Conflicts of Interest Disclosures: A University of Chicago Medical Center (UCMC)* Case Study

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* (1) University of Chicago Medical Center (UCMC) is a separate legal entity from the University of Chicago
(2) These materials and presentation are only about UCMC's conflict of interest policies and procedures and are not representative of the University of Chicago's conflict of interest policies and procedures

Conflicts of Interest
Regulations

- **Federal Regulations related to COI In Healthcare and Clinical Research**
  - Public Health Service (PHS)- PHS regulations address reporting requirements applicable to individual investigators and also provide general guidelines on institutional obligations to manage conflicts-of-interest. Defines Significant Financial Interest
  - Food and Drug Administration (FDA)- FDA regulations discuss minimizing bias in design, conduct, reporting, and analysis of clinical studies or its resulting data.
  - Office of Human Research Protections (OHRP)- OHRP regulations relate only to conflict of interest in IRB review of research.

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Conflicts of Interest
Regulations

- **Failure to Comply Carries Penalties**
  - PHS and FDA regulations cite to other federal regulations regarding failure to comply with federal policy. Penalties range from debarment to fines and prison time.
- **None address institutional conflicts of interest**
  - As stated earlier, conflicts of interest can be individual and/or institutional. However, federal regulations do not cover institutional conflicts of interest.

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Conflicts of Interest
PHS

- **45 CFR 50, Subpart F- Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought**
  - This federal regulation affects PHS governed agencies (e.g., the NIH) and applies specifically to grants and cooperative agreements (42 CFR 94- Contracts).
  - Any institution that applies for PHS grants or cooperative agreements and any investigator that participates in PHS funded research (except SBIR Program Phase I) is subject to this regulation.
  - Institutions must ensure that there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting interest.

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Conflicts of Interest
PHS

- **45 CFR 50, Subpart F- Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought**
  - Institutions must:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this subpart (investigators and sub-award recipients must be informed and comply),

(b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research,

(c) Require that investigators submit a listing of all known significant financial interest (of spouse and dependent children also) as part of the application to PHS,

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Conflicts of Interest
PHS

- **45 CFR 50, Subpart F- For Institutions and Investigators (42 CFR 94- Contracts) cont.**

(d) Provide guidelines for the designated official(s) on how to identify, manage, reduce, or eliminate the conflicting interest,

(e) Maintain records on all disclosures and actions taken on each conflict for three years (from date of final expenditure submission),

(f) Establish mechanism to enforce sanctions where appropriate,

(g) Certify that there is a written and enforced COI policy and report existing conflicts of interest before PHS funds are expended.

Conflicts of Interest
PHS

- **PHS Regulations Provides Sample Approaches for Management of Conflicts of Interest**
  - These regulations state that the designated official must review and determine whether the financial disclosures represent a significant financial Interest that could directly and significantly affect the design, conduct and reporting of PHS funded research.
  - If a significant financial interest exists, the designated official must impose the following to ensure that conflicts are managed, reduced, or eliminated :

(a) Require public disclosure of significant financial interests

(b) Require monitoring of research by independent reviewer

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Conflicts of Interest
PHS

- **PHS Regulations Provide Sample Approaches for Management of Conflicts of Interest (cont.)**
  - If a significant financial interest exists, the designated official may impose the following to ensure that conflicts are managed, reduced, or eliminated:

(a) Require public disclosure of significant financial interests,

(b) Require monitoring of research by independent reviewer,

(c) Require modification of the research plan,

(d) Require monitoring of research by independent reviewer

(e) Disqualification from participation in all or a portion of the research funded by the PHS;

(f) Require divestiture of significant financial interests;

(g) Require severance of relationships that create actual or potential conflicts.

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Conflicts of Interest
PHS

- **Remedies**
  - The regulation states that institutions must report noncompliance and any corrective actions taken or to be taken:

    "*If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken*."

Conflicts of Interest
PHS

- **Remedies (cont.)**
  - The regulations list when PHS and HHS get involved:

    "HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS- funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with this subpart"
  - The regulation states that PHS may suspend funding if it determines a conflict of interest will bias objectivity of PHS funded research;
  - If HHS determines that there was a conflict of interest that was not managed reduced or eliminated, the institution must require that the investigator disclose the conflicting interest in each public presentation of the results.

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Conflicts of Interest
FDA

- **42 CFR 54, Financial Disclosure by Clinical Investigators**
  - This federal regulation affects clinical investigators linked to clinical data submitted in marketing applications for drugs, biological products, and devices.
  - Applicants must disclose or certify information concerning the financial interests of a of all clinical investigators who conducted covered clinical studies:

(a) Attestation to the absence of financial interest and arrangements (completed FDA Form 3454)

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Conflicts of Interest
FDA

- **42 CFR 54, Financial Disclosure by Clinical Investigators cont.**

(b) Disclosure (FDA Form 3455) of:

- financial arrangements between sponsor and investigator,
- significant payments from sponsor to investigator
- proprietary interest (patent, trademark) in the test product held by investigator
- significant equity interest held by investigator

Significant payments are more than $25,000. Significant equity interest is any ownership interest, stock options, or other financial interest in a public corporation that exceeds $50,000. These thresholds are applicable during the time project and for 1 year after completion of the study.

Conflicts of Interest
FDA

- **42 CFR 54, Financial Disclosure by Clinical Investigators (cont.)**

  Applicants must ensure that appropriate steps have been taken in the design, conduct, reporting, and analysis of the studies to minimize bias.

  (c) Clinical investigators must provide the sponsor with accurate financial information for its certification or disclosure statements.

  (d) FDA may refuse to file a marketing application if there was no certification or disclosure of financial information.

Conflicts of Interest
FDA

- **The FDA Evaluates the Disclosures**
  - There is an evaluation of the submitted information to determine the impact of financial interest on the study.
  - The FDA may consider both the size and nature of a disclosed financial interest
  - The FDA will take into account the study purpose and design
  - The FDA may take the following actions if to ensure the reliability of the data:

(a) Audit the data derived from the investigator in question

(b) Request additional analyses to evaluate the impact of the investigators data on the entire study

(c) Request independent studies to confirm results in question

(d) Refuse to use the data as the basis for any agency action

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Conflicts of Interest
FDA

- **The FDA Requires Recordkeeping**
  - Applicants must keep complete records showing:
  (a) any financial interest or arrangement
  (b) Any significant payments to investigators by sponsors
  (c) Any financial interests held by investigators
  - Records must be retained for two (2) years after FDA approval

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Conflicts of Interest
OHRP

- **45 CFR 46.107(e), IRB Membership**
  - This regulation (and 21 CFR 56.107(e)) pertains to the IRB review of HHS supported research.
  - The rule is not specific to investigators or sponsors, only IRB members:

    "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB."
  - The common understanding of the regulation is that IRB members with a conflicting interest should recuse him/herself from the review of research.

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Conflicts of Interest
OHRP

- **HHS Guidance: Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection**
  - In May 2004 HHS published guidance recommending that IRBs, investigators and institutions consider whether financial relationships/interests adversely affect human subjects
  - The guidance document provides specific points of consideration for Institutions, IRBs and Investigators:

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HHS Guidance

Financial Interests and the Safety/Welfare of Human Subjects Points of Consideration		
Institutions	**IRBs**	**Investigators**
Establish a Conflicts of Interest Committee and Policies/Procedures on its Operation and Communication with the IRB	Determine If Methods to Manage Conflicts Adequately Protects Human Subjects or Whether Additional Actions are Necessary	Modify the informed consent process when a potential or actual financial conflict exists, by either • Having a another individual involved in the consent process or, • Using independent monitoring of the research.
Determine What Constitutes an Institutional Conflict of Interest	Determine the kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.	
Develop Policies/Procedures on the Financial Relationships that may/may not be held by those involved in research		

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Conflicts of Interest
Proposed PHS Legislation

- **Item:**
  - On May 8, 2009, The National Institutes of Health (NIH) issued an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register.
  - The purpose was to gain public input on whether modifications are needed to the PHS regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94).
- **Background:**
  - In 1995, the Public Health Service (PHS) and the Office of the Secretary of Health and Human Services (HHS) published the regulations at 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94:

(a) Provisions devised to promote objectivity in PHS-funded research.

(b) Establish standards to ensure that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements, or contracts was unbiased by any conflicting financial interest of an Investigator.

Conflicts of Interest

Proposed PHS Legislation

- **Since the promulgation of these regulations, rapid advancement in biomedical research and in bench to bedside research has led NIH to consider whether revision of policies would be advisable.**

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Conflicts of Interest
Proposed PHS Legislation

- **The NIH is specifically interested in comments regarding the:**
  - Expansion of the scope of the regulation and disclosure of interests;
  - Definition of “significant financial interest”;
  - Identification and management of conflicts by institutions;
  - Assurance of institutional compliance;
  - Provision of additional information to federal officials by research institutions; and
  - Broadening of the regulations to address institutional conflicts of interest.

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Conflicts of Interest

Proposed Legislation- Physician's Sunshine Act

- In January 2009, U.S. Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI) introduced The Physician's Sunshine Act which requires the reporting of payments made to physicians and physician-owned entities by group purchasing organizations and manufacturers.
- Originally introduced in 2007, but not taken up by Congress, this version still incorporates the bulk of the recommendations made by the Medicare Payment Advisory Commission (MedPAC).

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Conflicts of Interest

Proposed Legislation- Physician's Sunshine Act

- **The Bill's Provision (if passed in 2010) will require:**
  - Annual reporting of all physician payments with a cumulative value in excess of $100.00 on the following deadlines: March 31, 2011, to be made publicly available September 30, 2011.
- **The scope of the bill now includes many additional physician relationships, including health related business interests.**
- **Since "direct payment" systems are referenced, most company grants provided to education providers appear to be excluded.**

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Conflicts of Interest

Proposed Legislation- Physician's Sunshine Act

Items Required to be Reported	
Consulting Fees	Compensation for Services other than Consulting
Honoraria	Gifts
Entertainment	Food
Travel	Education
Research	Charitable Contributions
Royalties or Licenses	Current Prospective Ownership Contributions
Compensations for serving as faculty or speaker at continuing medical education program	Grant
Any other nature of payment or other transfer of value as defined by the secretary.*	
*If related to marketing, education, or research concerns, a specific covered drug device, biological or medical supply, companies will be obligated to report and include link to drug – also on whatever deemed appropriate by the Secretary of HHS.	

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Conflicts of Interest

Proposed Legislation- Physician's Sunshine Act

- **Some Reporting of Research Payments may be delayed by whichever date is earlier:**
  - Two (2) years after date or transfer of value occurred.
  - After the date of FDA approval.
- **Also Required: Reporting of Physician Ownership Interests in Private Companies:**
  - Dollar Amount Invested
  - Current Value
  - Any payment or transfer of value to the owner, including dividends or other payments.

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Conflicts of Interest

Proposed Legislation- Physician's Sunshine Act

Excluded from the Reporting Requirement	
Payments of less than $100 in aggregate	Product Samples
Patient education materials	Items for use as a patient
The loan of a device for fewer than 90 days	Warranty replacements
Discounts and rebates	In-kind items used in charity care
Dividends or distributions from a publicly traded company	

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Conflicts of Interest

Proposed Legislation- Physician's Sunshine Act

- **Penalties:**
  - Unintentional failure to report: $1,000 to $10,000 per offense with a cap of $150,000 per year.
  - Intentional failure to report: $10,000 to $100,000 per offense with a cap of $1 million per year.

- **Summary:**
  - The short implementation timeframe (bill affords Secretary of HHS until November 2009) to establish procedures and incomplete preemption of state reporting requirements make the future of this bill and its enactment somewhat unpredictable.
  - However, legislated transparency as to physician's financial relationships that may impact the delivery of patient care appear to be a trend receiving increasing traction.

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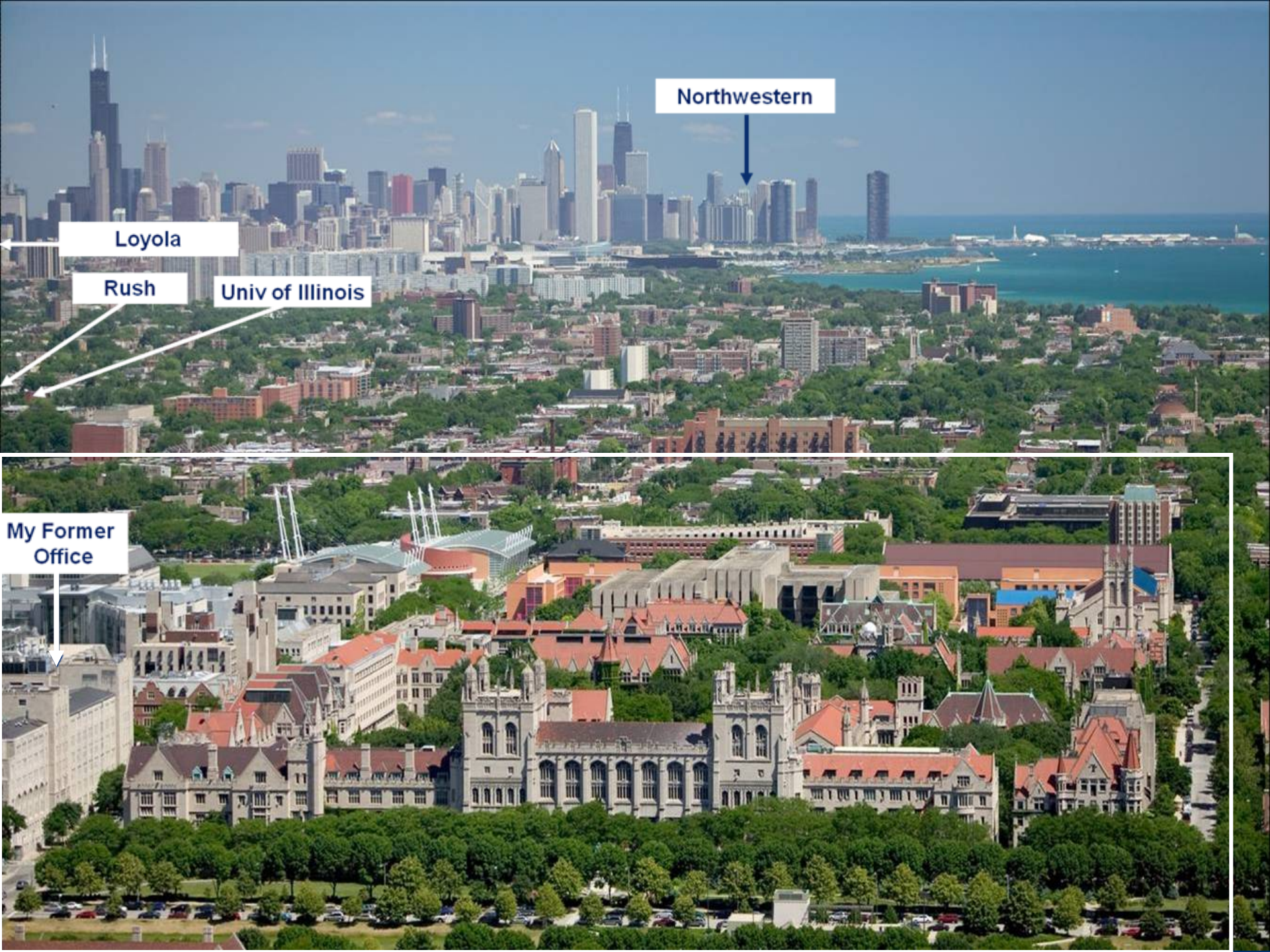
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Case Study: The University of Chicago Medical Center (UCMC)

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- (These materials and presentation are only about UCMC's conflict of interest policies and procedures and are not representative of the University of Chicago's conflict of interest policies and procedures)
- This project was undertaken by the UCMC on behalf of the Medical Center and Physicians' Practice Plan

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Case Study: The University of Chicago Medical Center (UCMC)

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

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Case Study: UCMC

- 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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UCMC Design Objectives

1. Improved, Centralized Collection of Disclosures
2. Auto-Emails & Reminders
3. Improved Completeness of Disclosures
4. Improved Tracking
5. Ease of Use, Especially for Faculty & Physicians
6. Improved, Centralized Review Process
7. Improved Follow-up and Management of Personal and Institutional Conflicts
8. Improved Documentation at all Stages

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UCMC Design Objectives (con't)

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

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COI Disclosure Options Considered

- Building our own disclosure management system
  - Time consuming, would require significant IT resources for development and on an ongoing basis

OR

- Buying and installing a disclosure management system
  - Nothing on the market met our perceived needs
  - Customization and maintenance would require significant IT resources on an ongoing basis

OR

- Partnering to design and develop a system that would then operate in an ASP mode

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COI Disclosure Options: The Solution

- Automated MYSQL database tool developed in partnership with an 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
- 8 months to program and test

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UCMC Management System

Improved, Centralized Collection of Disclosures

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

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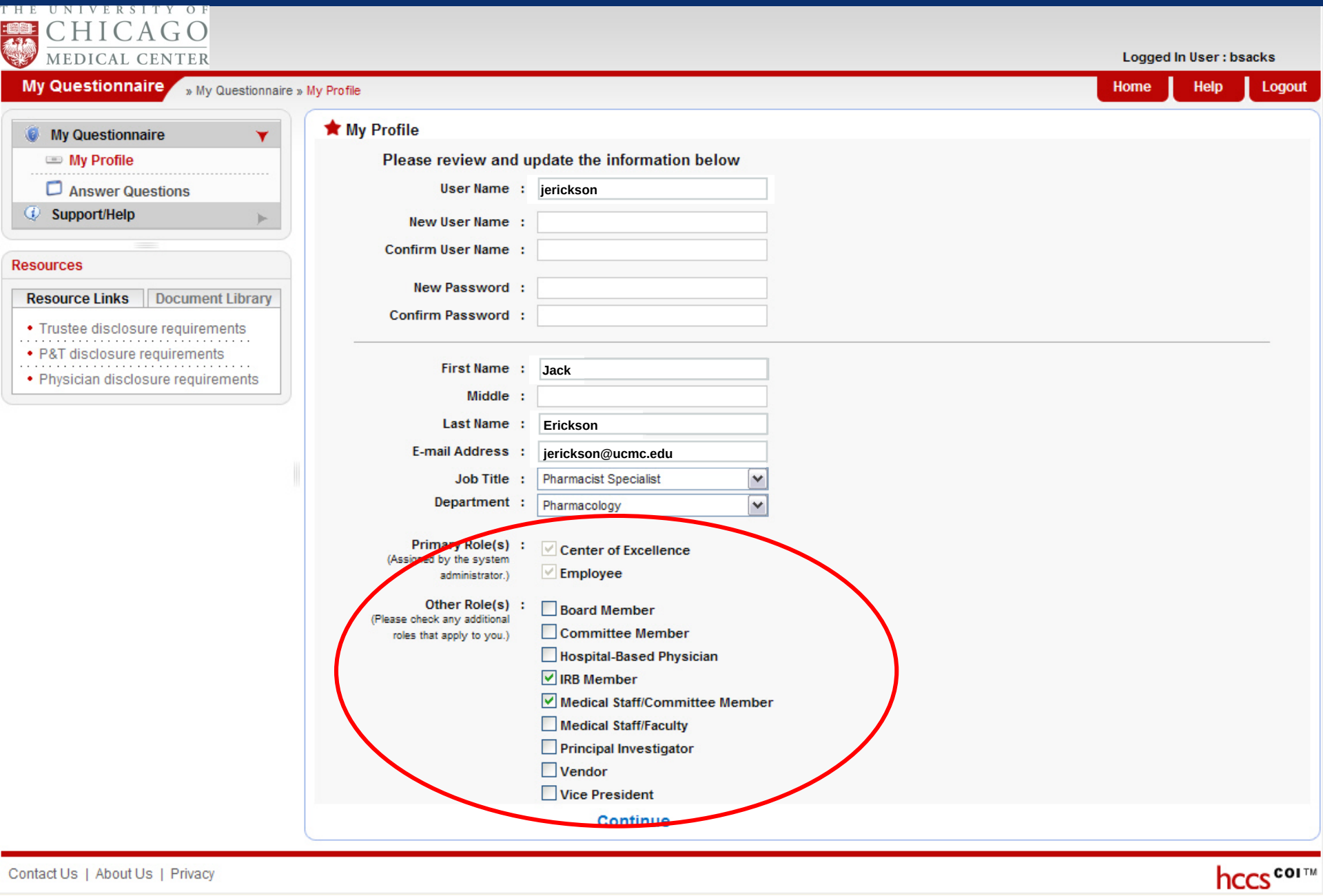
“My Profile” allows the respondent to confirm or add roles held within the organization. Roles determine the questions that appear on the questionnaire.



UCMC Management System

Auto-Emails & Reminders

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

UCMC Management System

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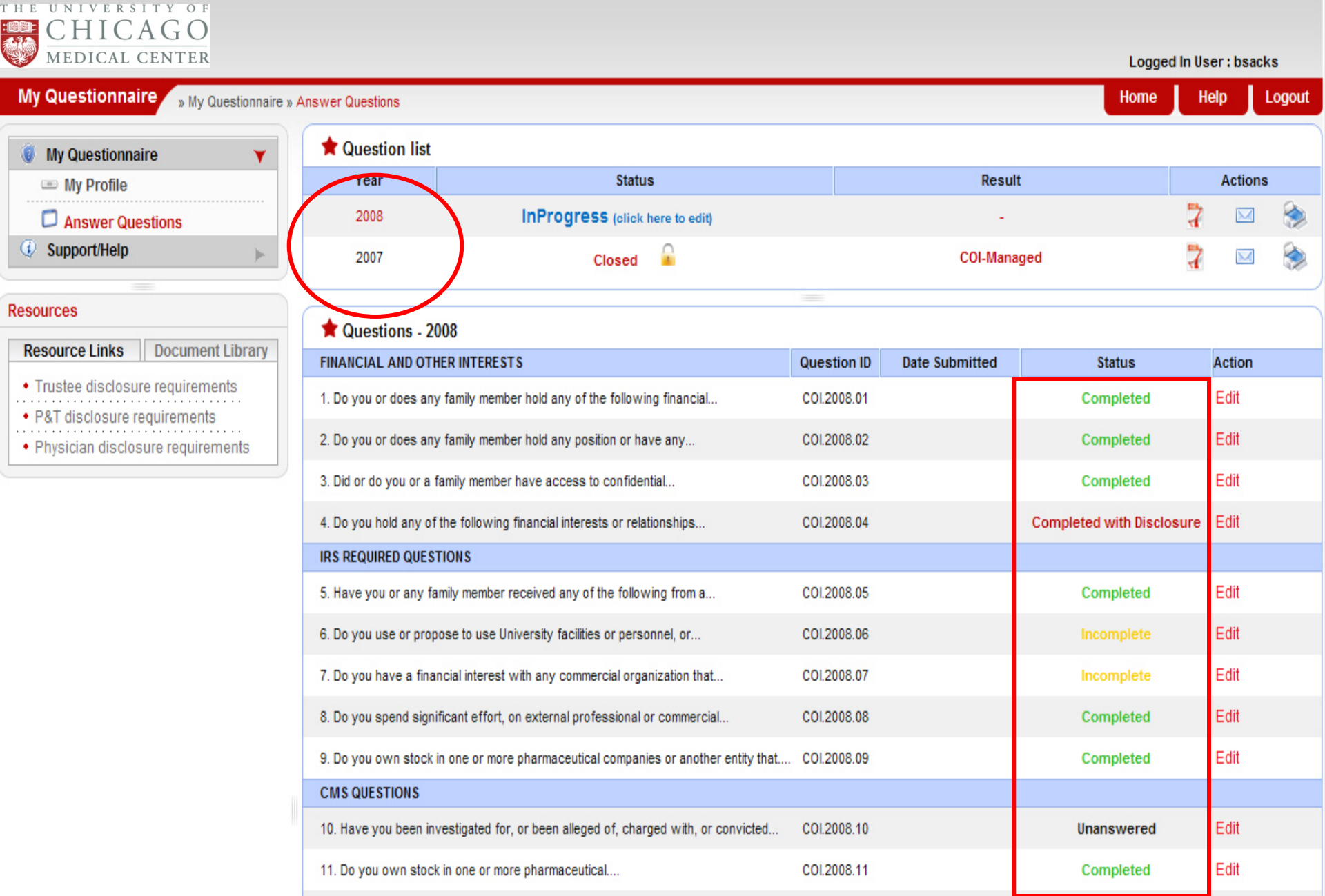
Questions are grouped into categories. Color coding indicates status of each question until the questionnaire is completed and submitted.



UCMC Management System

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.

UCMC Management System

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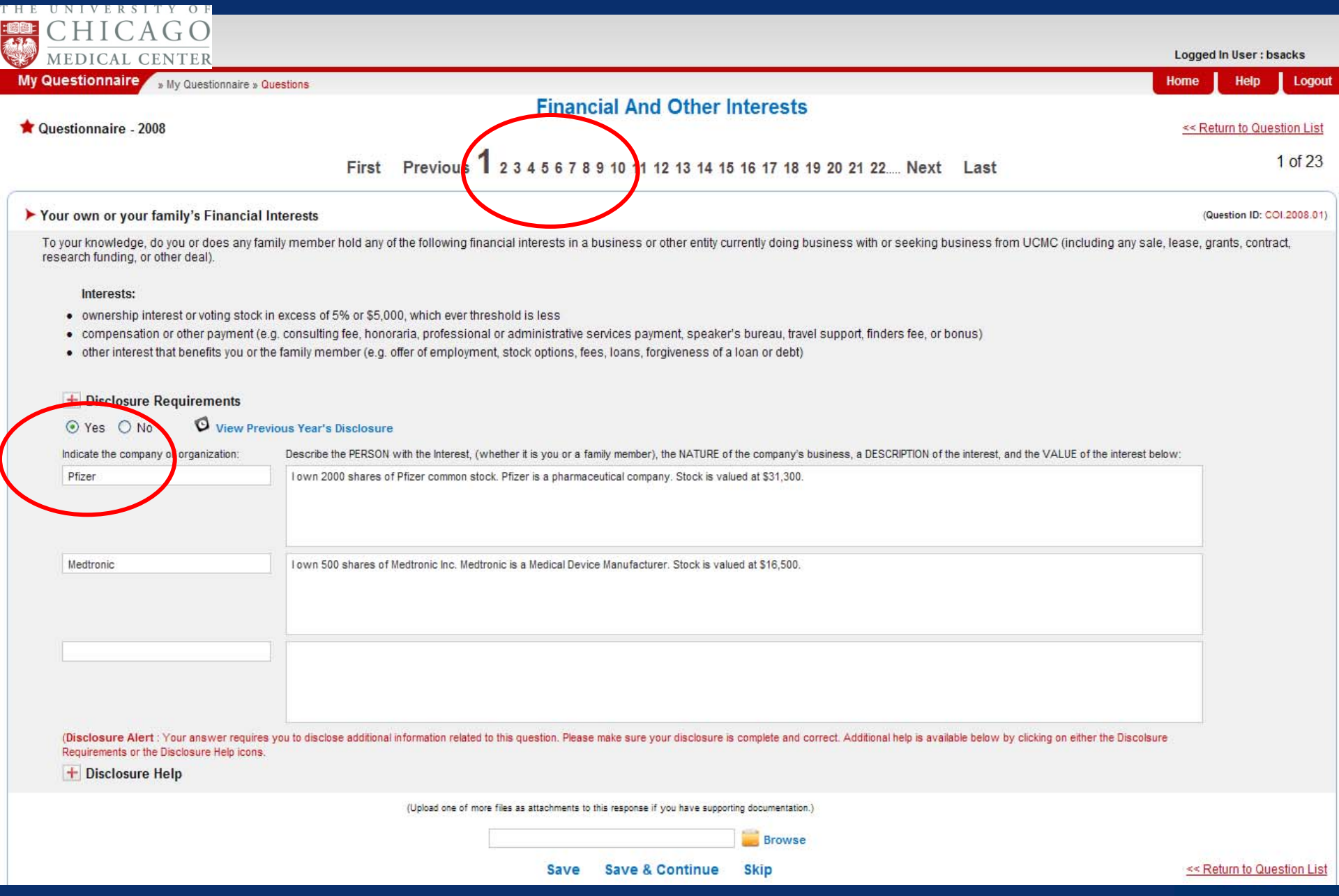
Each question is presented on its own page. Data is collected in searchable databases.



UCMC Management System

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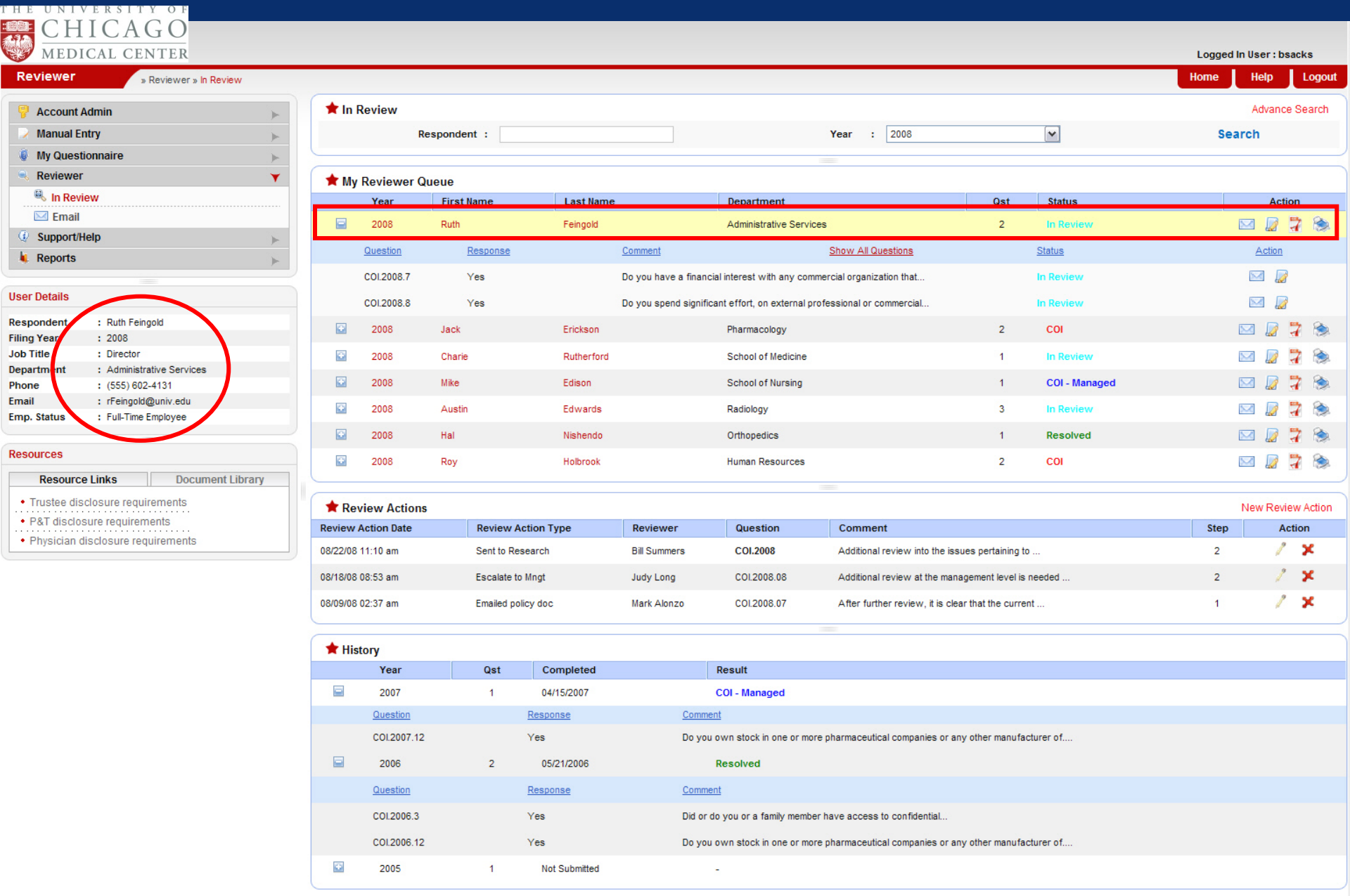
Questionnaires are assigned to Reviewers based on Roles and Departments. Reviewers log on and see a queue of questions requiring action.



UCMC Management System

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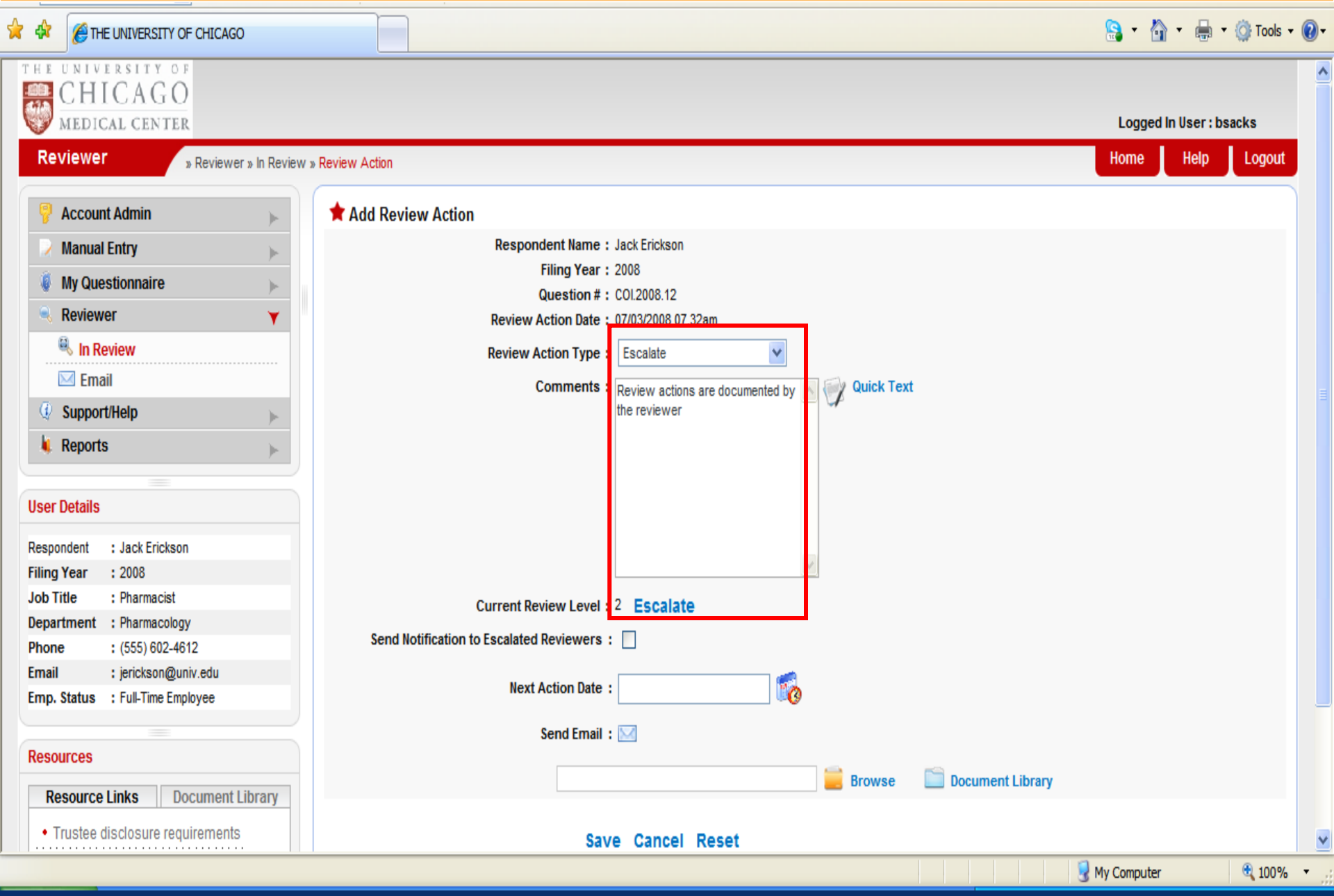
Reviewers document all review actions. Outgoing and incoming correspondence is tracked automatically in the system.



UCMC Management System

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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UCMC Management System

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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UCMC Management System

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

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UCMC Management System

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

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Questions? Clarifications? Reactions?

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Tomorrow's Doctors, Tomorrow's Cures

Learn

Serve

Lead

Sonnenschein

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