

Automating the COI Disclosure and Management System

A Case Study

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Automating the COI Process

- Move from theoretical to practical
- Overview of the Conflict of Interest Cycle
- Discuss steps involved in COI Disclosure and Management
- Case Study - Academic Medical Center
 - Issues and challenges
 - Development Process and Design
 - Important design elements
 - Lessons learned
 - Conclusions



Conflict of Interest Cycle



Elements of the COI Disclosure Process

- Managing distribution lists
- Mailing or e-mailing questionnaires
- Tracking of outstanding questionnaires and follow-up on delinquent ones
- Review of returned questionnaires to identify disclosures

Elements of the COI *Management* Process

- Classifying disclosures and distributing them to appropriate reviewers
- Follow-up on potential conflicts
- Development of management plans
- Ongoing *management* of management plans
- Compiling statistics and generating reports (including IRS 990 information)
- Filing disclosures for future reference

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Case Study: Academic Medical Center

Issues and Challenges

- Seven Legal Entities (each with its own disclosure process)
- 7,000 Paper questionnaires – manual follow-up
- Overlap and duplication
- Incomplete responses (caused by respondents ignoring questions thought to be irrelevant)
- Too much time chasing paper, not enough managing conflicts

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Case Study: Academic Medical Center Issues and Challenges

- No central database of responses
- Disparate processes for review of disclosures
- Difficulty tracking correspondence between respondents and reviewer
- No ability to search or compile information to evaluate institutional conflicts
- New Form 990 requirements added urgency

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COI Management System: Options Considered

- Building disclosure management system
 - Time consuming, would require significant IT resources for development and on an ongoing basis
- Buying and installing a disclosure management system
 - Nothing on the market met perceived needs
 - Customization and maintenance would require significant IT resources on an ongoing basis
- Partnering to design and develop a system that would then operate in an ASP mode

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COI Management System: The Process

- Committee convened by then-President of the University Medical Center
- 18 attended first meeting
- Design committee – 6 stakeholders from administration, compliance and internal audit
- Met 2-4 times a month for 7 months to design
- Continued to meet weekly during implementation and pilot

Design Objectives

- Centralized Collection of Disclosures
- Auto-Emails & Reminders
- Improved Completeness of Disclosures
- Improved Tracking of the COI Process
- Ease of Use, Especially for Faculty & Physicians
- Improved, Consistent Review Process
- Improved Follow-up and Management of Personal and Institutional Conflicts
- Improved Documentation at all Stages

Design Objectives

- System had to be flexible and adaptable to other uses
- System Administration had to be user friendly (minimal IT involvement)
- Reporting System had to be robust
- Cost was a factor in the short and longer term

COI Management System: The Solution

- Automated MYSQL database tool developed in partnership with outside vendor
- All development costs borne by vendor
- Contractual commitment to license tool upon approval of design, development, and acceptance testing
- 7 months to design
- 9 months to program and test

COI Management System: Features

- Centralized Collection of Disclosures
 - Centralized system and database
 - Secure single sign-on
 - System can create multiple questionnaires or automatically direct different questions to individuals with different roles in the organization

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“My Profile” allows the respondent to confirm or add roles held within the organization. Roles determine the questions that appear on the questionnaire.

Logged In User : tsacks

My Questionnaire x My Questionnaire x My Profile Home Help Logout

★ My Profile

Please review and update the information below

User Name : tsacks

New User Name :

Confirm User Name :

New Password :

Confirm Password :

First Name :

Middle :

Last Name :

E-mail Address :

Job Title :

Department :

Primary Role(s) :
(Assigned by the system administrator)

Center of Excellence

Employee

Other Role(s) :
(Please check any additional roles that apply to you.)

Board Member

Committee Member

Hospital Based Physician

JIB Member

Medical Staff/Committee Member

Medical Staff/Faculty

Principal Investigator

Vendor

Vice President

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COI Management System: Features

- **Auto-Emails & Reminders**
 - Scheduled announcements
 - Automatic reminders of deadlines
 - Automated late notices
 - Ability to create e-mail templates for easy follow-up

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COI Management System: Features

- **Improved Completeness of Disclosures**
 - Respondents get only appropriate questions based on their role (or roles) within the organization
 - All questions must be answered in the affirmative or negative
 - Questionnaire can not be submitted if incomplete
 - Attestation form and electronic signature attest to completeness and accuracy of disclosures
 - Distributed reporting so departments can take responsibility for seeing that disclosures are completed

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Questions are grouped into categories. Color coding indicates status of each question until the questionnaire is completed and submitted.

Logged in user : baacka

My Questionnaire > My Questionnaire > Answer Questions

Home Help Logout

My Questionnaire

- My Profile
- Answer Questions
- Support/Help

Resources

Resource Links Document Library

- Trustee disclosure requirements
- FST disclosure requirements
- Physician disclosure requirements

★ Question list

Year	Status	Result	Actions
2006	InProgress (click here to edit)	-	[Refresh] [Print] [Close]
2007	Closed	COI-Managed	[Refresh] [Print] [Close]

★ Questions - 2006

FINANCIAL AND OTHER INTERESTS	Question ID	Date Submitted	Status	Action
1. Do you or does any family member hold any of the following financial...	COI-2006-01		Completed	Edit
2. Do you or does any family member hold any position or have any...	COI-2006-02		Completed	Edit
3. Did or do you or a family member have access to confidential...	COI-2006-03		Completed	Edit
4. Do you hold any of the following financial interests or relationships...	COI-2006-04		Completed with Disclosure	Edit
IRS REQUIRED QUESTIONS				
5. Have you or any family member received any of the following from a...	COI-2006-05		Completed	Edit
6. Do you use or propose to use University facilities or personnel, or...	COI-2006-06		Incomplete	Edit
7. Do you have a financial interest with any commercial organization that...	COI-2006-07		Incomplete	Edit
8. Do you spend significant effort, on external professional or commercial...	COI-2006-08		Completed	Edit
9. Do you own stock in one or more pharmaceutical companies or another entity that...	COI-2006-09		Completed	Edit
CMS QUESTIONS				
10. Have you been investigated for, or been alleged of, charged with, or convicted...	COI-2006-10		Unanswered	Edit
11. Do you own stock in one or more pharmaceutical...	COI-2006-11		Completed	Edit

COI Management System: Features

- Improved Tracking
 - Simple (one-click) reporting can tell:
 - How many questionnaires were distributed
 - How many returned
 - How many opened
 - How many resolved
 - How many resulted in management plans
 - Etc.

COI Management System: Features

- Ease of Use, Especially for Faculty & Physicians
 - Navigation is self explanatory
 - Help screens and FAQ's built in to each question
 - Color coding indicates question status
 - Respondent can leave and return to questionnaire
 - Multi-leveled questions based on responses
 - View prior year's disclosure (at the question level) and bring forward responses for easy editing

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Each question is presented on its own page. Data is collected in searchable databases.

The screenshot displays a web-based questionnaire interface. At the top, it shows the user is logged in as 'hccs' and provides navigation links for 'Home', 'Help', and 'Logout'. The main heading is 'Financial And Other Interests'. Below this, there is a progress indicator showing 'Questionnaire - 2008' and a series of numbered tabs from 1 to 23, with '1' being the active tab. The question text asks: 'To your knowledge, do you or does any family member hold any of the following financial interests in a business or other entity currently doing business with or seeking business from UCMC (including any sale, lease, grants, contract, research funding, or other deal):'. A list of interests is provided, including ownership interest, compensation, and other benefits. Below the list, there is a 'Disclosure Requirements' section with radio buttons for 'Yes' and 'No', and a link to 'View Previous Year's Disclosure'. The form includes input fields for 'Company or organization' and 'Value of the interest', with two example entries: 'Pfizer' (1000 shares of Pfizer common stock, valued at \$11,300) and 'Medtronic' (1000 shares of Medtronic Inc. stock, valued at \$10,000). A 'Disclosure Alert' is present at the bottom, and there are buttons for 'Save', 'Save & Continue', and 'Skip'.

COI Management System: Features

- Improved, Centralized Review Process
 - Reviewers are assigned based on department and roles
 - Different questions can be directed to different reviewers
 - Reviewers are presented with a queue of respondent questions to review and resolve
 - All review actions are automatically tracked in the “Review History”
 - Outgoing and incoming e-mail is captured and retained in the system automatically

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Questionnaires are assigned to Reviewers based on Roles and Departments. Reviewers log on and see a queue of questions requiring action.

The screenshot displays the COI Management System interface for a reviewer. The interface includes a navigation menu on the left, a main content area with a search bar, and several data tables.

Reviewer Profile:

- Account Admin
- Manual Entry
- My Questionnaires
- Reviewer
- In Review
- Email
- Support/Help
- Reports

User Details:

- Respondent: Ruth Fergall
- Help Year: 2008
- Job Title: Director
- Department: Administrative Services
- Phone: (910) 402-4124
- Email: rfergall@hccs.edu
- Emp. Status: Full-Time Employee

Resources:

- Resource Links
- Document Library
- Trustee disclosure requirements
- PTF disclosure requirements
- Physician disclosure requirements

My Reviewer Queue:

Year	First Name	Last Name	Department	Qst	Status	Action
2008	Ruth	Fergall	Administrative Services	2	In Review	[Icons]
2008	Jack	Emerson	Pharmacology	2	COI	[Icons]
2008	Clare	Rutherford	School of Medicine	1	In Review	[Icons]
2008	Wita	Edison	School of Nursing	1	COI - Manager	[Icons]
2008	Austin	Edwards	Pathology	3	In Review	[Icons]
2008	Hai	Naranda	Osteopathy	1	Resolved	[Icons]
2008	Roy	Indrook	Human Resources	2	COI	[Icons]

Review Actions:

Review Action Date	Review Action Type	Reviewer	Question	Comment	Qst	Stop	Action
08/22/08 11:12 am	Sent to Research	Bill Summers	COI-2008	Additional review into the issues pertaining to ...	2	[X]	[X]
09/18/08 09:13 am	Escalate to Mgt	July Ling	COI-2008-08	Additional review at the management level is needed ...	2	[X]	[X]
09/09/08 02:37 am	Escalate policy doc	Mark Hinkle	COI-2008-07	After further review, it is clear that the current ...	1	[X]	[X]

History:

Year	Qst	Completed	Result
2007	0	04/10/2007	COI - Manager
2008	2	08/21/2008	Resolved
2008	1	Yes	Do you own stock in one or more pharmaceutical companies or any other manufacturer of ...
2008	1	Yes	Do you or do you or a family member have access to confidential ...
2008	1	Yes	Do you own stock in one or more pharmaceutical companies or any other manufacturer of ...
2008	1	Not Submitted	-

COI Management System: Features

- Improved Follow-up and Management of Personal and Institutional Conflicts
 - Customized list of “Review Actions”
 - Each review action assigned a “Step” number so progress can be tracked in the aggregate
 - Management plans approved, stored and tracked in the system

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Reviewers document all review actions. Outgoing and incoming correspondence is tracked automatically in the system.

The screenshot shows a web browser window displaying the 'Add Review Action' form in the COI Management System. The interface includes a navigation menu on the left with options like 'Account Admin', 'Manual Entry', 'My Questionnaire', 'Reviewer', 'In Review', 'Email', 'Support/Help', and 'Reports'. Below the menu is a 'User Details' section for the respondent Jack Erickson, listing his filing year (2008), job title (Pharmacist), department (Pharmacology), phone, email, and employment status. The main form area is titled '★ Add Review Action' and contains the following fields: Respondent Name (Jack Erickson), Filing Year (2008), Question # (COI2008-12), Review Action Date (07/03/2008 07:32am), Review Action Type (Escalate), and a Comments field with the text 'Review actions are documented by the reviewer'. Below the comments field, there are options for 'Current Review Level' (Escalate), 'Send Notification to Escalated Reviewers' (checkbox), 'Next Action Date' (calendar icon), and 'Send Email' (checkbox). At the bottom of the form are 'Save', 'Cancel', and 'Reset' buttons. The browser's address bar shows the user is logged in as 'jawaika'.

COI Management System: Features

- Improved Documentation at all Stages
 - “Permitted Value” lists correct spelling errors, helping to standardize responses
 - Comprehensive database design allows for data mining to track individual and institutional conflicts

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COI Management System: Features

- System had to be flexible and adaptable to other uses
 - Accommodates annual disclosure questionnaire and transactional disclosures
 - Useful for other survey functions
 - Provider exclusion from Medicare or Medicaid
 - Faculty surveys

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COI Management System: Features

- System Administration had to be user friendly (minimal IT involvement)
 - User friendly administrative interface to create:
 - Questionnaires
 - Email templates
 - Review actions
 - Easy assignment of reviewers by department and role
 - Security Profiles to determine system access

COI Management System: Features

- Reporting System had to be robust
 - A series of “one click” reports available
 - Custom reports can be created “on the fly”
 - Database can be exported for manipulation in Excel, Access

COI Management System: Lessons Learned

- If you plan to do this yourself...
 - It's going to take a lot longer than you think
 - It is going to take more resources than you think
 - It is going to be more expensive than you think
- The key to a successful management system is not in asking the questions, it is in managing the responses and the conflicts uncovered by those responses

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COI Management System: Conclusion

- Assess and document your current process
- Figure out what it is really costing you
 - Direct labor managing the disclosure process
 - Inefficiency – back and forth – how much time does it take you to bring ONE conflict to resolution?
 - Risk from lack of disclosure or inability to conduct useful analysis
- Evaluate alternatives for initial automation or enhancing current automation
- Take action

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Questions?
Clarifications?
Reactions?