InfoEd Implementation: Conflicts of Interest Module

RAPID Meeting Monday, September 14, 2015

Michelle A. Lewis, M.S. Director, Research Administration Interim Director, Research Integrity



Weill Cornell Medical College

Agenda

- I. General InfoEd Updates
- II. Overview of the Principles governing Conflicts of Interest & Commitment Management
- III. New COI Module: Go-live!
- **IV. COI Module Implementation Highlights**
- V. Communication & Training Strategy
- VI.Support
- VII. Next Steps

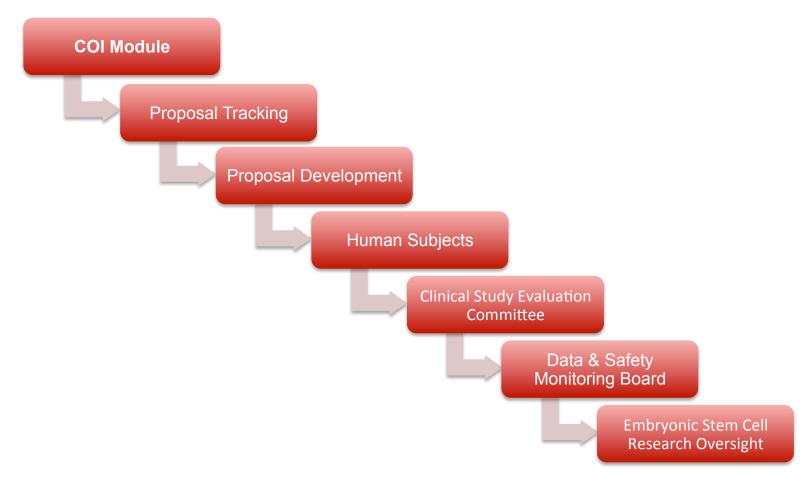


I. General InfoEd Updates



InfoEd Modules

The COI Module is the first of seven InfoEd modules to be implemented at WCMC





W E I L L . C O R N E L L . E D U

Weill Research Gateway (WRG) Portal

• "InfoEd" and "WRG" terminology will be used synonymously.

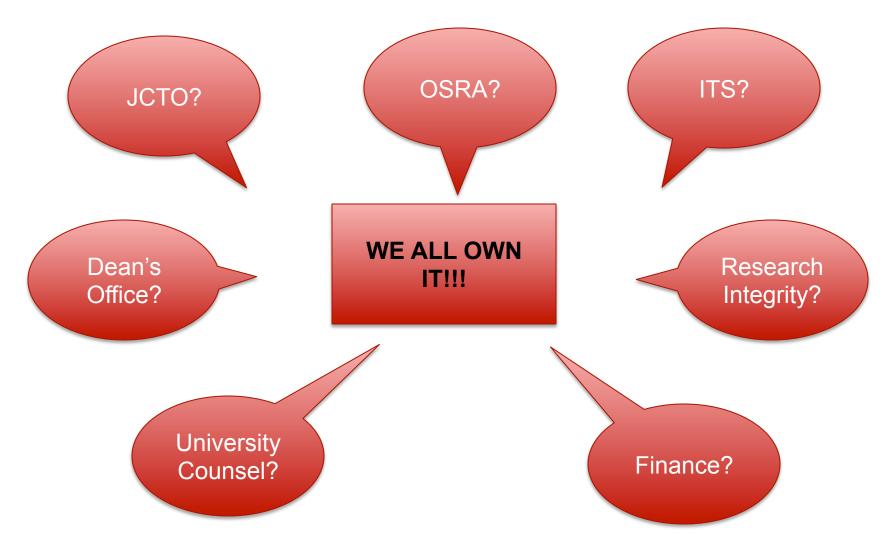
V	VF	RG	Logged in User: COI_FAC WCMC Find Funding CV Database	
Exit	? Help	i Support	Records Found: 0. My Open Action Items	Ordei
External Interests				
My Profile				

• The WRG not to be confused with the Weill Business Gateway (WBG)*.

*The WBG is portal by which we manage applications such as Employee Self-Service, Financials, Personnel, Compliance, Purchasing, Reporting and Other tasks.



Who will "own" InfoEd?





Weill Cornell Medical College

II. Overview of Principles governing Col & CoC Management



Million dollar question...



"A career? A life? Isn't that a conflict of interest?"



By a show of hands...

How many of you are familiar with the annual survey and understand why it is collected?

How many of you are familiar with the study-specific report and why it is collected?

Has anyone in the audience submit an Annual Survey and/or a Study-specific Report within the past 12 months?



Annual Survey

<u>Purpose</u>

The purpose of the Annual Survey is for individual's to disclose financial conflicts of interests and/or commitments to ensure the affairs of WCMC are handled in a manner consistent with an individual's primary commitment to the university, and to ensure the performance of their professional responsibilities are free from real or apparent bias motivated by self-interest.

Individuals are expected to evaluate and arrange their external interests and commitments in order to avoid compromising their ability to carry out their primary obligations to the university.



Study-specific report (SSR)

<u>Purpose</u>

The purpose of the study specific report is for individuals involved in the design, conduct, reporting, or direct administration of research at WCMC to provide information – on a study specific basis – regarding their individual or their family member's external commitment(s) and/or financial interest(s) that reasonably appears to be related to an individual's WCMC responsibilities.

The SSR must be made with each new grant proposal and/or research protocol (both human and animal subjects) application.



What is a Conflict of Interest (Col)?

A situation where an individual has the opportunity to influence the university's business, administrative, academic, or other decisions in ways that could lead to personal gain or advantage of any kind.



Source: Cornell University Policy 4.14



What is a Conflict of Commitment (CoC)?

A situation caused when an individual undertakes external commitments that *may* burden or interfere with his or her primary obligations and commitments to the university, even if the outside activity is valuable to the university or contributes to professional development and competence.

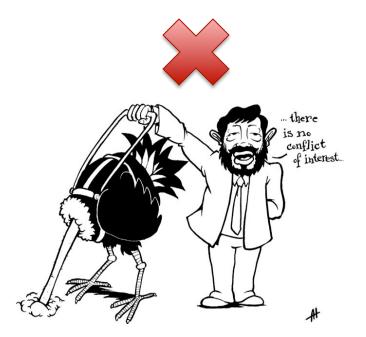


Source: Cornell University Policy 4.14



What is Conflict Management?

Measures taken to address the risk of bias or the appearance of bias when members of the university community have real or apparent conflicts of interest.







Who is responsible Conflict management at WCMC?

- Conflict Management Office (CMO)
- Conflicts Advisory Panel (CAP)
- University Counsel's Office

Ultimately the employee is responsible for the timely and accurate disclosure of all CoI and CoC.



What tool(s) are used to manage and disclose conflicts?

Today:

- 1. Huron's Click® System
- 2. Conflicts Memo uploaded to ERF
- 3. External COI Form
- 4. Shadow systems

Future: 1. InfoEd/WRG COI Module* 2. External COI Form

*Conflicts of interests disclosed by external collaborators (non-WCMC personnel) with no COI policies will be managed outside of InfoEd system utilizing the external COI pdf form.



III. COI Module: Go-live



InfoEd COI Module Go-Live

- New InfoEd COI module go-live date: October 19, 2015.
- What does "go-live" mean?
 - 1) COI Module will be accessible to all personnel, college-wide within the WRG as of 10/19/2015.
 - 2) <u>All</u> WCMC-NY and WCMC-Q personnel required to submit (annual) Conflicts survey within 30 days of go-live (new employees within 45 days from attending HR orientation).
 - 3) Personnel who have not disclosed within the past 12-months must complete Conflicts Survey.
 - Only in exceptional cases will extensions for disclosures be granted.*

*Contact the Conflicts Management Office to discuss any extenuating circumstances preventing timely disclosures.



InfoEd COI Module: Pre & Post Go-Live

- Series of emails, how to video's, FAQs, etc. leading up to and after go-live will be released to research community.
- After go-live DA's will be furnished with non-compliant report.
- Monthly communication to Department Chair or Department Heads to escalate non-compliant WCMC personnel post go-live.





Application / Tool

Current COI Management System:	Future COI Management System:
Huron's Click® System	InfoEd/WRG COI Module
Accessible via: <u>http://</u> <u>researchintegrity.weill.cornell.edu/</u> <u>conflicts_management_program/</u> <u>ann_dis_sta.html</u>	Accessible via: http://wrg.weill.cornell.edu/??? (some iteration of the above url)



Terminology

Current COI Management Terminology:	Future COI Management Terminology:
Annual Survey	Conflicts Survey





Current COI Management Policy:	Future COI Management Policy:
• Policy 4.14 COI and Commitment (Excluding Financial Conflicts of Interest Related to Research)	 Fall 2015 updated COI policies to be released to replace WCMC-specific content in CU Policy 4.14 and 1.7.
 Policy 1.7 <i>Financial Conflict of</i> <i>Interest Related to Research</i> Last updated Summer/Fall 2011 	

Sources:

- CU <u>Policy 4.14</u>
- CU <u>Policy 1.7</u>



Population

Current COI Population:	Future COI Population:
 All full-time, part-time, and voluntary faculty and staff members including <u>all</u> research- related personnel required to submit annual survey. 	 All paid, full-time and part-time faculty and non-faculty personnel including all research-related personnel are required to submit conflicts survey. Students being paid stipends required to submit Conflict Survey Students listed as Investigators on protocols and grants are required to submit Conflict Survey







Weill Cornell Medical College

W E I L L . C O R N E L L . E D U

Escalation Procedure

Current Escalation procedure:	Future Escalation procedure:
No escalation procedure for non- compliance.	New escalation procedure for non- compliance • Chairs & DA's



Annual/Conflicts Survey

Form has been streamlined to eliminate redundant and non-essential questions.

Current Annual Survey:	Future Conflicts Survey:
 No Conflicts reported →3 required questions Conflicts reported → 80 total questions COI disclosures occur arbitrarily regardless of recently updated interests. 	 No Conflicts reported → 2 required questions Conflicts reported → ~42 total questions COI disclosures occur on a rolling basis and thus due date for annual conflicts survey based
	upon last updated disclosure.



Travel Disclosures

Current COI Travel disclosure process:	Future travel disclosure process:
Part of the annual surveyUnstructured single field	 Separate form from the conflicts survey Structured table format to capture travel details



W E I L L . C O R N E L L . E D U

Study-specific reports (SSR)

Form has been streamlined to eliminate redundant and non-essential questions.

Current SSR:	Future SSR:
 Separate form from annual survey; however, the interests disclosed are <u>not</u> linked. User allowed to enter in a new interest on SSR not disclosed on annual survey. User must delete all interests that don't pertain. 	 Separate form from the conflicts survey; however, the interests disclosed <u>are</u> linked. User cannot enter in a new interest on SSR; must return to the conflicts survey. User will need to apply the interest(s) that pertain to the project.
 Conflicts reported → 102 total questions. 	 Conflicts reported → ~25 total questions.



W E I L L . C O R N E L L . E D U

<u>External COI Form</u> (for non-WCMC Investigators)

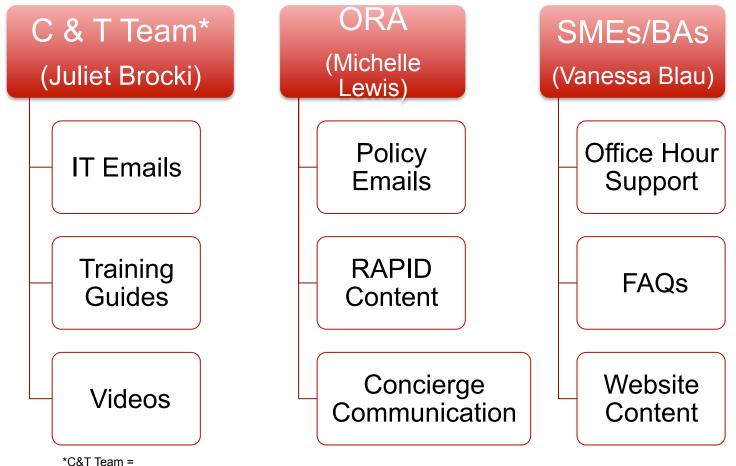
Current External COI form:	Future External COI form:
 Long, outdated and non-essential	 Form has been consolidated and
questions on form.	enhanced.



V. Communication & Training



Communication & Training Resources



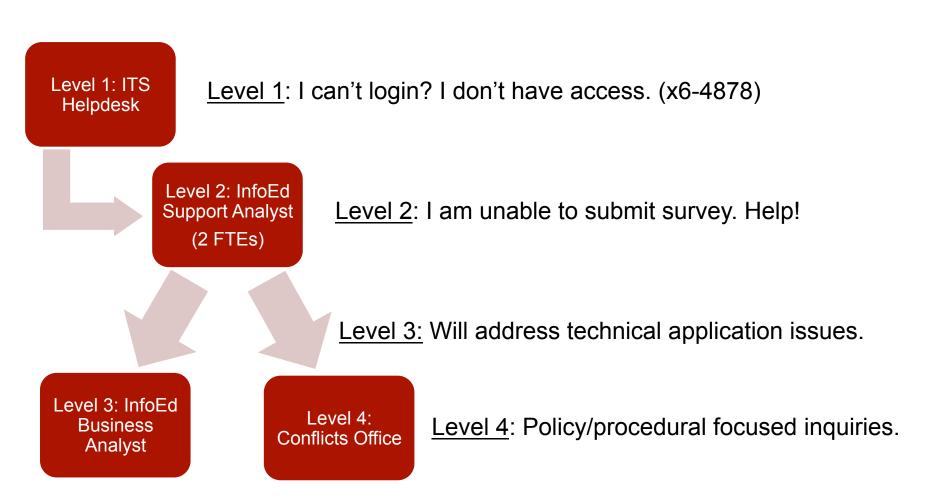
*C&T Team = Communications & Training Team



VI. Support



WRG Support Structure Post Go-Live





WRG Support Structure Post Go-Live

- Library will provide workstations for non-academic and part-time staff to comply with submitting annual survey.
- Engineering & Maintenance have designated areas for staff to comply with submitting annual survey.



VII. Next Steps



InfoEd COI Module Implementation: Next Steps

- 1. Dean Koretzky will inform the General Faculty Council on the WRG COI Module Implementation.
- 2. COI Website content will be updated by go-live.
- 3. Training materials (video tutorials/guides) will be developed.
- 4. Standard operating procedures will be accessible via the WRG.
- October RAPID session shorter COI presentation with screen shots for demonstration purposes will be offered.



InfoEd COI Module Implementation



Questions???

Any questions regarding this presentation can be directed to Michelle Lewis by email at <u>mil2006@med.cornell.edu</u> or by telephone at 646-962-4035.

Future inquiries (on or after October 19, 2015) can be emailed to: <u>WRG-Support@med.cornell.edu</u>

