A Conflict of Interest (COI) section appears in the following activities for a human subjects study application (HUM) or an amendment (AME): Accept Role, Submit Application, and Submit Amendment. The COI section has changed to:

- Reflect current federal regulations for outside interest disclosure and COI management
- Connect the eResearch Regulatory Management system to U-M’s M-Inform disclosure system

This change results in the PI or study team member seeing either the “old” or “new” COI section in certain circumstances (see COI Variations below for more information).

**“Old” COI Section: C1 – C.2.2**

**Conflict of Interest Detail: Required for all roles except Administrative Staff**

- **C1.** Do you, your spouse, domestic partner, or dependents have any outside interests or relationships to companies or entities related to this research that the IRS should consider?

Examples of outside interests include, but are not limited to the following:
- Receiving compensation whose value could be affected by the study outcome
- IN THE AGGREGATE, expecting to receive compensation from the sponsor of the research of $15,000 or greater in the next year
- Having a proprietary interest in the sponsor of the research, or a product tested by the research, which includes but is not limited to, a patent, trademark, copyright, or licensing agreement
- Or the right to receive royalties from product commercialization

Individually or collectively:
- Having an ownership interest (equity or stock options) in a company or product whose value could be affected by the study outcome
- IN THE AGGREGATE, having an ownership interest (equity or stock options) in the sponsor of the research or product being tested whose value cannot be readily determined through reference to public prices
- Individually or collectively having an ownership interest (equity or stock options) or a company or product whose value could be affected by the study outcome
- In the aggregate, having an ownership interest (equity or stock options) in the sponsor of the research that exceeds $1,000 or 1% of the sponsor’s market capitalization
- Receiving significant payments of either type with an aggregate value of $10,000 or more (or payment of $1000 amount to medical school or hospital employees) made directly by the sponsor of this research for unrestricted research or education, equipment, consultancy, or honorarium
- Having a position of management or leadership in company or entity related to this research, but not limited to, officer, director, or member of an advisory board
- Providing consulting services or serve a Speaker's Bureau, either paid or unpaid, to the financial or non-financial sponsor of this study
- When the sponsor is a publicly traded entity, having any ownership interest (equity or stock options) in the sponsor
- Expecting to receive any loan, educational support, contributions of in-kind for equipment, or any other non-compensatory payment from the sponsor of the research in the next year

**“New” COI Section: D1**

**Conflict of Interest:**

To view your current disclosure information detail in M-Inform or to make changes to your disclosure information in M-Inform, click here to go to M-Inform and follow instructions.

- **D1.** Do you, your spouse, domestic partner, or dependent entity that relates to this research in one of the following ways:
  - The entity is sponsoring this research
  - The entity’s products are used in the research
  - The entity’s product is material (e.g., instrument being used in the research)
  - The entity is a company that has a conflict of interest
  - Other relationship not listed above

  **Yes**  **No Clear**

**View Management Plan in M-Inform**

**“New” COI section has 1 question vs. 6. It offers:**
- Current disclosure status
- M-Inform access
- Shorter criteria list
- Option to view management plan vs. uploading it

**Reminder:** Study team members who are not affiliated with U-M (i.e., individuals with an eResearch “Friends Account”) will see and complete different COI questions (i.e., the Financial Interest Screening questions) and, if necessary, disclose outside of the M-Inform system via submission of a paper form. See the Outside Interest Disclosure Process web page for more information on non-affiliate disclosures.

**COI Variations: Who Sees What & When Starting 04/14/14**

PI and U-M study team members see the “new” COI section when:

- Listed on a new HUM application
- Added as a new study team member on an AME or on an existing HUM in a pre-approved state
- Updating their COI answer on an existing study via an AME (see below for instructions)

PI and U-M study team members see the “old” COI section when:

- Listed as an existing PI or study team member on an AME.
“New” COI Section: Study Team/PI Actions

The “new” COI section includes a link to M-Inform for the PI/study team member to enter or update an outside interest disclosure, if applicable. The requirements to disclose and subsequent action the PI/study team member takes depends on that person’s COI answer for the HUM/AME and their current M-Inform disclosure status.

<table>
<thead>
<tr>
<th>COI Answer</th>
<th>M-Inform Disclosure Status</th>
<th>Expected Action(s) for HUM/AME</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>N/A</td>
<td>Your disclosure is complete. Accept your study team role or submit the HUM/AME.</td>
</tr>
<tr>
<td>Yes</td>
<td>• No disclosure on file</td>
<td>You are required to complete a disclosure in M-Inform prior to accepting study team role or submitting the HUM/AME.</td>
</tr>
<tr>
<td></td>
<td>• Disclosure on file is outdated (&gt; 365 days)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Disclosure on file is current</td>
<td>You are encouraged to go to M-Inform to update your current disclosure. You are able to accept your study team role or submit the HUM/AME.</td>
</tr>
</tbody>
</table>

“New” COI Section: Overview of Features

- Shows the Study Team Member’s disclosure status
- Link to the M-Inform disclosure criteria
- Click to verify if a COI Management Plan exists for the individual in M-Inform. If available, the plan displays. If not, a message displays indicating a plan doesn’t exist. This button always appears in the COI section.
- Alternative: use the Documents tab to view management plans for all study team members (as applicable).
How to Update a COI Answer on an HUM that is Active Prior to 04/14/14

A PI or study team member needs to update their COI answer in an active HUM when:

- A new outside interest arises that is related to the study, or
- A change to an existing, related outside interest occurs, or
- An existing outside interest ends or is no longer related to the study

If a PI or study team member has edit rights to the HUM, they can create an amendment to update their current COI answer. To view the “new” COI section, they must first clear the answer in the “old” COI section.

Getting Started in M-Inform

When a PI or study team member links to M-Inform from within the HUM or AME, what they see and the action they take to start their disclosure depends on their current disclosure status and the state of the disclosure.

In M-Inform, the PI/study team member begins their disclosure using one of the following methods:

1. Clicking the Add/Update My Disclosure button on the Home Workspace when:
   
   a. They weren’t required to disclose in M-Inform for any other reason and, therefore, haven’t previously disclosed for the fiscal year.
   
   b. They were required to disclose and have disclosed for the fiscal year and unit/COI Office review of that disclosure is complete.

2. Selecting Unsign Disclosure from the Activities menu next to their disclosure in the Under Review list on the Home Workspace when they have previously disclosed, but unit/COI review is incomplete.

3. Selecting Introduction from the Edit menu next to their draft disclosure in the Action Required list on the Home Workspace when they have previously started a disclosure, but not yet submitted it for review.

See the Submit an Outside Interest Disclosure procedure to learn how to add, remove, or edit an outside interest once you’ve opened your disclosure record in M-Inform.