study coordinators) to ensure this information is accurately reported. The PI is responsible for confirming the information in the Smart Form is correct prior to submitting to the IRB.

4) What should I disclose?

Specific outside activities that must be disclosed are outlined in UH Policy CE-20. Some examples include: salary or other payment, ownership interest (publicly-traded or privately held-entities; mutual funds; UH competitors), and intellectual property.

5) When should I disclose?

UH Policy CE-20 requires outside activity disclosures on an annual basis. If new financial interests are acquired or discovered (e.g., through purchase, marriage, or inheritance), COI Smart disclosures must be updated within 30 days. All financial interests associated with a particular research study must be reported in SpartaIRB at initial submission. At the time of continuing review, the PI is responsible for reviewing all financial interest/COI information to ensure the Smart Form is still accurate. Changes to this information must be updated in SpartaIRB with a Modification/Amendment as soon as possible.



6) Why must I disclose?

Failing to disclose financial interests, disclosing them inaccurately, or not following the requirements outlined in a management plan may be considered non-compliance. Moreover, financial interests have the potential to compromise judgement, therefore outside review and management is essential. IRBs, for example, are responsible for protecting human subjects. One way they do this is to ensure financial interests are not biasing recruitment, the informed consent process, data analysis, etc. For this reason, research studies involving financial interests/COIs are reviewed at Full Board IRB meetings.

7) What happens if I have a COI?

When a disclosure is made, UH Compliance & Ethics will determine the significance of the financial interest and whether it constitutes a COI. If so, UH Compliance & Ethics will offer the conflicted individual four options for managing their COI (see UH Policy CE-20). A formal management plan may be developed to outline the conflicted individual's specific responsibilities and requirements for managing their COI. If the individual is involved in research at UH, a management plan will either be issued by UH Compliance & Ethics or the UH IRB, depending on the individual's role on the study. Management plans will outline the specific requirements necessary to manage the individual's COI (e.g., disclosure in the consent form).

If you have questions about the COI Smart disclosure process, please contact Catherine Clampitt, Compliance Specialist at [216-767-8224](tel:216-767-8224) or Catherine.Clampitt@UHhospitals.org. For SpartaIRB questions, please contact the UH IRB at [216-844-1547](tel:216-844-1547).

Source documents:

- UH Investigator Manual for IRB Submissions: <https://www.uhhospitals.org/for-clinicians/research-and-clinical-trials/core-offices/institutional-review-board/irb-policies>
- UH Policy CE-08 and CE-20: <https://uhcommunity.uhhospitals.org/SystemPolicies/ComplianceEthics/Forms/Library%20View.aspx>
- Code of Federal Regulations - 21 CFR 54: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRsearch.cfm?CFRPart=54>
- Code of Federal Regulations - 42 CFR 50: https://grants.nih.gov/grants/compliance/42_cfr_50_subpart_f.htm
- Code of Federal Regulations - 45 CFR 94: <https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=45:1.0.1.1.51>
- Identifying & Managing Conflicts of Interest GPS Online ([UH Employee](#) | [Non-Employees](#))
- Conflicts of Interest UH Webpage: https://uhcommunity.uhhospitals.org/Compliance/Pages/Conflicts_of_Interest.aspx

Additional questions contact UHIRB@UHhospitals.org