

USC Conflict of Interest Disclosure System (COIDS) System Requirements – V1.0 (Draft)

September 18, 2011

1. Purpose and Scope

This document provides the requirements for a Conflict of Interest Disclosure System (COIDS) to support the administration and management of disclosures that fall under the University of Southern California's policies for:

- Conflict of Interest in Research (Individual)
- Conflict of Interest and Ethics
- Institutional Conflict of Interest in Research
- Relationships with Industry

This system aims to provide an environment in which: (1) university employees disclose financial interests that may present conflicts; (2) conflicts are reviewed by university employees who have responsibility for administering conflict policies; (3) conflicts are reviewed by conflict of interest committee members; (4) decisions and management plans are recorded and communicated to affected individuals and units of the university on a need-to-know basis; and (5) status updates and reminders are provided to assist in the management of disclosed conflicts.

The COIDS is a component of the USC Research Administration System (RAS). It must interface with other RAS modules to assure that research does not commence prior to completion of necessary conflict of interest reviews. This may be accomplished by withholding account establishment, Institutional Review Board approval or Institutional Animal Care and Use Committee approval until the conflict of interest review is finished.

The system shall simplify administration of COI disclosures by:

- Creating a unified "one stop" interface for disclosing conflicts that fall under any of the university's policies;
- Minimizing data entry and reducing manual effort;
- Expediting exchange of information and data, and expediting disclosure;
- Automating submission of documents required for reviews;
- Unifying the system interface with a common "look and feel";
- Improving visibility of status for disclosures, automating reminders and simplifying report generation; and
- Reducing the time necessary to reach a decision.

The system shall also support web-based remote access, coupled with an authentication system that protects private information and manages user-specific privileges for information access and editing. The system shall also provide back-up and recovery capabilities to survive potential failures and disasters, and be sufficiently robust to accommodate significant variations in usage associated with proposal and reporting deadlines.

2. Background

USC receives approximately \$550 million per year in funding to support sponsored activities in the form of grants, cooperative agreements, subcontracts and contracts. The majority of this

funding comes from federal agencies, but USC also receives funding from foundations, corporations, state and local government and other entities. In addition, USC receives funding in the form of unrestricted gifts. While the financial management for gifts differs from grants and contracts, gifts are subject to many of the same regulatory requirements.

University employees are required to disclose potential conflicts of interest that fall under four separate policies -- individual conflicts of interest related to research; institutional conflicts of interest (e.g., a university investment in a research sponsor) related to research; individual relationships between health care providers and pharmaceutical/biotechnology companies and device and medical equipment manufacturers; and financial or other personal considerations that may pose a conflict of interest or commitment related to their responsibilities to the university. Each type of disclosure must be reviewed, and a decision rendered, as indicated below:

<u>Policy</u>	<u>Reviewers</u>
Conflicts of Interest in Research (Individual)	Office of Compliance COI in Research Committee Vice President of Research
Conflicts of Interest and Ethics	Deans
Institution Conflicts of Interest in Research	Office of Compliance COI in Research Committee Independent Outside Reviewers Vice President of Research
Relationships with Industry	Department Chairs

The policy and process on conflicts of interest in research are subject to federal regulation. Effective August 24, 2012, investigators who receive funding from the Public Health Service (including the National Institutes of Health) are required to disclose financial interests related to their institutional responsibilities at USC on an annual basis.

2.1 Users

The COIDS will be used by the following categories of employees, residing in the specified business units:

Disclosers: faculty and/or staff who are responsible for disclosing their outside financial interests under any of USC's COI policies.

School Administrators: staff employed by schools (or departments, centers, or institutes) with responsibility for assisting department chairs in the review or management of disclosed conflicts.

School Leadership: faculty appointed as department chairs, deans, associate or vice deans, or those who are responsible for implementing a COI management plan.

Research Compliance Administrators: staff responsible for ensuring that research is conducted in compliance with regulations and university rules.

University Research Leadership: staff and faculty in the Office of Research, who are responsible for oversight of the processes for COI in research.

Conflict of Interest in Research Committee (CIRC): staff and faculty responsible for reviewing COI in research disclosures and recommending actions to the VP or Research.

System Administrators: staff responsible for system maintenance and allocation of system permissions.

2.2 Processes Supported

The COIDS will support the “cradle-to-grave” lifecycle of disclosures related to conflicts of interest within the university, including these processes:

1. Verification of training and authentication of user
2. Annual and updated disclosures of financial interests
3. Transactional disclosures of potential conflicts of interest
4. Review of disclosures and financial interests
5. Management of disclosed conflicts of interest
6. Business intelligence on disclosure processing

2.3 External Systems Requiring Interfaces

The COIDS will be interfaced with the following modules of the RAS

Routing and Proposal Data Management: The COIDS will be notified whenever a proposal is submitted to designated sponsors that require annual disclosures. The COIDS will be notified whenever a proposal indicates a potential conflict of interest.

Online Training System: The university will create a system to train employees in conflict of interest processes and policies. This system will retain a list of employees that have completed required training. This list must be provided to the COIDS to determine employee qualifications for use of the system.

Account Establishment: The account establishment module will be notified when an identified conflict of interest associated with a sponsored project has been approved by the Vice President of Research. The account establishment module will be notified when it is determined that an investigator must disclose a potential conflict of interest but has not done so already and did not designate the COI at time of proposal submission. The approval letter and the required management plan will be provided to the Department of Contracts and Grants via the account establishment module. Account establishment will also be notified when an investigator has not complied with disclosure requirements or not complied with a designated management plan. Account establishment will periodically (weekly or monthly) provide a list of all actively funded research projects.

Protocol Submission and Review (iStar for IRB and IACUC): The COIDS will be notified whenever a protocol is submitted that designates a potential conflict of interest. The COIDS will notify the protocol submission and review modules when a decision is rendered related to an identified potential conflict of interest. The approval letter and the required management plan will be provided to the IRB and the IACUC via iStar.

Health Research Association (HRA): HRA will periodically (weekly or monthly) provide a list of all actively funded projects. The COIDS will notify HRA when a decision is rendered related to an identified potential conflict of interest affecting an HRA project. The approval letter and the required management plan will be provided to HRA.

2.4 System Environment.

The system environment is the same as specified in the RAS System Requirements document.

3. Requirements

The COIDS shall satisfy all general requirements for the RAS. In addition, the following unique requirements must be satisfied.

1. Verification of training and authentication of user

- 1.1 Compare identifier for user against database of individuals who have completed COI training.
- 1.2 Authenticate identity of user to manage access to records based on assigned privileges. Privileges will include these categories of access to records: **All** (e.g., Office of Compliance, VP Research); **School** (e.g., dean of school or designee) ; **Department, Center or Institute** (e.g., chair or director). The system must allow for the potential addition of user roles and associated access privileges as needed.
- 1.3 Enable system administrator to assign access privileges to users.
- 1.4 Record history of which individuals have accessed which records and any modifications that they have made.

Primary Users: Office of Compliance, Disclosers

2. Annual and updated disclosures of financial interests

- 2.1 Personal payments for consulting, speaking or other individual services, and description of work to be performed.
- 2.2 If required based on status of discloser, or if requested: compensation computed hourly, terms of consulting. Upload PDF of consulting agreement.
- 2.3 Reimbursed travel expenses
- 2.4 Managerial roles in outside entities
- 2.5 Equity/ownership interests in outside entity, including valuation
- 2.6 Use of students
- 2.7 Create reminders to investigators who are obligated to submit annual disclosure.

2.8 Notify Office of Compliance, VP of Research and DCG when an individual has not complied with disclosure requirements.

Primary Users: Disclosers

3. Transactional disclosures

3A. Transactional disclosures of potential research conflicts

- 3A.1 Description of research activity within the university
- 3A.2 Description of outside activity
- 3A.3 Compelling circumstance(s) justifying relationship (if applicable)
- 3A.4 Generate proposed management plan from template
- 3A.5 Modify or enter proposed management plan
- 3A.6 Load and store consulting agreements or other personal contracts when needed for assessing potential conflicts of interest.

Primary Users: Disclosers

3B. Transactional disclosure of personal or financial relationships covered by COI and Ethics policy

- 3B.1 Description of activity
- 3B.2 Description of current or prospective employee relationship with outside entity
- 3B.3 Amount of compensation received
- 3B.4 Time commitment associated with activity
- 3B.5 Generate proposed management plan
- 3B.6 Modify or enter proposed management plan
- 3B.7 Load and store relevant agreements when needed for assessing potential conflicts.

Primary Users: Disclosers

4. Review of disclosures and financial interests

- 4.1 Screen financial disclosures to identify those that may present a conflict of interest, and identify the relevant policies. Screening shall include association with funded research projects.
- 4.2 Screen disclosures of healthcare provider relationships with industry
- 4.3 Screen disclosures of personal or financial relationships that may create a conflict of interest and/or commitment under COI and Ethics policy.
- 4.4 Alert designated reviewer in Office of Compliance to act on potential conflicts of interest
- 4.5 Automatically route disclosures to person responsible for reviewing or acting on a potential conflict of interest or covered industry relationship; permit Office of Compliance to manually route disclosures to designated individuals as needed for further review.
- 4.6 Route disclosures to members of Conflict of Interest Review Committee when their review is needed.
- 4.7 Route RWI disclosures to Department Chairs for assessment and approval.

- 4.8 Route COI and Ethics disclosures to supervisor or Business Conflict Review Committee, as appropriate.
- 4.5 Record committee minutes for Conflict of Interest in Research disclosures, restricting access to only those given access to "All" records.
- 4.6 Record communication to discloser once decision is made, and automatically copy communication to affected units, including DCG, IRB, IACUC, HRA, department chair and dean.

Primary Users: Office of Compliance, Deans (or designees), VP Research, CIRC, BCRC

5. Management of disclosed conflicts of interest

- 5.1 Enter decision on whether conflict of interest is permissible.
- 5.2 Enter stipulations, to include: (a) required disclosure in publications, presentations and proposals; (b) required disclosure in informed consents; (c) whether students may participate in project and, if so, who is responsible for monitoring their academic progress; (d) required times for update; (e) stipulation on intellectual property negotiations;
- 5.3 Create reminders to act on management plan, to discloser, Office of Compliance, Dean, VP or Research, or anyone designated to oversee management plan.
- 5.4 Record any instances of non-compliance and actions taken as a result of non-compliance.
- 5.5 Store and record documents that demonstrate compliance with disclosure requirements.

Primary Users: Office of Compliance, Deans, VP Research

5. Management of disclosed relationships with industry

- 5.1 Enter decision on whether relationship is permissible.
- 5.2 Enter stipulations, to include: (a) limitations on scope of activity; (b) limitations on compensation associated with activity; (c) disclosures to students, residents, and fellows of activity.
- 5.3 Create reminders to update disclosures at specified interval.
- 5.4 Record any instances of non-compliance and actions taken as a result of non-compliance.
- 5.5 Store and record documents that demonstrate compliance with disclosure requirements.

Primary Users: Clinical Department Chairs and Designees, Office of Compliance,

5. Management of disclosed conflicts covered by COI and Ethics policy

- 5.1 Enter decision on whether relationship is permissible.
- 5.2 Enter stipulations, to include: (a) disclosure of conflict to parties involved in a business transaction; (b) recusal from participating in certain negotiations, decisions, or transactions; (c) recusal from managing or supervising particular faculty members, staff or student employees, consultants, temporary agency employees, volunteers, or others engaged by the university; (d) recusal from managing or overseeing certain business transactions; (e) severance of outside relationships posing conflicts; (f) appropriate monitoring and oversight; and (f) obtaining approval required by the Faculty Handbook, staff employment policies, or other relevant university policies.
- 5.3 Create reminders to update disclosures at specified interval.

- 5.4 Record any instances of non-compliance and actions taken as a result of non-compliance.
 5.5 Store and record documents that demonstrate compliance with disclosure requirements.

Primary Users: Deans or their Designees, Business Conflict of Interest Committee, Office of Compliance

6. Business intelligence on disclosure processing

- 6.1 Automatically generate performance statistics on a monthly basis providing number of disclosures made by type, time to reach decision, number of current disclosures being managed, status of managed disclosures.
 6.2 Enable queries to extract disclosures of specified types or for specified individuals.

Primary Users: VP Research, Office of Compliance, Deans

3.1 Interface Requirements Between Modules

Table 1 lists key interfaces between system modules.

Table 1. Key Interfaces

Interface Requirement	Source Module	Recipient Module
Notify when proposal is submitted to designated sponsors requiring annual disclosure	Routing and proposal data management	COIDS
Notify when proposal indicates potential COI	Routing and proposal data management	COIDS
Completion of training requirement	Online training system	COIDS
Failure to comply with disclosure requirements or management plan	COIDS	Account Establishment
Failure to designate a potential COI that requires disclosure and review	COIDS	Account Establishment
Approval of COI and associated management plan	COIDS	Account Establishment
Listing of all active research projects	Account Establishment	COIDS
Notify when protocol indicates potential COI	Protocol submission and review (iStar)	COIDS

Approval of COI and associated management plan	COIDS	Protocol submission and review (iStar)
Listing of all active research projects	HRA	COIDS
Approval of COI and associated management plan	COIDS	HRA

3.2 Work Flow

Annual financial disclosures are initiated by “disclosers” (typically faculty). Disclosures are the obligation of the individuals holding financial interests and cannot be delegated to other individuals. All financial disclosures are initially screened to determine whether the investigator is subject to annual disclosure requirements for research. If so, Office of Compliance will next evaluate disclosure to determine whether a COI disclosure is needed and if so, notify the affected individual. Financial disclosures are also routed to the school, department, center or institute if required under the Relationship with Industry Policy or the Conflict of Interest and Ethics Policy.

Transactional disclosures of potential conflicts are initiated in any of the following ways: (1) when a potential COI is designated at proposal submission; (2) when a potential COI is designated when submitting a protocol to the IRB or IACUC; (3) when Office of Compliance requests a disclosure as a result of review of the annual financial disclosure; (4) when an individual determines that a disclosure is needed as a result of a change in his/her financial interests or research activities. In any events, research will not be permitted to proceed until completion of the review process. Disclosures are the obligation of the individual holding the potential conflict of interest. Disclosures cannot be delegated to other individuals.

Review of disclosures COI in research disclosures are initially reviewed by the Office of Compliance to assess whether full committee review is required. If not, administrative action is taken by the Office of Compliance and communicated to the discloser and affected units, such as DCG, the IRB and the discloser’s dean. If committee review is required, the disclosure (including associated financial interest) is made available to all committee members, who will review, discuss and recommend an action in a meeting of the committee. Committee minutes are recorded. The recommended action is communicated to the VP of Research. Based on the recommendation, the VP or Research issues one of the following decisions: (1) permit the activity because it does not constitute a conflict of interest; (2) prohibit the activity as impermissible; (3) permit the activity subject to compliance with a designated management plan. The outcome is communicated to the discloser and affected units.

Management of disclosed conflicts are initiated upon approval by the VP of Research of a management plan. The Office of Compliance will periodically review each approved conflict to assess whether the plan is being followed (e.g., through examination of disclosures in publications, consent forms and proposals). In the event that an individual appears to have not

complied with a management plan, the Office of Compliance will notify the VP of Research, who will schedule the item for discussion at a meeting of the CIRC.

3.3 Operational Requirements.

Operational requirements for COIDS are the same as for the RAS.

4. System Development, Deployment and Maintenance

4.1 Priority for Deployment

The COIDS must be operational in time to support Health and Human Service Regulations on “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors.” USC must comply with these regulations by August 24, 2012. To meet this deadline, the COIDS must be fully tested and operational by April 30, 2012.

4.2 Acceptance Testing

Acceptance testing shall be consistent with the process defined in the RAS Systems Requirements document.

4.3 Training

Training and support will be provided in the following ways

1. On-line documentation will provide a basic instruction manual for each module and for the system as a whole.
2. On-line training will both explain regulations and policies surrounding COI and also provide instructions on use of software.
3. Help system, in same visual format as iStar for IRB, will provide “pop-up” response to questions. A chat option with the help desk will be provided.
4. Help desk support to respond to questions via email or phone.

The Office of Compliance will be responsible for training.