AGENDA

- Office of Technology Management Update
  - Gayathri Srinivasan, Ph.D., Licensing Officer
- New Financial Conflict of Interest (FCOI) Regulations
  - Thoru Pederson, Ph.D., Associate Vice Provost for Research
  - Elizabeth Rodriguez Delgado, Associate Counsel
- RFS Update
  - Diego Vazquez, Assistant Vice Provost, Research Funding Services

UMass Medical School

Office of Technology Management

Gayathri Srinivasan, Ph.D.
Licensing Officer

Research Administration

April 30, 2012

Outline of Presentation

An informative 45 minutes!

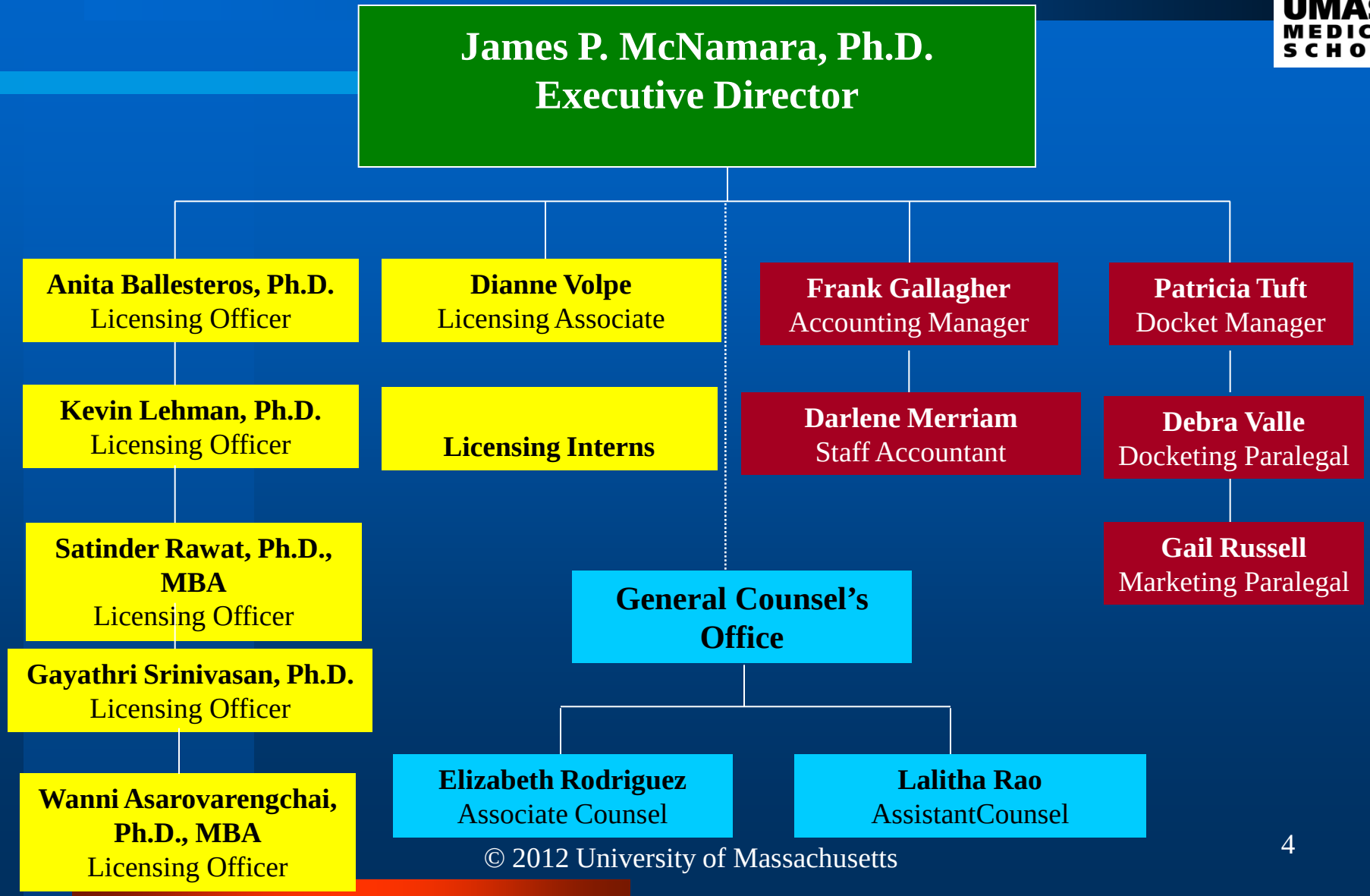
- Our mission
- Who are we
- What do we do
- What is Intellectual Property
- How do we protect it
- When to contact us
- Data and trends for our office
- Where are we located

The Mission of OTM

Make discoveries broadly available

- Intellectual Property (IP) – ideas, fruits of the mind!
  – tangible materials
- IP Management
  - Make research materials widely available to academic and industry researchers
  - File patents, copyrights or trademarks to protect discoveries and work products
  - Promote the development of medical products by industry for the public benefit
- Provide financial support for UMMS research

OTM Staff



Functions Performed by OTM

Effective protection & management of IP

- Confidential Disclosure Agreements (CDA)
- Material Transfer Agreements (MTA)
- Sponsored Research Agreements (SRA)
- Service Agreements (Core Facilities)
- Invention Disclosure Acceptance & Review
- Patent Management (filing & prosecution)
- License Agreements (commercial development)
- Company Spin-outs

Forms of IP Protection

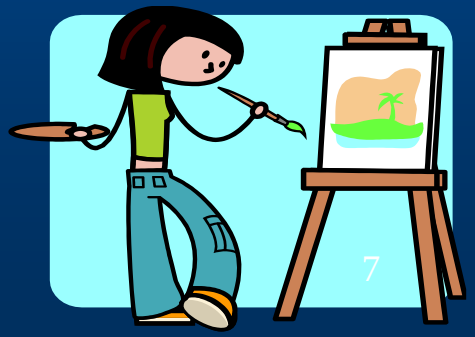
Intellectual Property takes many forms

- Intellectual Property (IP)
  - ideas, fruits of the mind!
  - discoveries, tangible materials!
- Copyright
- Trademarks, Service Marks
- Inventions
  - Trade Secrets (Know How)
  - Patents

Copyrights

Protection for original works of authorship

- Includes literary, dramatic, musical, artistic, and certain other intellectual works.
- Owner has the exclusive right to do and to authorize others to do the following:
  - To reproduce the work
  - To prepare derivative works based upon the work
  - To distribute copies of the work to the public by sale or other transfer of ownership, or by rental, lease, or lending
  - To perform the work publicly
  - To display the work publicly



Copyrights

Copyright protection last a very long time!

- Reports, Presentations (e.g., PowerPoint), Logos, Atlases, Software
- Protection is immediate, but can pay a fee and register with Copyright Office
  - © 2010 University of Massachusetts
  - Copyright 2010 University of Massachusetts
- Term is authors life plus 70 years
- Work made for hire: shorter of
  - 95 years from publication
  - 120 years from creation

Trademarks

Important for brand recognition

- **What is a trademark?**
  - a word, phrase, symbol or design, or a combination that identifies and distinguishes the source of the goods of one party from those of others.

- **What is a service mark?**
  - same as a trademark, except that it identifies and distinguishes the source of a service rather than a product.

Our Brand

Trademarks

Important for brand recognition

- **When can I use the trademark symbols TM, SM and ®?**
  - **TM or SM: when you are legitimately using your mark**
  - **® : when you have officially registered your mark**

- **Registration is not necessary but provides important benefits**
  - **constructive notice to the public of the registrant's claim of ownership of the mark**
  - **a legal presumption of the registrant's ownership of the mark and the registrant's exclusive right to use the mark nationwide on or in connection with the goods and/or services listed in the registration**
  - **the ability to bring an action concerning the mark in federal court**
  - **the use of the U.S registration as a basis to obtain registration in foreign countries**
  - **the ability to file the U.S. registration with the U.S. Customs Service to prevent importation of infringing foreign goods**

TM

SM

Trade Secrets & Know How

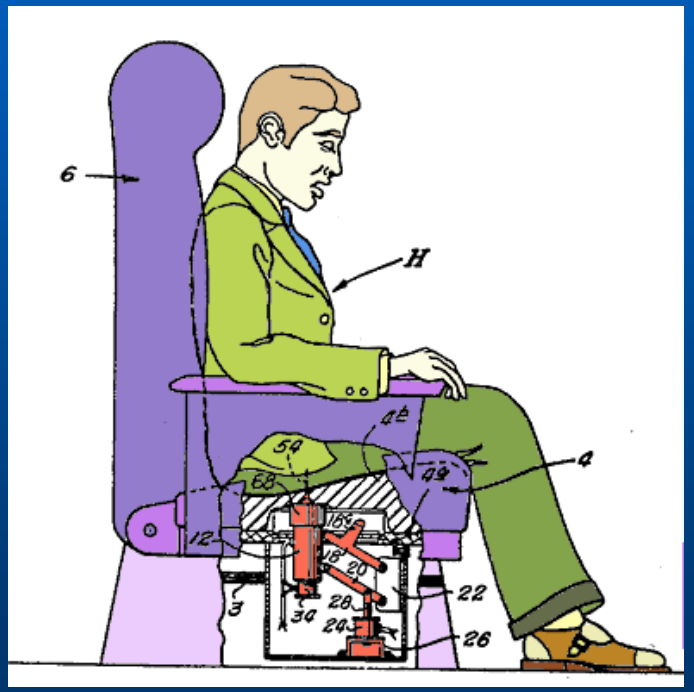
Invention Disclosures to License Agreement

- Know how is difficult to explain
  - It's not patented
  - May or may not be published
  - It's your skill or experience, e.g., cooks follow the same recipe with different results
  - Faculty and staff possess know-how
- Trade Secret is a form of Know How
  - Coke is the best example
  - Can be stronger protection than patents
  - In theory no expiration
  - Once discovered or disclosed, protection is lost
- Coke is a trademark, the formula is a trade secret
- Lonza's biologic manufacturing feed-stock is a trade secret

Inventions and Patents

Patents are the opposite of trade secrets

- An Invention can be protected with a Patent (a public record).
- Patents are encouraged to promote commerce.
- US Constitution (1:8) gives congress the power to grant patents
- Patents discourage trade secrets
- By disclosing your invention you gain exclusivity for a period of time



Hijacker Injector

What is Patentable?

Title 35 US Code, section 101

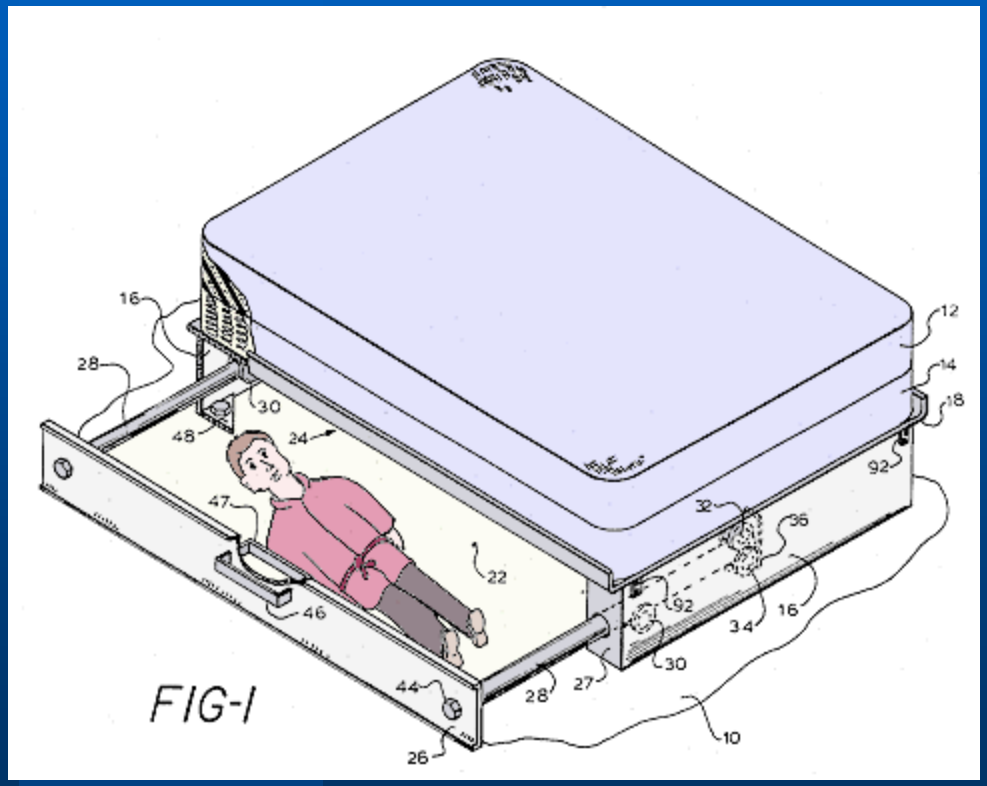
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent

- Composition of matter
- Machine
- Manufacture
- Process
- Life form
- New uses of the above
- Meet standards of:
  - Utility
  - Novelty
  - Non-obviousness
- Term is 20 years from filing

All Patents Expire

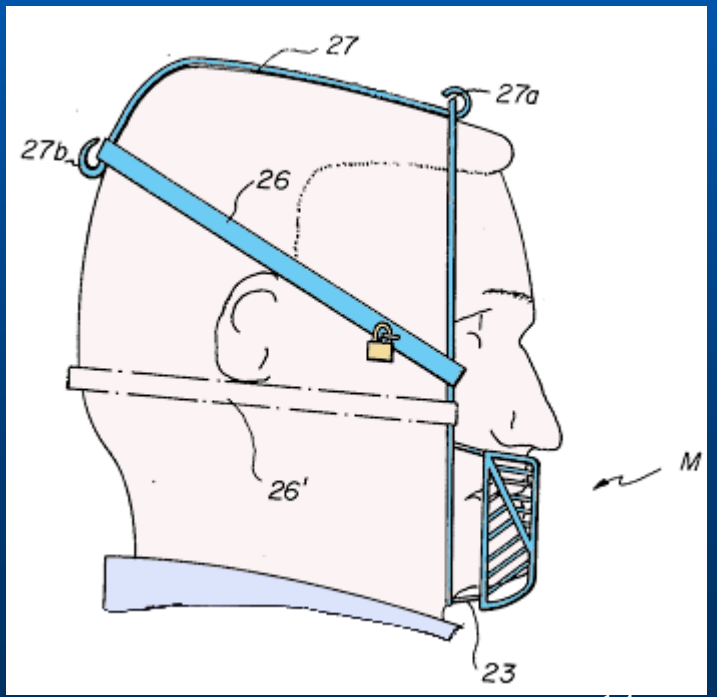
What is Patentable?

Did I say the invention had to be useful?



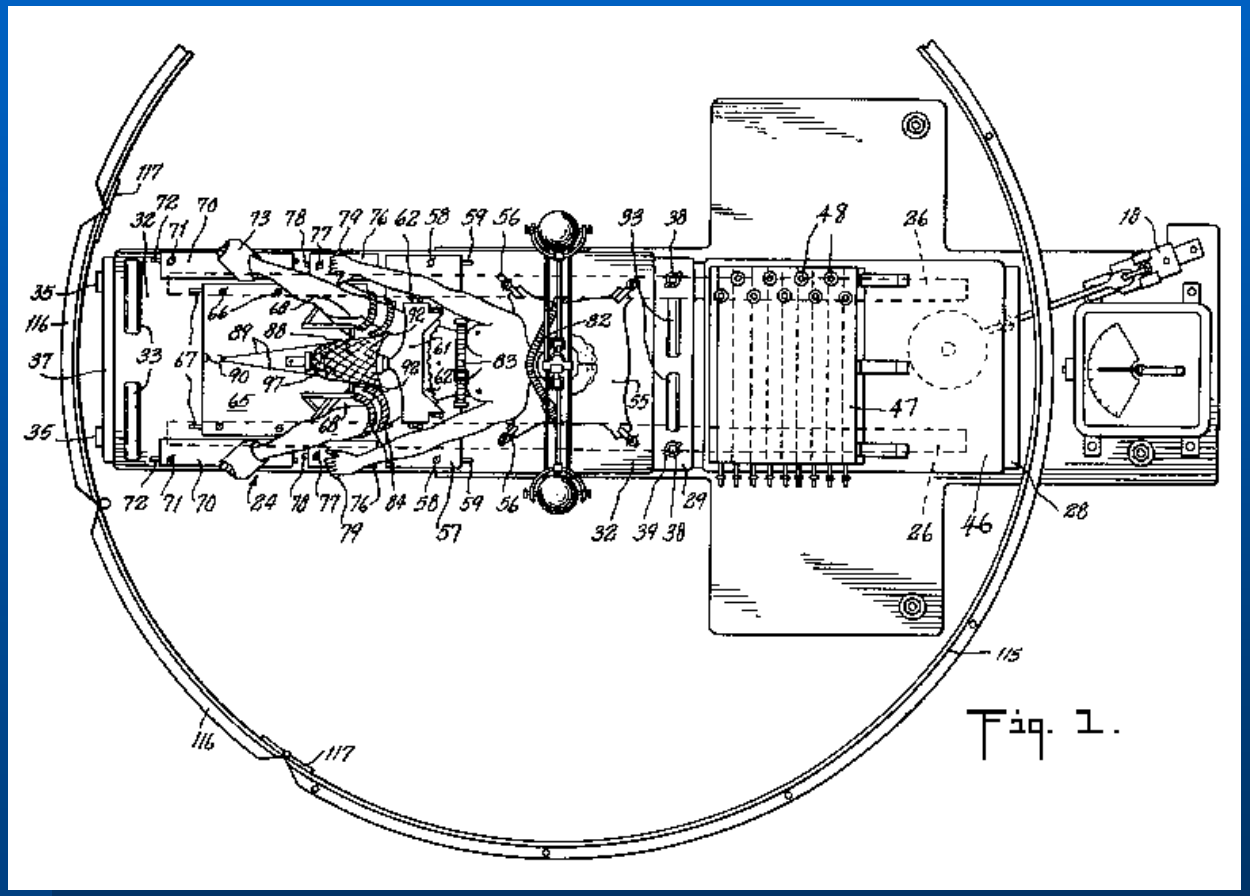
Hurricane Bed

Anti-Eating Mouth Cage



What is Patentable?

Husband and wife inventors!



APPARATUS FOR FACILITATING THE BIRTH OF A CHILD BY CENTRIGUGAL FORCE - Patented November 9, 1965

Confidential Disclosure Agreement

Faculty control dissemination of results

- Creates secrecy obligation
- Prevents loss of patent rights prior to filing!
  - Foreign jurisdiction, no grace period
  - USA, 1 year grace period to file
- Used with all outsiders including academic and corporate collaborators
- Used when disclosing and/or receiving unpublished information
- Brief - 2 pages, very standard terms
- One-way or two-way (mutual)

Material Transfer Agreement

In or out exchange of materials

- Materials are an important form of tangible Intellectual Property
- Protects rights to tangible biological materials (e.g., MAbs, plasmids, KO mice, drugs, etc.)
- Protects rights of academic and corporate researchers (e.g., publication, inventions)
- Limits liability to UMass, researcher
- Brief, 2 pages, very standard terms
- All transfers should use an MTA
- Companies often seek unfair advantage!
- MTAs can be a source of revenue

Material Transfer Agreement

Some important concepts to note!

- Materials are a form of Intellectual Property
  - Per policy: Owned by University or company, not scientist!
- Receiving Materials without a contract (MTA) is a theft of someone's property.
- Use of misappropriated Materials could jeopardize ownership of any resulting inventions.
- Need to stick to proposed research, avoid commercial uses.
- Sharing with others within UMMS may be limited, and may need approval from owner of material.
- Dianne Volpe is the OTM contact person for MTA processing!
- Testing an on-line submission process

Material Transfer Agreement

Horror Stories

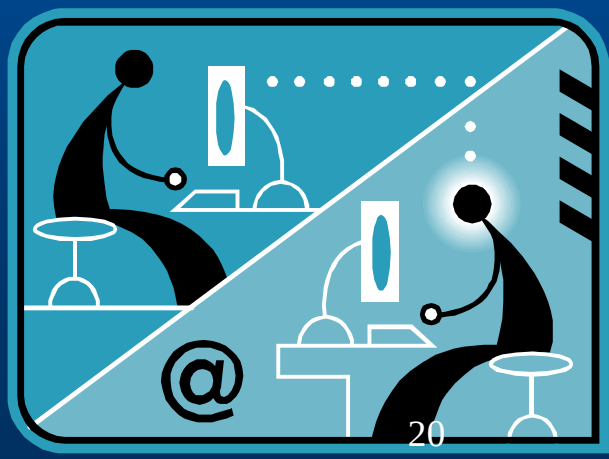
- Examples of problem terms with Companies:
  - agrees to provide antibody provided it gets a no-cost, royalty-free, exclusive license to any inventions.
  - agrees to supply oligos provided it can control patent prosecution.
  - wants to own research results and prevent or limit publication.
  - Wants ownership of any new uses to their material.

- Foreign entities have a take it or leave it attitude
  - Often around indemnification

Research & Service Agreement

Alternative source of research funding

- Fee for Service
  - Is the work routine? Standard protocol?
  - Does it primarily use equipment? E.g., MRI, MS
  - What is the likelihood of inventions from the work?
  - Will the results be publishable?
- Sponsored Research
  - Who's idea was it?
  - Is our scientist designing and directing the research?
  - Is it collaborative with the sponsor?
  - Do we expect to publish the results?
  - Do we anticipate inventions?
  - Is it relying on UMMS IP or proprietary models?
- Collaborative Research
  - Similar questions as sponsored research
  - May not involve financial support
  - May result in joint ownership of inventions.



Sponsored Research Agreement

Alternative source of research funding!

- Non-governmental funding
  - Industry, foundation sponsorship
  - Often collaborative research
- Can be complex agreements
  - Companies have lots of lawyers
  - Sponsors want rights to results
  - Ownership of inventions
  - Option to license IP results
  - Indemnification issues
- OOR approves budget

Sponsored Research Agreement

Get OTM involved early!

- Important considerations
  - Budget & statement of work
  - Indirect Cost rate
    - 70% is full recovery, the real rate!
    - 64% NIH rate is negotiated!
- Contract negotiations
  - Work with OTM/OOR on budget and SOW before discussing with company
  - OTM will try to get full IDC, may have to settle for NIH rate.
  - IDC less than NIH rate, need OOR approval
- Research/department administrators
  - Proposal routing form
  - COI disclosure form

Service Agreements

Routine research or core services

- Core facilities provide services
  - Industry projects help support the cores for our use.
  - Our services may be more economical for smaller companies.
  - Cores have pricing schedules worked out.
- Agreements should be simpler!
  - Legal has produced some standard agreements.
  - Assumes no inventions.
  - Companies may want IP provisions.
  - Option to license IP results.
- Discuss with OTM/OOR if not sure whether it is research or service.

Invention Disclosures

The first step in protecting your IP

- Provide background and description of the invention
  - What are the novel aspects of your invention?
  - What is the commercial use of your invention?
  - What is the stage of your research?
  - Have you published/presented your invention?
- Nothing happens without an Invention Disclosure
  - It documents the date of invention
- You can help – remind faculty, postdocs and students to file ID when preparing grants, papers!
- ID Form can be found at the OTM web site
  - Testing an on-line submission process

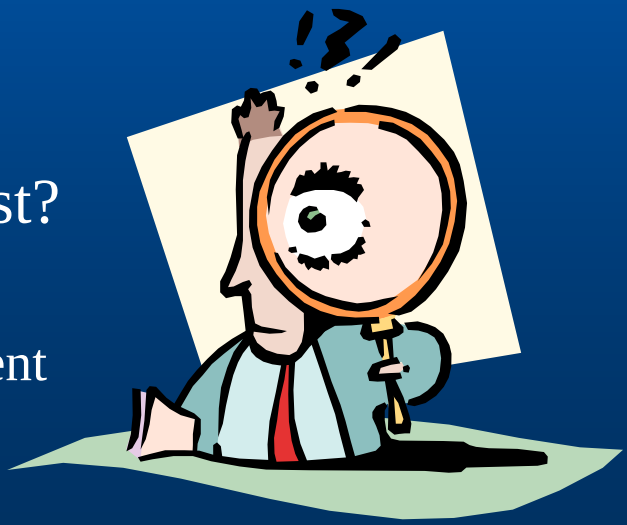
Talk to us

www.umassmed.edu/otm/

Disclosure Review Process

Lots to consider

- Is it good science?
  - Important but not crucial?
- What does the prior art look like?
  - Will we face a difficult prosecution?
  - Are we likely to get commercially valuable claims?
- If we get a patent, will anyone care?
  - Is or will there be any commercial interest?
- Is a patent even necessary?
  - Certain technologies can be licensed without patent protection!
  - Could we police our patent if issued?



Patent Management

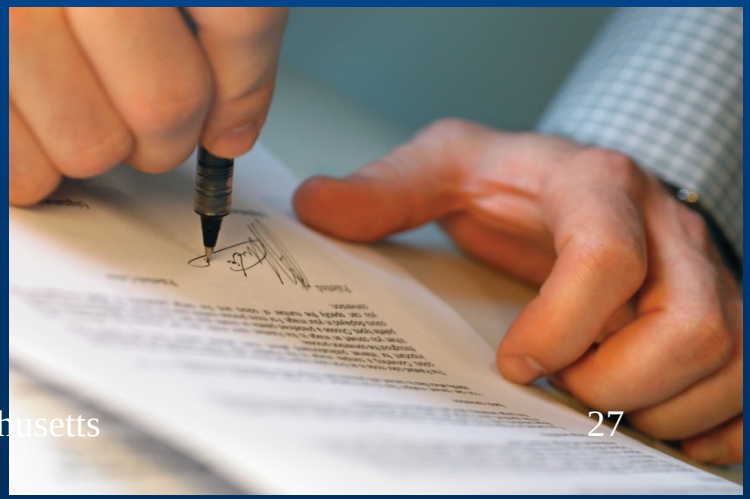
Invention Disclosures to License Agreement

- ID will be reviewed for commercial potential
- Patent application will be prepared & filed
- Invention will be marketed by direct mailings, company contacts, and posting on technology exchange web sites
- OTM will negotiate licenses and close agreements
- OTM will manage relationships with companies following licensing
  - Insuring diligent development efforts

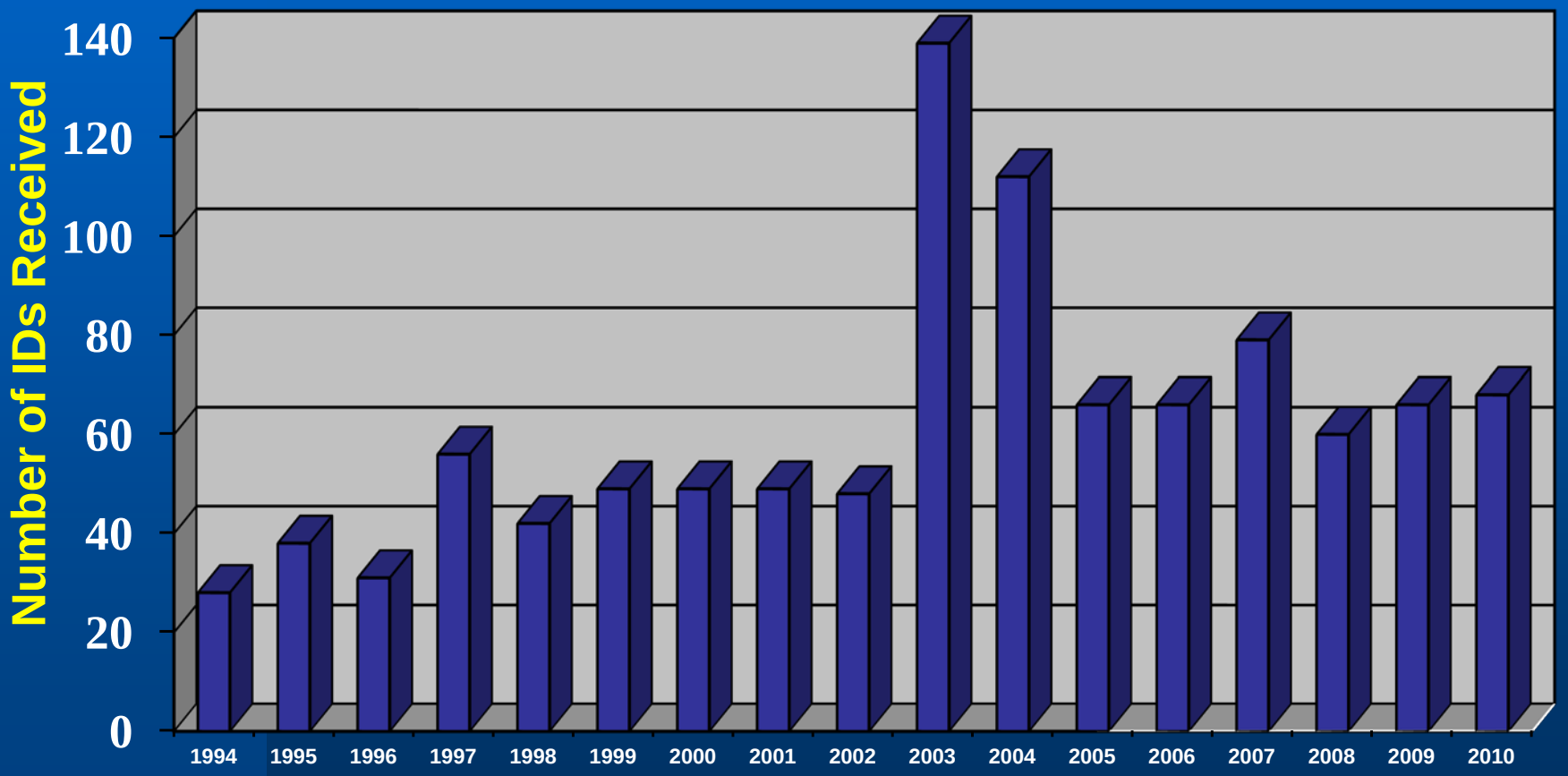
Patent License Agreement

Products, processes and materials

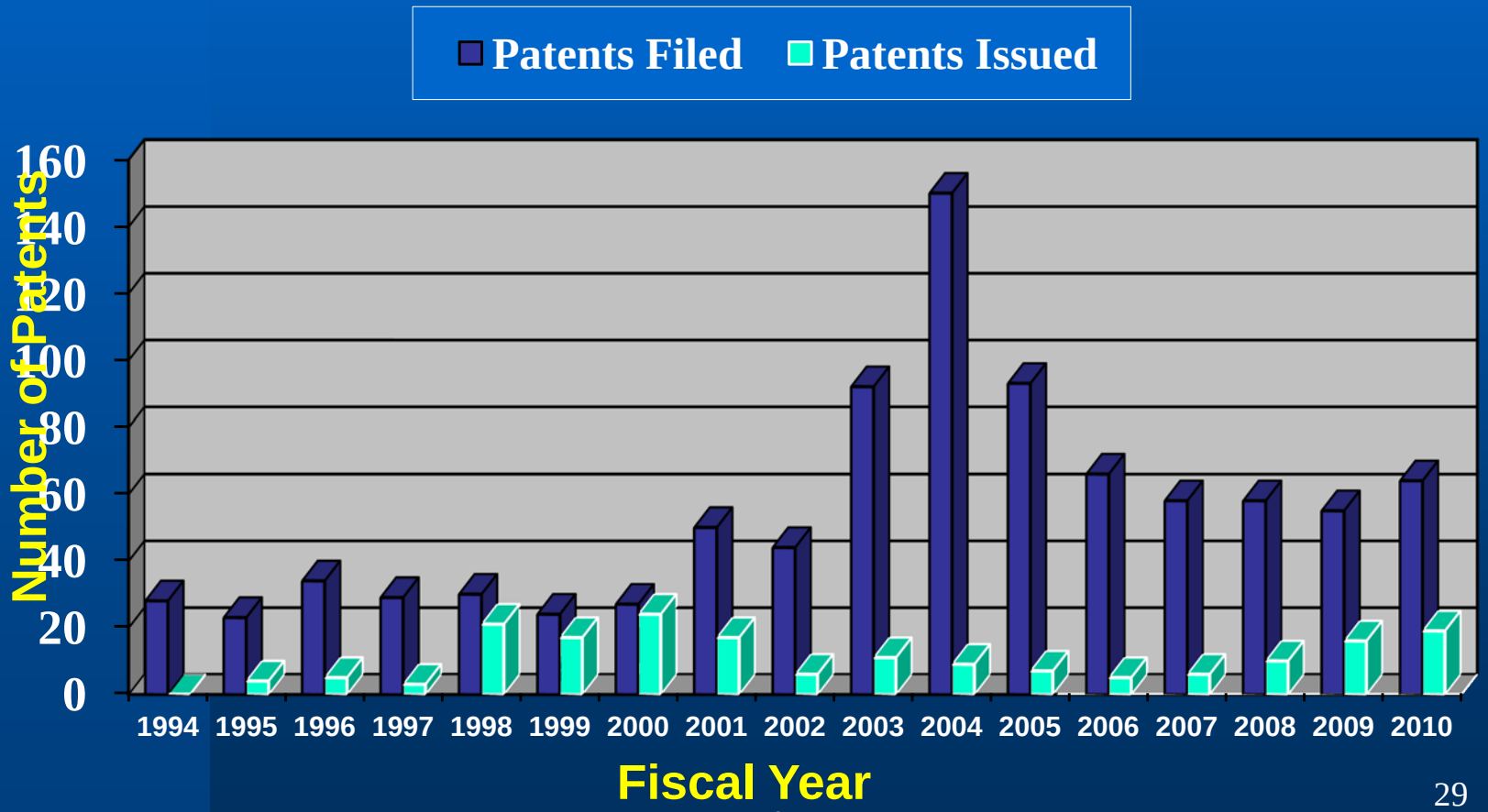
- Patents allow one to prohibit the making, using, or selling the patented invention
- License grants rights to others to practice UMass technology
- Companies commercialize covered products
- Can be complex - 10+ pages
  - Provides Limited Liability/Indemnification
  - Diligent Development
- Can be very lucrative!
- Deals vary
  - Thousands to millions
  - Reagents to drugs



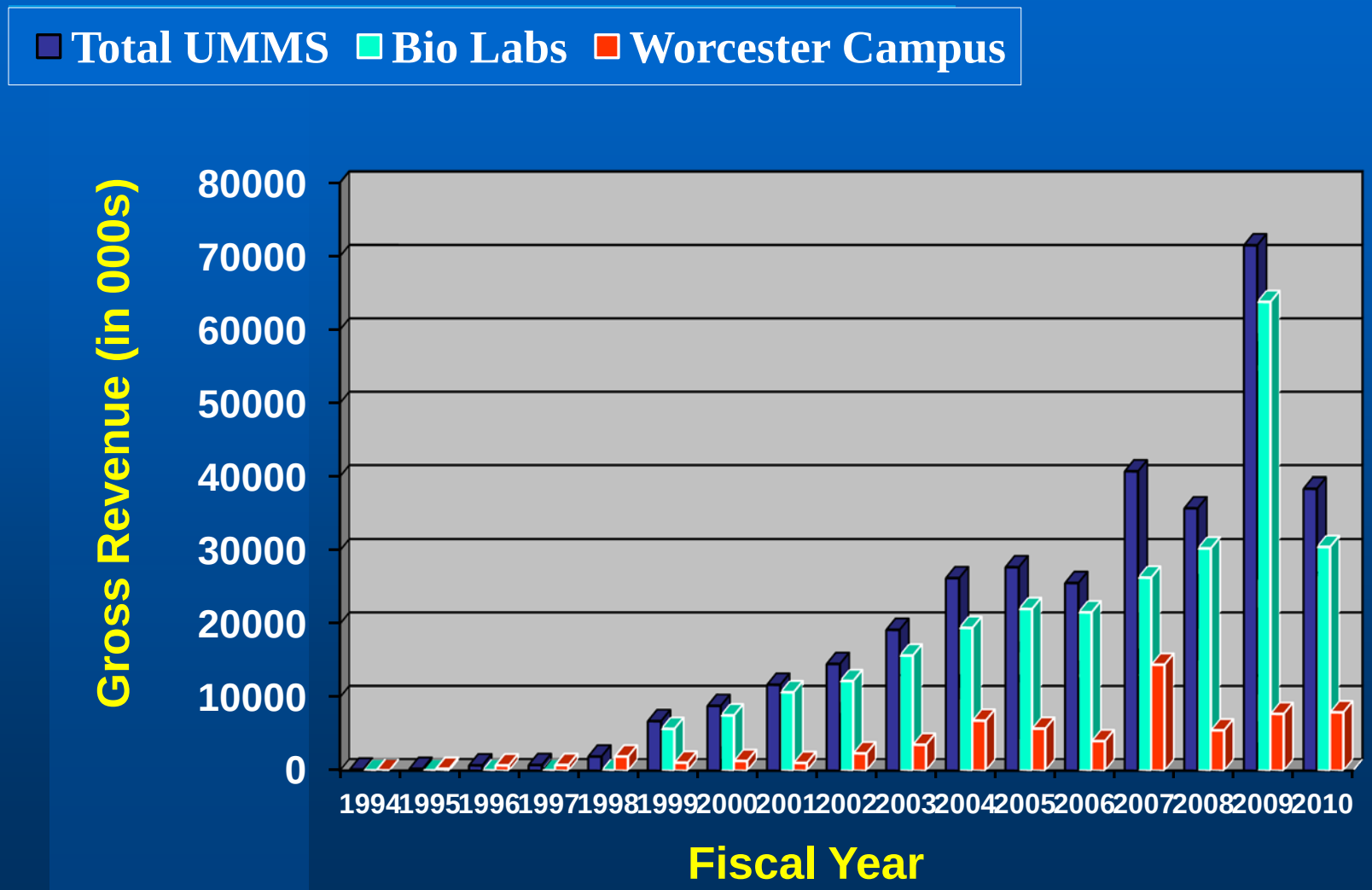
Invention Disclosures Received



Patent Applications



License Revenue at UMMS



IP Policy and Royalty Distribution

The university shares generously

- "Covered Individuals" includes all faculty and staff
- Use of university resources results in UMass ownership
- Inventor/Creator assigns ownership rights to UMMS
- UMass (OTM) commercializes the IP, distributes net income
- 30% of revenue to Inventors
- 70% of revenue to UMass Medical School
  - 15% OTM administration & cost recovery
  - 15% Inventor's department
  - 40% Campus/Chancellor's office

Contact Information

Phone, email, web surf, or visit

http://www.umassmed.edu/otm/

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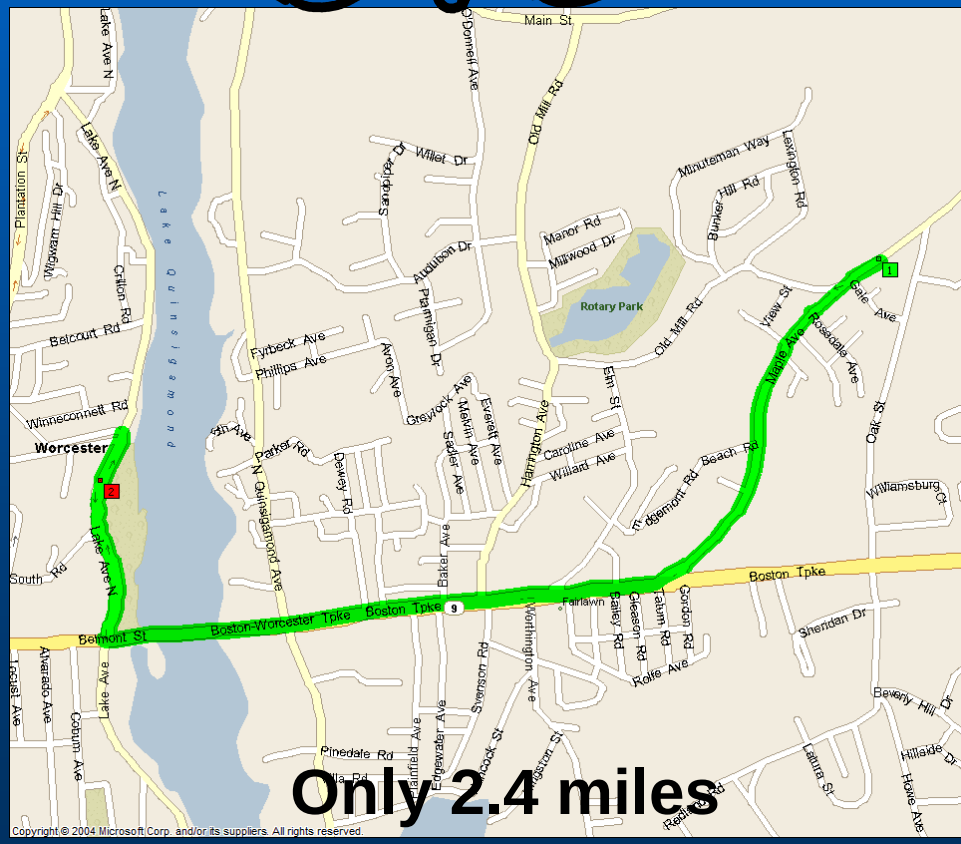

Thank you!

University of Massachusetts
UMASS Medical School

New Financial Conflict of Interest (FCOI) Regulatory Requirements

April 30, 2012

Thoru Pederson, Ph.D., Associate Vice Provost For Research
Elizabeth Delgado Rodriguez, Associate Counsel

FCOI Regulations - Final Rule

- Rule published 8/25/11 revises the regulations on *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*
  - http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf
- Implementation required no later than 365 days after publication of the final rule in the Federal Register, i.e., 8/24/12.
- In the interim:
  - Institutions comply with 1995 regulations, revise policies, establish procedures for compliance, and train Investigators
- New UMMS FCOI policy will go live 8/1/12.

What is the Purpose of the Regulation?

- The regulation is aimed at ensuring that the design, conduct, or reporting of research funded under PHS grants and cooperative agreements will not be biased by any conflicting financial interest of the Investigators responsible for the research.

Major Changes to the 1995 Regulations Include:

- More inclusive definition of Investigator
- Lower financial disclosure thresholds
- New conflict of interest training requirement
- Increased transparency for travel reimbursement
- Detailed information reported to PHS
- Information made accessible to the public

Definition of Investigator

1995

- Anyone involved in the design, conduct, and reporting of the research

2011

- Project Director/Principal Investigator as well as any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which includes subawardees and may include collaborators or consultants

SFI vs. FCOI

- A significant financial interest (SFI) is one that could directly and significantly affect the design, conduct, or reporting of funded research
- A Significant Financial Interest (SFI) is not always an FCOI
- An FCOI exists when a designated Institutional official reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of the funded research

Significant Financial Interests (SFI) Threshold

1995

- De minimis threshold of $10,000 for disclosure generally applies to payments aggregated for the Investigator and the Investigator's spouse and dependent children
- Equity: An equity interest that exceeds $10,000 in value or more than a 5% ownership interest in any single entity

2011

- De minimis threshold of $5,000 for disclosure applies to any remuneration received from the entity aggregated together with the value of any equity interest.
- Includes any equity interest in non-publically traded entities
- The COI threshold for research involving human subjects is $0 and subject to UMMS Human Subjects Guidelines

Which SFIs Need to be Disclosed Once Threshold is Met?

1995

- Only those SFI the Investigator deems related to the PHS-funded research

2011

- All SFI related to the Investigator's institutional responsibilities
- Updates required within 30 days of change or occurrence (travel)

Excluded from Disclosure Requirement

1995

- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; income from service on advisory committees or review panels for public or nonprofit entities
- Combined equity interest for the Investigator, their spouse and dependent children that doesn't exceed $10K in value and doesn't represent more than a 5% ownership interest in any single entity.

2011

- Income from seminars, lectures, or teaching engagements, or service on advisory committees or review panels sponsored by:
  - Federal, state, or local government agencies
  - Institutions of higher education
  - Academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education.
- Income or service for any other type of organization must be reported.

SBIR/STTR Phase I Grants

1995	2011
• Excluded	• Excluded

Intellectual Property (IP)

1995

- Royalties are included among the "payments" subject to the $10,000 threshold.

2011

- The threshold of $5,000 applies to licensed IP rights (e.g., patents, copyrights), royalties from such rights, and agreements to share in royalties related to licensed intellectual property rights.
- When? Upon filing of a patent application or receipt of income related to such rights and interest, whichever comes first.
- Excluded: Unlicensed IP that doesn't generate income; IP rights assigned to the Institution and agreements to share in royalties related to such rights

Travel Reimbursements and Sponsored Travel

1995

- Not included

2011

- Disclose the occurrence of any reimbursed travel or sponsored travel related to institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration).
- NOT required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- Does not require disclosure of the monetary value of the travel . The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

Subrecipients and Reporting of Identified FCOIs

1995

- Institutions must take reasonable steps to ensure Subrecipient Investigators comply with the regulations by requiring those Investigators to comply with the institution's policy, or by providing assurances that will enable the institution to comply

2011

- Include in subaward whether the policy of the prime recipient or that of the subrecipient will apply to and include time periods to meet disclosure and/or reporting requirements
- Subrecipients that rely on their FCOI policy must report identified FCOIs to the prime recipient with sufficient time so the prime can meet NIH reporting obligations.

FCOI Training

1995

- No requirement

2011

- Each Investigator must complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under the following circumstances:
  - If institutional FCOI policies change in a manner that affects Investigator requirements, an Investigator is new to an Institution, an Institution finds an Investigator noncompliant with Institution's FCOI policy or management plan.

Per new regulation, Investigator is defined as: Project Director/Principal Investigator as well as any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which includes subawardees and may include collaborators or consultants.

Public Accessibility Requirement

1995

- No requirement

2011

- Make identified FCOI information via a publicly accessible web site or by a written response to any requestor within 5 business days of a request

- Minimum Information to Provide:
  - Investigator name, title and role
  - Name of the entity in which the SFI is held
  - Nature of the SFI
  - The approximate dollar value of the SFI
  - (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)

Application Date of Final Rule

- No later than August 24, 2012 and immediately upon making the institutional FCOI policy publicly accessible.
- UMMS go live date will be August 1, 2012
- The revised regulations will apply to each grant or cooperative agreement with an issue date on the NOA that is after the go live date and to solicitations issued and research contracts awarded after the go live date.

Office of Extramural Research (OER) Web Site

Return to Financial Conflict of Interest Page

Public FAQs
NIH Staff FAQs

Frequently Asked Questions

Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50 Subpart F) applicable to grants and cooperative agreements (2011 Revised Regulations)

Initial Posting: September 30, 2011
Last Revised: March 21, 2012

The objectivity of research is of paramount importance and the basis for obtaining and maintaining public trust. To address the increasing complexities of the financial interests held by biomedical and behavioral researchers and the resulting interactions among Government, research Institutions, and the private sector, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) published revised regulations on the *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought* and *Responsible Prospective Contractors* (commonly known as the Financial Conflict of Interest (FCOI) regulations). These regulations establish new standards and clarify previously established standards to be followed by Institutions that apply for or receive research funding from PHS Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts. The 2011 revised regulations were written to increase accountability, add transparency, enhance regulatory compliance and effective Institutional management of Investigators' financial conflicts of interest, and strengthen NIH's compliance oversight. The primary goal is to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements and contracts will be free from bias resulting from Investigator financial conflicts of interest.

As part of NIH's continuing efforts to provide useful resources for extramural recipients, we compiled answers to the most frequently asked questions regarding the implementation of the revised regulations for grants and cooperative agreements. The questions are arranged by topic, indicating to whom (Institution and/or Investigator) they pertain. The purpose of the FAQs is to clarify issues that may arise and will assist Institutions as they develop and/or revise an Institution's FCOI policy that meets or exceeds the requirements of the regulation; the FAQs pertain only to grants and cooperative agreements. Questions regarding the applicability and/or compliance with the revised contract regulation provided at 45 CFR Part 94 should be directed to fcoicontracts@mail.nih.gov.

On This Page: I. All Questions

I. All Questions

A. General Questions

B. Administration

C. Applicability

D. Definitions

Investigator)

4. As referenced in the 2011 revised regulation, who are the "senior/key personnel" in NIH-funded research? (Institution and Investigator)
5. Who is considered an "Investigator" for the purpose of this regulation? Is it only the Principal Investigator? (Institution and Investigator)
6. What are "institutional responsibilities?" (Institution and Investigator)
7. What is a "Financial Conflict of Interest?" (Institution and Investigator)
8. What financial interests are covered by the regulation and what is a Significant Financial Interest? (Institution and Investigator)

E. Disclosure

1. How does the definition of Significant Financial Interest under the 2011 revised regulation differ from the 1995 regulatory definition of Significant Financial Interest? (Institution and Investigator)
2. Who is required to disclose financial interests? (Institution and Investigator)
3. What information must the Institution obtain from Investigators and when should it be collected? (Institution and Investigator)
4. What about financial interests acquired or discovered during the award period subsequent to the submission of the initial report? (Institution and Investigator)
5. What about payments to or assets held by my spouse or dependent children? Must these financial interests to be disclosed? (Investigator)
6. How long does an Investigator have to disclose a newly acquired or discovered Significant Financial Interest? (Institution and Investigator)
7. Do I need to disclose salary paid to me by my Institution as an Investigator? (Investigator)
8. Do I need to disclose the occurrence of any reimbursed or sponsored travel related to my institutional responsibilities? (Investigator)
9. Does an Investigator need to disclose all reimbursed or sponsored travel, no matter the dollar level, if it is reimbursed or sponsored by sources other than those excluded from disclosure (i.e., Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education)? (Institution and Investigator)
10. To whom should I disclose my financial interests? (Investigator)
11. When should I disclose my financial interests to the Institution? (Investigator)
12. What happens if my financial interests change during the award period? (Investigator)
13. I am an Investigator in an NIH-supported clinical trial network. My network has developed a study-wide policy for the trial that requires me to disclose my Significant Financial Interests to my network's steering committee/operations office on an annual basis. Do I need to disclose my Significant Financial Interests to my Institution as well? (Investigator)
14. Is income from all non-profit institutions excluded from the definition of Significant Financial Interest? (Institution and Investigator)
15. What must be disclosed when an Investigator is employed by a University and has equity in a for-profit company? (Institution and Investigator)
16. Am I required to disclose interests in mutual funds or retirement accounts? (Institution and Investigator)
17. What about stock and stock options? (Institution and Investigator)
18. Are foreign investments (e.g., shares in a foreign corporation) covered by the financial disclosure requirement? (Institution and Investigator)
19. What about "blind trusts?" Are those included in this final rule? (Institution and Investigator)
20. Is income from royalties subject to this regulation? (Institution and Investigator)
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I. All Questions

A. General Questions

1. **What is the purpose of this regulation? (Institution and Investigator)**
   The 2011 revised regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. This regulation is commonly referred to as the Financial Conflict of Interest (FCOI) regulation. (http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf).

2. **When are Institutions required to comply with the 2011 revised regulation? (Institution)**
   An Institution applying for or receiving NIH funding from a grant or cooperative agreement must be in compliance with all of the revised regulatory requirements no later than 365 days after publication of the regulation in the Federal Register, i.e., August 24, 2012, and immediately upon making the Institution's Financial Conflict of Interest policy publicly accessible as described in 42 CFR part 50.604(a).

3. **How does an Institution signify compliance with the 2011 revised regulation? (Institution)**

   When the Institution posts its Financial Conflict of Interest policy (or, if the institution does

not have a current presence on a publicly accessible Web site, makes the policy publicly accessible by written request), it signifies that the Institution applying for or receiving PHS funding from a grant or cooperative agreement that is covered by the 2011 revised regulation is in full compliance with all the regulatory requirements. The Institution must be in compliance with the 2011 revised regulation no later than August 24, 2012.

4. **Is the 2011 revised regulation retroactive? (Institution)**
No. The revised regulation will apply to each grant or cooperative agreement with an issue date of the Notice of Award that is subsequent to the compliance dates of the final rule (including noncompeting continuations) no later than August 24, 2012 and immediately upon making its Financial Conflict of Interest policy publicly accessible. Through their policies, however, Institutions may choose to apply the revised regulations to all active PHS awards. For example, Institutions may choose, in their Financial Conflict of Interest policy, to implement the regulation on a single date for all PHS-funded awards rather than implementing the regulation sequentially on the specific award date of each individual project.

5. **What is the most significant difference between the 1995 regulation and the 2011 revised regulation? (Institution and Investigator)**

   The 2011 revised regulation includes comprehensive changes, focusing on these areas in particular:

   - Definition of Significant Financial Interest
   - Extent of Investigators' disclosure of information to Institutions regarding their Significant Financial Interests;
   - Institutions' management of identified Financial Conflicts of Interest
   - Information reported to the PHS funding component (e.g., NIH);
   - Information made accessible to the public (i.e., Institutional FCOI policy and FCOIs of senior/key personnel); and
   - Investigator training.

6. **Where can I find additional information? (Institution and Investigator)**

   More information specific to grants and cooperative agreements is available on the Financial Conflict of Interest Web Page of the Grants Policy and Guidance section of the NIH Office of Extramural Research home page (http://grants.nih.gov/grants/policy/coi/index.htm.)

7. **May an Institution have conflict of interest policies that go beyond the regulation (e.g., impose more stringent requirements than those in the regulation)? (Institution and Investigator)**
Yes, as long as the Institution's policies meet the minimum requirements of the PHS regulation. The regulation states the Institution's policy must inform each Investigator of the Institution's policy on Financial Conflict of Interest; of the Investigator's Significant Financial Interest disclosure responsibilities; and of the PHS regulation. If an Institution adopts a policy that includes more restrictive disclosure thresholds than those in the 2011 revised regulation, the Institution must adhere to the requirements of the policy's more restrictive standards. Institutions must report all identified FCOIs to the NIH, including any financial conflicts of interest identified in accordance with the Institution's own more restrictive standards, in the time and manner specified in the regulation (see "Reporting" section for additional information).

8. **I have heard there is a special requirement for clinical research. Is this true? (Institution and Investigator)**
Yes. In any case in which the HHS determines that an NIH-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting

interest that was not managed or reported by the Institution as required by the regulation, the Institution must require the Investigator(s) involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations. Institution's Financial Conflict of Interest policy may have additional requirements.

9. **For how long must Institutions keep records of financial disclosures and any resulting actions under the Institution's policy or following a retrospective review, if applicable? (Institution)**

   Institutional policies must be followed regarding maintenance of records as long as they are in compliance with the PHS regulation. Under the regulation, the Institution is required to keep all records of all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest), and all actions under the Institution's policy or retrospective review, if applicable, as follows:

   - Records of financial disclosures and any resulting action must be maintained by the Institution for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 74.53(b) and 92.42 (b) for different situations.

   NIH expects Institutions to retain records for each competitive segment as provided in the regulation.

10. **What is the purpose of this regulation? (Institution and Investigator)**
    The 2011 revised regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. This regulation is commonly referred to as the Financial Conflict of Interest (FCOI) regulation. (http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf).

B. Administration

1. **Which offices within an Institution should be involved in administering the regulation? (Institution)**
   An Institution may administer its policy through whichever office or structure it chooses as long as the policy is applicable to all Investigators and the policy meets all requirements of the regulation.

2. **What are the responsibilities of the Institution's designated official(s)? (Institution)**

   The Institution's designated official(s) must review all financial disclosures by Investigators and determine whether any Significant Financial Interest is related to a NIH-funded research and a Financial Conflict of Interests exists by making a reasonable determination that the Significant Financial Interest: could be affected by the NIH-funded research or is in an entity whose financial interest could be affected by the research.

3. **Can an Investigator be involved in the designated official(s)'s determination of whether a Significant Financial Interest is related to the NIH-funded research? (Institution and Investigator)**

   Yes. The institution's designated official(s) may involve the Investigator to determine whether the Significant Financial Interest is related to the NIH-funded research. In accordance with the 2011 revised regulation, a Significant Financial Interest is related to the research when the Significant Financial Interest: could be affected by the NIH-funded research; or is in an entity

whose financial interest could be affected by the research.

4. **What actions should be taken in the event that an Investigator fails to comply with the Institution's Financial Conflict of Interest policy or management plan? (Institution)**

   When an Investigator fails to comply with the Institution's Financial Conflict of Interest policy or the management plan, the Institution shall within 120 days:

   a. a) complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine any bias in the design, conduct or reporting of research;
   b. b) document the retrospective review consistent with the regulation; and
   c. c) document the Institution's determination as to whether any NIH-funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with the Institution's Financial Conflict of Interest policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research.

   If bias is found, the Institution shall notify the NIH promptly and submit a mitigation report to the NIH that shall address the following:

   - impact of the bias on the research project and
   - the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.

   Thereafter, the Institution shall submit FCOI reports annually, in accordance with the regulation. Depending on the nature of the Financial Conflict of Interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date that the Financial Conflict of Interest is identified and the completion of the Institution's independent retrospective review, in accordance with 42 CFR 50.605(a)(3) and 42 CFR 50.605(b)(3).

   In addition, if the NIH determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

5. **What does "prior to the Institution's expenditure of any funds" mean as provided at 42 CFR Part 50.605? (Institution)**

   After NIH issues a grant or cooperative agreement award, "prior to the Institution's expenditure of any funds" is the period of time before an expense is recorded in the official records of the Institution.

6. **What are the penalties/fines for failure to comply with the 2011 revised regulation? (Institution)**

   The FCOI regulation (42 CFR Part 50 Subpart F) does not include a "fine structure" for noncompliance. However, Section 50.604 (j) requires Institutions to establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate. In addition, Section 50.506 permits NIH to take appropriate action or direct the Institution to take action to maintain appropriate objectivity in Public Health Service-funded research.

   In addition, the NIH Grants Policy Statement (GPS) (10-1-2011) (http://grants.nih.gov/grants/policy/nihgps_2011/index.htm), which serves as a term and condition of all NIH awards, provides information in chapter 8.5 Special Award Conditions and Enforcement Actions on actions NIH may take in those situations when a grantee fails to comply with the terms and conditions of award

(http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch8.htm#_Toc271264977).

Depending on the severity and duration of the noncompliance, NIH may to take one or more actions. For example, NIH may impose special conditions on a grant to allow the grantee to take corrective action. In addition, if a grantee has failed to materially comply with the terms and conditions of award, NIH may take action to wholly or partly suspend the grant, pending corrective action, or may terminate the grant. The regulatory procedures that pertains to suspension and termination are specified in 45 CFR parts 74.61 and 74.62, and in part 92.43.

7. **How would an Institution pay for expenses related to a retrospective review? (Institution)**

   The cost of implementing the amended regulations, including the cost to conduct a retrospective review, is an allowable cost that may be eligible for reimbursement as a Facilities and Administrative cost on Public Health Service supported grants and cooperative agreements.

C. Applicability

1. **Who is covered by the regulation? (Institution and Investigator)**
   The regulation is applicable to each Institution that is applying for, or that receives, NIH research funding by means of a grant or cooperative agreement and, through the implementation of the regulation by the Institution, to each Investigator who is planning to participate in, or is participating in, such research. The regulation, however, does not apply to Phase I Small Business Innovative Research or Small Business Technology Transfer applications. For purposes of financial disclosure only, the regulation covers the Investigator's spouse and dependent children. The regulation also applies to those few cases where an individual, rather than an Institution, is applying for or receives NIH research funding. However, in those cases, the NIH will make case-by-case determinations on the steps an Institution or an Investigator must take, consistent with the regulation, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from a Financial Conflict of Interest of the individual.

2. **Does this regulation apply to all grants and cooperative agreements awarded by the NIH? (Institution and Investigator)**
   No. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) Small Business Technology Transfer (STTR) applications. The regulation applies to research and includes any activity for which research funding is available from the NIH through a grant or cooperative agreement. The regulation explicitly applies to research authorized under the PHS Act or other statutory authority, such as a research grant, career development grant, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

3. **Does the regulation apply to conference grants (R13 and U13 award mechanisms) in support of sponsored and directed international, national, or regional meetings, conferences and workshops? (Institution and Investigator)**
   Yes. The regulation defines "Research" as any such activity (described at 42 CFR 50.603) for which research funding is available from a PHS Awarding Component (e.g., NIH) through a grant or cooperative agreement. The definition of the term "Research" provides a non-exhaustive list of examples of the different types of NIH-funding mechanisms to which the regulation applies such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Institutional training grant, program project, or research resources award. The only award programs that are excluded from the regulation are the Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) Phase I applications.

4. **Does the regulation apply to an S06 (Minority Biomedical Research Support) or other "S"**

award mechanisms? (Institution and Investigator)
Yes. The regulation defines "Research" as any such activity (described at 42 CFR 50.603) for which research funding is available from a PHS Awarding Component (e.g., NIH) through a grant or cooperative agreement. The definition of the term "Research" provides a non-exhaustive list of examples of the different types of NIH-funding mechanisms to which the regulation applies such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Institutional training grant, program project, or research resources award. The only award programs that are excluded from the regulation are the Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Phase I applications.

5. **Does the regulation apply to subrecipients, subgrantees and collaborators (e.g., subcontractors or consortium members)? (Institution)**

   Yes. The 2011 revised regulation is applicable to each Institution that applies for or receives NIH funding for research through grants or cooperative agreements and, through the implementation of the regulation by each Institution, to each Investigator planning to participate in, or participating in, such research. A subrecipient relationship is established when federal funds flow down from or through an awardee Institution to another individual or entity and the subrecipient will be conducting a substantive portion of the NIH-funded research project and is accountable to the awardee institution for programmatic outcomes and compliance matters. Accordingly, as a recipient of federal funds from an awardee Institution, the Financial Conflict of Interest regulation applies to subrecipients (e.g., subcontractors or consortium members). See 42 CFR 50.604 (c).

6. **I am a collaborator/consultant/subgrantee/subcontractor/subrecipient performing research funded by the NIH but am not employed directly by the Institution that received the award. Does this regulation apply to me? (Investigator)**
   Yes. If you meet the definition of an "Investigator," the PHS regulation applies to you. The awardee institution is required to incorporate as part of a written agreement with the subrecipient terms that establish whether the Financial Conflict of Interest policy of the awardee Institution or that of the subrecipient apply to the subrecipient's Investigators. Please consult the appropriate Institutional official or the written agreement to determine which policy applies.

7. **I am a post-doctoral fellow receiving funding from the NIH. Does this regulation apply to me? (Investigator)**
   Yes. If you meet the definition of an "Investigator," the PHS regulation applies to you. The regulation is applicable to each Institution that applies for or receives NIH grant awards or cooperative agreements for research and, through the implementation of the regulation by each Institution, to each Investigator who is planning to participate in, or is participating in such research. As noted above, an Investigator is defined as the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding. Thus, if a post-doctoral fellow meets the definition of an Investigator, he or she would be subject to the regulation if the NIH funding is for research. You should consult with your Institution's designated official(s) to ensure you comply with the appropriate requirements.

8. **I am a graduate student working on research funded by the NIH. Am I subject to the requirements of the Financial Conflict of Interest regulation? (Investigator)**
   Yes. If you meet the definition of an "Investigator," the PHS regulation applies to you. As stated above, the term "Investigator" is defined to encompass individuals "responsible for the design, conduct or reporting" of research funded by the NIH. Be sure to confirm with your Institutional designated official(s) whether you, as a graduate student, meet this definition.

9. **I have heard about the financial disclosure requirements imposed by the Ethics in Government Act for Investigators employed at the NIH. Do these regulations apply to me? (Institution and Investigator)**

No. The Financial Conflict of Interest regulation discussed in this FAQ document (42 CFR Part 50 Subpart F) is distinct from the ethics rules that apply to NIH employees.

10. **Do these new regulations apply to all Federal funding, or only funding from NIH? (Institution)**

    As noted in Section 50.602 of the regulation, the Final Rule applies to Institutions that apply for, or that receive Public Health Service (PHS) research funding by means of a grant or cooperative agreement. Section 50.603 defines "PHS", "PHS Awarding Component" and "Research" as follows:

    > PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
    >
    > PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.
    >
    > Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (*e.g.,* a published article, book or book chapter) and product development (*e.g.,* a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

    Therefore, this regulation applies to institutions that receive Federal funding for research by a PHS Awarding Component. The NIH is a PHS Awarding Component. Institutions should contact the applicable PHS Awarding Component to determine whether the 2011 revised regulation applies to a PHS-funded award.

D. Definitions

1. **What is the Public Health Service? (Institution and Investigator)**
   PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the NIH.

2. **For purposes of the Financial Conflict of Interest regulation, what is an "Institution?" (Institution and Investigator)**
   Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives NIH research funding.

3. **What is an "Entity" as used in the Financial Conflict of Interest regulation? (Institution and Investigator)**

   Entity means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

4. **As referenced in the 2011 revised regulation, who are the "senior/key personnel" in NIH-funded research? (Institution and Investigator)**
   Senior/Key Personnel means the Project Director/Principal Investigator (PD/PI) and any other person *identified* as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under the regulation.

5. **Who is considered an "Investigator" for the purpose of this regulation? Is it only the Principal Investigator? (Institution and Investigator)**

   No. "Investigator" means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk is that an unidentified FCOI may compromise the research enterprise increases.

   In addition, the Investigator's spouse and dependent children have been eliminated from the definition of "Investigator" under the 2011 revised regulation; however, they are referenced in the definition of "Significant Financial Interest" because the Investigator must also disclosure Significant Financial Interests of his/her spouse and dependent children. (see definition of Significant Financial Interest).

6. **What are "institutional responsibilities?" (Institution and Investigator)**
   "Institutional responsibilities" are defined by the 2011 revised regulation as an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on Financial Conflict of Interest, which may include, for example, activities such as research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards. The Institution can include other professional responsibilities within the definition, as appropriate.

7. **What is a "Financial Conflict of Interest?" (Institution and Investigator)**
   A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

8. **What financial interests are covered by the regulation and what is a Significant Financial Interest? (Institution and Investigator)**

   The regulation covers all financial interests that have monetary value, whether or not the value is readily ascertainable.

   The 2011 revised regulation defines a "Significant Financial Interest" as follows:

   > "(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
   >
   > (i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
   >
   > (ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education."

The Institution may have more stringent financial disclosure requirements. Please refer to the Institution's conflict of interest policy and confer with the Institution's designated official(s) to determine the Institution's disclosure requirements.

E. Disclosure

1. **How does the definition of Significant Financial Interest under the 2011 revised regulation differ from the 1995 regulatory definition of Significant Financial Interest? (Institution and Investigator)**

   The definition of Significant Financial Interest under the 2011 revised regulation differs from the 1995 definition of Significant Financial Interest in a number of respects.

   - *Institutional responsibilities:*

     Under the 2011 FCOI regulation, Significant Financial Interests that are subject to disclosure by an Investigator to an Institution are those that reasonably appear to be related to the Investigator's "Institutional responsibilities," as defined by the Institution. As a result, when read in conjunction with the revised Investigator disclosure requirements under 42 CFR 50.604, the revised Significant Financial Interest definition results in the disclosure by Investigators to Institutions of a wider array of interests on a more frequent basis. In addition to their own, Investigators are required to disclose the Significant Financial Interests of his/her spouse and dependent children.

Under the 1995 regulation, Investigators were required to disclose their Significant Financial Interests related to their PHS-funded research.

- *Monetary threshold:*

  The 2011 Significant Financial Interest definition lowers the de minimis threshold to $5,000 and, in some circumstances, eliminates the existing monetary thresholds for disclosure.

  Under the 1995 FCOI regulation, a Significant Financial Interest did not include an equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, met both of the following tests: Did not exceed $10,000 in value and did not represent more than a five percent (5%) ownership interest in any single entity. Similarly, a Significant Financial Interest did not include payments (*e.g.,* salary) that, when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, were not expected to exceed $10,000.

  The 2011 definition also differentiates between remuneration to the Investigator (and the Investigator's spouse and dependent children) from a publicly traded entity and remuneration from a non-publicly traded entity. With regard to a publicly traded entity, a monetary threshold of $5,000 applies to the aggregated amount of any remuneration received from the entity in the twelve months preceding disclosure and the value of any equity interest as of the date of disclosure. With regard to a non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

- *Timing:*

  The revised Significant Financial Interest definition changes the timing for determining whether remuneration represents a Significant Financial Interest.

  The 1995 regulation excluded aggregated payments (including salary and royalties) that were "not expected to exceed" the monetary threshold "over the next twelve months."

  Under the 2011 definition, at issue is any remuneration received from an entity "in the twelve months preceding the disclosure and the value of any publicly traded equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000."

- *Examples of payment for services:*

  The 1995 definition referenced as examples of payments for services receipt of consulting fees or honoraria.

  The 2011 revised regulation adds "paid authorship" as an additional example of payment for services.

- *Royalties & Intellectual Property:*

  Under the 1995 regulation, royalties were subject to the $10,000 threshold if not received from the applicant institution.

  Under the 2011 revised regulation, the preamble clarifies that a threshold of $5,000 applies to licensed intellectual property rights (e.g., patents, copyrights), royalties from such rights, and agreements to share in royalties related to licensed intellectual property rights (see page 53265.) However, intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights are still excluded from the

Significant Financial Interest definition.

- *Reimbursed or Sponsored Travel:*

  Under the 1995 regulation, there was no specific requirement to disclose reimbursed or sponsored travel.

  Under the 2011 revised regulation, and with the express exceptions noted therein, Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's institutional responsibilities as prescribed by the Institution's Financial Conflict of Interest (FCOI) policy (i.e., specify the details of the disclosure which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration). The institutional official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with PHS-funded research. This disclosure is addressed in the definition of "Significant Financial Interest," (SFI) which makes it subject to the following considerations:

  (1) Investigators who are planning to participate in PHS-funded research must disclose their SFIs over the previous twelve-month period to their Institution no later than at the time of application for PHS-funded research.

  (2) Each Investigator who is participating in PHS-funded research must submit an updated disclosure of SFIs at least annually, in accordance with the specific time period prescribed by the Institution, during the period of award.

  (3) Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFIs within 30 days of discovering or acquiring a new SFI.

- *Exclusions:*

  The 2011 revised regulation modifies the types of interests that are specifically excluded from the Significant Financial Interest definition. The exclusions are:

  - salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
  - intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights
  - any ownership interests in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization
  - income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
  - income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined in 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
  - income from service on advisory committees or review panels for a federal, state, or local government agency, or an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Unlike in the 1995 Financial Conflict of Interest regulation, income from non-profit entities other than federal, state, or local government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes that are affiliated with an Institution of higher education for the types of activities described above would be subject to the Significant Financial Interest definition.

In addition, the SBIR/STTR applicant exclusion under the 1995 regulation was broadened to include any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization (whether or not an SBIR/STTR applicant).

2. **Who is required to disclose financial interests? (Institution and Investigator)**
Under the 2011 revised regulation, Investigators (as defined by the regulation) who are planning to participate in, or are participating in, NIH-funded research, with the exception of Phase I SBIR/STTR applications, are required to disclose to the designated official(s) of the Institution a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.

3. **What information must the Institution obtain from Investigators and when should it be collected? (Institution and Investigator)**

   Under the 2011 revised regulation, Investigators are required to disclose their Significant Financial Interests (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities:

   (1) no later than at the time of application for NIH-funded research;

   (2) within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest; and

   (3) at least annually, in accordance with the specific time period prescribed by the Institution, during the period of award.

4. **What about financial interests acquired or discovered during the award period subsequent to the submission of the initial report? (Institution and Investigator)**
Investigators have an ongoing obligation to disclose Significant Financial Interests throughout the awarded project period. Under the 2011 revised Financial Conflict of Interest regulation, Investigators must update financial disclosures of Significant Financial Interests to their Institutions within thirty (30) days of acquiring or discovering (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest. The Institution's designated official(s) will have sixty (60) days to review the Significant Financial Interest disclosure, determine whether the Significant Financial Interest is related to NIH-funded research, determine whether a Financial Conflict of Interest exists, and if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage the Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institution must submit an FCOI report to the NIH within this same 60-day period.

5. **What about payments to or assets held by my spouse or dependent children? Must these financial interests to be disclosed? (Investigator)**
Yes. Please see the question on the definition of "Significant Financial Interests." The financial interests that must be disclosed by the Investigator include the aggregated amounts or values of financial interests held by the Investigator and his/her spouse and dependent children.

6. **How long does an Investigator have to disclose a newly acquired or discovered Significant Financial Interest? (Institution and Investigator)**

   Under the 2011 revised regulation, each Investigator who is participating in the NIH-funded research must submit to his/her Institution an updated disclosure of Significant Financial

Interests within thirty (30) days of acquiring or discovering a new Significant Financial Interest or a Significant Financial Interest that was not disclosed timely.

7. **Do I need to disclose salary paid to me by my Institution as an Investigator? (Investigator)**
   No. Salary, royalties, or other remuneration from your employing or appointing Institution is not included.

8. **Do I need to disclose the occurrence of any reimbursed or sponsored travel related to my institutional responsibilities? (Investigator)**

   Yes. The regulation requires Investigators to disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the Investigator's institutional responsibilities. However, the disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

   - a federal, state, or local government agency,
   - an Institution of higher education as defined at 20 U.S.C. 1001(a),
   - an academic teaching hospital,
   - a medical center, or
   - a research institute that is affiliated with an Institution of higher education.

   Check with your Institution's FCOI policy since it will specify the details of this disclosure, which will include, at a minimum, the following:

   - purpose of the trip,
   - the identity of the sponsor/organizer
   - the destination, and
   - the duration.

   In addition, the Institution's FCOI policy may also determine if additional information is needed, such as a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest with the NIH-funded research.

9. **Does an Investigator need to disclose all reimbursed or sponsored travel, no matter the dollar level, if it is reimbursed or sponsored by sources other than those excluded from disclosure (i.e., Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education)? (Institution and Investigator)**

   Yes. The 2011 revised regulation does not provide a de minimis threshold for the disclosure of reimbursed or sponsored travel. The 2011 revised regulation requires disclosure of basic information about such travel including at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration but not including the dollar amount. As provided in the regulation, the Institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research. The regulation does not specify the process to be used by Institutions for review of Investigator travel disclosures; however, the Institution is responsible for determining whether such travel constitutes a Financial Conflict of Interest with PHS-funded research. Travel to scientific meetings and to present Investigator's research to colleagues and other interested parties is an integral part of the scientific research enterprise and affords many important opportunities for forging relationships and collaborations among researchers. The provisions in the revised regulations are not intended to discourage this type of travel but require the disclosure of the occurrence

of any reimbursed or sponsored travel related to the Investigator's institutional responsibilities provided the travel is not sponsored or reimbursed by those identified sources excluded in the final rule.

10. **To whom should I disclose my financial interests? (Investigator)**
Your Institution will designate an Institutional official(s) to solicit and review financial disclosure statements. Please consult your Institution's conflict of interest policy and procedures and/or your Institution's designated official(s) for more information about the disclosure requirements and procedures at your Institution.

11. **When should I disclose my financial interests to the Institution? (Investigator)**
Please refer to your Institution's conflict of interest policy. In accordance with the 2011 revised regulation, Significant Financial Interests must be disclosed to the Institutional designated official(s) by the time an application is submitted to the NIH for funding, within thirty (30) days of discovering or acquiring a new Significant Financial Interest, and on an annual basis at intervals thereafter to be determined by your Institution.

12. **What happens if my financial interests change during the award period? (Investigator)**
The 2011 revised regulation requires each Investigator who is participating in NIH-funded research to submit an updated disclosure of Significant Financial Interest to the Institution's designated official(s) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest. Be sure to check with your Institutional policy since the policy may have a more restrictive reporting requirement. The Institution's designated official(s) are required to review the updated financial disclosure of Significant Financial Interest, determine whether the Significant Financial Interest is related to the NIH-funded research and, if so related, whether the Significant Financial Interest is a Financial Conflict of Interest and take appropriate action to manage any Financial Conflict of Interests and report such FCOI(s) to NIH.

13. **I am an Investigator in an NIH-supported clinical trial network. My network has developed a study-wide policy for the trial that requires me to disclose my Significant Financial Interests to my network's steering committee/operations office on an annual basis. Do I need to disclose my Significant Financial Interests to my Institution as well? (Investigator)**
Reporting your Significant Financial Interests to a steering committee or other entity overseeing an NIH-supported clinical trial may not fulfill your responsibilities under your Institution's Financial Conflict of Interest policy. If you are an Investigator as defined by the regulation an NIH-supported grant award, then you must disclose your Significant Financial Interests to your Institution in accordance with its Financial Conflict of Interest policy. Please refer to your Institution's policy (which may integrate network disclosures) and/or consult the appropriate Institutional designated official(s) to verify your Institution's disclosure requirements and how they apply to your research.

14. **Is income from all non-profit institutions excluded from the definition of Significant Financial Interest? (Institution and Investigator)**

No. The 2011 revised regulation states that income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education is excluded from the definition of Significant Financial Interest. Such income from all other sources is included in the definition of Significant Financial Interest and, accordingly, must be disclosed.

15. **What must be disclosed when an Investigator is employed by a University and has equity in a for-profit company? (Institution and Investigator)**
It depends. If the Investigator is supported by a NIH grant through the University (i.e., the University is the grantee), the Investigator must disclose the equity interest in the for-profit

company to the University if the Significant Financial Interest is related to the Investigator's institutional responsibilities. If the Investigator is supported by a NIH grant through a for-profit company (i.e., the for-profit company is the grantee), the Investigator would not need to disclose the equity interest to the University or the for-profit company because (1) the University is not the grantee, and (2) an ownership interest held by an Investigator in a commercial or for-profit organization is excluded from disclosure. The disclosure of equity interest would only be excluded in those cases when the for-profit company is the Institution that is applying for, or that receives, NIH research funding.

16. **Am I required to disclose interests in mutual funds or retirement accounts? (Institution and Investigator)**
Maybe. The 2011 revised regulation does not require the disclosure of income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles. Please refer to your Institution's Financial Conflict of Interest policy for disclosure requirements for mutual funds since the Institutional policy may be more restrictive.

17. **What about stock and stock options? (Institution and Investigator)**
Please refer to your Institution's Financial Conflict of Interest policy. Stock option assets are to be reported by the time an application for funding is submitted, and then reported annually or as new stocks are obtained, in the same manner as all other assets. The documentation needed to determine the value of a stock option is defined by the Institution.

18. **Are foreign investments (e.g., shares in a foreign corporation) covered by the financial disclosure requirement? (Institution and Investigator)**
Maybe. Financial interests are defined as anything of monetary value, whether or not the value is readily ascertainable. Any financial interest that meets the definition of Significant Financial Interest under the regulation must be disclosed. Foreign investments are covered financial interests under the regulation, if the investments satisfy the definition of Significant Financial Interest. The Investigator must disclose Significant Financial Interests (and those of the Investigator's spouse and dependent children). Disclosure requirements and the documentation needed to determine the value of foreign investments should be defined by the Institution's Financial Conflict of Interest policy and procedures.

19. **What about "blind trusts?" Are those included in this final rule? (Institution and Investigator)**
Please refer to your Institution's Financial Conflict of Interest policy. Institutions may determine that the research will not be affected by qualified blind trust assets not known to the Investigator that are managed by an independent fiduciary. Because such assets would not be known to an Investigator, an Institution might determine that they could not directly and significantly affect the design, conduct or reporting of the research. Of course, an Investigator is aware of the assets originally placed in the trust at the time of its formation and would be required to disclose any such assets that would reasonably appear to be related to his/her institutional responsibilities. The Institution may determine that only new assets purchased with the proceeds from the original assets would be unknown to the Investigator.

20. **Is income from royalties subject to this regulation? (Institution and Investigator)**

It depends. Financial interests are defined as anything of monetary value, whether or not the value is readily ascertainable. Royalties are potentially subject to disclosure, as are other interests related to intellectual property. Royalties from and agreements to share in royalties related to intellectual property rights paid to an Investigator (or his/her spouse or dependent children) are covered by the regulation and are subject to the $5,000 threshold as described in the preamble (page 53265). If the royalties paid to the Investigator (or his/her spouse and dependent children) satisfy the definition of "Significant Financial Interest," then they must be disclosed. However, if the royalties or agreement to share in royalties relate to intellectual property owned by the employing or appointing applicant or awardee Institution and are licensed or potentially licensed through the applicant or awardee Institution (i.e., they are not

personally owned by the Investigator), they are considered remuneration from the Institution and would not be considered a Significant Financial Interest of the Investigator. Royalties received by the Investigator from the Institution would be excluded from the definition of Significant Financial Interest if the Investigator is currently employed or otherwise appointed by the Institution.

Unlicensed intellectual property that does not generate income is also excluded from the definition of Signficant Financial Interest. Nonetheless, such interests have the potential to become significant and generate income, at which point they would become subject to the regulation. Disclosure requirements and the documentation needed to verify the value of royalties or agreements to share in royalties should be defined by the Institution's Financial Conflict of Interest policy and procedures. (See definition of Significant Financial Interest).

21. **Is an Investigator required to disclose all financial interests received from a foreign Institution of higher education or the government of another country? (Institution and Investigator)**

    Yes. In each case when the regulation refers to exclusions of higher education as defined in 20 U.S.C. 1001(a) or a federal, state or local government agency, the reference is made to a United States (U.S.) Institution of higher education or a federal, state or local government agency within the U.S.

22. **Does an individual who participates as a subrecipient "Investigator" under a Phase I SBIR/STTR award need to disclose his/her significant financial interest to his/her Institution (e.g., University)? (Institution and Investigator)**

    It depends. The requirement for an Investigator to disclose his/her significant financial interest (SFI) depends upon if the Investigator, at the subrecipient Institution, is a Public Health Service (PHS)-supported Investigator. If the subrecipient Investigator does not receive PHS funding, the Investigator would not be required to disclose his/her SFI to their Institution (e.g., University) unless it was a requirement of the Institution (e.g., University's FCOI policy).

    On the other hand, if the subrecipient Investigator is a PHS-funded Investigator, he/she must disclose his/her SFI in accordance with the 2011 Revised FCOI regulation.

23. **Does the regulation require the Investigator to keep up with day-to-day changes in value of publicly traded stock or other similar interests with fluctuating value? (Institution and Investigator)**

    No. Generally, the annual disclosure requirement will be sufficient to allow the Investigator to disclose updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

24. **Under the 2011 revised regulation, is an institution able to prescribe certain details of the Investigator's disclosure of sponsored or reimbursed travel? (Institution and Investigator)**

    Yes. In recognition of the different needs and resources of the diverse Institutions funded by the PHS, the regulation seeks to maximize Institutions' flexibility and minimize administrative burden by deferring to the Institutions' FCOI policies to prescribe the details of the Investigator's disclosure of sponsored or reimbursed travel and the protocol that Institutions should use to review Investigators' sponsored or reimbursed travel disclosures, as long as such details and protocol are consistent with the regulation. The following are several illustrations of how the Institution may "prescribe the details of disclosure" in its FCOI policy:

    a. Institutions may prescribe the timing of disclosures.

    The 2011 revised regulation requires that Investigators submit an updated disclosure of SFIs at least annually, as prescribed by the Institution, during the period of award. Annual updated disclosures include any information that was not disclosed initially to the

Institution or in a subsequent disclosure of SFIs. An updated SFI disclosure must be made within 30 days of discovering or acquiring the new SFI. However, the rule does not require that each SFI be disclosed individually. Thus, an Institution has flexibility to prescribe the timing of disclosures.

For example, an Institution could require Investigators to disclose their planned or anticipated reimbursed or sponsored travel in a prospective manner (e.g., over the next twelve months) at the time of the annual update of financial disclosures or at another time of the Institution's choosing, with a requirement to update the details of the travel annually. Once the Investigator has disclosed planned sponsored or reimbursed travel in this manner, the Investigator would have met the regulatory requirement to disclose it and would not have to disclose it again "within 30 days" of the travel (assuming there were no changes to the threshold reporting details of purpose of the trip, identity of the sponsor/organizer, destination, and duration). It should be noted, however, that under such an Institutional policy, an Investigator would continue to be required to disclose a new source of travel (i.e., that was not anticipated and disclosed at the annual reporting) within 30 days, as required by the regulation.

b. **Institutions may prescribe the details of review requirements in their FCOI policy.**

Institutions are required to determine if Investigators' reimbursed or sponsored travel constitutes an FCOI; however, Institutions have the discretion to determine which details of the sponsored or reimbursed travel, for example, source of funding, destination, duration of travel, etc., drive further institutional review. We note that the Preamble to the Final Rule states, "…depending on the source of funding and other circumstances (e.g., destination, duration) of specific travel, the Institution may consider whether that sponsored travel could affect the design, conduct, or reporting of PHS-funded research."

For example, an Institution could determine that Investigator travel to participate in annual meetings of professional societies or Gordon Conferences, while requiring disclosure in accordance with the regulatory requirements, may not require further institutional review to determine if the travel constitutes a FCOI.

c. **Institutions may prescribe the details of Investigator disclosure.**

Institutions may prescribe the details of the disclosure of sponsored or reimbursed travel that are consistent with the requirements of the 2011 revised regulation. The 2011 revised regulation requires that such disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Institutions have discretion under the 2011 revised regulation to prescribe what other details, if any, are appropriate to particular travel-related disclosures or categories of disclosures.

For example, an Institution could require only the minimum details set forth in the 2011 revised regulation for certain categories of travel such as travel within the Continental United States to attend professional society meetings, while requiring greater disclosure detail for travel for any reason outside the Continental United States.

25. **Is an Investigator required to disclose remuneration received in excess of $5,000 from an outside entity for services performed (e.g., data analysis) when the payment is made directly to the Investigator's Institution. (Institution and Investigator)**
No. Since the payment for services is paid to the Institution, Investigator disclosure is not required. However, if payment for services is paid directly to the Investigator, the remuneration must be disclosed by the Investigator, no matter if the Investigator turns the money over to the Institution or if the money will be used to support the Investigator's future research activities.

F. Management

1. **How can an Institution manage conflicting financial interests? (Institution and Investigator)**

   How an Institution manages an Investigator's conflicting financial interest is left to the Institution's policies and procedures. Examples of conditions or restrictions that might be imposed to manage an Investigator's Financial Conflict of Interest include, but are not limited to:

   - Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to Institution's Institutional Review Board(s);
   - For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
   - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
   - Modification of the research plan;
   - Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
   - Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
   - Severance of relationships that create financial conflicts

2. **What must the management plan include? (Institution)**

   Neither the Financial Conflict of Interest regulation nor the NIH prescribes a specific format for an Institution's management plan. The regulation defines, however, key elements of the FCOI report and a description of the management plan is one of the key elements of the FCOI report. The regulation requires that the FCOI report contain a description of the key elements of the Institution's management plan including the following:

   (A) The role and principal duties of the conflicted Investigator in the research project;

   (B) Conditions of the management plan;

   (C) How the management plan is designed to safeguard objectivity in the research project;

   (D) Confirmation of the Investigator's agreement to the management plan;

   (E) How the management plan will be monitored to ensure Investigator compliance; and

   (F) Other information as needed.

   Updated or annual FCOI reports must include the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted to the NIH.

G. Public Accessibility

1. **Is the Institution required to make its policy on Financial Conflict of Interest publicly accessible? (Institution)**

   Yes. The Institution is required to make its policy on Financial Conflict of Interest publicly

available via a publicly accessible Web site. If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the PHS award, the requirement to post the information on that Web site will apply within 30 calendar days.

When the Institution posts its Financial Conflict of Interest policy or otherwise makes the policy publicly accessible, it signifies that the Institution applying for or receiving PHS funding from a grant or cooperative agreement that is covered by the 2011 revised regulation is in full compliance with all the regulatory requirements. The Institution must be in compliance with the 2011 revised regulation no later than August 24, 2012.

2. **What are the requirements for making information on Financial Conflict of Interest of senior/key personnel publicly accessible? (Institution and Investigator)**

   Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response within five business days of a request, of information concerning any Significant Financial Interest disclosed to the Institution that meets the following three criteria:

   A. The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH;
   B. The Institution determines that the Significant Financial Interest is related to the NIH-funded research; and
   C. The Institution determines that the Significant Financial Interest is a **Financial Conflict of Interest.**

   The information that the Institution makes available via a publicly accessible Web site or written response shall include, at a minimum, the following:

   i. Investigator's name;
   ii. Investigator's title and role with respect to the research project;
   iii. Name of the entity in which the Significant Financial Interest is held;
   iv. Nature of the Significant Financial Interest; and
   v. Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) 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.

   Institutions have inquired about the need to include a contact person's name or provide a dedicated mailing address or email address where individuals can send in their written request for the information above. Although information beyond what is specified in the regulation is not required by NIH, Institutions may determine that designating a contact in this manner is a helpful step in satisfying their obligation to make the information publicly accessible.

3. **What is meant by responding to a written request within five business days? (Institution)**

   The Institution's response should be postmarked or dated (if replying by electronic means) within five business days of the receipt of the written request.

4. **When should information be updated when the Institution makes information available on a publicly accessible Web site? (Institution)**
   If the institution uses a publicly accessible Web site for making the information publicly

accessible, the information shall be updated at least annually. In addition, the Institution shall update the Web site within sixty (60) days of the Institution's receipt or identification of information concerning any additional Significant Financial Interests of the senior/key personnel for the NIH-funded research project that was not previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel; or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the NIH-funded research, if the Institution determines that the Significant Financial Interest is related to the NIH-funded research and is a Financial Conflict of Interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new Financial Conflict of Interest. If the Institution responds to written requests, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new Financial Conflict of Interest, which should be requested subsequently by the requestor.

5. **If a prime Institution performs research through a subrecipient, which Institution is responsible for making information on identified FCOIs for senior/key personnel publicly accessible (i.e., posting the FCOI information on a Web site or making the information available upon request within five business days)? (Institution)**

   In all cases it is the prime Institution's responsibility to make FCOI information publicly accessible. However, when the subrecipient Investigator is required to comply with the subrecipient's FCOI policy, the subrecipient Institution will also make such information publicly accessible. Therefore, in these situations, the prime Institution may consider including the requirement for the subrecipient Institution to make FCOI information publicly available as part of the written subaward agreement.

H. Reporting Requirements

1. **How should the FCOI report be submitted to NIH? (Institution)**

   For awarded grants and cooperative agreements, Institutions must submit all FCOI reports to the NIH through the electronic Research Administration (eRA) Commons FCOI Module. See *NIH Guide for Grants and Contracts*, Notice No. NOT-OD-09-072. Refer to the FCOI Module User Guide for additional information.

   Until such time as the Institution implements the requirements of the 2011 revised regulation, Institutions must continue to comply with the 1995 regulation and report Investigator FCOIs to the NIH as required in the 1995 regulation.

   Once the institution is required to be in full compliance with the regulatory requirements, the additional reporting requirements must be met. Therefore, if the eRA Commons FCOI Module is not updated by the time this occurs, the FCOI report should include an attachment that addresses the minimum elements of the FCOI report as stated below or as provided in 42 CFR 50.605(b)(3).

2. **When must annual FCOI reports be submitted to the NIH? (Institution)**

   Initial Reports: Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution must provide to the NIH an FCOI report regarding any Investigator Significant Financial Interest found by the Institution to be a Financial Conflict of Interest in accordance with the regulation. The Institution must also provide an FCOI report whenever an Investigator does not timely disclose a Significant Financial Interest or whenever the Institution, for whatever reason, does not review a disclosed Significant Financial Interest and the Institution then determines that a Financial Conflict of Interest exists.

   Submission of Initial FCOI reports during an Ongoing NIH-funded Research Project:

A. The Institution must submit an FCOI report within sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to the Institution during the period of award.

B. *Whenever* an Investigator does not disclose timely a previously existing Significant Financial Interest or the Institution fails to review a previously existing Significant Financial Interest during an ongoing NIH-funded project, the Institution's designated official(s) shall, within sixty (60) days: review the Significant Financial Interest; determine whether it is related to the NIH-funded research; determine whether a Financial Conflict of Interest exists. If so, the Institution must implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such Financial Conflict of Interest going forward and submit an FCOI report to the NIH.

In addition to the FCOI report, the Institution must, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's research activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research.

Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward.

If bias is found, notify the NIH promptly and submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effects of the bias. Thereafter the Institution will submit FCOI reports annually.

Annual FCOI Report: For any Financial Conflict of Interest previously reported by the Institution, the Institution shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. Annual FCOI reports must be submitted to the NIH (e.g., through the eRA Commons for grants and cooperative agreements) for the duration of the project period (including extensions with or without funds) at the same time as when the Institution is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable.) Please note that the annual FCOI report is not to be submitted as part of the annual progress report. The annual FCOI report is submitted to NIH separately through the eRA Commons FCOI Module.

3. **Is an Institution required to submit an FCOI report if the Institution eliminates the conflicting financial interest prior to the submission of the initial FCOI report? (Institution)**
No. In cases in which the Institution identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of NIH-awarded funds, the Institution shall not submit an FCOI report to the NIH.

4. **Is an Institution required to submit an FCOI report when a conflicting financial interest ceases to exist during the period of award? (Institution)**
Yes. When a conflicting financial interest ceases to exist during the ongoing project period, the Institution should update the status of the Financial Conflict of Interest at the time of the next annual FCOI report submission deadline (i.e., at time of the submission of the annual

progress report). The annual FCOI report shall address the status of the Financial Conflict of Interest and any changes to the management plan. The FCOI report shall specify whether the financial conflict is still being managed or include an explanation why the Financial Conflict of Interest no longer exists.

5. **What must the FCOI report include? (Institution)**

All FCOI reports must include sufficient information to enable the NIH to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of the Institution's management plan. The regulation provides key elements that must be included in the FCOI report to NIH. These include but are not necessarily limited to the following:

i. Project number;
ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
iii. Name of the Investigator with the Financial Conflict of Interest;
iv. Name of the entity with which the Investigator has a Financial Conflict of Interest;
v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
vi. Value of the financial interest (dollar ranges are permissible: $0-$4,999; $5,000- $9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), 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;
vii. A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research;
viii. A description of the key elements of the Institution's management plan, including:
(A) Role and principal duties of the conflicted Investigator in the research project;
(B) Conditions of the management plan
(C) How the management plan is designed to safeguard objectivity in the research project;
(D) Confirmation of the Investigator's agreement to the management plan;
(E) How the management plan will be monitored to ensure Investigator compliance; and
(F) Other information as needed.
See the "Management" section for the questions for guidance on the minimum requirements for the management plan.

NIH grant and cooperative agreement award recipients should continue to submit FCOI reports using the electronic Research Administration (eRA) Commons FCOI Module. Once the institution is required to be in full compliance with the regulatory requirements, the additional reporting requirements must be met. Therefore, if the eRA Commons FCOI Module is not updated by the time this occurs, the FCOI report should include an attachment that addresses the minimum elements of the FCOI report as stated above and provided in 42 CFR 50.605(b)(3).

6. **What is meant by submitting annual FCOI reports to the NIH "in the time and manner specified by the PHS Awarding Component?" (Institution)**

Institutions are required to submit to the NIH an annual FCOI report that addresses the status of the Financial Conflict of Interest and any changes to the management plan for the duration of the NIH-funded research project. Annual FCOI reports are required to be submitted (i.e., through the eRA Commons FCOI Module for grants and cooperative agreements) for the duration of the project period (including extensions with or without funds). The annual FCOI report is due at the same time as when the Institution is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable.) Please note that the annual FCOI report is not to be submitted as part of the annual progress report. The annual FCOI report is submitted to NIH separately through the eRA Commons FCOI Module.

7. **How should the value of a Significant Financial Interest be reported to NIH? (Institution)**

   The disclosure requirements in the regulation speak to "the value of any remuneration received from the entity" in the twelve months preceding the disclosure and "the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000," must be disclosed to the awardee Institution. Accordingly, the Institution will be required to report to the NIH the cumulative or aggregated value of each Significant Financial Interest that resulted in the determination of a Financial Conflict of Interest. The reported value of the financial interest will include permissible dollar ranges: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), 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.

8. **What is NIH going to do with the information collected from Institutions? Will NIH follow up on each report? (Institution)**
   NIH professional and scientific staff will evaluate the information received to determine whether an Institution's actions are sufficient to manage the identified Financial Conflict of Interest given program's knowledge about the NIH-funded project. NIH will utilize the information to monitor the Institution's compliance with the regulation. NIH will follow-up when additional information is needed to complete NIH's review and/or address specific questions.

9. **Can the NIH request more information from an applicant and/or grantee Institution about Financial Conflict of Interest matters? (Institution)**
   Yes. The NIH may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a Financial Conflict of Interest, including a requirement to submit, or permit on site review of, all records pertinent to compliance with the regulation.

10. **What actions may NIH take after the receipt and review of a FCOI report? (Institution)**

    NIH professional and scientific staff will evaluate the information provided by the Institutions as specified in the regulation, as well as other information that may be requested from an Institution during the review process.

    NIH may inquire at any time (i.e., before, during, or after award) into any Investigator disclosure of financial interests and the Institution's review of, or response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a Financial Conflict of Interest. An Institution is required to submit, or permit on site review of, all records pertinent to compliance with the regulation.

    If NIH decides that a particular Financial Conflict of Interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed the Financial Conflict of Interest in accordance with the regulation, NIH may, consistent with the regulations and the NIH Grants Policy Statement (which is a term and condition of all NIH grant awards), determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.

11. **Must an Institution submit an FCOI report prior to the expenditure of any funds for a Type 2 (Renewal) or Type 3 (Revision) award when there have been no changes in circumstances related to an ongoing FCOI? (Institution)**

    Yes. A "new" FCOI report should be submitted to the NIH through the eRA Commons FCOI Module prior to the expenditure of any funds under a Renewal (Type 2) or Revision (Type 3) award. Annual FCOI reports are submitted at the same time as when the Institution is required to submit the annual progress report, including a multi-year funded progress report, or at the time of extension.

12. **Must an Institution submit a new FCOI report when there are changes to an Investigator's Significant Financial Interests? (Institution)**

    The Institution must submit a new FCOI report if any of the following elements of a previously submitted FCOI report changes:

    - Project Number
    - Name of Investigator with the FCOI
    - Name of the entity
    - Nature of the Significant Financial Interest

    If the value of a reported SFI changes during the year, the Investigator should disclose the change to the Institution in his/her annual disclosure. Changes in the value of an SFI do not constitute a "new" FCOI report. The annual FCOI report will provide the status of the existing FCOI and any changes to the management plan that may result due to the increase in value.

I. Retrospective Review and Mitigation Report

1. **What is a retrospective review and when is it required? (Institution)**

   Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

   - Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
   - Failure by the Institution to review or manage such a Financial Conflict of Interest; or
   - Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

   the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

2. **What are the key elements for documenting the retrospective review? (Institution)**

   The Institution shall document the retrospective review which must include at least the following key elements:

   A. Project number;
   B. Project title;
   C. PD/PI or contact PD/PI if a multiple PD/PI model is used;
   D. Name of the Investigator with the FCOI;
   E. Name of the entity with which the Investigator has a financial conflict of interest
   F. Reason(s) for the retrospective review;
   G. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
   H. Findings of the review; and
   I. Conclusions of the review.

3. **What should the Institution do if bias is found during the retrospective review? Is a mitigation report required? (Institution)**

   If bias is found, the Institution must notify NIH promptly and submit a mitigation report to the

NIH. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually as prescribed by the regulation.

J. SBIR/STTR Applicants/Awardees

1. **Does the regulation apply to Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) programs and/or awards? (Institution)**
   The revised 2011 regulation does not apply to Phase I SBIR/STTR applications but the revised 2011 regulation does apply to Phase II SBIR/STTR applications/awards.

2. **If the Investigator holds an equity interest in a company that applies for or receives an SBIR/STTR award, is the Investigator's equity interest considered an SFI that must be disclosed to the company? (Institution and Investigator)**

   As defined in Section 50.603 Definitions, a "Significant Financial Interest" does not include "….any ownership interest in the [applicant or awardee] Institution held by the Investigator, if the Institution is a commercial or for-profit organization;…". Therefore, the Investigator's equity interest is excluded from the disclosure requirement when the for-profit company is the Institution that is applying for, or that receives, the PHS research funding in which the Investigator is participating. (The 1995 regulation had a similar exclusion: "…Any ownership interests in the institution, if the institution is an applicant under the SBIR Program….".)

3. **Does the exclusion for SBIR/STTR Phase I applications extend to sub-recipient institutions (e.g., subcontract, or sub-award) from the Phase I awards? (Institution)**

   As stated above, the regulation does not apply to applications and awards supported under the SBIR/STTR Phase I program and therefore would not be passed through to a subrecipient. Therefore, a University, for example, that is a subawardee under a Phase I SBIR/STTR award, is not required to make an FCOI determination as it relates to the subaward under the Phase I SBIR/STTR award.

K. Subrecipients

1. **What are the responsibilities of the Institution for subrecipients (e.g., subcontractors or consortium members)? (Institution)**

   The awardee Institution is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified financial conflicts of interests for subrecipient Investigators to the NIH. Awardee institutions must incorporate as part of a written agreement with a subrecipient terms that establish whether the Financial Conflict of Interest policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or Financial Conflict of Interest reporting requirements.

   Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interests to the awardee Institution in sufficient time to allow the awardee Institution to report the Financial Conflict of Interest to the NIH to meet its reporting obligations.

   Subrecipient institutions that must comply with the awardee Institution's policy must submit all

Investigator disclosures of Significant Financial Interests to the awardee in sufficient time to allow the awardee to review, manage and report identified FCOIs to the NIH.

Awardee Institutions are responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest to the NIH.

L. Training Requirements

1. **Does the regulation require Investigator training? (Institution and Investigator)**

   Yes. Each Investigator (as defined by the regulation), including subrecipient Investigator(s), must complete training prior to engaging in NIH-funded research and at least every four years, and immediately under the designated circumstances:

   - Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements
   - An Investigator is new to an Institution
   - An Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest policy or management plan.

   Institutions may utilize resources available on NIH's Office of Extramural Research Financial Conflict of Interest Web page found at http://grants.nih.gov/grants/policy/coi/ to satisfy some of the training requirements. However, Institutions must also provide additional training regarding Investigator's responsibilities for disclosure of Significant Financial Interests and of the Institution's specific policy on financial conflicts of interests.

2. **When is an Investigator required to complete Financial Conflict of Interest training if they are currently funded under a NIH grant or cooperative agreement at the time the Institution's FCOI policy is implemented and posted? (Institution and Investigator)**

   Institutions are expected to develop and implement their Financial Conflict of Interest policies during the 365-day implementation period provided in the 2011 revised regulation. Once the Institution implements and posts their Financial Conflict of Interest policy as required under the final rule, Investigators are expected to then complete required training prior to engaging in NIH-supported research or by the issue date of the Notice of Award issued subsequent to the Institution's implementation date.

3. **Can an Institution implement the regulatory requirements prior to having all of its Investigators trained on Financial Conflict of Interest as required under the 2011 revised regulation? (Institution)**

   Yes. The implementation date can precede the date when all Investigators have been trained. If the implementation date falls on the 365th day (i.e., August 24, 2012), it is expected that all Investigators who are supported by the NIH will complete their training obligations prior to engaging in NIH-supported research or by the issue date of the Notice of Award issued subsequent to the Institution's implementation date.

4. **Institutions are required to train Investigators "immediately" upon certain situations. How is "immediately" defined in this context? (Institution)**
   NIH expects Institutions to define "immediately" in the Institution's Financial Conflict of Interest policy, which would establish a reasonable timeframe when Investigators must complete training under the prescribed circumstances. Although the regulation does not define a precise timeline, the expectation is that Institutions will make it a priority to ensure Investigators understand and comply with the requirements of the regulation and the Institution's Financial Conflict of Interest policy, which reinforces the need for training to be handled expeditiously.

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New Indirect Cost Agreement Signed

- The new rate agreement is dated March 21, 2012 and replaces the previous agreement dated June 15, 2011. The on-campus organized research rate will increase to 66.00% effective 7/1/12.
  - The full indirect cost rate agreement can be accessed on the Research Funding Services website at: http://www.umassmed.edu/uploadedFiles/Rate_Agreement_FY12_3.21.pdf

SECTION I: INDIRECT COST RATES

RATE TYPES: FIXED FINAL PROV. (PROVISIONAL) PRED. (PREDETERMINED)

EFFECTIVE PERIOD

TYPE	FROM	TO	RATE(%)	LOCATION	APPLICABLE TO
PRED.	07/01/2011	06/30/2012	64.50	On-Campus	Research
PRED.	07/01/2012	06/30/2013	66.00	On-Campus	Research
PRED.	07/01/2013	06/30/2014	66.50	On-Campus	Research
PRED.	07/01/2014	06/30/2015	67.50	On-Campus	Research
PRED.	07/01/2011	06/30/2015	26.00	Off-Campus	Research
PRED.	07/01/2011	06/30/2015	68.00	On-Campus	Res.DOD Cont.
PRED.	07/01/2011	06/30/2015	27.80	Off-Campus	Res.DOD Cont.
PRED.	07/01/2011	06/30/2015	18.25	All Locations	OSA-CM(SR#6)
PRED.	07/01/2011	06/30/2012	34.50	On-Campus	Other Spon Act
PRED.	07/01/2012	06/30/2015	36.00	On-Campus	Other Spon Act
PRED.	07/01/2011	06/30/2012	25.90	Off-Campus	Other Spon Act
PRED.	07/01/2012	06/30/2015	26.00	Off-Campus	Other Spon Act

March Metrics

Proposals Submitted to RFS		
On Time	44	46%
Late	45	47%
After the fact	7	7%
Total	**96**	**100%**
Expedited Request (3 days or less)	33	34%

MONTH TO MONTH COMPARISON

PROPOSALS	October	November	December	January	February	March
On Time	52%	41%	43%	60%	61%	46%
Late	44%	49%	49%	36%	33%	47%
After the fact	4%	9%	8%	4%	6%	7%
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**
Expedited Request (3 days or less)	40%	36%	33%	24%	23%	34%

March Metrics

Progress Reports Submitted to RFS		
On Time	18	45%
Late	15	38%
After the fact	7	17%
Total	**40**	**100%**
Expedited Request (3 days or less)	12	30%

MONTH TO MONTH COMPARISON

PROGRESS REPORTS	October	November	December	January	February	March
On Time	32%	72%	45%	50%	41%	45%
Late	58%	27%	44%	47%	49%	38%
After the fact	10%	1%	11%	3%	10%	17%
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**
Expedited Request (3 days or less)	63%	28%	45%	44%	41%	30%