

# Mandatory Training Course: Federal Regulations and Cambridge Health Alliance Policy on Financial Conflicts of Interest in Research



# **Purpose of this Course**

- New federal regulations addressing conflicts of interest (COI) in research go into effect 24 August 2012.
- New regulations will apply to Investigators and institutions participating in research funded by the U.S. Public Health Service (PHS).
- Some of the requirements impose real burdens on Investigators and on Cambridge Health Alliance (CHA), but they are requirements of federal law; we do not have a choice.
- This training was designed to fulfill a requirement in the new regulations that Investigators be educated on the regulations, the Investigator's responsibilities under the regulations, and CHA policies on COIs.
- The new <u>Promoting Objectivity in Research</u> regulations are online.



## **Overview of Course**

### In this training you will learn:

- The purpose and key provisions of the federal regulations.
- The purpose and key provisions of CHA policies on financial conflicts of interest (FCOI).
- What financial interests you are required to disclose and when they must be reported to CHA.
- What happens to the information you disclose.
- Which interests you are not permitted to hold.
- What happens if you fail to disclose a financial interest in a timely manner.
- Where to find more information and assistance.



## Why is this relevant to you?

- Everyone who is responsible for the design, conduct, or reporting of (1) PHS-funded research, or (2) research funded by a foundation that has adopted the requirements of the federal regulations is an "Investigator" subject to these regulations.
- According to CHA records, you are one of these Investigators. If you think these regulations and this training course do not apply to you, contact the CHA Compliance Office at (617) 499-8303.



# What are the key new requirements?

- These are key new requirements that the regulations place on you, as one of these Investigators:
  - On-going obligation to report certain new financial interests, including direct company-paid travel expenses, as they arise, within 30 days.
  - Mandatory training (this course!)
    - o NOTE: If you <u>only</u> participate in research funded by other sources (*e.g.*, industry, the Department of Defense), then you are <u>not</u> subject to these two key new requirements.



### Part I: Introduction to financial interests

# Why are outside financial interests a concern?



Part I - Introduction to financial interests

## Why are outside financial interests a concern?

- They create the concern that CHA research may be biased, or be perceived as biased, by those financial interests.
- Real, and perceived, bias can damage an individual's and an institution's reputation, erode public trust, undermine CHA community initiatives, or create legal exposures.
- CHA is committed to ensuring objectivity and independence in research and to helping its investigators comply with these regulations.



#### Part I - Introduction to financial interests

## Why are outside financial interests a concern?

- The design, conduct, and reporting of CHA research must be characterized by integrity, independence, and objectivity.
- If the outside financial interest creates a FCOI:
  - The objectivity of study design, data collection/analysis, conclusions, or reporting may be compromised.
  - Protection of human research participants could be compromised.
  - Students, staff, trainees, junior colleagues, collaborators, etc., could be exploited.



## Part II: Overview of Federal regulations

- Purpose and effective dates.
- What kind of research is subject to the regulations?
- What CHA Investigators are subject to the regulations?



Part II – Overview of Federal regulations

## Purpose and effective dates

#### Purpose:

- To promote objectivity in PHS-funded research.
- To establish standards that provide a reasonable expectation that the *design*, *conduct*, *and reporting* of research funded by the PHS that is conducted at, or through, CHA will be free from bias resulting from Investigator FCOIs.
- To safeguard the trust of patients, human research participants, students, staff, trainees, collaborators, and the public.

#### Effective Dates:

- Since 1995, the US government has regulated FCOIs in federally sponsored research.
- On 24 August 2012, the new Federal regulations become effective, supplementing those in effect since 1995.
- Key new requirements are indicated in these slides by <a></a>.



Part II - Overview of Federal regulations

## What research is subject to these regulations?

- <u>All</u> research that is funded by the PHS.
- CHA is required to extend the Federal regulations to foundations and other non-profits that have *chosen* to follow these regulations.
- CHA has <u>not</u> extended the requirements of the new regulations to research funded by other government agencies, non-profits, or industry.



Part II – Overview of Federal regulations

## Who is subject to the regulations?

The following CHA Investigators are subject to the regulations:

- Project Directors/Principal Investigators (PD/PI),
- Co-Principal Investigators,
- Senior/Key Personnel, and
- Any other person, *regardless of title*, responsible for the design, conduct, or reporting of research funded by the PHS or an applicable foundation.
  - Contractors, consortium participants, collaborators, post-docs, graduate students, and consultants may be responsible for the design, conduct, or reporting of research.

#### Part II - Overview of Federal regulations

## **QUIZ!**

1. A CHA PI on a National Institutes of Health (NIH)-funded grant is subject to the requirements of the Federal regulations.

True False

- 2. Dr. Smith is a CHA clinician in a clinical study funded by the NIH. She is not the PI, PD, or Senior/Key Personnel, but she is responsible for enrolling study participants. She is <u>not</u> subject to the requirements of the Federal regulations. True False
- 3. Department of Energy is subject to the requirements of the Federal regulations. True False
- 4. A CHA PI on a grant funded by a pharmaceutical company is subject to the requirements of the Federal regulations.

True False



- What must be disclosed?
- What are an Investigator's "Institutional Responsibilities"?
- What is a Significant Financial Interest (SFI)?
- Exceptions from SFIs.
- New SFIs that must be disclosed within 30 days.
- When and how do I disclose a new SFI?
- What happens if I do not report a new SFI within 30 Days?
- What happens to the information I disclose?
- What information must be made public?
- What other responsibilities do I have under Federal regulations?



#### What must be disclosed?

- Previously, in connection with your PHS research grants, you were required to disclose to CHA your SFIs, including those of your spouse and dependent children, that were related to your research.
- Under the new regulations, you are required to disclose
   SFIs, including those of your spouse and dependent children, that are related to your *Institutional Responsibilities*.
- This is a broader scope of disclosure!



## What are "Institutional Responsibilities?"

- An Investigator's "Institutional Responsibilities" means the investigator's professional responsibilities on behalf of the institution.
- CHA defines your Institutional Responsibilities as all of your hospital or other CHA activities, including research, clinical care, education, and other CHA activities, such as involvement in purchasing, or serving on a CHA or hospital committee or board.



## When must you disclose?

- At the time of application for funding.
- Within 30 days of discovering or acquiring a new SFI,
   and
- Annually, at a time required by CHA for the duration of the award.

More information on the 30 day update requirement is provided later in this section.

#### What is a SFI?

A SFI consists of the following interests of the Investigator (plus those of the Investigator's spouse and dependent children):

- Any income from any entity that exceeds \$5,000 in a rolling 12 month period.
  - \$5,000 is a new, lower threshold required by the new regulations (the former regulatory threshold was \$10,000)
- Income received in a 12 month period from and equity interests currently held in a publicly-traded entity that in the aggregate exceed \$5,000.
- Any equity in a publicly traded company that exceeds \$5000 in value.
- **ANY** equity/ownership interest in a non-publicly traded company.

continued



#### What is a SFI?

#### A SFI also includes:

- Income from intellectual property rights, except for royalties through a CHA institution, that exceeds \$5,000 in a rolling 12 month period.
- ANY travel expenses that are reimbursed to the Investigator by the outside entity or sponsored by an outside entity.

  ("Sponsored" travel manns travel expenses paid directly by an

("Sponsored" travel means travel expenses paid directly by an outside entity on behalf of the Investigator and not reimbursed to him/her.)

More information on travel expenses later.



## **SFI Exceptions**

You are <u>NOT</u> required to disclose:

- Salary, royalties, or other remuneration paid to you by CHA.
- Equity and related income from investment vehicles, such as mutual funds and retirement accounts, over which you have no control.
- Income from seminars, lectures, or teaching engagements sponsored by, or payment of travel by:
  - Government agencies,
  - US institutions of higher education and research institutes affiliated with them,
  - Academic medical centers,
  - Teaching hospitals.



**NOTE:** Income and travel from professional organizations and societies and non-profit organizations are <u>NOT</u> excluded!!

• Travel expenses paid directly by a company to CHA under a CHA agreement and not directly reimbursed by the company to the Investigator.



### When do I have to disclose a new SFI?

- New SFIs must be disclosed to CHA within 30 days of the
   receipt of payment or acquisition of equity.
  - This applies to payments for consulting, honoraria, or other compensation to you.
  - This also applies to reimbursement of travel expenses.
  - With respect to "sponsored travel" (travel paid directly on your behalf by an outside entity instead of reimbursed to you), you don't receive payment, so the 30-day clock begins on the occurrence of the travel or event.



- You are a paid consultant for XYZ Pharmaceutical Company. You are paid \$2,000 on 01 November 2012 and \$4,000 on 01 March 2013. You have never previously received payment from XYZ Pharmaceutical.
  - The 01 March payment, when aggregated with the earlier payment, means that the total amount of income you received from XYZ Pharmaceutical over the preceding 12 months exceeded \$5,000 as of 01 March 2013.
  - This is a SFI that must be disclosed to CHA within 30 days of receipt of the \$4,000 payment (by 30 March 2013).



- On 01 October 2012 you purchase \$7,000 in stock from Company XYZ, a publicly-traded company.
- You previously held no other interests neither stock nor income in Company XYZ.
- Because the value of the stock exceeds \$5,000, you must disclose it within 30 days of making the purchase by 01 November 2012.



- You currently own stock in XYZ Biotech, Inc., a publicly-traded company, and you receive a cash payment on 01 January 2013 of \$2,000 (your first ever from XYZ Biotech) for consulting services for XYZ Biotech, Inc.
- The value of your XYZ Biotech stock is \$4,000 on 01 January 2013, bringing the combined total of income and equity to \$6,000.
- Because the combined total of income plus equity over the preceding 12 months exceeded \$5000 as of 01 January 2013, this is a SFI that must be disclosed to CHA within 30 days of receiving the payment (by 30 January 2012).



- You travel to New York to give a talk and ABC Biotech Company pays the airline directly for your flight. The cost of the flight is \$300.
- The occurrence of sponsored travel (*i.e.*, the \$300 flight paid for by ABC Biotech) is a SFI that must be disclosed to CHA within 30 days of occurrence, whether or not you have ever received any payments or have any other interests in ABC Biotech.



## How do I disclose a new SFI?

- CHA has developed a new disclosure form to help Investigators report a new SFI.
- The Investigator completing the form will check-off a box on the form to indicate if the SFI is to report information for travel expenses or to report all other new SFIs or both.
- The electronic forms are available on <u>staffnet</u>.



## How and when do I disclose a new SFI?

- Calculating when you have a new SFI, other than travel, within the previous 12 months that has to be reported within 30 days may be difficult and the consequences for failure to report a new SFI in a timely manner are serious.
- As a result, CHA recommends that you report ANY new financial interest, regardless of amount, within 30 days.



## What happens if I do not report a new SFI within 30 days?

If/when CHA learns that a new SFI has not been reported within 30 days CHA must, within 60 days, determine whether the SFI creates a FCOI. If so, then CHA must:

- Implement a management plan and report the FCOI and the plan to the PHS.
- Within 120 days of late disclosure:



- Conduct a <u>retrospective review</u> of the Investigator's activities and research to determine whether the research conducted during non-compliance was biased.
- Document the review and report it to the PHS.
- If bias is found, submit a mitigation report to the PHS.

A retrospective review is burdensome and will require extensive time from you and your colleagues.



## What happens to the information I disclose?

- CHA understands and respects that the information you disclose is personal. As a result, CHA has put measures in place to protect the confidentiality.
- CHA will use and share internally the information you disclose only as needed to fulfill its obligations under the regulations and under its own policies to determine steps that must be taken.
- Under the regulations, CHA is required to use the information you disclose about your SFIs to determine if any of them create a FCOI that must be managed.

continued



## What happens to the information I disclose?

- Details of all FCOIs must be provided to the PHS.
  - The details of all SFIs you disclose are not provided; only details in situations where CHA determines that the SFI creates a FCOI.
- The PHS may request any and all information you disclose; some of this information may be subject to public disclosure laws.
- If you are Senior/Key personnel on the research, and if your SFI is determined to be a FCOI, certain information about your FCOI must be made publically available.
  - CHA does not make public the details of all SFIs you disclose to CHA; only certain details in situations where CHA determines that a SFI constitutes a FCOI of Senior/Key Personnel, including their spouse/dependent children.



## What information must be publically available?

- CHA must make publicly available information concerning FCOIs held by Senior/Key Personnel either by posting the information on a public website, or by providing a written response within 5 business days of a request from anyone.
  - > CHA intends to use the 5-day response approach initially.
- With respect to an identified FCOI of a Senior/Key Personnel, CHA must make available, at a minimum, the following:



- Investigator's name,
- Investigator's title and role with respect to the research project,
- Name of the entity in which the SFI is held,
- Nature of the SFI (*e.g.*, equity, consulting fees, travel reimbursement, honoraria),
- Approximate dollar value of the SFI (dollar ranges are permissible) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.



## What other responsibilities do I have?

#### Federal regulations also require that:

• You complete this training course:



- Before engaging in any PHS-funded research at CHA.
- Every 4 years thereafter.
- If you are out of compliance with CHA COI policy or a management plan.
- If CHA changes its policy you will be required to take an updated course.
- You comply with all FCOI management plans developed by CHA.
- You comply with the CHA policy on COIs in research.



## **QUIZ!**

- 1. You must disclose SFIs related to your institutional responsibilities <u>only</u> when CHA notifies you that you must complete a disclosure form.

  True False
- It is your responsibility to disclose every new SFI related to your institutional responsibilities to CHA within 30 days of receiving or acquiring it.
- 3. You do not have a SFI if you hold \$4000 in stock in a publicly traded company and your spouse receives \$4000 per year in consulting income from the same company. True False
- 4. Within the past 12 months, you received a \$3,000 payment from company XYZ. You had no previous financial interest in the company. You receive an additional \$2500 today. You have a new SFI as of today.

  True False



- What is CHA required to do?
- What Is non-compliance?
- What happens if there is non-compliance?
- Sub-recipients
- Public accessibility



## What responsibilities does CHA have?

#### Federal Regulations require CHA to:

- Maintain an up-to-date, written, and enforced policy.
- Make the CHA FCOI policy publicly available.
- Inform each Investigator of, and train each Investigator on, the Federal regulations, CHA's FCOI policy, and the Investigator's disclosure responsibilities.
- Designate institutional officials to solicit and review disclosures of SFIs, according to guidelines, from each Investigator who is planning to participate in, or is participating in, PHS-funded research.
- Analyze your disclosures of SFIs to determine if a FCOI exists. The analysis consists of:
  - Determining whether the SFI could be affected by the research, or is in an entity whose financial interests could be affected by the research, and if so
  - Whether the SFI could directly and significantly affect the design, conduct, or reporting of the research.
  - If the answer to both questions is "yes," then you have a FCOI as defined by the Federal regulations.



## What is CHA required to do?

If CHA finds that a FCOI exists, CHA must:

- Manage, which may include eliminate, the FCOI.
- Report required information to the PHS on FCOIs within certain time periods; the PHS may impose special award conditions or suspension of funding or other enforcement actions if it finds bias.
- Monitor compliance with management plans.
- Keep records and, upon request from the PHS, report any information relating to the disclosure and review of SFIs, whether or not a FCOI was found.
- Establish enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance with the policy.



## What constitutes non-compliance?

- The regulations require CHA to take certain actions when the following types of non-compliance with the regulations occurs:
  - An Investigator fails to report a new SFI within 30 days.
  - An Investigator fails to comply with a FCOI management plan.
  - CHA fails to review or manage a FCOI within required time periods.



## What happens if non-compliance occurs?

- If/when non-compliance occurs, CHA must:
  - Determine if there is a FCOI, and if so, implement at least on an interim basis a management plan, where applicable.
  - Complete and document a <u>retrospective review</u> within 120 days to determine whether the research was biased, and if so, to take action to mitigate the bias.
  - During a retrospective review, CHA must:
    - o Review the Investigator's activities/research project.
    - o Determine whether the research was biased.
    - o If so, submit a mitigation report.
- The PHS may require additional actions

Retrospective reviews are burdensome for the Investigator.



## Sub-recipients; Public Accessibility

### CHA is also required to:

- Take reasonable steps to ensure that any sub-recipient Investigator complies with the Federal regulations.
- Make publicly available specific information concerning FCOIs held by Senior/Key Personnel by providing a written response within 5 business days of a request from anyone.

## **QUIZ!**

1. CHA is required to analyze a SFI that you disclose to determine if it constitutes a FCOI.

True False

2. If you do not disclose a SFI in a timely manner and CHA determines the SFI creates a FCOI, you will need to cooperate in a prompt process to retrospectively review your research activities to evaluate whether the research has been biased.

True False

3. CHA must make available to the public certain information about FCOIs of Senior/Key Personnel.

True False



## **Summary**

- Requirements of the regulations apply to all Investigators responsible for the design, conduct, or reporting of PHS-funded research, and some foundations.
- There are broader reporting obligation:
  - Lower dollar threshold (\$5,000 instead of \$10,000 under the old regulations) measured on a rolling 12 month basis.
  - All SFIs related to your Institutional Responsibilities.
- Timing of disclosure: On-going obligation to report as new SFIs acquired
  - 30 day window for reporting.
  - Includes <u>all</u> travel expenses reimbursed by or paid by an outside entity, regardless of the dollar value.
- Investigators must undergo training.
- Retrospective reviews must be conducted if Investigators fail to report a SFI in a timely manner.
- Information about FCOIs of Senior/Key Personnel must be made public
- These are mandates of Federal law.



### **Resources and Contacts**

- Information related to Federal grants and cooperative agreements:
  - http://grants.nih.gov/grants/policy/coi/
- Information related to Federal contracts:
  - http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf
- Information related to the CHA COI policies:
  - <a href="http://staffnet/Reference/Policies/RegulatoryCompliance/A-COM-0009.pdf">http://staffnet/Reference/Policies/RegulatoryCompliance/A-COM-0009.pdf</a>
  - <a href="http://staffnet/Reference/Policies/RegulatoryCompliance/A-COM-0012.pdf">http://staffnet/Reference/Policies/RegulatoryCompliance/A-COM-0012.pdf</a>
- Information related to HMS policies:
  - http://hms.harvard.edu/content/hms-policy
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