Research Administrators Forum

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Today’s Topics

• Conflicts of Interest in Research - an update

• Physician Payments Sunshine Act – a preview of coming attractions
“Publicity is justly commended as a remedy for social and industrial diseases. Sunlight is said to be the best of disinfectants; electric light the most efficient policeman”

- Justice Louis D. Brandeis
Revised Public Health Service Regulations

- Went into effect on August 24, 2012
- Intended to expand and add transparency to investigators’ disclosures of Significant Financial Interests
- Changed definitions and reduced thresholds for disclosure (*Significant Financial Interests*)
- Requires broader disclosures (*related to institutional responsibilities*)
- Increased disclosure requirements (*initial, 30 day and annual updates*)
Revised Public Health Service Regulations

- Increases review requirements (*2 step*)
- Increases reporting requirements (*more detail*)
- Adds an education/training requirement
- Adds a new public accessibility requirement (*must respond promptly to inquiries*)
- Adds new monitoring requirements
- Adds requirements for conducting retrospective reviews and looking for bias in instances of noncompliance
UCLA’s experience

- Between August 10, 2012 and June 30, 2013:
  - 2331 individuals submitted annual certifications through the electronic Disclosure Gateway (eDGE)
  - 2039 (87.5%) individuals certified that they had no Significant Financial Interests to report
  - 292 (12.5%) individuals reported one or more Significant Financial Interests
  - 492 SFIs were disclosed in total
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<th>FY 2011-2012</th>
<th>FY 2012 – 2013</th>
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<td>111 disclosures were forwarded to the RPC for review under “old” PHS rules</td>
<td>OCGA sent &gt;1000 requests to RPC triggering reviews to determine whether the PI or any other Investigators on a particular contract or grant had disclosed any “related” SFI</td>
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<td>All 111 disclosures were reviewed by the CIRC to make a determination about whether the SFI constituted Financial Conflicts of Interest</td>
<td>84 SFI were determined to be related to PHS-activities and were forwarded to the CIRC for review</td>
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<td>~61 FCOIs were identified</td>
<td>~70 FCOIs were identified</td>
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Much more work
Not many more FCOIs identified
Physicians Payment Sunshine Act

- Intended to promote transparency and decrease the potential for conflicts of interest
- Regulations directed to manufacturers
- Requires applicable manufacturers to report payments made to physicians* and medical centers to the federal Center for Medicare and Medicaid Services (CMS)

*doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors
Physicians Payment Sunshine Act

- Applicable manufacturers will be required to report payments and transfers of value of $>10 or smaller payments that add up to $>100 during a calendar year.
- Reports will include research agreements to institutions.
- Reports will include payments to individuals for such things as consulting fees, honoraria, speakers fees (but not for accredited CME), food and drink, and more.
Physicians Payment Sunshine Act

• Reports will be made public
• Only the individual for whom the report is made will be able to check his/her listing(s) and if necessary contest accuracy before reports are made publicly available
• Not sure how/if reported information will be used or by whom
Resources

CMS Fact Sheet for Physicians:

CMS Open Payments:
RPC is working with the School of Medicine Deans Office and the Medical Enterprise Corporate Compliance Office to determine how to disseminate information to the campus.
Questions?

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