

Quick Start / Reference Sheet for Investigators Completing their First Certification in the KU Conflict of Interest Reporting System

Main task for Investigators in the COI system for the first time:

- Complete Research Certification(s) related to PHS compliant projects on the KU-Lawrence or KUMC campuses.

Accessing the System and Logging in

1. The KU COI System can be accessed through the link in the e-mail that is generated by a research project administrator. Log in using your KU Online ID and password.
2. In **My Inbox**, click on [Research Initiated Certification for \[Your Name\]: PeopleSoft Project #](#)
3. Read **Research Certification Instructions** and **Notes to Discloser** on the Summary tab screen.
4. Click **Edit Disclosures and Certify** in upper left corner to open the certification form.

Completing your Certification

- I. **Institutional Responsibilities-** Answer 7 questions about your responsibilities at KU or KUMC.
- II. **Which FCOI Policy Applies (KU-L or KUMC)-** Answer 2 questions to be routed to the appropriate criteria.
- III. **What to Disclose-** Read this informational page of disclosure criteria based on your responses in section II.
- IV. **Disclosure Details-** Adding **New Disclosure** will launch the Disclosure SmartForm, guiding you through various screens depending on your relationship with the disclosed entity. The six possible sub-screens are: Equity, Remuneration, Intellectual Property Income, Sponsored Travel, Board Position, and Time Commitment
 - A. If you have nothing to disclose, **Continue** will advance you to section V.
 - B. If you have completed details for this entity, a **Disclosure Summary** will display your information. Review and click **Finish** or <<Back to edit and finish when ready.
 - C. If you have another entity to disclose, click **New Disclosure** again to repeat this process.
 - D. If you have completed details for all entities you are disclosing, **Continue** will advance you to section V.
- V. **Research Information-** Respond to a question about the relation of any disclosures to the research project.
- VI. **Assurance and Certification-** Confirm details of your report.
 - A. Submit the certification by checking the box AND clicking **Finish**.
 - B. Save your draft for later submission by just clicking **Finish**.

Checking the Status of your Certification

You may view the status of your certification on the Summary tab screen on the top bar marked in yellow. They include:

Draft- You have not submitted this Certification yet.

No Review Required- Certification has been submitted, AND, you have no Significant Disclosures (no potential conflicts).

Administrative Review- Certification has been submitted, AND, it contains significant financial interest that must be reviewed by Research Integrity.

Supervisory Review- This will not appear on Research certifications, as your supervisor only reviews annuals and updates.

Under Management/Mitigation Plan- You have a current Management/Mitigation plan (this will not display on anyone's screen on the initial certification).

Key Terms / Definitions

Covered Persons: All faculty, all other unclassified academic and professional staff, and all Investigators as defined below. Financial interests of a Covered Person include those of the individual's family or household members as described in the applicable campus reporting forms.

Investigator: The project director or principal investigator or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research conducted under the auspices of the University. Investigators may include, for example, collaborators or consultants not employed by the University. For the purposes of 42 CFR Part 50 and 45 CFR Part 94 -the new COI Regulations, "investigator" refers only to those identified by the PI on a PHS compliant proposal or sponsored project (effective 8-24-2012).

University Responsibilities: An individual's responsibilities on behalf of the University, which may include (but are not limited to), activities such as teaching, research, research consultation, administration, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Financial Conflict of Interest: A conflict of interest that arises in a situation in which a Significant Financial Interest of a Covered Person compromises or has the appearance of compromising the fulfillment of professional duties; teaching, clinical or scientific judgment; integrity of research data and the research process; or the safety and welfare of patients and/or research subjects.

Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting or other fees, honoraria, paid authorship, commissions, etc.)

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.

Governmental or Educational Entities include federal, state, or local government agencies; institutions of higher education as defined at 20 U.S.C. 1001(a); and academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education.

QUICK LINKS:

Individual Financial Conflict of Interest Policy <https://documents.ku.edu/policies/Chancellor/IndividualCOI.htm>

More to come! Check out our new web page <http://www.rcr.ku.edu/~rcr/coi/index.shtml>