

HHS Annual Disclosure Update

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What is the HHS COI Rule?



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- 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.
- Requires new HHS investigator training in COI, and repeated training at least every 4 years.
- Went into effect 8/24/12

Who needs to complete an annual HHS disclosure?



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- Required for all HHS Investigators
 - An “**Investigator**” is the PI, co-PI, contact PI, or co-I. Other persons may be an investigator if they have independent responsibility for some aspect of the design, conduct, or reporting of research.
- Applies to those proposing for or with existing HHS-supported research

When does it need to be done?



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For investigators with existing HHS funding:

- Must disclose annually
- Any NEW financial interests must be updated within 30 days

For first time HHS investigators:

- Must disclose and complete training prior to proposal submission

How to disclose?

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- diSClose – a “one-stop” electronic system to meet all disclosure requirements

<https://disclose.usc.edu>

- HHS annual
- COI in Research
- RWI
- COI and Ethics (purchasing or personnel conflicts)

2015 Annual HHS disclosure schedule

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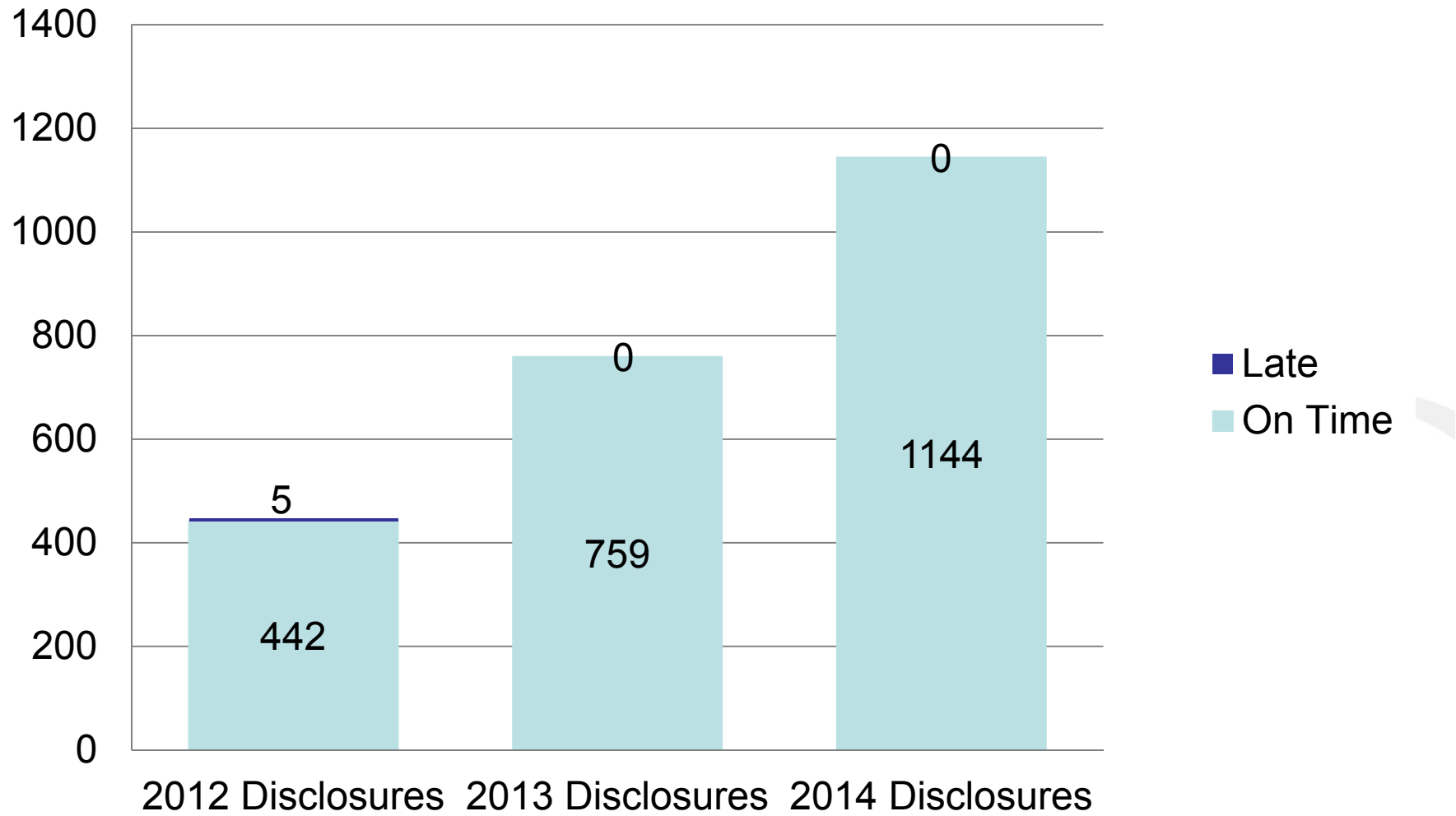
- 6/1/2015 – 2015 annual disclosure period opened in diSClose
- 7/31/2015 – 2015 annual HHS disclosures due
- 8/1/2015 – relevant Deans notified
- 8/24/2015 – HHS accounts frozen for any investigator not in compliance

Currently at 35%, 402 complete out of 1,137

HHS Annual Disclosures



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Programming Changes

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You Are Here: [_Disclosure Certification - Th...](#) > [_Disclosure Certification - Mo...](#)

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To:

Disclosure Selection

What relationships do I have to disclose? 

Reviewing Campuses

1.0 Select the campus(es) that will need to review this disclosure (i.e. where your primary appointment is, where your research is being conducted, and/or where your grant or award is being administered):

- USC-Health Sciences Campus (HSC)
- USC-University Park Campus (UPC)
- Children's Hospital Los Angeles (CHLA)

Annual HHS Disclosure

2.0 Do you need to make or update an annual HHS (NIH CDC HRSA) disclosure?

- Yes No [Clear](#)

Programming Changes - Upcoming

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Conflict of Interest in Research Disclosure (University of California, Los Angeles): Related Research Projects

You noted a connection between your financial interest and your research. Please indicate which projects you are involved with are related to this financial interest.

1.0 Related Proposals and Awards: (select all that apply)

Institutional Proposal Number	USC Award Number	Project Title	Prime Sponsor Name	Sponsor Name	Project Start Date	Co Investigators
<input type="checkbox"/>	00015999	Innovations for Maternal and Newborn Health in Africa		VentureWell	7/1/2015	

2.0 Related IRB Studies: (select all that apply)

ID	Name	Status
There are no items to display		

3.0 Related IACUC Protocols: (select all that apply)

ID	Name	Status
There are no items to display		

4.0 If your project is not listed in 1.0, 2.0, or 3.0, please add the related research below:

Project Title	Funding Agency	Role On Project	Involves Human Subjects	Estimated Start Date	
<input type="button" value="Add"/>					
<input type="button" value="Update"/>	Building Infrastructure for Clinical Trials for Familiar Alzheimer's in Mexico	University of California, Los Angeles	Other Role (responsible for the design, conduct or reporting of research)	2/1/2015	<input type="button" value="Delete"/>
<input type="button" value="Update"/>	Community Partnership with Asian Organizations for Domestic Violence	University of California, Los Angeles	Other Role (responsible for the design, conduct or reporting of research)	3/1/2015	<input type="button" value="Delete"/>

5.0 * Do you intend to use students that are enrolled in a course you teach or who you are otherwise supervising in an academic capacity to perform services for the entity that is the subject of this disclosure?

Yes No [Clear](#)

6.0 * Will you receive any incentive payment, bonus or finder's fee related to this research?

Yes No [Clear](#)

7.0 * Will publication rights relating to the research be restricted beyond reasonable delays to protect proprietary rights of the sponsor (i.e. a 45 day delay to permit patent filing)?

Yes No [Clear](#)

8.0 * Will you, or have you, received any gifts, gratuities, or special favors from the sponsor in excess of \$50 in value?

Yes No [Clear](#)

AAMC COI Metrics Project

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Analysis



IN BRIEF

Volume 15, Number 4
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Association of
American Medical Colleges

Implementing the Regulations on Financial Conflicts of Interest: Results from the AAMC Conflict of Interest Metrics Project

Revised regulations related to the identification and management of potential conflicts of interest had a substantial impact on the costs and personnel at medical schools and teaching hospitals conducting federally funded research. In 2011, the U.S. Department of Health and Human Services issued changes to the regulations designed to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias.¹ The revised rule maintained the previous regulatory framework but made specific changes to

the values and types of financial interests that investigators must disclose to their own institutions (significant financial interests, or SFIs)² as well as the processes institutions must undertake to review SFIs and manage any identified financial conflicts of interest (FCOIs).³ This situation posed a unique opportunity to assess the institutional impact of a single regulatory scheme and to create a model for a retrospective evaluation of regulatory burdens and benefits.

This *Analysis in Brief* presents key results from the first two years of the AAMC Conflict of Interest (COI) Metrics Project, which was initiated to understand the impact of these changes by comparing the information reviewed by institutions

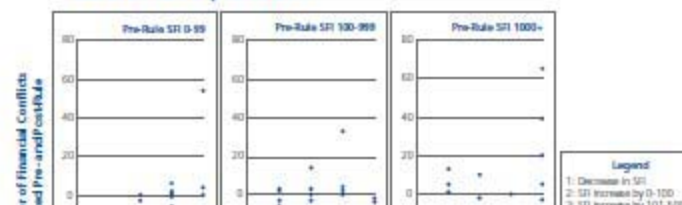
and the resources needed to comply with the regulations in the year prior to the implementation deadline with the resources needed for compliance in the following years.

Through the COI Metrics Project, the AAMC will provide the National Institutes of Health (NIH) with detailed, de-identified aggregate data to assist in the agency's assessment of this rule, should it undertake such a review. Agency-level review of regulatory burden is mandated by a January 2011 Executive Order recognizing that "our regulatory system must ... identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends" and requiring that federal agencies "consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned."⁴

Methods

The AAMC invited all member medical schools and teaching hospitals to participate in the COI Metrics Project by providing the association with

Figure: Change in the Number of Financial Conflicts of Interest Reported as a Function of the Number of Significant Financial Interests Disclosed to Institutions Before and After Rule Implementation



Questions?



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NIH website (links to new rule and FAQs):

<http://grants.nih.gov/grants/policy/coi/>

Office of Compliance website:

<http://ooc.usc.edu/conflict-interest>

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