

Conflicts of Interest and the Age of Transparency

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COI-Related Disclosure Requirements



Fight On


Biomedical researchers and physicians are bombarded with ever-expanding disclosures of their outside activities in multiple contexts:

- Physician relationships with the pharmaceutical/medical device industry/Physician Payment Sunshine Act
- NIH Annual Disclosure
- Research Conflict of Interest
- Clinical care
- Continuing Medical Education
- Peer review (Journals, federal sponsors)
- Journals
- Conferences
- Medical education
- Procurement of drugs/devices



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Relationships With Industry



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What drove a need to update USC Policy

- AAMC Reports
 - Task Force of Industry Funding of Medical Education
 - Task Force on Conflict of Interest in Clinical Care
 - AAMC/Association of American Universities Advisory Committee on Financial Conflicts of Interest in Clinical Research
- Continuing Government Enforcement
- Impact of Industry Disclosures; Healthcare Reform

4

Fundamental USC Position



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- USC supports meaningful interactions with Industry.
- USC recognizes that these collaborations have led to the discovery of new knowledge which has directly benefited patients/public health.
- USC seeks to maintain a culture of ethics in its business relations and to minimize conflicts of interest or even the appearance of conflicts of interest.

5

AAMC: Principles for Assessing Interactions between Academic Medicine and Industry



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- The interactions should serve to **enhance the health of the public.**
- The interaction should be **transparent.**
- All of the interactions between academic medical centers and industry must reflect **high standards of medical professionalism** that reach beyond applicable laws and regulations.
- The **interactions should involve knowledgeable parties** on both sides of the interactions.
- Compensation** and arrangements should be structured to **support the above principles.**

6

Relationship with Industry Policy

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Scope

- Policy is applicable whether on or off campus.

Industry Sponsored Frequent Speaking Engagements for Non-CE Events

- Strongly discouraged

Disclosure of Consulting Arrangements

- Required disclosure and approval by the chair/or designee, of contracts for consulting and other types of service arrangements with Industry **prior** to the initiation of the consulting.
- Disclosure of consulting/service arrangements when participating in activities relating to purchasing (ex Pharmacy and Therapeutics Committee) and disclosure to students, residents and fellows when relevant.

Gifts, Food, Free Services and Cash Payments from Industry

- Food is now defined as a gift and may not be accepted directly from Industry.

Ghostwriting

- This section now adopts the AAMC definition of ghostwriting.

7

Relationship with Industry Policy

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Pharmaceutical Samples

- Pharmaceutical samples dispensed on either campus, must be delivered to a campus pharmacy.

Site Access by Pharmaceutical and Device Manufacturer Representatives

- All Industry Representatives must register with the Centralized Industry Representative Tracking System.
- Pharmaceutical Industry Representatives may only access the campus subsequent to registering as noted above, upon invitation from a USC Healthcare Provider, by appointment and in non patient care areas.
- Device Industry Representatives may only access the campus subsequent to registering as noted above, upon invitation from a USC Healthcare Provider, by appointment and only in patient care area's when the proper HIPAA compliant patient consent has been obtained.

8

Relationship with Industry Policy

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Purchasing

- New language describes a USC Healthcare Provider's obligation to disclose to the appropriate parties, their relationship with an industry company when that company's product is under consideration for purchase and to recuse themselves from any purchasing decisions pertaining to the company's products.

Enforcement

- New language defines enforcement actions that USC may take against industry representatives who fail to comply with this policy.

9


Relationship with Industry Policy

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Education Grants and Trainee Scholarships


- Education grants received from Industry must be clearly documented and signed by authorized signer for USC.
- Education events must comply with ACCME Standards for Commercial Support.
Key Question: Budget? , Educational Objectives? , Target audience?
- Fellowship funding must not exceed the direct cost of fellowship.
Key Question: Will this be a billing fellow?
- Education funding should not originate from company's sales/ marketing.
- Industry can not influence educational event / content.

10



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Sunshine Act. . . A New Era of Transparency



Physician Payment Sunshine Act
(Section 6002 of the Affordable Care Act)

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Final Rule Issued 2/1/13

- **Goal:** Increase transparency between Industry Manufacturers/Group Purchasing Organizations and physicians/ teaching hospitals.
- **Who:** MDs, DDS, DOs, Optometrists and Chiropractors
- **What:** Annual national public reporting to an electronic, searchable, easily downloadable database.
- **Penalties:**
 - Unknowing Failure--\$1,000-\$10,000 per line item up to \$150,000 per year.
 - Knowing Failure---\$10,000-\$100,000 per line item up to \$1,000,000 per year.

12

What will be reported?



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- Recipient name
- Recipient business address
- Recipient specialty
- Recipient National Provider Identifier (NPI)
- Amount, date, form and nature of payment
- Associated covered drug, device, biological or medical supply
- Name of entity paid



13

What is excluded from reporting?



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- A transfer of anything valued at less than \$10
- Samples
- Educational materials
- Loan of a device for **short term trial period** defined as **less than 90 days.**
- Documented discounts
- In-Kind used for **provision of charity care**

14

Definition of Payment



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- Gift;
- Food;
- Entertainment;
- Travel or trip;
- Consulting Fees (speaking, advisory boards);
- Educational Grant;
- Charitable Contribution;



15

Definition of Payment



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- Ownership or investment interest;
- Royalties; Stock Option Grants; Dividends;
- License fee;
- Any categories of information the secretary determines appropriate

16

USC Relationships with Industry (RWI) Policy



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- Current RWI Policy positions USC well for Sunshine Act disclosures
 - No free food; proper documentation of educational grants, fellowships, or other offerings of value from Industry
 - Industry representatives must only visit with appointments and register first with RepTrax
 - Disclosure to Purchasing Committees
 - Consulting Arrangements
 - Must be in writing with a well defined Scope of Service.
 - Offered at Fair Market Value
 - Term is limited to one year
 - Determine if the arrangement presents COI in Research or Conflict of Commitment
 - Reviewed and approved by Chair under the requirements of the policy prior to initiating consulting
 - New diSClose system will be utilized to submit consulting arrangements to Chair

17

Start Dates



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Data collection begins: 8/1/13



Release of data: 9/30/14

18

Who will be watching?

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- Government Agencies
- Reporters
- Malpractice carriers
- Patients



19

USC Makes the News

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- December 19, 2010- ProPublica : “Med Schools Flunk at Keeping Faculty off Pharma Speaking Circuit”

“The key word is “control” – a word that appears in policies across the country but is interpreted differently. At some schools this means that speakers need to prepare their own slides and speech — or not give the talk. But at UCSF and schools such as the University of Southern California, speakers can say they are in “control” if they agree with what the drug company has provided.”

- <http://www.propublica.org/article/medical-schools-policies-on-faculty-and-drug-company-speaking-circuit>

HHS Final Rule on Conflicts of Interest

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HHS Final Rule on Conflict of Interest in Research

21

Introduction

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A Conflict of Interest in Research (COI) is a situation where financial or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgment in proposing, conducting, supervising or reporting research.

"The public trust in what we do is just essential, and we cannot afford to take any chances with the integrity of the research process." — Dr. Francis Collins, Director, NIH

22

Major Changes in HHS COI Rule – 8/24/12

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- **NEW** Requires annual disclosure of all significant financial interests related to any professional responsibilities on behalf of the institution (research, clinical care, instruction, service or committee work) regardless if there is a COI.
 - Disclosure must be updated to reflect new entities within 30 days.
 - **BEFORE** Only COIs had to be disclosed.
- **NEW** Institution has larger role in COI determination.
 - **BEFORE** Investigator initiated COI disclosure.
- **NEW** COI information related to PHS funding must be made accessible to the public, either by request or through a publicly available website.
 - **BEFORE** No requirement.

23

Major Changes (cont.)

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- **NEW** Requires NIH investigator training in COI at least once every 4 years.
 - **BEFORE** No mandatory training requirement.
- **NEW** Details on COIs related to PHS funding must be reported to sponsor and updated annually.
 - **BEFORE** Only the existence of a COI was reported.
- **NEW** Reporting threshold lowered to \$5,000 for payments for service.
 - **BEFORE** \$10,000 threshold.

24

Other Changes



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- **NEW** If an investigator fails to disclose or update a conflict related to HHS research in a timely fashion, or to comply with the management plan, USC must conduct a retrospective review to assess research bias.
 - **BEFORE** No such requirement.
- **NEW** If bias is found, USC must document the review and submit a mitigation plan to the sponsor.
 - **BEFORE** No such requirement.

25

Definitions: Who Must Disclose?



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- **Investigator** - is the principal investigator, co-principal investigator, contact principal investigator, or co-investigator. Other persons may be an investigator, but only if they have independent responsibility for some aspect of the design, conduct, or reporting of research.
- **Close Relation** - the spouse, domestic partner, or dependent child of an Investigator or Research Personnel.

26

Definitions: What Must be Disclosed?

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- **Financial Interest thresholds:**

1. Any equity in a non-publicly traded entity
2. Equity in a publicly traded entity of \$5,000 or more
3. Payments for services from either entity type of \$5,000 or more in the last 12 months
4. Any combination of 2 and 3 of \$5,000 or more
5. IP rights (excluding royalty payments from USC)
6. Any reimbursed or sponsored travel (except from excluded sources)

27

COI Process

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- USC policy requires disclosure to COI in Research Committee.
- Committee makes recommendation to allow or disallow the activity to the VP of Research.
- If allowed, activity is subject to a management plan which must be followed and annual or semi-annual monitoring by Research Compliance.

28

Conflict Management Challenge



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- You have a policy for both physician relationships with the pharmaceutical industry, and for researchers with conflicts of interest.
- You have a disclosure and management process under both policies.

So this is enough, right?

29

Scenario



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Dr. Grant is an orthopedic surgeon and researcher at Baldwin University. Dr. Grant's clinical care profile includes performing hip implants. Dr. Grant serves on the advisory board for a well-known hip implant manufacturer, ABC Device Company. He receives approximately \$10,000 annually for this work.

Dr. Grant is also a well-funded researcher and is the Principal Investigator on an ABC-sponsored clinical trial studying a new generation of hip implants.

30

Scenario



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Dr. Grant discloses his outside activity to Baldwin University's research conflict committee. The committee decides to manage the conflict by requiring Dr. Grant to:

- Assign a co-investigator without a financial relationship with ABC Device Company.
- Disclose his financial interest in all publications and during the informed consent process.
- Recuse himself from any contractual or intellectual property negotiations with ABC.
- Notify all students supporting his research of his conflict.
- Disclose his relationship under Baldwin University's Industry Relations policy.

31

Scenario



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Dr. Grant makes another disclosure to the School of Medicine, who is charged with reviewing/approving all physician relationships with the pharmaceutical/medical device industry. As part of this review, the School of Medicine evaluates the proposed consulting to ensure:

- Appropriate Statement of Work
- Fair Market Value Proposed Fees
- Limited Term

THIS IS NOT A LEGAL REVIEW

32

Scenario



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Finally, Dr. Grant approaches Baldwin University's Value Analysis Committee and asks that ABC's implant be placed on Baldwin University's formulary so that he can use it in his practice.

He argues that no other hip manufacturer's implant should be considered because ABC is at the cutting edge of implant technology and no other manufacturer's product is comparable. The committee does a detailed analysis of the product, agrees and places the implant on the formulary.

33

Scenario



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Once these reviews are done, the university and Dr. Grant have done their jobs, right?

Maybe Not.



34

Scenario



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Three months later, a reporter from *The Tribune* calls the Dean of the Medical School and asks for comment on the fact that Dr. Grant consults and conducts research on behalf of ABC Device Company. And, “by the way, it seems that your University has just inked a deal with ABC to exclusively begin using their implants.”

35

Multiple Conflict Disclosure Requirements



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Risks/Burdens

- Information overload!! (Faculty and university)
- Faculty burden – 2012 FDP survey indicates that faculty currently spend 42% of their time on pre and post-award administrative burdens unrelated to their research.
- Inconsistent disclosures/ management
- Piecemeal sharing of disclosure/management information



36

Scenario

Fight On

Dr. Grant has made various disclosures, but the information resides with different committees and stakeholders all over Baldwin University. Each may have followed their own rules, but none are aware of any other disclosures/reviews.

COI in
Research

Industry
Relations

Procurement

Clinical Care

37

Effective Conflict Management

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Effective conflict management requires more than multiple policies mandating disclosure. It requires sharing conflict disclosure/management information across the institution.

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Conflict
Management

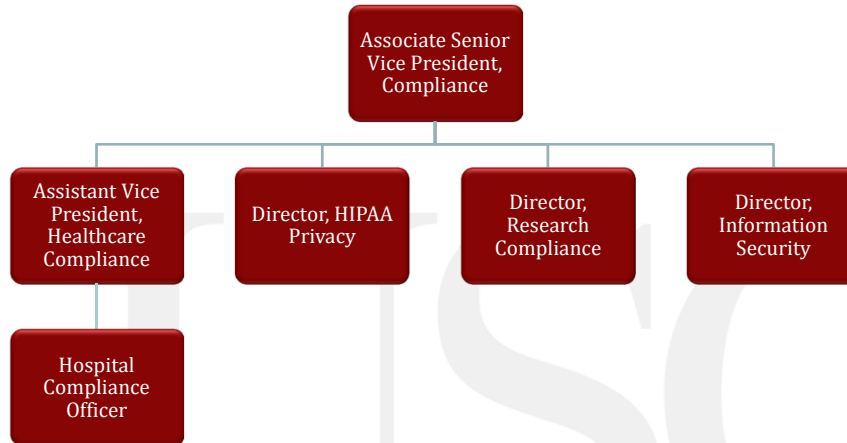
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38

Conflict Management Integration at USC

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Integration of Compliance Function at USC



39

Conflict Management Integration at USC

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Integration of Conflict Reviews – Policy Requirements

Research: When making annual or transactional disclosure, faculty are required to disclose if their activity is covered by USC's Industry Relations or Business Conflict policy.

Healthcare: Disclosers are required to disclose whether they are conducting any research on behalf of the company.

Procurement: When Healthcare Professionals are requesting products, the requestors are required to disclose whether they have any outside relationship with the company whose drug or device they are advocating that the University place on formulary.

40

Conflict Management Integration at USC



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Integration of Conflict Reviews – Policy Requirements

*All approvals are contingent upon obtaining review/approval
under other USC policies.*



41

Conflict Management Integration at USC

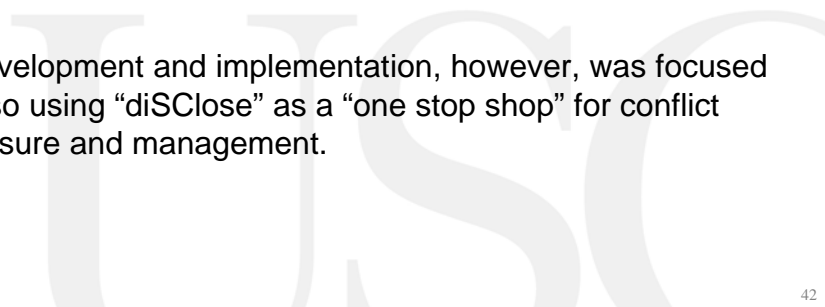


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Integration of Conflict Reviews – Technology

After the issuance of the NIH Final Rule on Conflict of Interest in 2011, USC licensed “diSClose”, an on-line disclosure and conflict management system, initially to meet the burden associated with the new NIH rules.

All development and implementation, however, was focused on also using “diSClose” as a “one stop shop” for conflict disclosure and management.



42

Conflict Management Integration at USC



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“diSClose”

How does diSClose promote integration of conflict management across different disclosure types?

First, the system asks the discloser to specify the reason he or she is making a disclosure.



43

The screenshot shows a web browser window with the URL [https://disclose.usc.edu/disclose/ResourceAdministration/Project/ProjectEditor?ProjectType=_Disclosure%](https://disclose.usc.edu/disclose/ResourceAdministration/Project/ProjectEditor?ProjectType=_Disclosure%...). The page header features the USC logo and the text "diSClose". Below the header, there are navigation links for "Back" and "Save | Print...". The main content area is titled "Disclosure Selection" and contains the following text and form elements:

What relationships do I have to disclose? ⓘ

1.0 Are you a **Healthcare Professional**? Yes No

2.0 Please check all that apply:

Research

- I am making/Updating an **annual financial disclosure** - HHS researchers only (NIH, CDC, HRSA)
- I am making/Updating a disclosure of a potential **conflict of interest related to research**

Relationship with Industry ("RWI")

- I have a **relationship** with a pharmaceutical or medical device company to disclose/update

Business/Personal Conflict

- I have a potential **conflict of commitment** to disclose/update
- I have a potential **personal conflict** to disclose/update
- I have a potential **business conflict** to disclose/update

Conflict Management Integration at USC



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“diSClose”

Next, the discloser is asked questions specific to the disclosure type.



45

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USC diSClose

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: Research Disclosures

Annual HHS Financial Disclosure for Benjamin Bell

Under HHS regulations, you must disclose all financial relationship(s) with an external company or organization maintained by you or your [Close Relation\(s\)](#) that relate to your

This does not include payments from:

- a research sponsor to perform research at USC;
- a federal, state, or local government agency;
- another university or research institute affiliated with another university; or
- an academic medical center or teaching hospital

1.0 **Do you or your [Close Relations](#) maintain any of the following financial relationships?**

Financial Interests

Private Equity Interest

Public Equity Interest (not including mutual funds)

Payment for Services (i.e. consulting, paid speaking, advisory board, steering committee)

Management Role (paid or unpaid)

Travel Sponsorship / Reimbursement

Intellectual Property Rights (not including USC IP rights)

Other outside activity

No, I have no relationships to disclose

Yes

[Clear](#)

University of Southern California [US] https://disclose.usc.edu/disclose/ResourceAdministration/Project/ProjectEditor?Project=com.webbridge.ent

USC diSClose

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<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - Disclosure General Information -

Disclosure for Benjamin Bell : Entity Information

You have selected the following entity. If this is not accurate, click "Clear" and enter the appropriate entity:

* Entity Organization: **Genentech, Inc.** Select... Clear

- or -

If you cannot find the entity in the above list, select "Other" above and enter the name as text below

1.0 * Does this entity sponsor your research or that of your close relation?
 Yes No Clear

2.0 * Has USC issued or does USC have an existing subaward with this entity to sponsor your research or that of your Close Relation?
 Yes No Clear

3.0 * Could there be a financial impact to the entity based on the outcome of any of your current research? (i.e. entity owns or has licensed IP, drug, device, material, etc.)
 Yes No Clear

4.0 * Does your relationship with this entity relate to any of your professional responsibilities to USC (i.e. research, teaching, clinical, service)?
 Yes No Clear

5.0 * Is this entity a pharmaceutical company, device manufacturer, biotechnology company, or other healthcare supplier?
 Yes No Clear

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USC diSClose

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COI In Research Disclosure for Benjamin Bell in Genentech, Inc.: Management Plan

All management plans shall contain, at a minimum, these elements. Examples of additional elements to include in the management plan are provided in USC's Conflict of Interest Policy and Recommendations.

- All relevant **publications, proposals and presentations** must contain a statement disclosing support received from, or financial interests in, any source outside of USC that is not permitted to consent human subjects;
- All **informed consent documents** in the context of human subjects research must disclose support received from, or financial interests in, any source outside of USC that is not permitted to consent human subjects;
- The Investigator and/or Research Personnel and their Close Relations will not participate in any **intellectual property** negotiations, or other contractual negotiations, that could result in a conflict of interest if the student is to perform as a research assistant on the research, along with a right of first refusal, and the appointment of a third party faculty member as a monitor of the situation.

1.0 Please propose additional management plan elements (if applicable) to ensure objectivity in your research.

* Required

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USC diSClose

You Are Here: Disclosure Certification - We... disclosure #10001093 for Benj...

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - Payment of Services (HHS/COI + RWI) -

Disclosure for Benjamin Bell in Genentech, Inc.: Payment for Services (HHS and/or COI + RWI)

Please provide details about your Consulting, Advisory Board, Management Roles and Promotional Speaking with the above Entity:

1.0 *** Please select all that apply with respect to this arrangement:**

- The arrangement has the potential to enhance the health of the public
- The arrangement serves USC's academic mission
- The arrangement supports academic standards of medical professionalism
- Other (please explain below)

1.1 **If you selected 'Other,' please explain why this is an appropriate activity to engage in:**

2.0 *** Please describe the services to be provided in reasonable detail**

3.0 *** What is the average number of hours per month you have spent over the past 12 months performing services for this outside entity?**

4.0 *** What is the average number of hours per month you intend to spend over the next 12 months performing services for the outside entity?**

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USC diSClose

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Disclosure for Benjamin Bell : COI and Ethics

1.0 *** Please provide the name of the person to whom you report:**

2.0 *** Please provide the contact information of the person to whom you report:**

3.0 *** Summarize your conflict. In doing so, please provide the following information, as applicable:**

- The name of the outside entity;
- The nature of your relationship with the outside entity;
- The nature of the current or prospective business relationship between the outside entity and USC;
- The precise nature of any services performed and the amount of compensation received over the last twelve months; and
- The nature and value of any equity interest.

4.0 *** Please propose a management plan to address your conflict of interest. Management of a conflict could include:**

- Appropriate disclosure of the conflict to parties involved in a transaction;
- Recusal from participating in certain negotiations, decisions, or transactions;
- Recusal from managing or supervising particular faculty members, staff or student employees, consultants, temporary agency employees, volunteers, or others;
- Recusal from managing or overseeing certain business transactions;
- Severance of outside relationships that pose conflicts;
- Appropriate monitoring and oversight by University management, including but not limited to the BCRC;
- Obtaining approval required by the Faculty Handbook, Staff Employment Policies and Procedures, or other relevant University policies.

Conflict Management Integration at USC



Fight On

“diSClose”

- If the discloser selects more than one box, he or she is asked all questions specific to the categories checked.
- Once disclosure is complete, which may include asking the discloser to provide a suggested management plan, the system routes the disclosure to the appropriate reviewer as designated by USC’s Conflict/Industry Relations policy.
- The reviewer can request additional data through the system if necessary.
- Once review is complete, an approval/denial is sent through the system to the discloser.

51

Conflict Management Integration at USC



Fight On

“diSClose”

- The Office of Compliance has a “super user” role that enables it to track where in the process a particular review is.
- This information is also visible to the discloser, so that he or she can be made aware, for example, that a research conflict review is completed, but an industry relations review is still underway.

52

Conflict Management Integration at USC



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“diSClose”

- The system is configured to send automatic reminders to NIH researchers regarding their annual disclosure obligation.
- The system is also accessed by USC's Department of Contracts and Grants, who verifies that a current annual disclosure is in place before submitting a grant proposal to HHS.

53

USC

Discussion/Questions