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Outside activity reports (OARs), COI, IRB COI policy change

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Case study

Roche has agreed to sponsor Dr. Smith's proposed human subjects research project to be conducted at the medical center. The study involves research on using antiemetics to reduce the side effects caused by chemotherapy. In 2020, Roche gave Dr. Smith $8,000 in honoraria for speaking about their products and he expects to receive approximately the same amount in 2021.

Does a specific conflict of interest exist?

Is there an increased risk to human subject safety?

Should Dr. Smith be allowed to conduct the Roche sponsored research?

Safeguards needed?

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Role of COI Office

- COI Office ensures that UC is in compliance with federal and state laws and regulations as well as institutional rules and policies governing conflicts of interest in research
- COI Office evaluates:
  - Individual financial disclosures
  - Individuals who create a discovery or invention and who desire to transition that discovery into a company (startup)
- COI training (required once every 4 years) – embedded into the Outside Activity Report (OAR) system
- Coordinates the development, review and approval of conflict management plans (CMPs)
- Assists with the review and management of institutional conflicts of interest.

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Outside Activity—UC Policy

- An outside activity is a non-university activity that is **not part of an employee's university duties**, including duties performed at UC and unpaid activities. Outside activities include employment, consulting, service on boards, and business activities including managerial positions.

- All financial interests, including but not limited to stock, cash and Limited Liability Company (LLC) interests should be reported and approved by the university. (Board Rules 30-21-02 and 30-21-03)

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Does the university oppose outside activity?

- Generally, no.
- The university supports faculty and staff engaging in outside professional activities and community service. University policy allows employees to participate in outside activities and hold financial interests as long as the conflict is disclosed, appropriately managed, and approved by the university *prior* to commencing the activity.

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Outside Activity Report (OAR)

The **Outside Activity Report (OAR)** is the University of Cincinnati's web-based system for disclosure, review, approval, and management of:

- Collateral employment and outside activities
- Relationships or interest in other entities that may involve a conflict of interest
- Engagement of research, creative and/or scholarly work outside of UC

The information reported is confidential; only disclosed/used as required by university policy, rules, and applicable law. Access the OAR website at https://webcentral.uc.edu/oarv2/.

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Who must report?

1. All employees, faculty and staff, with a full-time equivalency (FTE) of 50% or more.

2. All faculty and staff who engage in research, creative, and/or scholarly work at UC are required to complete the OAR (Outside Activity Report) regardless of their FTE percentage.

3. Faculty and staff at less than 50% FTE may also be required to complete an OAR at the discretion of the administrative unit head.

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UC Policy

- Disclosure Threshold:
- UC has a $0 disclosure threshold
- This means that all outside activities (paid/unpaid) need to be disclosed to the university for review
- Significant Financial Interest (SFI) (federal definition)
  - A significant financial interest (value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest, when aggregated, exceeds $5,000) could become a financial conflict of interest if UC determines that the significant interest is reasonably related (perceived or actual) to the research
- Financial Conflict of Interest
  - SFI that could directly and significantly affect the design, conduct, or reporting of research.

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Conflict of Interest Training, 2020

- Every four years, all employees who **engage in research, scholarship and/or creative work** must complete the COI Training.
- Training is available through CPD (Continuous Professional Development website)—routed from OAR.
- 7-minute video that provides critical information on what's required to be disclosed, how often, and the review/approval process.
- The OAR cannot be submitted without completing the training.
- https://ce.uc.edu/CPD/Workshops/Index/OART

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Disclosure, prior approval

Per **30-21-02** Employment: policy on collateral employment for faculty members and librarians

- The faculty member provides information regarding the proposed collateral employment **in advance** to the dean of the college…
- Does not interfere with nor is inconsistent with the performance of the individual's university duties; and
- Does not raise questions of conflict of interest in connection with other interests or work with which the individual, or the university, is involved.

- Prior to acceptance of a foreign academic title, department head and dean should understand expectations of foreign appointment (academic or industry).
- **Disclose in the OAR applies year-round. Update within 30 days of acquisition or discovery of a new relationship.**

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What must be disclosed?

1. Activities: consulting, speakers bureaus, service on advisory boards or committees, *board of directors*, legal consultation, expert testimony, honoraria, lectures, teaching/instruction, professional publications, etc.
2. Equity interests (such as stock, stock options, or other ownership interests). *Income from investment vehicles, such as mutual funds and retirement accounts, as long as the employee does not directly control the investment decisions in these vehicles, should NOT be disclosed*.
3. Income (such as licensing fees or royalties) from intellectual property rights (such as patents or copyrights).
4. Licensed intellectual property (even if income has yet to be received).
5. Activities must be disclosed whether they are paid or unpaid.
6. Faculty/Staff/Student startup companies.
7. Outside activities (e.g., employment, consulting, etc.) during off-semesters.

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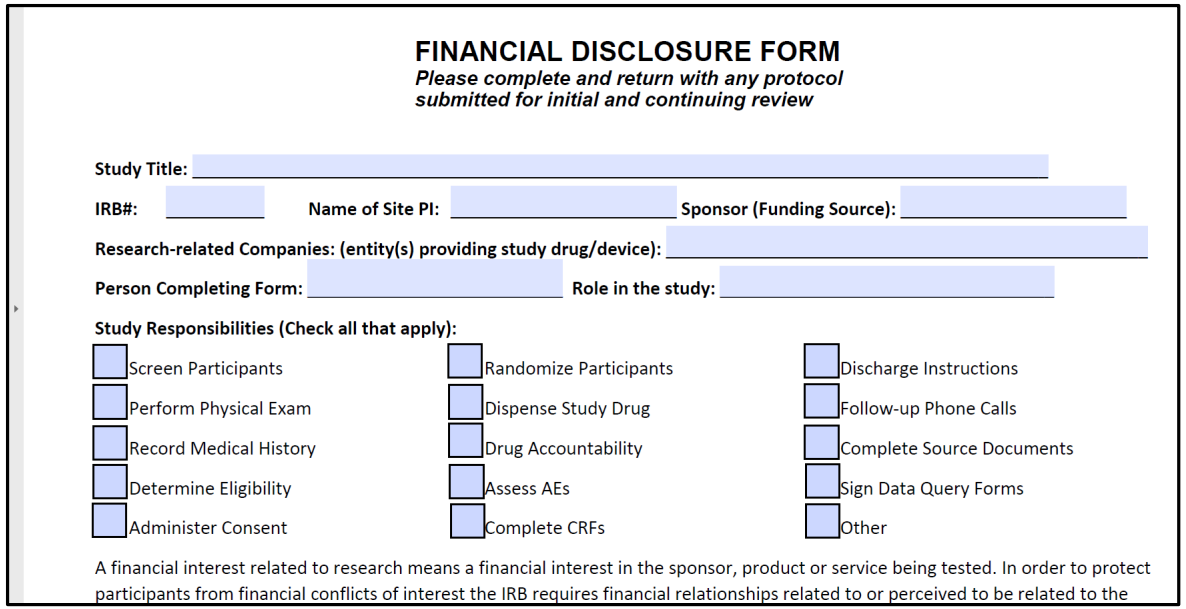
Disclosure to IRB

- Separate, additional disclosure for clinical researchers (in addition to the OAR)
- Human Subjects Research: all faculty/staff who conduct HSR are required to complete an additional disclosure form that is **research specific**
- **COI Disclosure Form (paper form from HRPP library) → PDF Fillable form (same form)**



FINANCIAL DISCLOSURE FORM

Please complete and return with any protocol submitted for initial and continuing review

Study Title: _____

IRB#: _____ **Name of Site PI:** _____ **Sponsor (Funding Source):** _____

Research-related Companies: (entity(s) providing study drug/device): _____

Person Completing Form: _____ **Role in the study:** _____

Study Responsibilities (Check all that apply):

☐ Screen Participants	☐ Randomize Participants	☐ Discharge Instructions
☐ Perform Physical Exam	☐ Dispense Study Drug	☐ Follow-up Phone Calls
☐ Record Medical History	☐ Drug Accountability	☐ Complete Source Documents
☐ Determine Eligibility	☐ Assess AEs	☐ Sign Data Query Forms
☐ Administer Consent	☐ Complete CRFs	☐ Other

A financial interest related to research means a financial interest in the sponsor, product or service being tested. In order to protect participants from financial conflicts of interest the IRB requires financial relationships related to or perceived to be related to the

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Relatedness Assessment

- Review the individual's personal financial interests and those of their spouse and/or dependent children disclosed in the form and determine whether it's related (or could be perceived to be related) to that individual's research.

- Relatedness to research? Questions to assess:
  - Are the activities of the entity related to the subject of the research?
  - Could the research directly benefit the entity?
  - Does the entity support or sponsor the research?
  - Does the entity own or license intellectual property studied in the research?

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Additional follow-up

Commonly asked questions to determine relatedness:

- Please briefly describe your role and responsibilities that you provide to the company (e.g. drugs you may speak on behalf of the company)
- Amount of compensation received in the past 12 months from the company.
- Does the relationship you have with the company relate to or appear to relate to the NIH research being proposed? If they are separate, please explain how there is no overlap.
- Could the relationship with the company inappropriately influence the proposed research?
- Does the company have any scientific interests in or products that compete with the research you are doing for the NIH?

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What is a conflict of interest?

A university employee has a conflict when their outside activity or financial interest could potentially interfere with the employee's professional obligations to the university.

A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a **primary interest** will be unduly influenced by a **secondary interest**.

- **Primary interests** refer to the principal goals of the profession or activity, such as the conducting responsible research, delivering effective education, meaningful mentoring, etc.
- **Secondary interests** include not only financial gain but also such motives as the desire for professional advancement and the wish to do favors for family and friends. (Board rule 10-17-08 & 10-17-09)

Why do we care?

- Relationships between the pharmaceutical industry and physicians have benefited patients through the development of drugs that improve survival and quality of life.

- However, there is widespread concern that pharmaceutical industry's role in medical practice and research unduly influences professional behavior and judgment (Rosenbaum L, 2015), (DeJesus-Morales, Prasad V, 2017)

How do we handle financial COI: Can’t we just rely on integrity?

No, it has not worked—problems persist, and…

Dana and Loewenstein, JAMA, 2003

- Detail social science studies in which participants exhibited a self-interest bias in decision-making
- Authors conclude that self-interest bias is:

  Unintentional, because it remains even when participants are motivated to be impartial

  Unconscious, because individuals succumb to bias even when explicitly instructed about it

  Acts indirectly, and seems to affect the way individuals weigh pieces of information in the decision-making process

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How to handle financial COI: common responses

Disclosure

Manage

- Reduce roles
- Divest
- Protect data integrity (independent oversight, audit, independent observer)

Recuse / eliminate

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Safeguards for COI, UC Policy

Disclosure of $10K or less

- Disclosure in the informed consent document

Disclosure $10K to $24,999

- Disclosure in ICD
- Independent oversight (research process: data analysis)
- Removal of PI (dependent on risk/benefit analysis)
- Cannot consent/enroll participants
- Cannot determine eligibility criteria

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IRB COI Policy Change

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Non-Complion Users—Nothing disclosed

In an effort to improve efficiency:

1. Complete the **PDF Fillable disclosure form**: allows for electronic signature rather than printing and scanning. The fillable form asks the same questions as the word doc.

2. If all boxes are checked “NO”, **do NOT** upload it to RAP.

3. Keep on file for research purposes (e.g., documentation and audit)

4. Document negative and positive responses for key personnel in the RAP ManageCOI activity

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Non-Complion Users—Positive disclosure

1. At least one box checked YES for a study member = positive disclosure.
2. Upload **only positive disclosure PDF forms** into RAP for HRPP notification and COI Office review.
3. Keep all disclosure forms on file for research purposes (positive and negative).
4. Document negative and positive responses for key personnel in the RAP ManageCOI activity.

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Complion Users

In an effort to improve efficiency:

1. Have the study member complete the financial disclosure form provided in Complion.
   a) This form attests that the study member **does not** currently have nor has had a financial relationship in the past 12 months related to any of the research-related companies and/or sponsors listed above.
   b) If this form is signed by the study team member, document the negative response for the study member in the RAP ManageCOI activity.
2. If the study member cannot sign the form due to a financial relationship that requires disclosure:
   a) Require the study member to complete the **PDF Fillable form**, sign and return the form to you.
   b) Upload **only the positive form** into RAP for HRPP notification and COI Office review.
3. Document negative and positive responses for key personnel in the RAP ManageCOI activity.

Complion User Form

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FINANCIAL DISCLOSURE FORM

Please complete and return with any protocol submitted for initial and continuing review.

Study Title: _____
IRB#: _____
Funding Source/Sponsor: _____
Research-related Companies: _____ (entity(s) providing study drug/device)
Name of Site PI: _____

A financial interest related to research means a financial interest in the research-related companies and/or sponsor, product or service being tested. In order to protect participants from financial conflicts of interest the IRB requires financial relationships related to or perceived to be related to the research during the past 12 months be disclosed. If the IRB determines that a conflict exists that could influence the research or jeopardize the well-being of participants, the IRB may require additional information about the relationship or may require that the conflict be resolved before the research is approved. In addition, it may require that the conflict be disclosed to the participant in the Informed Consent Document.

I or a member of my immediate family (spouse, children, parent, in-laws, and siblings) **do not currently have nor had in the past 12 months** any of the relationships described below in any of the **research-related companies and/or sponsor** listed above:

- Own(s) equity (stock ownership, stock options, convertible note(s), or other ownership interest in any amount);
- Created inventions that the research-related company/sponsor holds patent rights to;
- Hold(s) a position of senior management officer, executive leadership, board member, or director;
- Receive(d) payments for providing scientific advice, consulting or speaking (including direct or indirect payments, honoraria, and all other forms of compensation);
- Entitled to royalty income or income from the sale of product if a device, technique, software, or procedure involved in the research is marketed;
- A financial interest that may appear to conflict with the protection of participants or which should be disclosed to participants in order to secure informed consent;
- A financial interest or relationship with a company/sponsor that competes with the company/sponsor listed above.

I or a member of my immediate family (spouse, children, parent, in-laws, and siblings) **do not currently have nor had in the past 12 months** any of the relationships described below in any of the **research-related companies and/or sponsor** listed above:

- Own(s) equity (stock ownership, stock options, convertible note(s), or other ownership interest in any amount);
- Created inventions that the research-related company/sponsor holds patent rights to;
- Hold(s) a position of senior management officer, executive leadership, board member, or director;
- Receive(d) payments for providing scientific advice, consulting or speaking (including direct or indirect payments, honoraria, and all other forms of compensation);
- Entitled to royalty income or income from the sale of product if a device, technique, software, or procedure involved in the research is marketed;
- A financial interest that may appear to conflict with the protection of participants or which should be disclosed to participants in order to secure informed consent;
- A financial interest or relationship with a company/sponsor that competes with the company/sponsor listed above.

****IF you have a financial relationship with the research related companies and/or sponsor, please contact** *[Insert Contact Name]* **at** *[Insert email address]* **to complete an IRB financial disclosure form.**

By signing below, I certify that I have disclosed **no relationship as described above** with the research-related companies and/or sponsor of the study currently and/or in the past 12 months. I agree to contact the study coordinator and HRPP to update this disclosure form within 30 days if my relationships change and may impact this clinical study. Failure to disclose a financial relationship related to this protocol may result in suspension of the research and/or my eligibility to participate on the protocol.

My signature below is my representation that I have accurately completed this form to the best of my knowledge.

Signature & Print Name _____ Date _____

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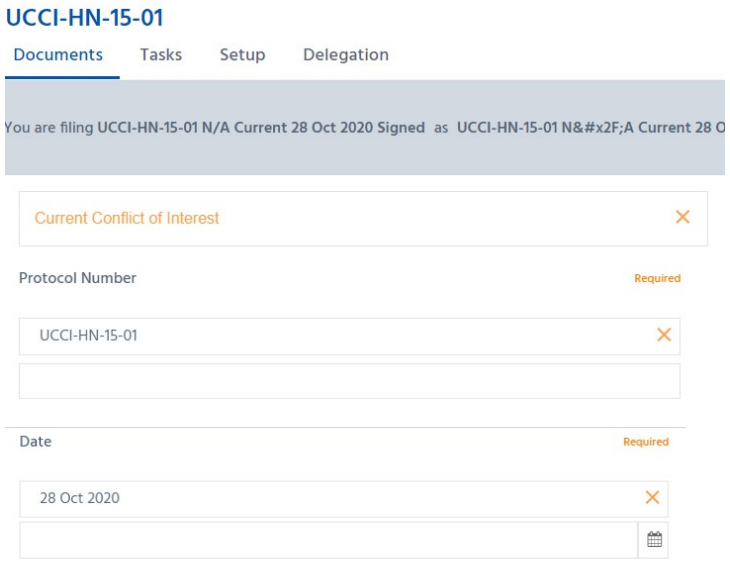
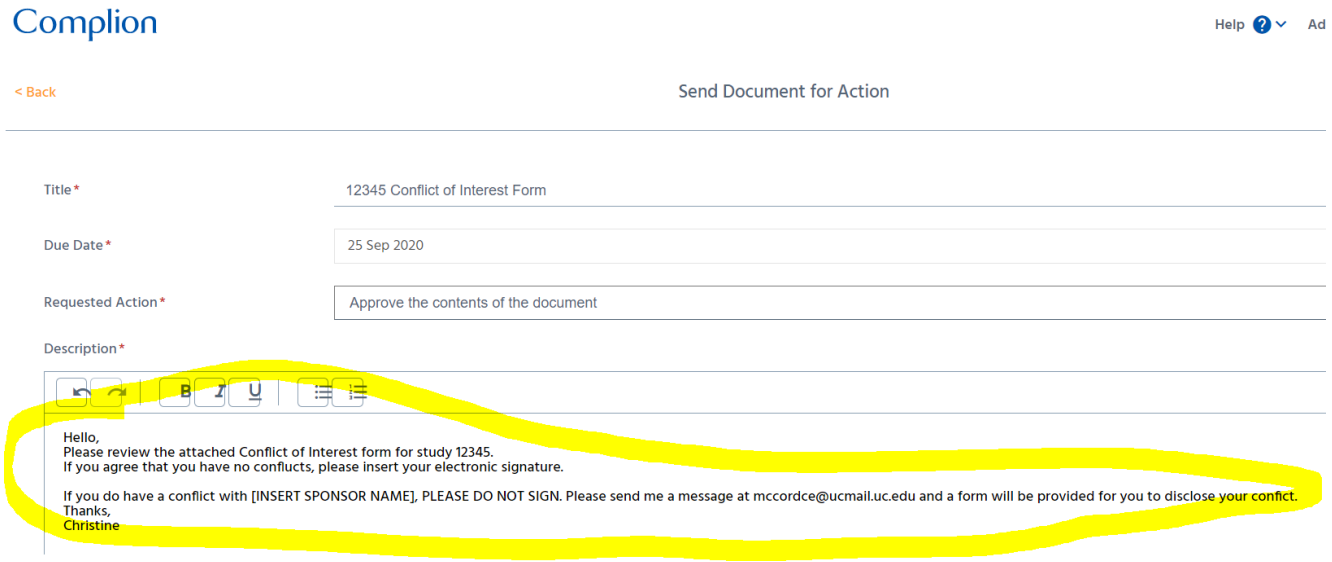
Complion Process

1. File COI form in Complion.



2. Send Document for Action.

Route COI to all study staff. Below is template message to be sent to Study Personnel explaining action to take on the COI form. They should only sign Complion form if they DO NOT have a conflict to disclose.



If Study Personnel does have a conflict, they will not sign Complion COI. They will complete fillable COI form to disclose conflict.

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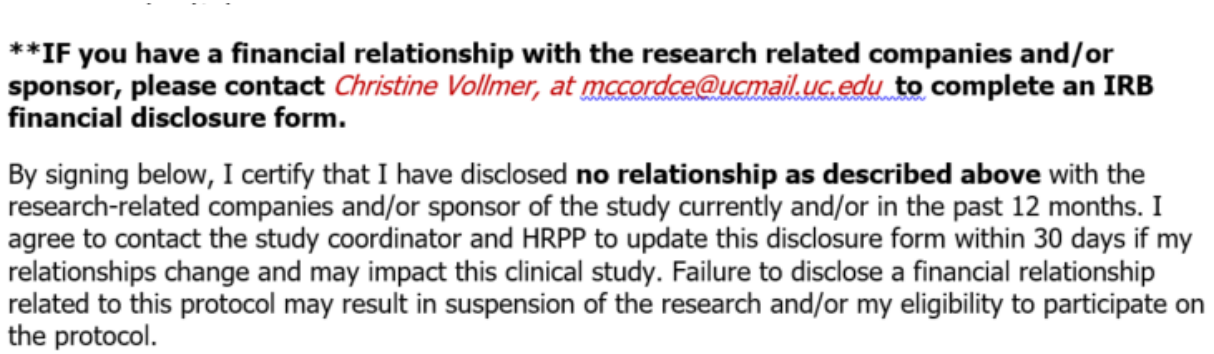
Complion Process

Important!

If a Study Personnel does have a conflict, they will not sign the Complion COI. They will reach out to the contact provided in the COI and request a fillable COI form to disclose conflict.



****IF you have a financial relationship with the research related companies and/or sponsor, please contact** *Christine Vollmer, at mccordce@ucmail.uc.edu* **to complete an IRB financial disclosure form.**

By signing below, I certify that I have disclosed **no relationship as described above** with the research-related companies and/or sponsor of the study currently and/or in the past 12 months. I agree to contact the study coordinator and HRPP to update this disclosure form within 30 days if my relationships change and may impact this clinical study. Failure to disclose a financial relationship related to this protocol may result in suspension of the research and/or my eligibility to participate on the protocol.

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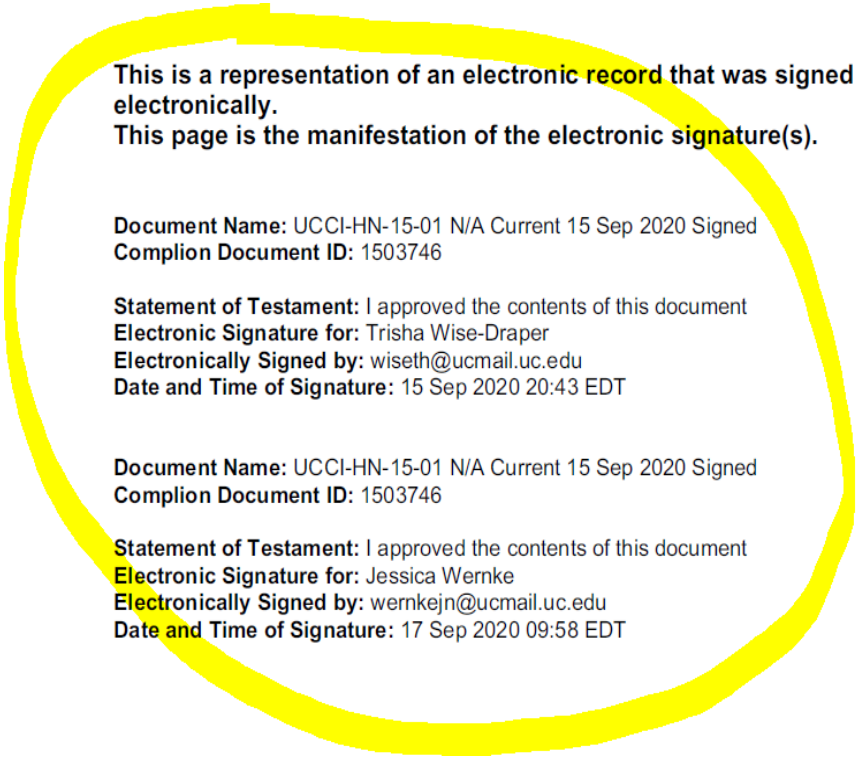
Complion Process

1. The Disclosure statement indicating NO financial relationships sent through Complion will contain signatures of all staff with no financial relationship. This document will remain filed in Complion and will not be uploaded into RAP.
    a. UC HRPP may request to audit records of disclosure statements.

2. Only Positive disclosures for study personnel will be uploaded into RAP for HRPP notification and COI Office review



This is a representation of an electronic record that was signed electronically.
This page is the manifestation of the electronic signature(s).

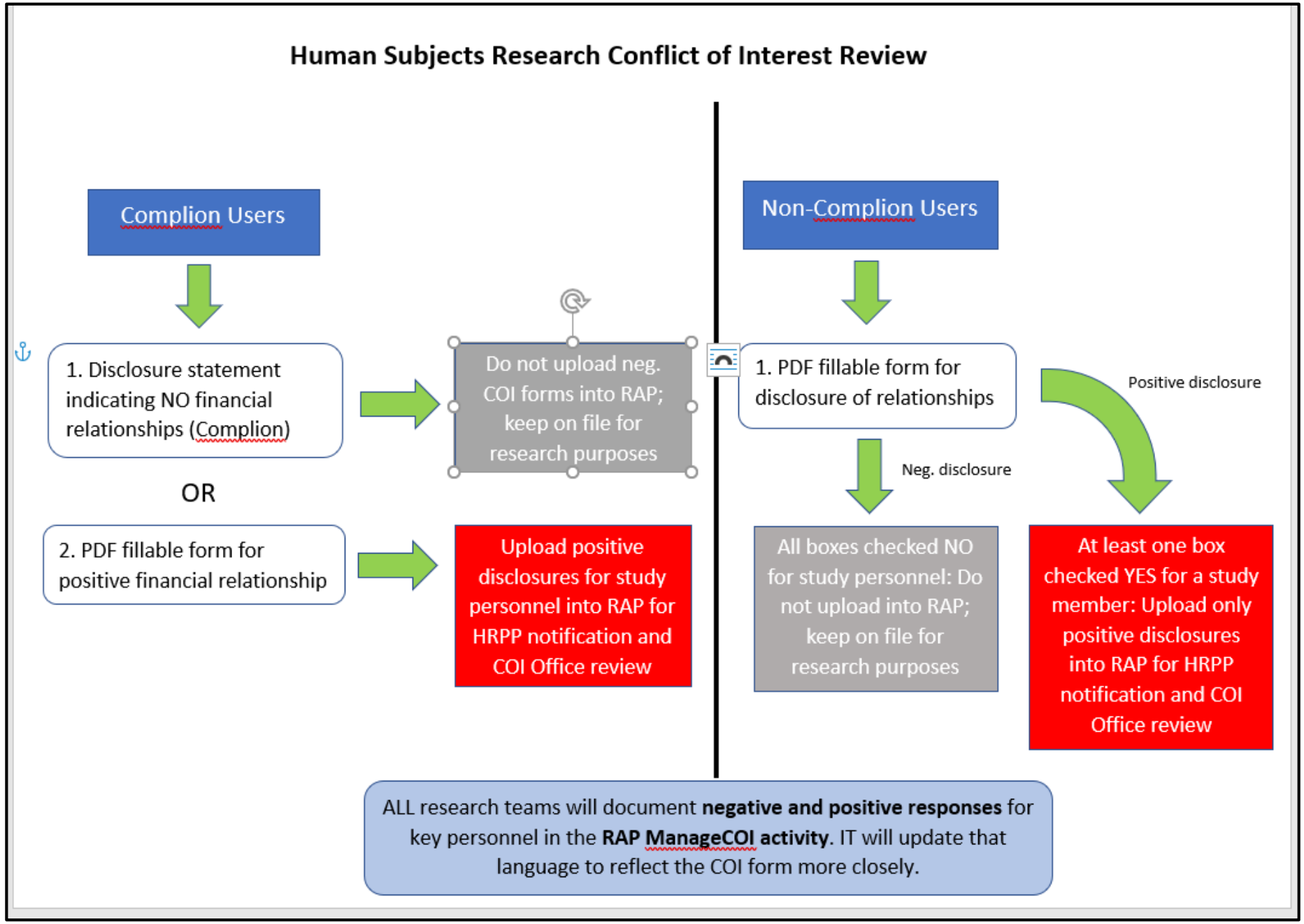
Document Name: UCCI-HN-15-01 N/A Current 15 Sep 2020 Signed
Complion Document ID: 1503746

Statement of Testament: I approved the contents of this document
Electronic Signature for: Trisha Wise-Draper
Electronically Signed by: wiseth@ucmail.uc.edu
Date and Time of Signature: 15 Sep 2020 20:43 EDT

Document Name: UCCI-HN-15-01 N/A Current 15 Sep 2020 Signed
Complion Document ID: 1503746

Statement of Testament: I approved the contents of this document
Electronic Signature for: Jessica Wernke
Electronically Signed by: wernkejn@ucmail.uc.edu
Date and Time of Signature: 17 Sep 2020 09:58 EDT

Human Subjects Research Conflict of Interest Review



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Complion Process
UCCC Lessons Learned

1. Speak to your Investigators/Staff about this process before sending COIs in Complion. It is very important they understand their signature on a COI in Complion indicates no Conflict.

2. Remember that if there is any update to the information on the COI (PI/Sponsoring Company/etc), a new COI would need to be loaded into Complion for signatures.

3. A COI in Complion may be sent for signature more than once. Ie Initial Study COI and at time of Continuing Review. Complion will document both timestamps and signatures.

Reach out to Christine Vollmer (Mccordce@ucmail.uc.edu) for additional guidance if needed!

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Last reminders, contact info

- Reminder: COI verification needs to occur *prior* to submitting the protocol in RAP. Coordinators need to verify disclosure information prior to answering questions in RAP about whether or not there's a COI to report.

- Minimum requirement: Disclosure of **any relationship >$0** results in a policy requirement for disclosure in the informed consent document.

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