

FINANCIAL CONFLICT OF INTEREST - NEWEST

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1.1 Introduction

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

Financial Conflict of Interest (FCOI) Office of Extramural Research (OER) National Institutes of Health (NIH)

Introduction

Welcome to the Office of Extramural Research's course on Financial Conflict of Interest, or FCOI. You can use this course in two ways: as a course to get a certificate of completion or as a reference guide for FCOI policies. If you are taking it for a certificate, you'll have to answer the review questions.

Notes:

Financial Conflict of Interest (FCOI) Office of Extramural Research (OER) National Institutes of Health (NIH)

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1.2 Introduction

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Introduction

This course is designed to supplement institutional training programs regarding the implementation of the 2011 revised FCOI regulation for NIH grants and cooperative agreements which are included in [42 CFR Part 50 Subpart F](#), the part of the code which addresses promoting objectivity in research.

This course will highlight key Federal requirements an investigator, an institution, and the NIH are accountable for under the regulation. This course is not intended to be a substitute for the comprehensive review and implementation of federal regulations or your institution's specific regulations.

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It will cover the following objectives:

- ✓ Describe the purpose of the FCOI regulation
- ✓ Recognize and define key FCOI terms, including investigator, institution, and Significant Financial Interest
- ✓ **(for investigators)** Describe the compliance and reporting requirements on investigators under the FCOI regulation
- ✓ **(for institutions)** Describe the compliance and reporting requirements on institutions and institution-designated officials under the FCOI regulation
- ✓ Describe the process that occurs if an investigator is found to be noncompliant with his or her institution's FCOI policy or management plan
- ✓ Describe NIH's role and responsibilities under the FCOI regulation

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- (for investigators) Describe the compliance and reporting requirements on investigators under the FCOI regulation
- (for institutions) Describe the compliance and reporting requirements on institutions and institution-designated officials under the FCOI regulation
- Describe the process that occurs if an investigator is found to be noncompliant with his or her institution's FCOI policy or management plan
- Describe NIH's role and responsibilities under the FCOI regulation

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Introduction

During this course several terms will be used regularly. During the course, you can visit the Glossary to see specific definitions for all terms. Please take special note of the definitions of:

- ✓ **Investigator**
- ✓ **Institution**
- ✓ **Significant Financial Interest (SFI)**

Notes:

During this course several terms will be used regularly. During the course, you can visit the Glossary to see specific definitions for all terms. Please take special note of the definitions of "Investigator", "Institution", and "Significant Financial Interest", often abbreviated S-F-I.

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Introduction

For the purpose of this tutorial:

"Investigator" refers to the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of NIH-funded research, including subgrantees, contractors, consortium participants, collaborators, or consultants

"Institution" refers to any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for, or that receives, NIH research funding

"Regulation or FCOI regulation" refers to 42 CFR Part 50 Subpart F, Promoting Objectivity in Research, which applies to both grants and cooperative agreements

"Disclosure" refers to the investigator's disclosure of Significant Financial Interests (SFIs) to their institution; and

"Report" refers to the institution's report of identified FCOIs to the NIH

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Introduction

Finally,

"Significant Financial Interest (SFI)" is defined by the regulation as:

(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;

Notes:

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"Significant Financial Interest (SFI)" is defined by the regulation as:

(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:

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(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.

Notes:

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

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(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.

Notes:

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(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.

Notes:

(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.

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Introduction

Let's join our colleagues to find out more about FCOI regulations. We'll hear from Sue, the narrator; Mary, who represents the institution; and Kirby, who represents an investigator.

Sue **Mary** **Kirby**

A photograph of three people standing side-by-side. On the left is Sue, a woman with short brown hair wearing a black blazer over a pink shirt, holding a black folder. In the center is Mary, a woman with short dark hair wearing a grey patterned sleeveless top, with her hand on her hip. On the right is Kirby, a man with short dark hair wearing a teal button-down shirt.

Notes:

Let's join our colleagues to find out more about FCOI regulations. We'll hear from Sue, the narrator; Mary, who represents the institution; and Kirby, who represents an investigator.

1.11 Kirby Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

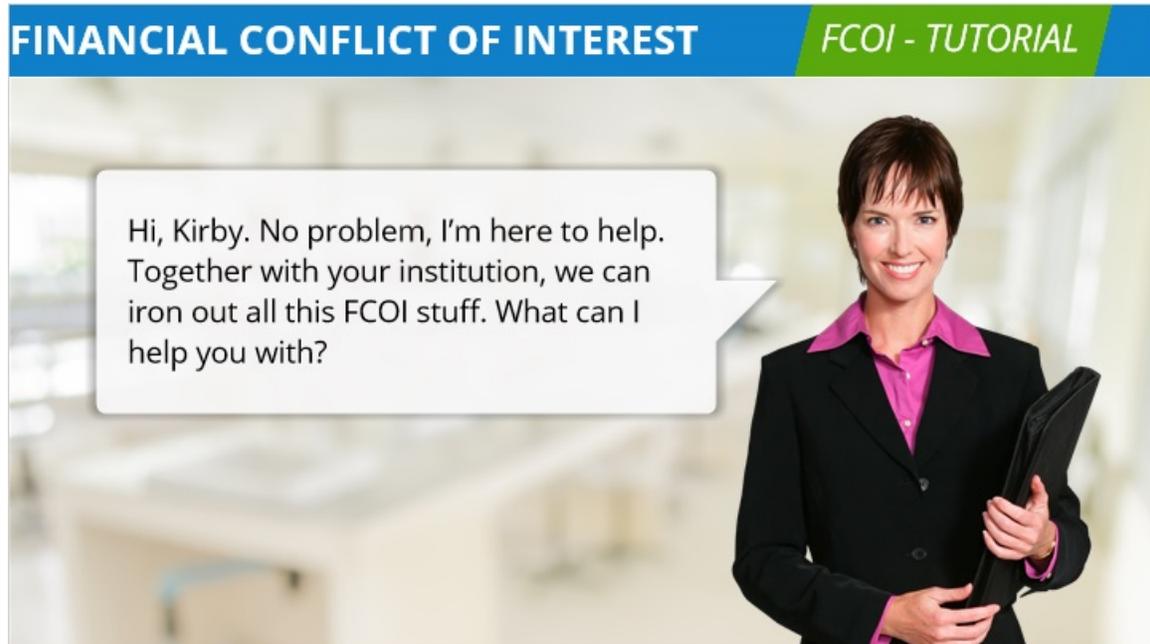
A photograph of Kirby, the man in the teal shirt, smiling. A white speech bubble is positioned to his right, containing text.

I'm a new investigator at Mary's institution, and I know there are these FCOI regulations. I want to make sure I follow the rules, but they seem so complicated.

Notes:

I'm a new investigator at Mary's institution, and I know there are these FCOI regulations. I want to make sure I follow the rules, but they seem so complicated.

1.12 Sue Talking



Notes:

Hi, Kirby. No problem, I'm here to help. Together with your institution, we can iron out all this FCOI stuff. What can I help you with?

1.13 Kirby Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A man in a teal shirt stands in a blurred office setting. A speech bubble points to him containing the text: "What's the purpose of the FCOI regulation?"

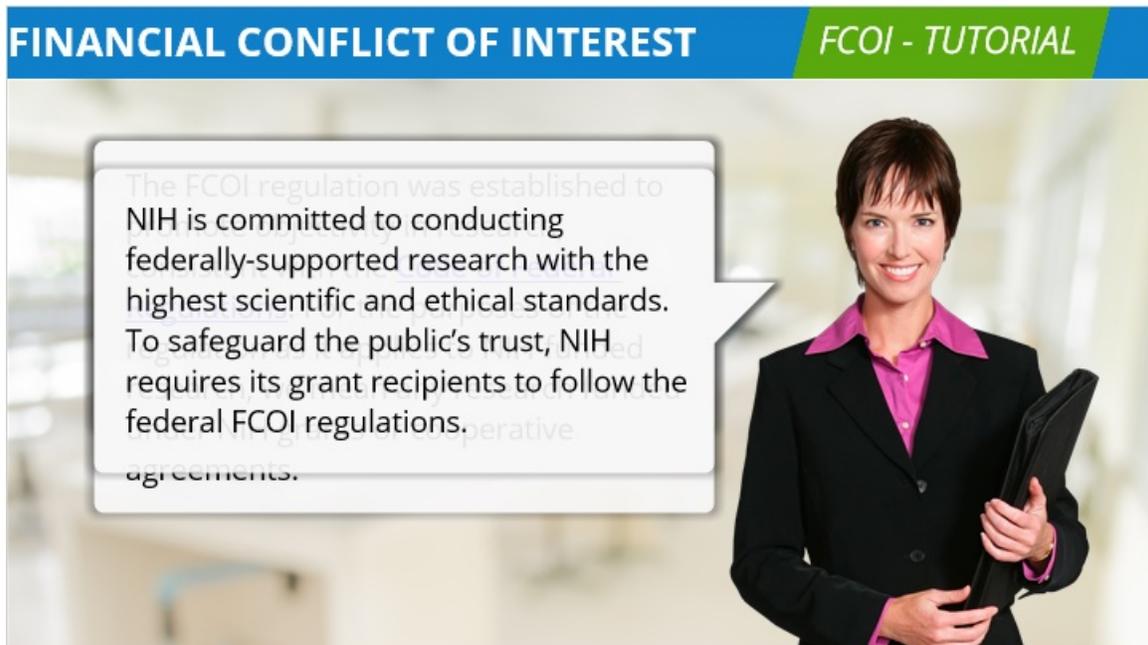
What's the purpose of the FCOI regulation?

Notes:

What's the purpose of the FCOI regulation?

1.14 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman in a black blazer and pink shirt holds a folder. A speech bubble points to her containing the text: "The FCOI regulation was established to NIH is committed to conducting federally-supported research with the highest scientific and ethical standards. To safeguard the public's trust, NIH requires its grant recipients to follow the federal FCOI regulations. cooperative agreements."

The FCOI regulation was established to NIH is committed to conducting federally-supported research with the highest scientific and ethical standards. To safeguard the public's trust, NIH requires its grant recipients to follow the federal FCOI regulations. cooperative agreements.

Notes:

NIH is committed to conducting federally-supported research with the highest scientific and ethical standards. To safeguard the public's trust, NIH requires its grant recipients to follow the federal FCOI regulations.

The FCOI regulation was established to promote objectivity in research, consistent with the Code of Federal Regulations. For the purposes of the regulation as it applies to NIH-funded research, we mean any research funded under NIH grants or cooperative agreements. The standards established by the FCOI regulation provide a reasonable expectation that the design, conduct, and reporting of NIH research will be free from the bias of investigators' financial conflicts of interest.

1.15 Kirby Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

Ok, thanks. I'm a new investigator, so a lot of this is new to me. **Does the regulation apply to me as an individual or to the institution as a whole? Who and what is covered by this regulation?**

Notes:

Ok, thanks. I'm a new investigator, so a lot of this is new to me. Does the regulation apply to me as an individual or to the institution as a whole? Who and what is covered by this regulation?

1.16 Sue Talking

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Great question, because the regulation applies at different levels. The FCOI regulation applies to **both institutions and investigators**. Let's look at how each is affected. We'll start with institutions, and for that, we turn to Mary.



Institutions



Investigators

Notes:

Great question, because the regulation applies at different levels. The FCOI regulation applies to both institutions and investigators. Let's look at how each is affected. We'll start with institutions, and for that, we turn to Mary.

1.17 Mary Talking

FINANCIAL CONFLICT OF INTEREST FCOI - TUTORIAL

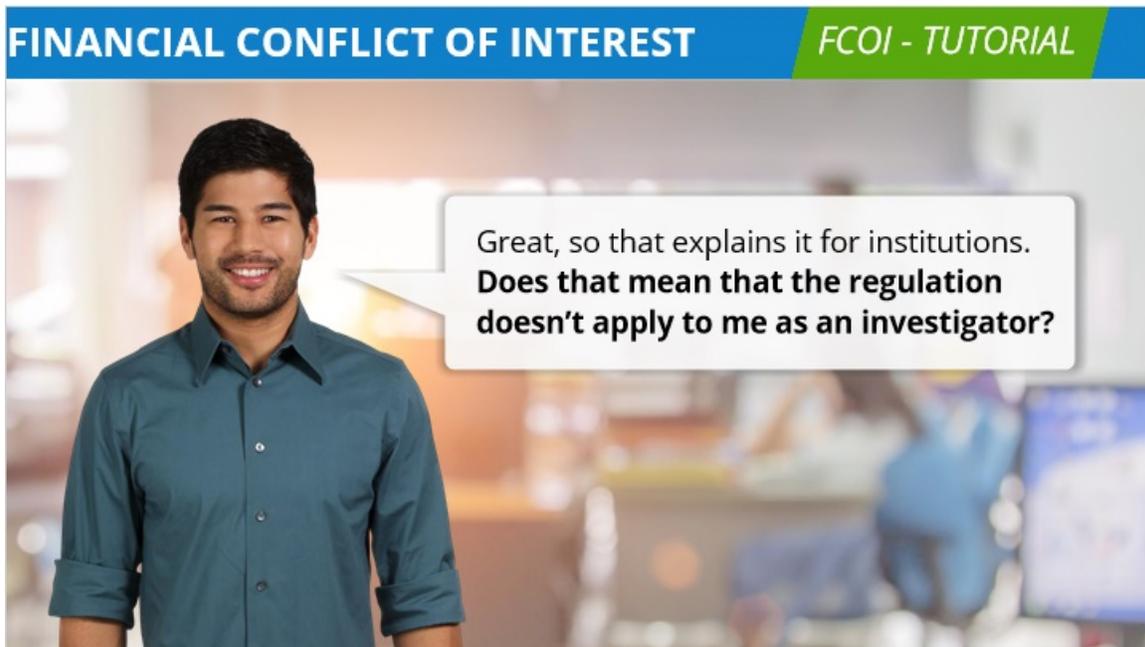
Thanks, Sue. For institutions, the regulation applies to any domestic or foreign, public or private, entity or organization, excluding a federal agency, that applies for or receives NIH research funding. Remember, NIH research funding means funding obtained by means of a grant or cooperative agreement.



Notes:

Thanks, Sue. For institutions, the regulation applies to any domestic or foreign, public or private, entity or organization, excluding a federal agency, that applies for or receives NIH research funding. Remember, NIH research funding means funding obtained by means of a grant or cooperative agreement. In the few cases where an individual, rather than an Institution, is applying for or receives NIH research funding, NIH will make case-by-case determinations on how that individual can comply with the FCOI regulation.

1.18 Kirby Talking



Notes:

Great, so that explains it for institutions. Does that mean that the regulation doesn't apply to me as an investigator?

1.19 Sue Talking

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Yes, Kirby, it does apply – remember, it applies to both institutions and investigators. Here’s how it applies to investigators.



The slide features a woman in a black blazer and pink shirt holding a folder. To her left is a speech bubble containing text. Below the speech bubble are two icons: a blue building icon and a blue document icon with a magnifying glass, both enclosed in a green circle.

Notes:

Yes, Kirby, it does apply - remember, it applies to both institutions and investigators. Here’s how it applies to investigators.

1.20 Untitled Slide

FINANCIAL CONFLICT OF INTEREST FCOI - TUTORIAL

FCOI Regulation

- ✓ Investigator

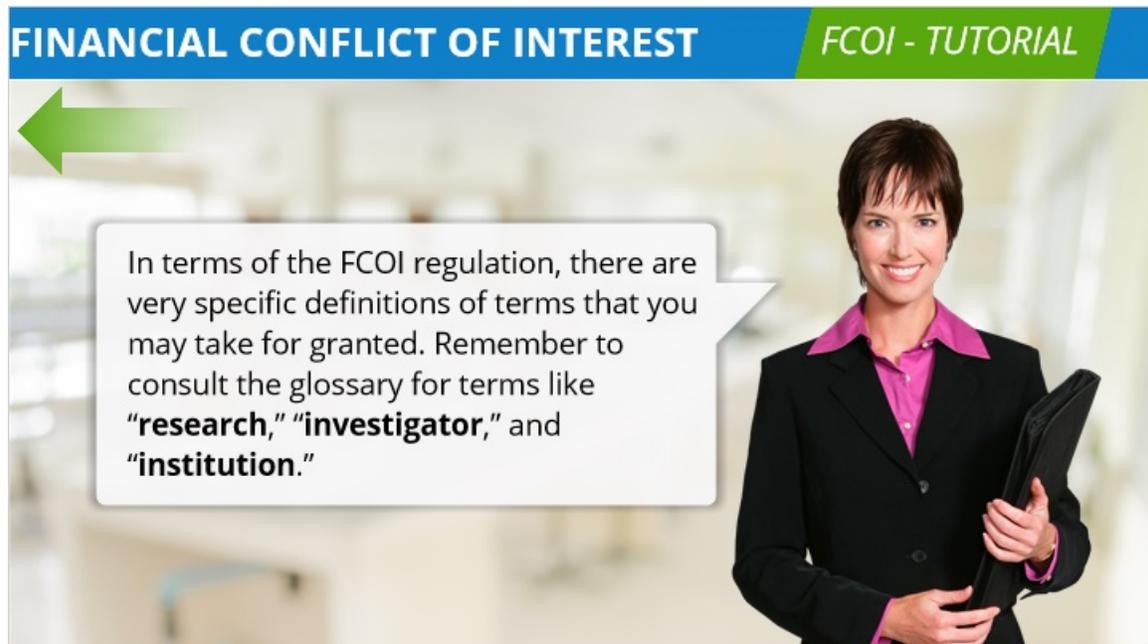
FCOI Regulation does not apply to:

- ✗ Small Business Innovative Research (SBIR)
- ✗ Small Business Technology Transfer (STTR)

Notes:

For investigators, the regulation applies to an individual who meets the regulatory definition of “investigator” who is planning to participate in or is already participating in NIH-funded research. There is a subset of awards that the FCOI regulation does not apply to - those are the Small Business Innovative Research, or S-B-I-R, and Small Business Technology Transfer, or S-T-T-R, Phase I applications or awards.

1.21 Sue Talking



FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

In terms of the FCOI regulation, there are very specific definitions of terms that you may take for granted. Remember to consult the glossary for terms like “**research**,” “**investigator**,” and “**institution**.”

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1.22 Kirby Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A man with dark hair and a beard, wearing a teal button-down shirt, is smiling and looking towards the camera. He is standing in a blurred office environment. A white speech bubble with a black border is positioned to his right, containing the text "And what is NIH's role?".

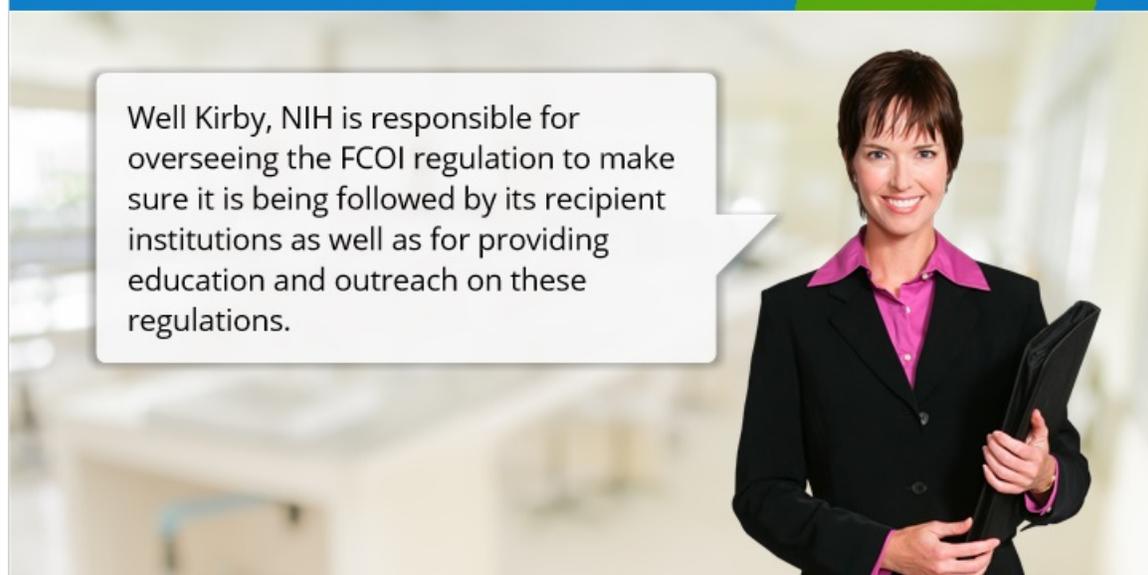
And what is NIH's role?

Notes:

And what is NIH's role?

1.23 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

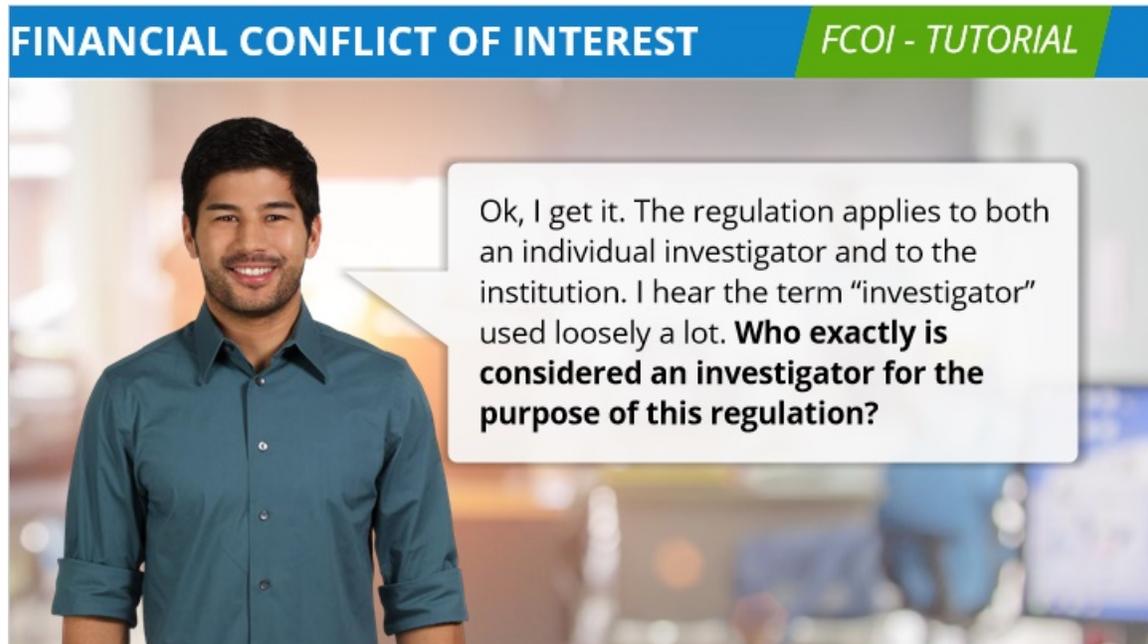
A woman with short brown hair, wearing a black blazer over a pink shirt, is smiling and holding a black folder. She is standing in a blurred office environment. A white speech bubble with a black border is positioned to her left, containing the text "Well Kirby, NIH is responsible for overseeing the FCOI regulation to make sure it is being followed by its recipient institutions as well as for providing education and outreach on these regulations.".

Well Kirby, NIH is responsible for overseeing the FCOI regulation to make sure it is being followed by its recipient institutions as well as for providing education and outreach on these regulations.

Notes:

Well Kirby, NIH is responsible for overseeing the FCOI regulation to make sure it is being followed by its recipient institutions as well as for providing education and outreach on these regulations.

1.24 Kirby Talking



Notes:

Ok, I get it. The regulation applies to both an individual investigator and to the institution. I hear the term "investigator" used loosely a lot. Who exactly is considered an investigator for the purpose of this regulation?

1.25 Sue Talking

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Great point, Kirby. You can consult your glossary to get the exact definition of an “investigator”. But in general, note that the FCOI requirements are not limited to the PD or PIs, or even to the senior or key personnel. The regulation applies to all individuals who are responsible for the design, conduct, or reporting of research.



Notes:

Great point, Kirby. You can consult your glossary to get the exact definition of an “investigator”. But in general, note that the FCOI requirements are not limited to the PD or PIs, or even to the senior or key personnel. The regulation applies to all individuals who are responsible for the design, conduct, or reporting of research. The definition may seem broad, but the concern was that a more limited definition would increase the risk that some FCOIs would not be identified and would therefore not be managed appropriately.

1.26 Kirby Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

What if I have questions about how the FCOI regulation applies to me?
Or to some other individual?

Notes:

What if I have questions about how the FCOI regulation applies to me? Or to some other individual?

1.27 Sue Talking

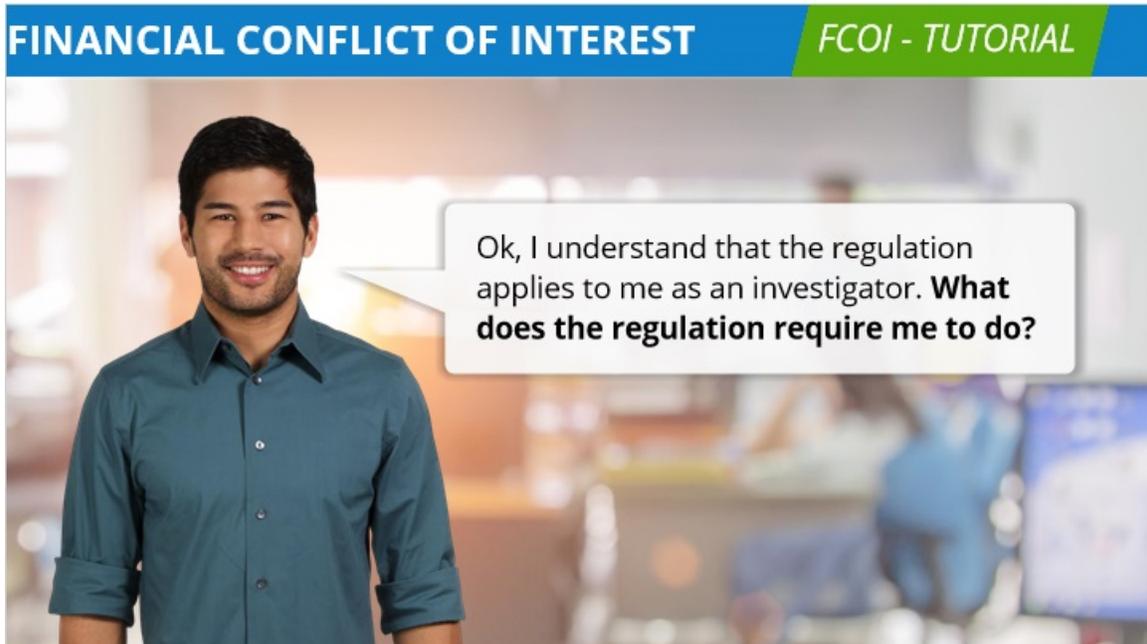
FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

Those questions should be addressed in your institution's policies and procedures. If there are still questions, you can ask your institution's designated officials.

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1.28 Kirby Talking



Notes:

Ok, I understand that the regulation applies to me as an investigator. What does the regulation require me to do?

1.29 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

First, you have to follow your institution's FCOI policies and procedures, which may be more restrictive than the FCOI regulation. Check with your institution to know what their policies and procedures are. You should be able to find a copy of your institution's FCOI policy on the institution's website, since posting the policy on the website is another regulatory requirement.



Notes:

In general, you'll have to do three things: follow your institution's FCOI policies and procedures, complete FCOI training, and submit your known significant financial interests, or SFIs, as well as those of your spouse and dependent children, to a designated official. Let's look at those three items in greater detail. First, you have to follow your institution's FCOI policies and procedures, which may be more restrictive than the FCOI regulation. Check with your institution to know what their policies and procedures are. You should be able to find a copy of your institution's FCOI policy on the institution's website, since posting the policy on the website is another regulatory requirement.

1.30 Untitled Slide

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

Complete FCOI Training...

Immediately if:

- ✓ Your institution revises its FCOI policies and procedures
- ✓ You are new to an institution
- ✓ An institution finds that an investigator is not in compliance with the institution's FCOI policy or management plan

BEFORE you engage in **NIH-Funded research**

EVERY 4 YEARS after that



Notes:

You'll also have to complete FCOI training prior to doing certain things.

You'll have to complete training before you engage in NIH-funded research and every four years after that. But there are other circumstances that would cause you to need FCOI training. You would also have to complete training immediately if and when any of the following apply:

your institution revises its FCOI policies and procedures in any way that affects the requirements of investigators; or you are new to an institution; or an institution finds that an investigator is not in compliance with the institution's FCOI policy or management plan.

1.31 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*



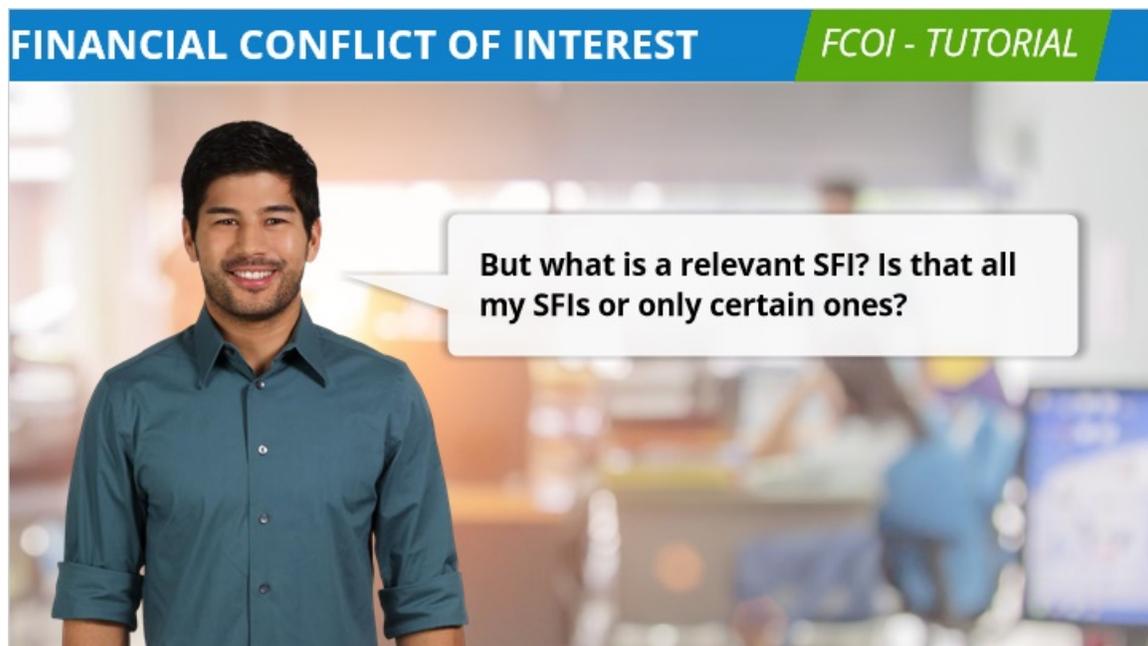
The third thing you have to do as an investigator is to **submit relevant SFIs to an institutional official**. This must be done before the expenditure of NIH funds, and the list must include any SFIs of your spouse and dependent children.

Notes:

The third thing you have to do as an investigator is to submit relevant SFIs to an institutional official. This must be done before the expenditure of NIH funds, and the list must include any SFIs of your spouse and dependent children.

1.32 Kirby Talking

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But what is a relevant SFI? Is that all my SFIs or only certain ones?

Notes:

But what is a relevant SFI? Is that all my SFIs or only certain ones?

1.33 Sue Talking



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There is one more rule about SFIs, Kirby. During the period of award, you must update all financial disclosures to your institution according to its policy, on an annual basis and within 30 days of acquiring or discovering a new SFI.

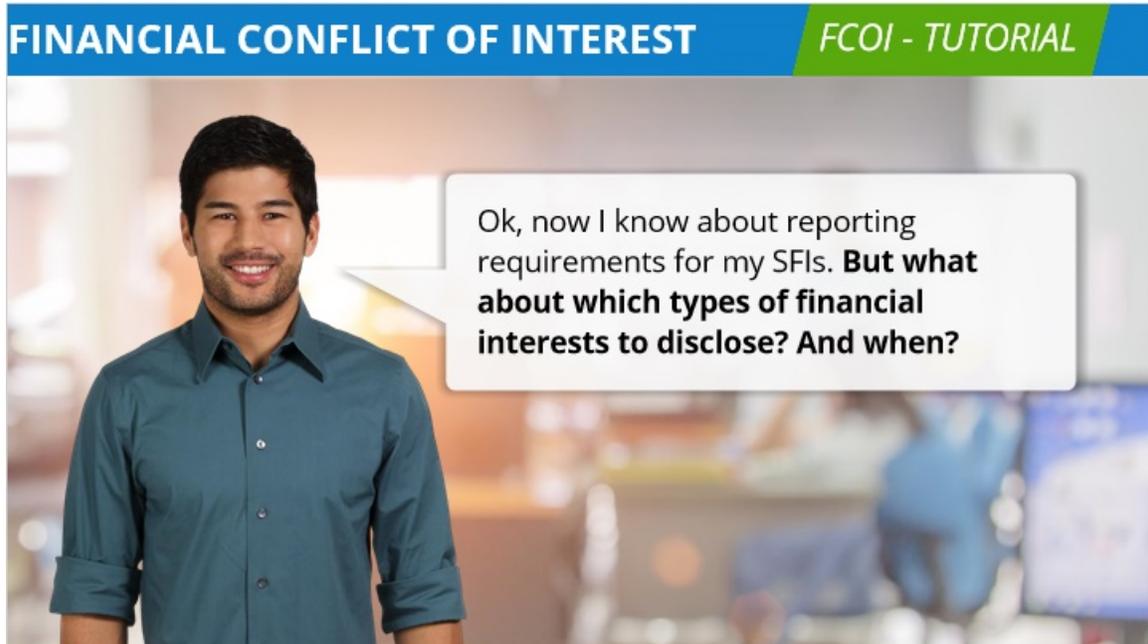
Notes:

You're really picking up on the details, Kirby! You only have to report certain SFIs. These are SFIs that reasonably appear to be related to the investigator's institutional responsibilities; such as remuneration, equity interest, intellectual property rights and interests and any reimbursed or sponsored travel that are received in the prior 12 months of disclosure that meet or exceed the prescribed thresholds.

There is one more rule about SFIs, Kirby: during the period of award, you must update all financial disclosures to your institution according to its policy, on an annual basis and within 30 days of acquiring or discovering a new SFI.

1.34 Kirby Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A man in a blue shirt is smiling. A speech bubble next to him contains text about reporting requirements for SFIs and a question about which types of financial interests to disclose and when.

Ok, now I know about reporting requirements for my SFIs. **But what about which types of financial interests to disclose? And when?**

Notes:

Ok, now I know about reporting requirements for my SFIs. But what about which types of financial interests to disclose? And when?

1.35 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman in a black blazer and pink shirt is smiling and holding a folder. A speech bubble next to her contains text explaining the scope of FCOI regulation.

The FCOI regulation covers all financial interests of monetary value, whether or not the value is readily ascertainable. Investigators are required to disclose their SFIs, and those of their spouse and dependent children, that reasonably appear to be related to the investigator's institutional responsibilities.

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1.36 Untitled Slide



Notes:

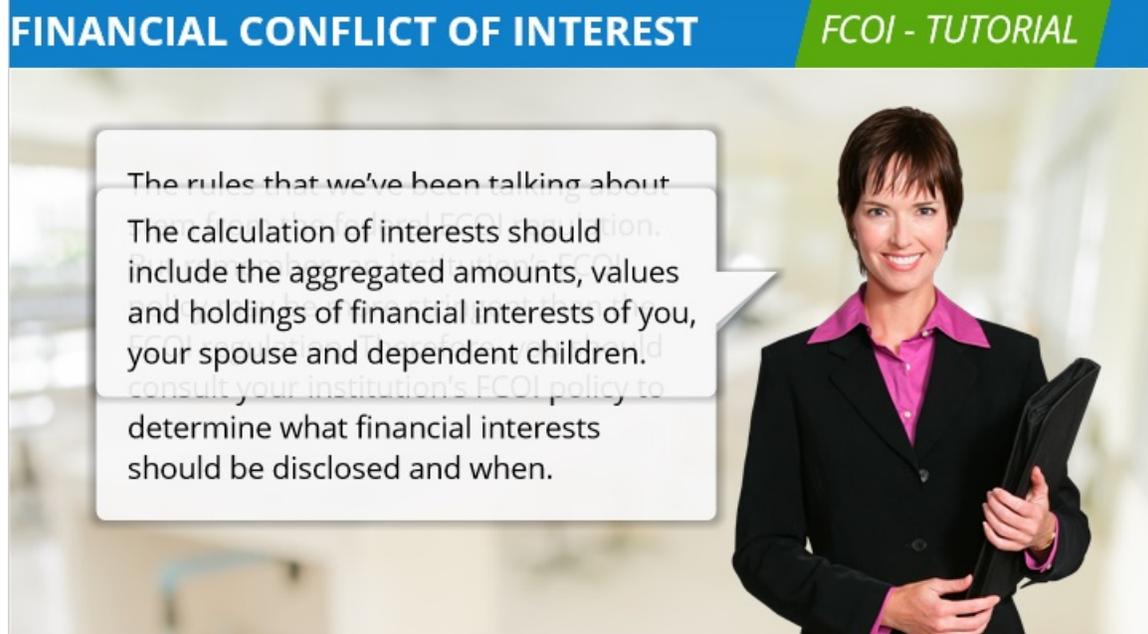
This disclosure must be done within a set timeframe that has the following three components:

1. No later than at the time of application for NIH-funded research
2. Within thirty days of discovering or acquiring a new SFI
3. At least annually, in accordance with the specific time period prescribed by the institution, during the period of award

Examples of "acquiring" a new SFI are through purchase, marriage, or inheritance.

1.37 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*



The rules that we've been talking about stem from the federal FCOI regulation. But remember, an institution's FCOI policy may be more stringent than the FCOI regulation. Therefore, you should consult your institution's FCOI policy to determine what financial interests should be disclosed and when.

The calculation of interests should include the aggregated amounts, values and holdings of financial interests of you, your spouse and dependent children.

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The calculation of interests should include the aggregated amounts, values and holdings of financial interests of you, your spouse and dependent children.

1.38 Kirby Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*



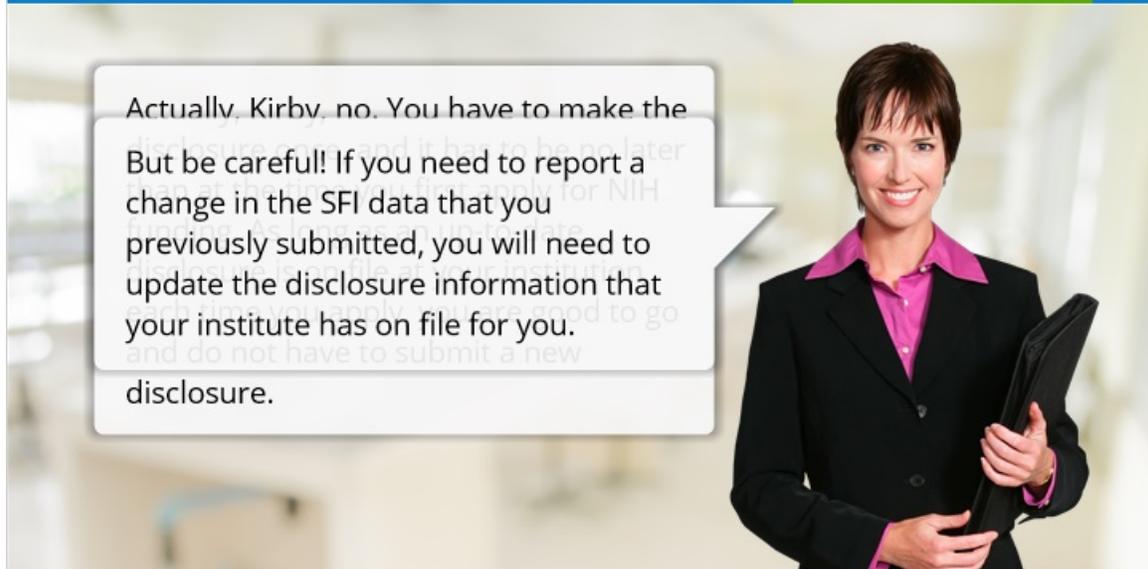
You said that I have to disclose my SFIs no later than when I apply for NIH-funded research. **Does this mean I have to make a new disclosure each time I apply for funding?**

Notes:

You said that I have to disclose my SFIs no later than when I apply for NIH-funded research. Does this mean I have to make a new disclosure each time I apply for funding?

1.39 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*



Actually, Kirby, no. You have to make the disclosure only once and it has to be no later than when you apply for NIH funding. But be careful! If you need to report a change in the SFI data that you previously submitted, you will need to update the disclosure information that your institute has on file for you. Each time you apply, you are good to go and do not have to submit a new disclosure.

Notes:

Actually, Kirby, no. You have to make the disclosure once, and it has to be no later than at the time you first apply for NIH funding. As long as an up-to-date disclosure is on file at your institution each time you apply, you are good to go and do not have to submit a new disclosure. But be careful! If you need to report a change in the SFI data that you previously submitted, you will need to update the disclosure information that your institute has on file for you.

1.40 Mary Talking

FINANCIAL CONFLICT OF INTEREST **FCOI - TUTORIAL**

Wait a minute....Through experience, I know that sometimes we ask new investigators to disclose FCOI information before they apply for NIH funding. That way, we have everything we need on file when they do apply.

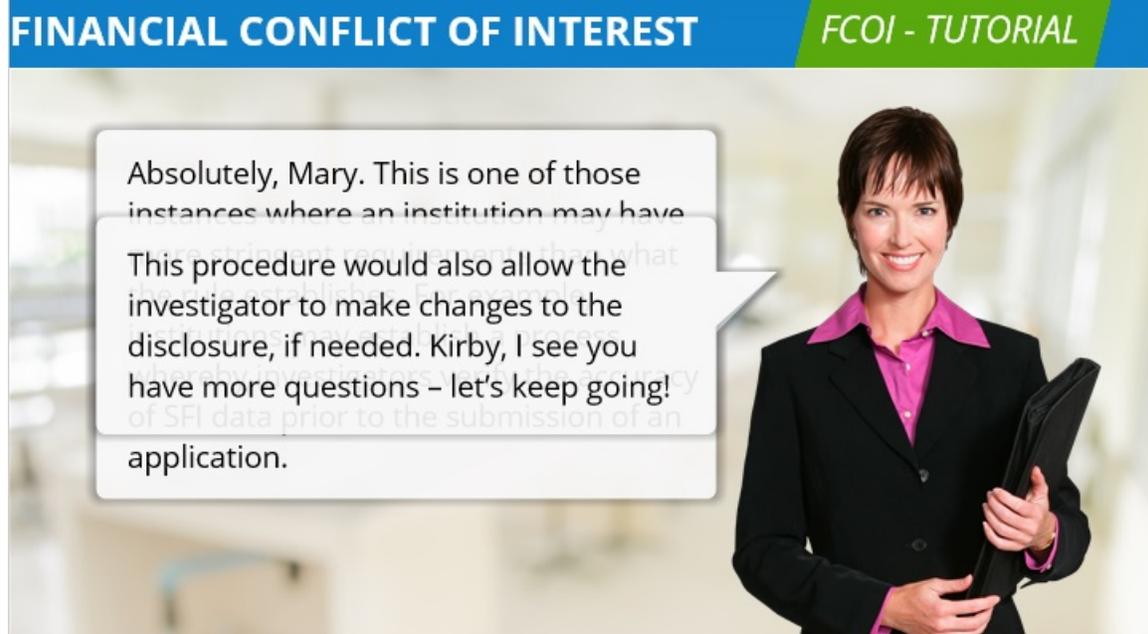
Are institutions allowed collecting SFI data before an investigator first applies for NIH funding?

Notes:

Wait a minute....Through experience, I know that sometimes we ask new investigators to disclose FCOI information before they apply for NIH funding. That way, we have everything we need on file when they do apply. Are institutions allowed collecting SFI data before an investigator first applies for NIH funding?

1.41 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*



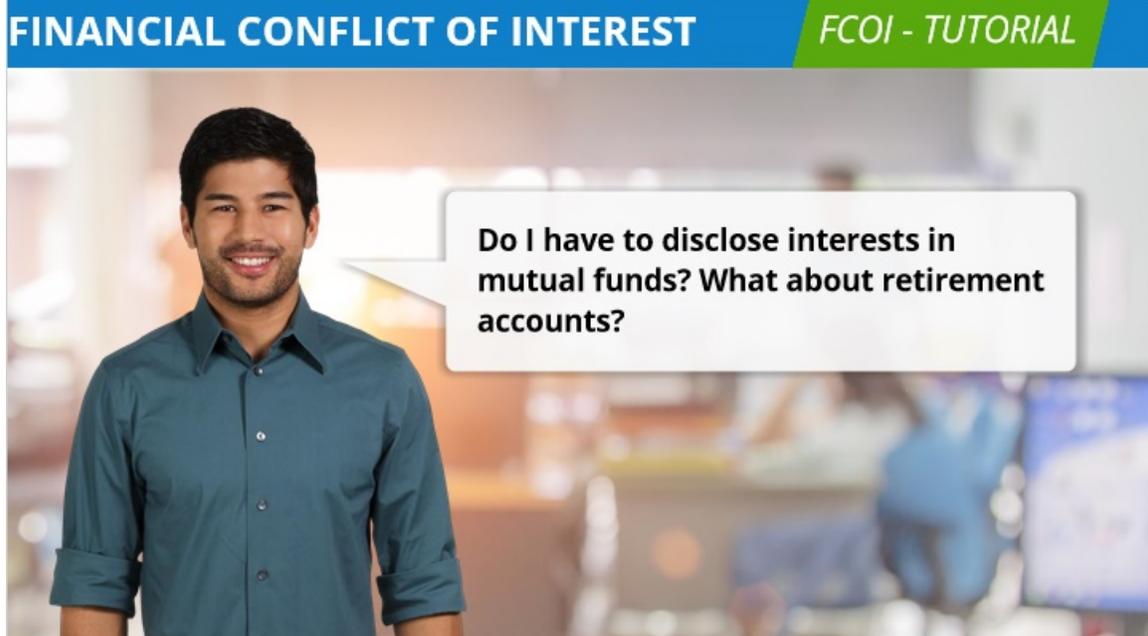
Absolutely, Mary. This is one of those instances where an institution may have more stringent requirements than what the rule establishes. For example, institutions may establish a process whereby investigators verify the accuracy of SFI data prior to the submission of an application. This procedure would also allow the investigator to make changes to the disclosure, if needed. Kirby, I see you have more questions - let's keep going!

Notes:

Absolutely, Mary. This is one of those instances where an institution may have more stringent requirements than what the rule establishes. For example, institutions may establish a process whereby investigators verify the accuracy of SFI data prior to the submission of an application. This procedure would also allow the investigator to make changes to the disclosure, if needed. Kirby, I see you have more questions - let's keep going!

1.42 Kirby Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A man in a blue shirt stands in an office setting. A speech bubble next to him contains the text: "Do I have to disclose interests in mutual funds? What about retirement accounts?"

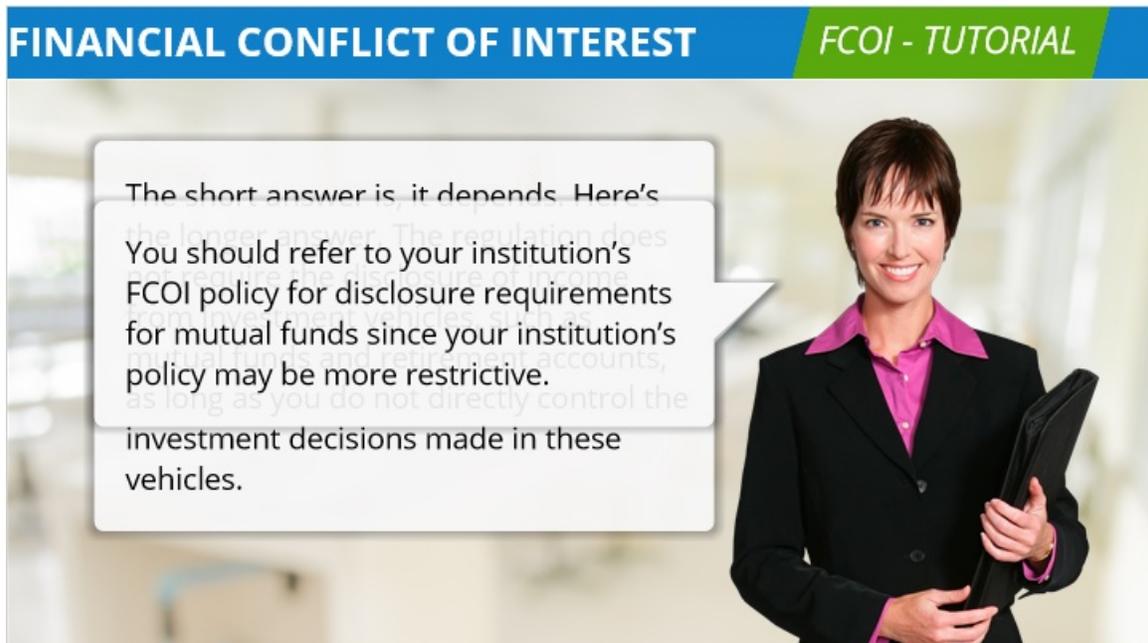
Do I have to disclose interests in mutual funds? What about retirement accounts?

Notes:

Do I have to disclose interests in mutual funds? What about retirement accounts?

1.43 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman in a black blazer and pink shirt stands in an office setting, holding a folder. A speech bubble next to her contains the text: "The short answer is, it depends. Here's the longer answer. The regulation does require the disclosure of income from mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles."

The short answer is, it depends. Here's the longer answer. The regulation does require the disclosure of income from mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles.

Notes:

The short answer is, it depends. Here's the longer answer: the regulation does not require the disclosure of income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles. You should refer to your institution's FCOI policy for disclosure requirements for mutual funds since your institution's policy may be more restrictive.

1.44 Kirby Talking



Notes:

What about disclosing stock and stock options?

1.45 Sue Talking

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

Stock option assets are to be reported in the same manner as all other assets. In other words, they are to be reported by the time of application submission, and then reported annually or as new stocks are obtained. The documentation needed to determine the value of a stock option is defined by the institution, so you should refer to your institutional policy.

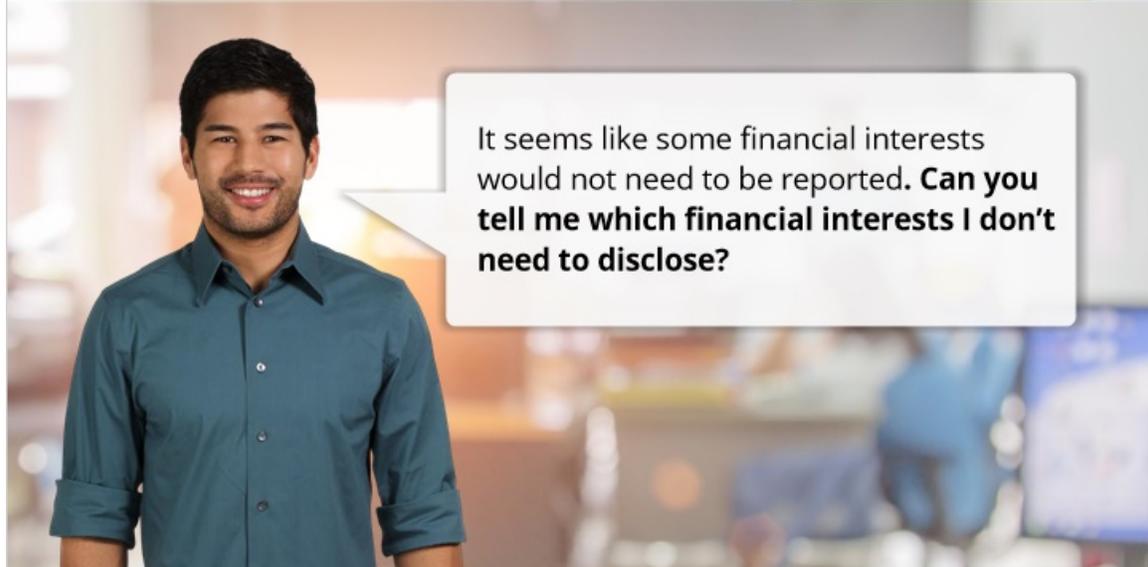


Notes:

Stock option assets are to be reported in the same manner as all other assets. In other words, they are to be reported by the time of application submission, and then reported annually or as new stocks are obtained. The documentation needed to determine the value of a stock option is defined by the Institution, so you should refer to your institutional policy.

1.46 Kirby Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*



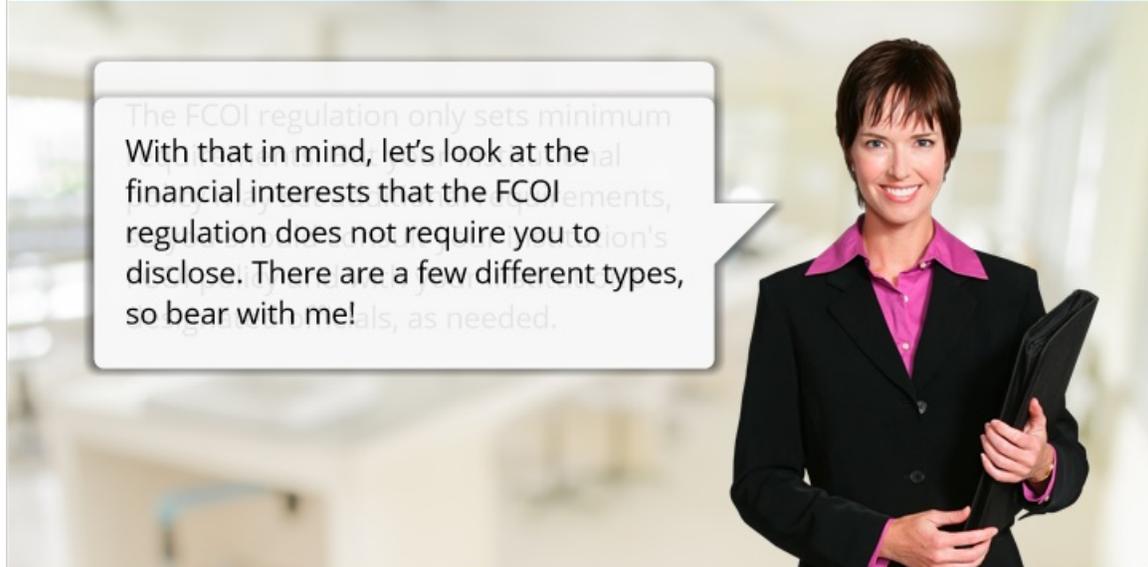
It seems like some financial interests would not need to be reported. **Can you tell me which financial interests I don't need to disclose?**

Notes:

It seems like some financial interests would not need to be reported. Can you tell me which financial interests I don't need to disclose?

1.47 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*



The FCOI regulation only sets minimum requirements. With that in mind, let's look at the financial interests that the FCOI regulation does not require you to disclose. There are a few different types, so bear with me!

Notes:

The FCOI regulation only sets minimum requirements. But your institutional policy may set additional requirements, so you should consult your Institution's FCOI policy and with your institution's designated officials, as needed. With that in mind, let's look at the financial interests that the FCOI regulation does not require you to disclose. There are a few different types, so bear with me!

1.48 Untitled Slide

The slide features a blue header with the text 'FINANCIAL CONFLICT OF INTEREST' and a green header with 'FCOI - TUTORIAL'. The main content is a white box with the title 'Do I Need to Disclose?' and a table with two columns: 'If...' and 'You do not need to disclose:'. The table lists four conditions and their corresponding disclosure exemptions.

If...	You do not need to disclose:
you are currently employed or otherwise appointed by the institution	salary, royalties, or other remuneration paid to you by the institution.
the institution is a commercial or for-profit organization	any ownership interests in the institution that you hold
you do not directly control the investment decisions made in investment vehicles	income from investment vehicles, such as mutual funds and retirement accounts
your seminars, lectures, or teaching engagements are sponsored by certain institutions in the United States	income from seminars, lectures, or teaching engagements

Notes:

The first type applies if you are currently employed or otherwise appointed by the institution. If that is the case, then you do not need to disclose salary, royalties, or other remuneration paid to you by the institution. This includes intellectual property rights assigned to the institution and agreements to share in royalties related to such rights.

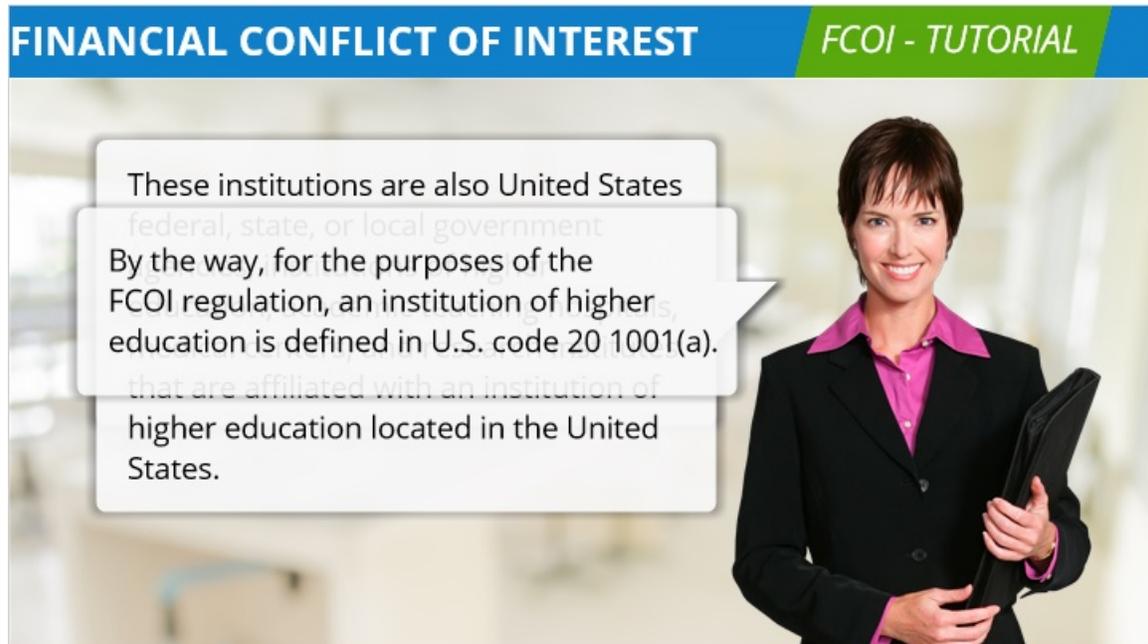
The second type of financial interest that the FCOI regulation does not require you to disclose is any ownership interests in the institution that you hold, if the institution is a commercial or for-profit organization.

Got that? Ok, let's move on to the third type, which is one we actually already spoke about. According to the FCOI regulation, you do not need to disclose income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles.

And fourth, the FCOI regulation does not require you to disclose income from seminars, lectures, or teaching engagements that are sponsored by certain institutions that are located in the United States. These institutions are federal, state, or local government agencies, institutions of higher education as defined by 20 US code 1001(a); and academic teaching

hospitals, medical centers, and research institutes that are affiliated with an institution of higher education. However, any interests received from a foreign institution or any foreign government must be disclosed.

1.49 Sue Talking



FINANCIAL CONFLICT OF INTEREST FCOI - TUTORIAL

These institutions are also United States federal, state, or local government agencies, institutions of higher education; academic teaching hospitals, medical centers, and research institutes that are affiliated with an institution of higher education located in the United States.

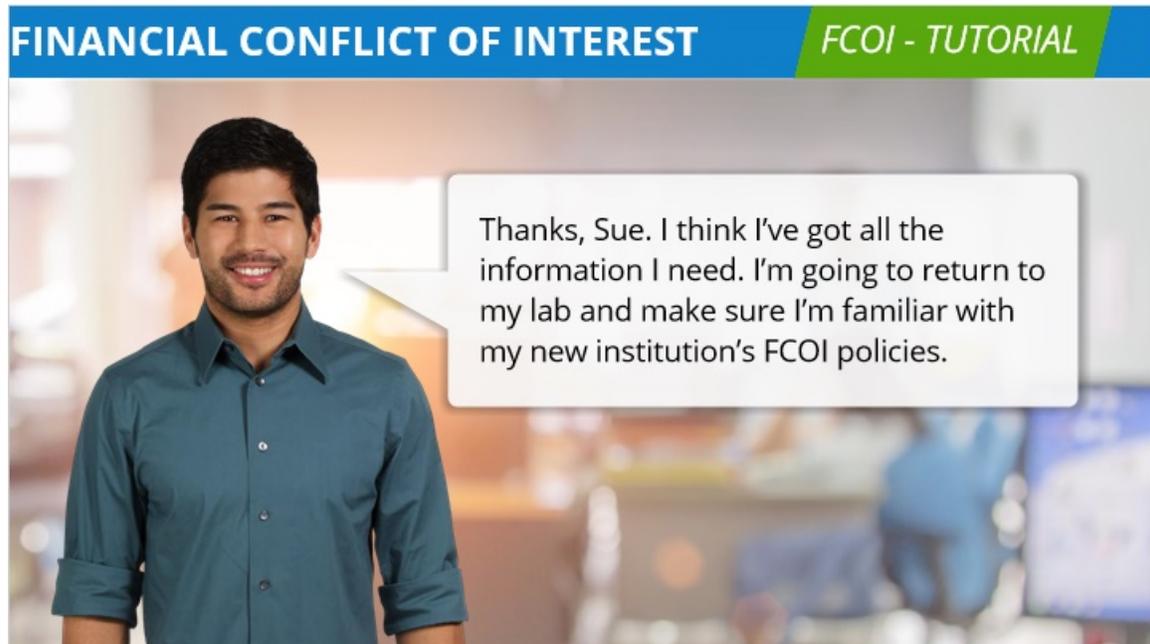
By the way, for the purposes of the FCOI regulation, an institution of higher education is defined in U.S. code 20 1001(a).

Notes:

And lastly, the FCOI regulation does not require you to disclose income from service on advisory committees or review panels for certain institutions. These institutions are also United States federal, state, or local government agencies, institutions of higher education; academic teaching hospitals, medical centers, and research institutes that are affiliated with an institution of higher education located in the United States.

By the way, for the purposes of the FCOI regulation, an institution of higher education is defined in U.S. code 20 1001(a).

1.50 Kirby Talking



Notes:

Thanks, Sue. I think I've got all the information I need. I'm going to return to my lab and make sure I'm familiar with my new institution's FCOI policies.

1.51 Sue Talking



Notes:

You're welcome, and good luck!

1.52 Mary Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

Hi, Sue. I think you did a great job explaining how the FCOI regulation applies to Kirby, but what about me?
How does it apply to institutions?

Icons: School building, Document with magnifying glass.

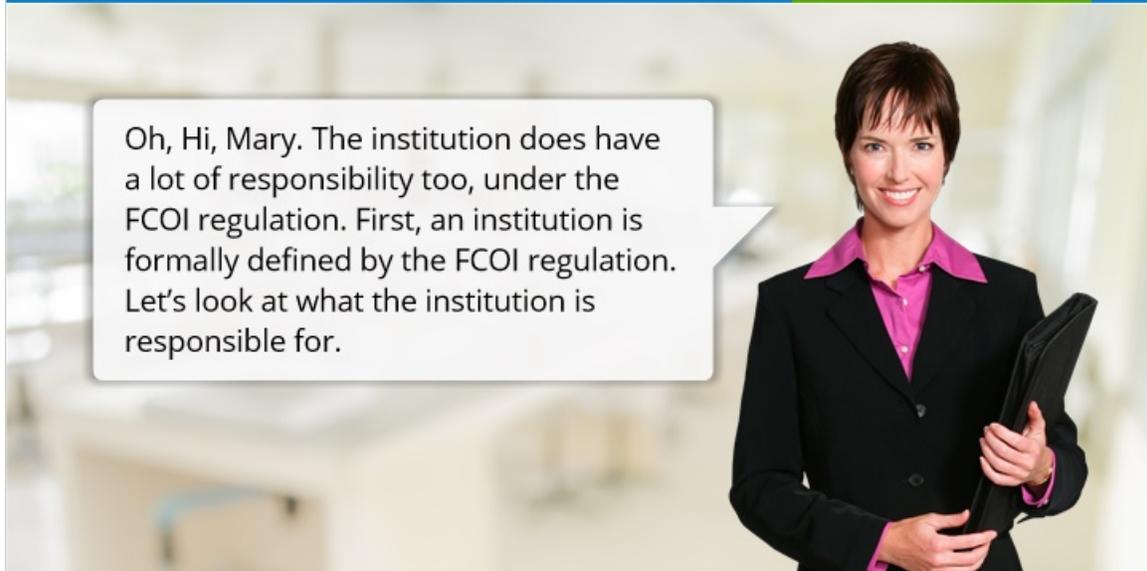
Notes:

Hi, Sue. I think you did a great job explaining how the FCOI regulation applies to Kirby, but what about me? How does it apply to institutions?

1.53 Sue Talking

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL



Oh, Hi, Mary. The institution does have a lot of responsibility too, under the FCOI regulation. First, an institution is formally defined by the FCOI regulation. Let's look at what the institution is responsible for.

Notes:

Oh, hi, Mary. The institution does have a lot of responsibility too, under the FCOI regulation. First, an institution is formally defined by the FCOI regulation. Let's look at what the institution is responsible for.

1.54 Untitled Slide

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

Responsibilities of Institutions

- Create Policy**
- Make Policy Accessible**
- Inform Investigators**
- Require Training**
 - the institution's policy
 - responsibility to disclose SFIs
 - the regulation itself

Notes:

The institution has to create and maintain an up-to-date, written and enforced policy that complies with the regulation.

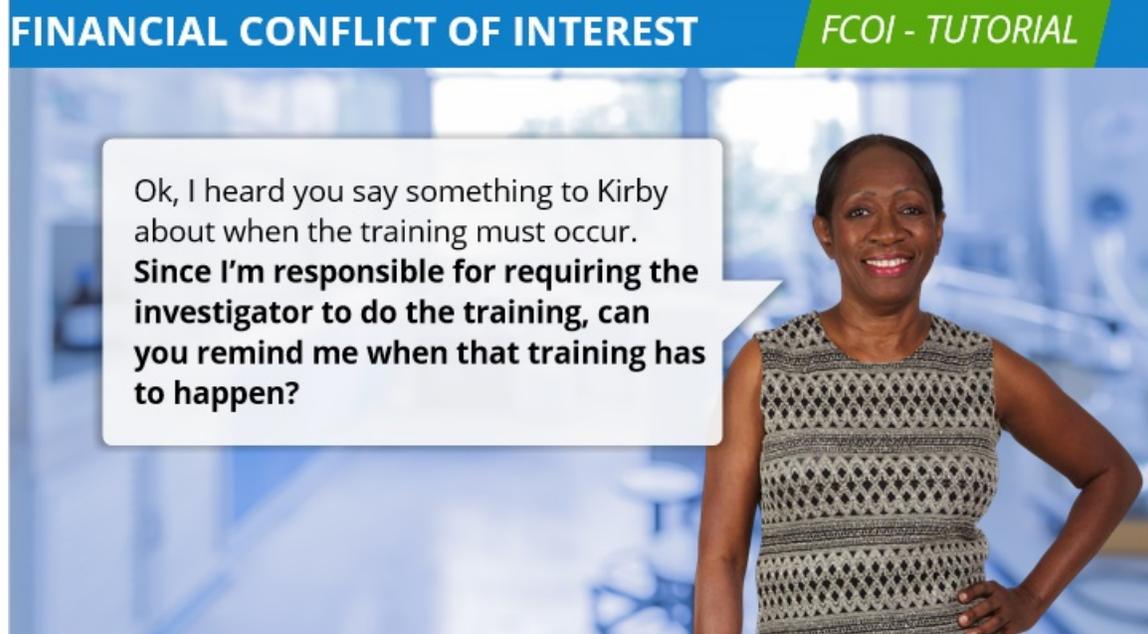
The institution must also make its policy publicly available via a publicly accessible website or available to any requestor within five business days of a request.

The institution must also inform each investigator of the FCOI regulation, the institution's FCOI policy, and the investigator's disclosure responsibilities that meet or exceed the regulatory requirements.

Next, the institution must also require each investigator to complete training on certain items. These are the institution's policy, the investigator's responsibility to disclose SFIs, and the regulation itself.

1.55 Mary Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman with dark hair, wearing a patterned sleeveless top, stands with her hand on her hip. A speech bubble points to her from the left.

Ok, I heard you say something to Kirby about when the training must occur. **Since I'm responsible for requiring the investigator to do the training, can you remind me when that training has to happen?**

Notes:

Ok, I heard you say something to Sue about when the training must occur. Since I'm responsible for requiring the investigator to do the training, can you remind me when that training has to happen?

1.56 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman with short brown hair, wearing a black blazer over a pink shirt, holds a black folder. A speech bubble points to her from the left.

Sure thing, Mary. There are three times when this training must occur:

Notes:

Sure thing, Mary. There are three times when this training must occur:

1.57 Untitled Slide

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

Require FCOI Training...

Immediately if:

- ✓ The institution revises its FCOI policies and procedures in any way that affects the investigators' requirements
- ✓ The institution has a new investigator
- ✓ An institution finds that an investigator is not in compliance with the institution's FCOI policy or management plan

Prior to engaging in any NIH-funded research

Every 4 years

Notes:

Prior to engaging in any NIH-funded research;

Every four years; or

immediately when any of the following circumstances apply:

The institution revises its FCOI policies and procedures in any way that affects the investigators' requirements

The institution has a new investigator

An institution finds that an investigator is not in compliance with the institution's FCOI policy or management plan

1.58 Mary Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman with short dark hair, wearing a patterned sleeveless top, stands in a laboratory setting. A speech bubble points to her with the text: "Is there anything else an institution has to do?".

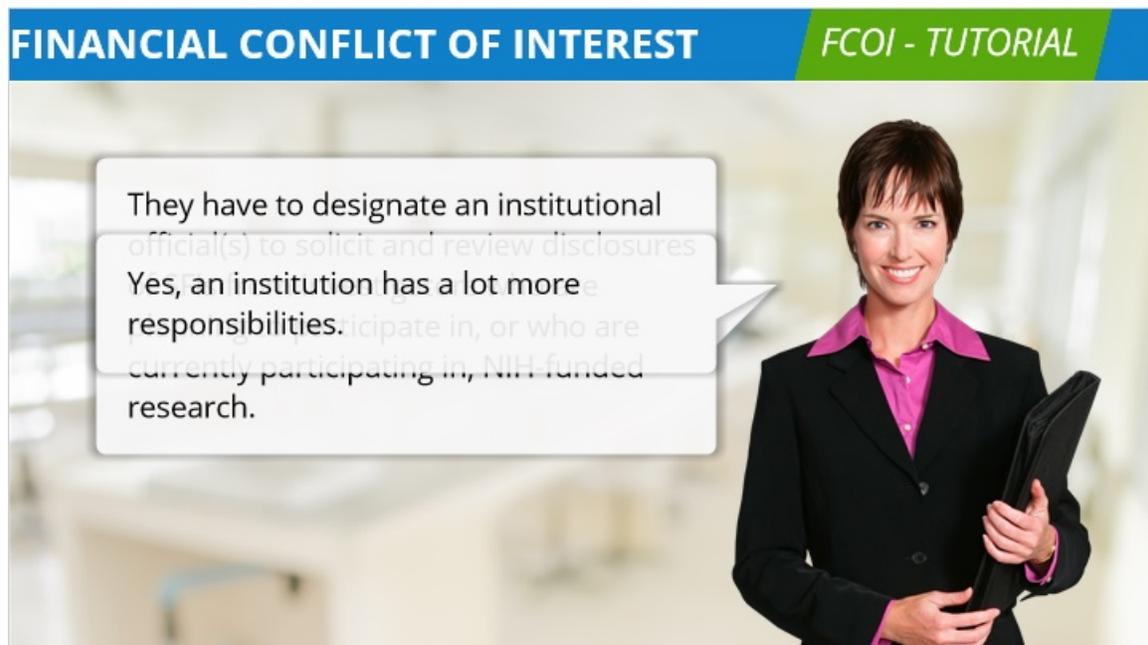
Is there anything else an institution has to do?

Notes:

Is there anything else an institution has to do?

1.59 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman with short brown hair, wearing a black blazer over a pink shirt, stands in a laboratory setting. A speech bubble points to her with the text: "They have to designate an institutional official(s) to solicit and review disclosures. Yes, an institution has a lot more responsibilities. participate in, or who are currently participating in, NIH-funded research."

They have to designate an institutional official(s) to solicit and review disclosures. Yes, an institution has a lot more responsibilities. participate in, or who are currently participating in, NIH-funded research.

Notes:

1.61 Mary Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman with dark hair, wearing a patterned sleeveless top, stands in a brightly lit office hallway. A speech bubble points to her with the text "This is a lot to remember!".

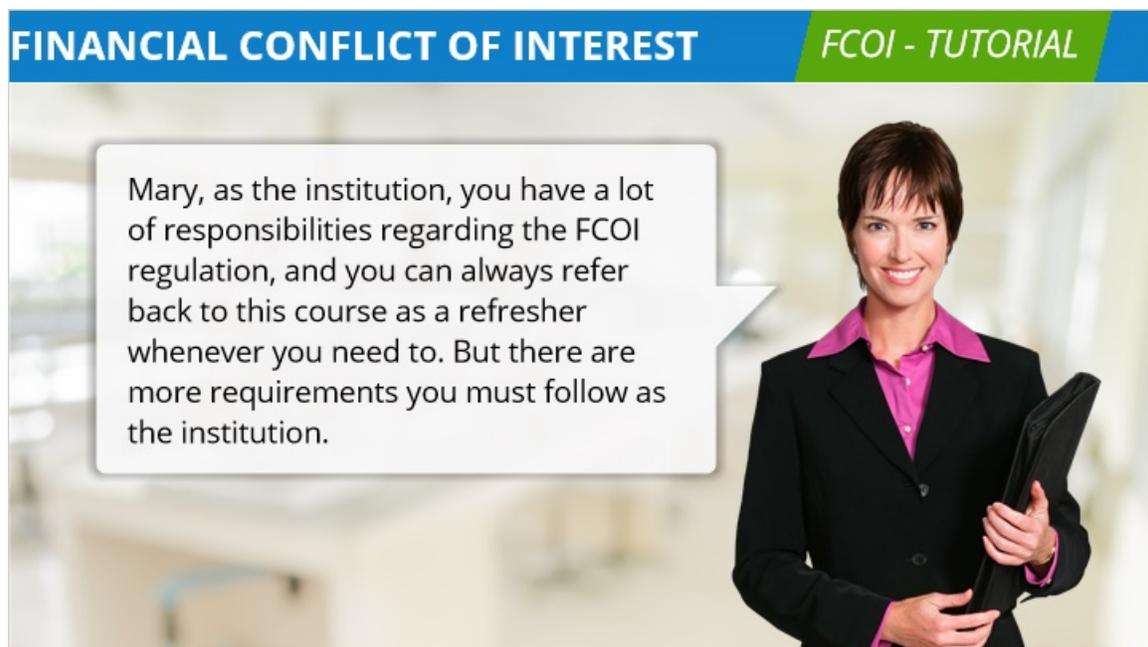
This is a lot to remember!

Notes:

This is a lot to remember!

1.62 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman with short brown hair, wearing a black blazer over a pink shirt, stands in a brightly lit office hallway. She is holding a black folder. A speech bubble points to her with the text "Mary, as the institution, you have a lot of responsibilities regarding the FCOI regulation, and you can always refer back to this course as a refresher whenever you need to. But there are more requirements you must follow as the institution."

Mary, as the institution, you have a lot of responsibilities regarding the FCOI regulation, and you can always refer back to this course as a refresher whenever you need to. But there are more requirements you must follow as the institution.

Notes:

Mary, as the institution, you have a lot of responsibilities regarding the FCOI regulation, and you can always refer back to this course as a refresher whenever you need to. But there are more requirements you must follow as the institution.

1.63 Untitled Slide

FINANCIAL CONFLICT OF INTEREST **FCOI - TUTORIAL**

Requirements for Institutions

- ✓ Provide guidelines consistent with the regulation for the designated institutional official(s) to determine whether an investigator's SFI is related to NIH-funded research
- ✓ Provide initial and annual FCOI reports to the NIH through the required eRA Commons FCOI Module
- ✓ Take the necessary actions to manage FCOIs, including any financial conflicts of a subrecipient investigator pursuant to the Code of Federal Regulations
 - Information must be available prior to the expenditure of funds and it must be updated annually at a minimum or within 60 days of a newly identified FCOI

Notes:

You must provide guidelines consistent with the regulation for the designated institutional official(s) to determine whether an investigator's SFI is related to NIH-funded research. If the SFI is related to NIH-funded research, you must also provide guidelines for the official to determine whether the SFI is an FCOI.

The institution must also take the necessary actions to manage FCOIs, including any financial conflicts of a subrecipient investigator pursuant to the Code of Federal Regulations. This management may require development and implementation of a management plan by the Institution if the institution's FCOI policy applies to subrecipient investigators. We'll talk more about subrecipient investigators later in this course.

The institution must also complete and document a retrospective review when applicable and, if bias is found, develop and submit a mitigation report, pursuant to the Code of Federal Regulations.

The institution must also provide initial and annual FCOI reports to the NIH through the required eRA Commons FCOI Module.

The institution must also make information concerning identified FCOIs held by senior/key personnel publicly accessible for a period of three years from the most recent update. This

information must be available prior to the expenditure of funds and it must be updated annually at a minimum or within 60 days of a newly identified FCOI.

1.64 Untitled Slide

The slide features a blue header with the text 'FINANCIAL CONFLICT OF INTEREST' and a green header with 'FCOI - TUTORIAL'. The main content is in a white box with a blue title 'Institutions Must:'. It lists two requirements:

- 2.** Establish adequate records and appropriate enforcement mechanisms, employee sanctions or other administrative actions to ensure investigator compliance, as appropriate.
- 3.** Upon request, agree to make information promptly available to the NIH relating to any investigator disclosure of financial interests, and the institution's review of and response to such disclosure. This information must be provided to NIH whether or not the disclosure resulted in the institution's determination of an FCOI.

Notes:

There are three more things that an institution must do.

They must maintain certain records for a minimum of three years. The records that must be maintained are the ones related to all investigator disclosures of financial interests; related to the institution's review and/or response to these disclosures (whether or not a disclosure resulted in the institution's determination of an FCOI); and those related to all actions under the institution's policy or retrospective review, if applicable. These records must be maintained for a minimum of three years from the date the final expenditures report is submitted to the NIH or, where applicable, from other dates specified in the Code of Federal Regulations for different situations.

Institutions must establish adequate and appropriate enforcement mechanisms, employee sanctions or other administrative actions to ensure Investigator compliance, as appropriate.

And lastly, institutions must, upon request, agree to make information promptly available to the NIH relating to any investigator disclosure of financial interests, and the institution's review of

and response to such disclosure. This information must be provided to NIH whether or not the disclosure resulted in the institution's determination of an FCOI.

1.65 Mary Talking



FINANCIAL CONFLICT OF INTEREST FCOI - TUTORIAL

Sue, that certainly was a lot of requirements for me, but I've got my notes right here.

I think I've got another question... because we also have subcontractors and consortium participants on NIH-supported research that is awarded to our institution. **What are the responsibilities related to subrecipients?**

Notes:

Sue, that certainly was a lot of requirements for me, but I've got my notes right here.

I think I've got another question... because we also have subcontractors and consortium participants on NIH-supported research that is awarded to our institution. What are the responsibilities related to Subrecipients?

1.66 Sue Talking

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

In the written agreement with the NIH-funded subrecipient, you have to incorporate terms that establish whether the FCOI policy of the awardee institution or the FCOI policy of the subrecipient institution will apply to the subrecipient's investigators. Depending on which institutional policy applies, different things will need to happen.



Notes:

If the institution carries out the NIH-funded research through a subrecipient, such as a subcontractor or consortium members, the institution must take reasonable steps to ensure that any subrecipient investigator complies with the regulation. These steps, consistent with the Code of Federal Regulations, are as follows:

In the written agreement with the subrecipient, you have to incorporate terms that establish whether the FCOI policy of the awardee institution or the FCOI policy of the subrecipient institution will apply to the subrecipient's investigators. Depending on which institutional policy applies, different things will need to happen.

1.67 Untitled Slide



FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

Steps for Subrecipient Compliance

- ✓ If the subrecipient's FCOI policy applies to subrecipient investigators, then the subrecipient will need to certify in the agreement that its policy complies with the regulation.
 - If the subrecipient cannot provide this certification, the agreement must state that subrecipient investigators are subject to the FCOI policy of the awardee institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee institution
- ✓ The agreement must specify time period(s) for the subrecipient to report all identified FCOIs to the awardee institution

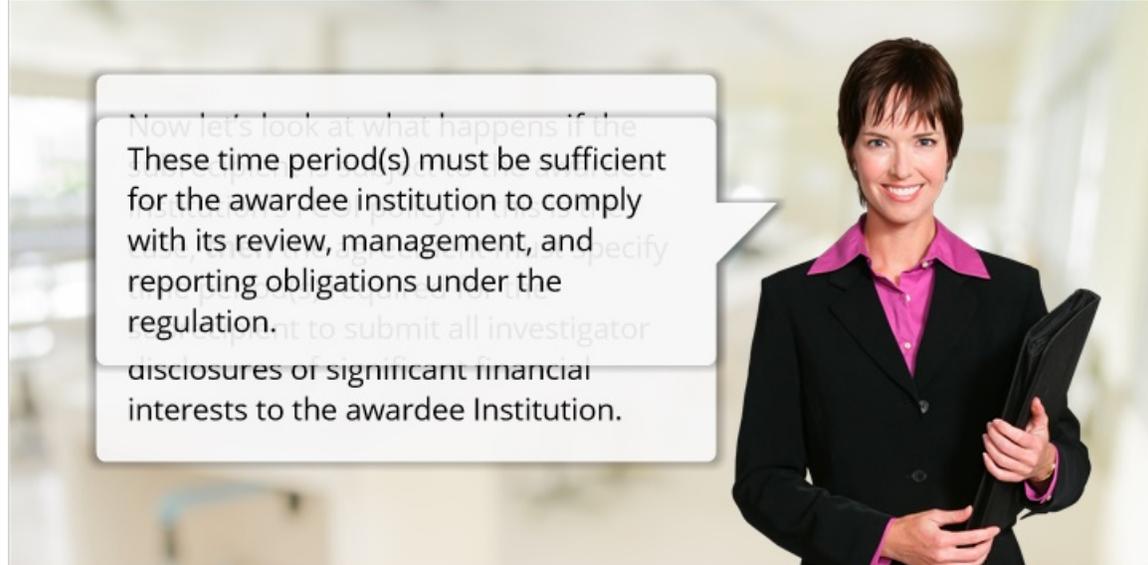
Notes:

If the subrecipient's FCOI policy applies to subrecipient investigators, then the subrecipient will need to certify in the agreement that its policy complies with the regulation. If the subrecipient cannot provide this certification, the agreement must state that subrecipient investigators are subject to the FCOI policy of the awardee institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee institution.

Moreover, the agreement must specify time period(s) for the subrecipient to report all identified FCOIs to the awardee institution. These time period(s) must be sufficient for the awardee institution to provide timely FCOI reports to the NIH.

1.68 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*



Now let's look at what happens if the subrecipient is subject to the awardee institution's FCOI policy. If this is the case, **then** the agreement must specify time period(s) required for the subrecipient to submit all investigator disclosures of significant financial interests to the awardee Institution. These time period(s) must be sufficient for the awardee institution to comply with its review, management, and reporting obligations under the regulation.

Notes:

Now let's look at what happens if the subrecipient is subject to the awardee institution's FCOI policy. If this is the case, **then** the agreement must specify time period(s) required for the subrecipient to submit all investigator disclosures of significant financial interests to the awardee institution. These time period(s) must be sufficient for the awardee institution to comply with its review, management, and reporting obligations under the regulation.

1.69 Untitled Slide

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

Steps for Subrecipient Compliance

- ✓ The awardee institution will submit any FCOI reports for subrecipient investigators to the NIH
- ✓ **Whether the subrecipient is bound by its own institution's policy or that of the awardee institution**, the awardee institution in both cases, is responsible for reporting all identified FCOIs for subrecipient investigators to the NIH.

Notes:

The awardee institution will submit any FCOI reports for subrecipient investigators to the NIH

Whether the subrecipient is bound by its own institution's policy or that of the awardee institution, the awardee institution in both cases, is responsible for reporting all identified FCOIs for subrecipient investigators to the NIH.

1.70 Mary Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman with dark hair, wearing a patterned sleeveless top, stands with her hand on her hip. A speech bubble points to her from the left.

Thanks, Sue. I've heard a lot about public accessibility. **What are the requirements for making an institution's FCOI policy publicly accessible?**

Notes:

Thanks, Sue. I've heard a lot about public accessibility. What are the requirements for making an institution's FCOI policy publicly accessible?

1.71 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman with short brown hair, wearing a black blazer over a pink shirt, holds a black folder. A speech bubble points to her from the left.

When the institution posts its FCOI policy or otherwise makes the policy publicly accessible, it signifies that the institution applying for or receiving NIH funding from a grant or cooperative agreement that is covered by the 2011 revised regulation is in full compliance with all the regulatory requirements.

Notes:

Institutions are required to make their FCOI policy publicly available. If the institution has a publicly accessible website, the policy must be available via a publicly accessible website. If the institution does not have a publicly accessible website, then the institution must make the written policy available to any requestor within five business days of the request. If the institution acquires a presence on a publicly accessible website during the time of the NIH award, the institution has to post the policy information on that website within 30 calendar days. Having the FCOI policy publicly accessible is a way to help ensure that the institution is in full compliance with all regulatory requirements.

When the institution posts its FCOI policy or otherwise makes the policy publicly accessible, it signifies that the institution applying for or receiving NIH funding from a grant or cooperative agreement that is covered by the 2011 revised regulation is in full compliance with all the regulatory requirements.

1.72 Mary Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

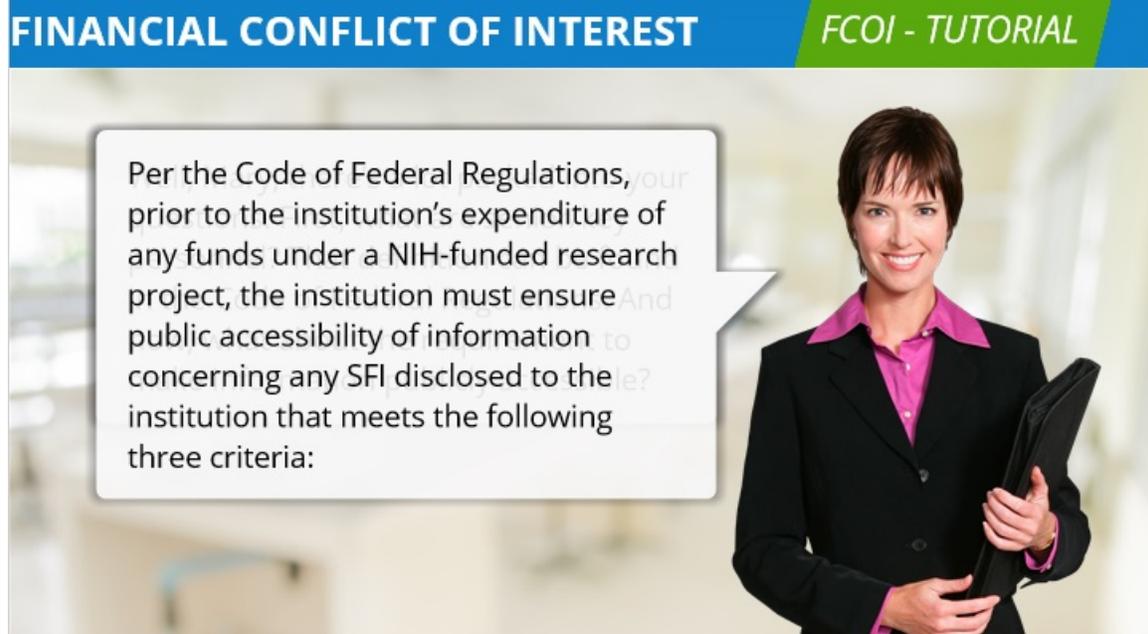
Ok, that seems logical enough. **Do I, as the institution, have to make any FCOI information public? What are the requirements for making information on FCOI of senior/key personnel publicly accessible?**

Notes:

Ok, that seems logical enough. Do I, as the institution, have to make any FCOI information public? What are the requirements for making information on FCOI of senior/key personnel publicly accessible?

1.73 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*



Per the Code of Federal Regulations, prior to the institution's expenditure of any funds under a NIH-funded research project, the institution must ensure public accessibility of information concerning any SFI disclosed to the institution that meets the following three criteria:

Notes:

Well, Mary, there's a lot packed into your questions. First, what are senior/key personnel? That definition can be found in the Code of Federal Regulations. And now, what about the requirement to make information publicly accessible?

Per the Code of Federal Regulations, prior to the institution's expenditure of any funds under a NIH-funded research project, the institution must ensure public accessibility of information concerning any SFI disclosed to the institution that meets the following three criteria:

1.74 Untitled Slide

FINANCIAL CONFLICT OF INTEREST **FCOI - TUTORIAL**

Criteria:

- 1.** The SFI 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
- 2.** The institution determines that the SFI is related to the NIH-funded research
- 3.** The institution determines that the SFI is an FCOI

Notes:

1. The SFI 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
2. The institution determines that the SFI is related to the NIH-funded research; and
3. The institution determines that the SFI is an FCOI

1.75 Sue Talking

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

This information must be publicly accessible, via a publicly accessible website or by written response within five business days of a request. The information that the institution makes available must include, at a minimum, the following:



Notes:

This information must be publicly accessible, via a publicly accessible website or by written response within five business days of a request. The information that the institution makes available must include, at a minimum, the following:

1.76 Untitled Slide

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

Available Information

- a. The investigator's 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
- b. The investigator's title and role with respect to the research project
 - If the approximate dollar values are given, the permissible dollar ranges are: \$0 to \$4,999 dollars; \$5,000 to \$9,999 dollars; \$10,000-\$19,999 dollars; amounts between \$20,000 and \$100,000 by increments of \$20,000 dollars; or amounts above \$100,000 by increments of \$50,000 (dollars)
- c. The name of the entity in which the SFI is held
- d. The nature of the SFI, such as equity interest, consulting fees, travel reimbursement, honoraria, etc.

Notes:

- a. The investigator's name
- b. The investigator's title and role with respect to the research project
- c. The name of the entity in which the SFI is held
- d. The nature of the SFI, such as equity interest, consulting fees, travel reimbursement, honoraria, etc.; and
- e. 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. If the approximate dollar values are given, the permissible dollar ranges are: \$0 to \$4,999 dollars; \$5,000 to \$9,999 dollars; \$10,000-\$19,999 dollars; amounts between \$20,000 and \$100,000 by increments of \$20,000 dollars; or amounts above \$100,000 by increments of \$50,000 dollars)

1.77 Mary Talking

FINANCIAL CONFLICT OF INTEREST **FCOI - TUTORIAL**

I keep hearing a lot about the institutional officials. **What are the responsibilities of the institution's designated official(s) to review and address FCOI?**

Notes:

I keep hearing a lot about the institutional officials. What are the responsibilities of the institution's designated official(s) to review and address FCOI?

1.78 Untitled Slide

FINANCIAL CONFLICT OF INTEREST **FCOI - TUTORIAL**

Responsibilities of Institutional Officials

Institutional officials must establish guidelines consistent with the regulation for the institution's designated official(s) to solicit and review disclosures of SFIs from each investigator who is planning to participate in, or is participating in, the NIH-funded research. After reviewing the financial disclosure, the designated official(s) must determine whether the investigator's SFI is related to NIH-funded research, and if so, whether an FCOI exists. If an FCOI exists, the designated official(s) must take such actions as necessary to manage the FCOI, including any financial conflicts of interest of subrecipient investigators, if applicable.

Designated officials must determine whether the investigator's SFI is related to NIH-funded research, and if so, whether an FCOI exists. If an FCOI exists, the designated official(s) must take such actions as necessary to manage the FCOI, including any financial conflicts of interest of subrecipient investigators, if applicable.

- the SFI is in an entity whose financial interests could be affected by the research
- The institution may involve the investigator in the designated official(s)'s determination of whether an SFI is related to the NIH-funded research

Notes:

The institution must establish guidelines consistent with the regulation for the institution's designated official(s) to solicit and review disclosures of SFIs from each investigator who is planning to participate in, or is participating in, the NIH-funded research. After reviewing the financial disclosure, the designated official(s) must determine whether the investigator's SFI is related to NIH-funded research, and if so, whether an FCOI exists. If an FCOI exists, the designated official(s) must take such actions as necessary to manage the FCOI, including any financial conflicts of interest of subrecipient investigators, if applicable.

An SFI is related to NIH-funded research when the institution, through its designated official(s), reasonably determines that the SFI: could be affected by the NIH-funded research; or the SFI is in an entity whose financial interests could be affected by the research. The institution may involve the investigator in the designated official(s)'s determination of whether an SFI is related to the NIH-funded research.

An FCOI exists when the institution, through its designated official(s), reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

1.79 Mary Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

When must the institution provide information to the NIH and what must be provided?

Notes:

When must the institution provide information to the NIH and what must be provided?

1.80 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

There are a few times in the award cycle when the institution must provide information or ensure that it has completed certain certifications or requirements.

Notes:

There are a few times in the award cycle when the institution must provide information or ensure that it has completed certain certifications or requirements.

1.81 Untitled Slide

FINANCIAL CONFLICT OF INTEREST **FCOI - TUTORIAL**

At Time of Application:

The Institution Provides a Certification That:

1. It has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOIs with respect to all research projects for which funding is sought or received from the NIH; and
2. That it promotes and enforces investigator compliance with the regulatory requirements including those pertaining to disclosure of SFIs; and
3. That it manages any FCOI and provides initial and annual FCOI reports to the NIH consistent with the regulation; and
4. That it agrees to make information available, promptly upon request to the NIH relating to 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 an FCOI; and
5. That it fully complies with the requirements of the regulation.

Notes:

At the time of the application, the institution provides a certification that:

1. It has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOIs with respect to all research projects for which funding is sought or received from the NIH; and
2. That it promotes and enforces investigator compliance with the regulatory requirements including those pertaining to disclosure of SFIs; and
3. That it manages any FCOI and provides initial and annual FCOI reports to the NIH consistent with the regulation; and
4. That it agrees to make information available, promptly upon request to the NIH relating to 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 an FCOI; and
5. That it fully complies with the requirements of the regulation.

1.82 Sue Talking



FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

Prior to spending any funds under an NIH award, the institution must submit an FCOI report for any identified FCOI of each investigator and manage the FCOI. If the FCOI is eliminated prior to the submission of the initial report, no FCOI report is required. In addition, the institution must submit an FCOI report for any FCOI(s) identified for subrecipient investigators, if applicable.

After an award is made, there are also other requirements that the institution must fulfill.

Notes:

So those statements are part of the certification at the time of application. Now let's talk about what happens after award.

Prior to spending any funds under an NIH award, the institution must submit an FCOI report to the NIH for any identified FCOI of each investigator and manage the FCOI. If the FCOI is eliminated prior to the submission of the initial report, no FCOI report is required. In addition, the institution must submit an FCOI report for any FCOI(s) identified for subrecipient investigators, if applicable.

After an award is made, there are also other requirements that the institution must fulfill.

1.83 Untitled Slide

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

Institution Requirements After Award

For an FCOI that is identified during an ongoing NIH-funded project, institutions must..



- Review Disclosure of SFI**
- Determine Whether it is Related to the Research**
- Implement a Management Plan**
- Submit the FCOI Report to the NIH**

Notes:

For an FCOI that is identified during an ongoing NIH-funded project, the following must occur within 60 days. The institution must submit an FCOI report through for any SFI that the institution identifies as an FCOI subsequent to the institution's initial FCOI report during an ongoing NIH-funded research project. For example, the institution may find an FCOI exists for an investigator who is newly participating in the project or for an existing investigator who discloses a new SFI to the institution during the period of award. The institution must review the disclosure of SFI; determine whether it is related to the research; and, if so, implement on at least an interim basis, a management plan that shall specify the actions that have been and will be, taken to manage such FCOI; and submit the FCOI report to the NIH.

1.84 Sue Talking

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

There are certain circumstances when deadlines may have passed, and then there are other requirements that must be met. Within 60 days of the investigator's disclosure of an SFI that was not disclosed in a timely manner by the investigator, or if the institution fails to review a previously existing SFI during an ongoing NIH-funded project, the institution's designated official(s) must comply with the following requirements:



Notes:

There are certain circumstances when deadlines may have passed, and then there are other requirements that must be met. Within 60 days of the investigator's disclosure of an SFI that was not disclosed in a timely manner by the investigator, or if the institution fails to review a previously existing SFI during an ongoing NIH-funded project, the institution's designated official(s) must comply with the following requirements.

1.85 Untitled Slide

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

Institution Requirements After Deadlines

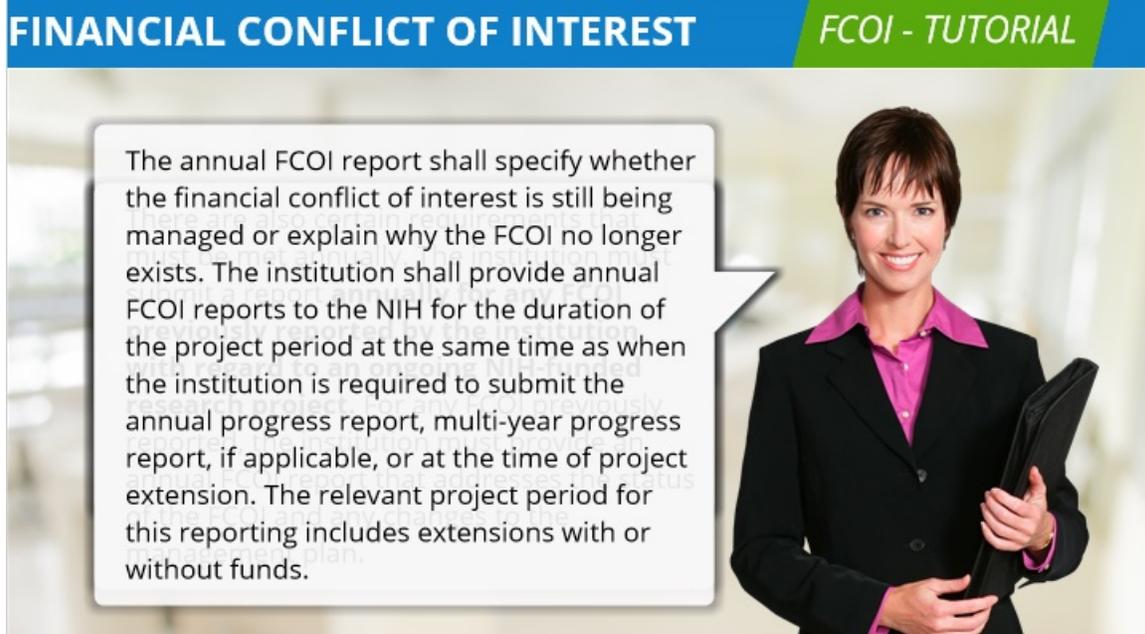
- ✓ The official(s) must **review the SFI**; determine whether it is related to the NIH-funded research; and determine whether an FCOI exists. **If an FCOI exists**, the institution must implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such FCOI and submit an FCOI report to the NIH.
- ✓ **Within 120 days** of the institution's determination of noncompliance, it must also 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 period of noncompliance, was **biased in the design, conduct, or reporting** of such research.
- ✓ Based on the results of the retrospective review, if appropriate, the institutional official(s) must **update the previously submitted FCOI report**, specifying the actions that will be taken to manage the FCOI going forward.

Notes:

The official(s) must review the SFI; determine whether it is related to the NIH-funded research; and determine whether an FCOI exists. If an FCOI exists, 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 FCOI and submit an FCOI report to the NIH. Within 120 days of the institution's determination of noncompliance, it must also 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 period of noncompliance, was biased in the design, conduct, or reporting of such research.

Based on the results of the retrospective review, if appropriate, the institutional official(s) must update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

1.86 Sue Talking



FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

The annual FCOI report shall specify whether the financial conflict of interest is still being managed or explain why the FCOI no longer exists. The institution shall provide annual FCOI reports to the NIH for the duration of the project period at the same time as when the institution is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of project extension. The relevant project period for this reporting includes extensions with or without funds.

Notes:

There are certain circumstances that will obligate the institution to report to the NIH as soon as the circumstance is discovered.

At any time during the award, the institution must promptly notify NIH when bias is found in the design, conduct, or reporting of NIH-funded research. The institution must promptly notify NIH and submit a mitigation report if bias is found based on the results of the retrospective review. The mitigation report must include the key elements documented in the retrospective review and a description of the impact of the bias on the research project. The mitigation report must also include 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.

There are also certain requirements that must be met annually. The institution must submit a report annually for any FCOI previously reported by the institution with regard to an ongoing NIH-funded research project. For any FCOI previously reported, the institution must provide an annual FCOI report that addresses the status of the FCOI and any changes to the management plan. The annual FCOI report shall specify whether the financial conflict of interest is still being managed or explain why the FCOI no longer exists. The institution shall provide annual FCOI reports to the NIH for the duration of the project period at the same time as when the institution is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of project extension. The relevant project period for this reporting includes extensions with or without funds.

1.87 Mary Talking



FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

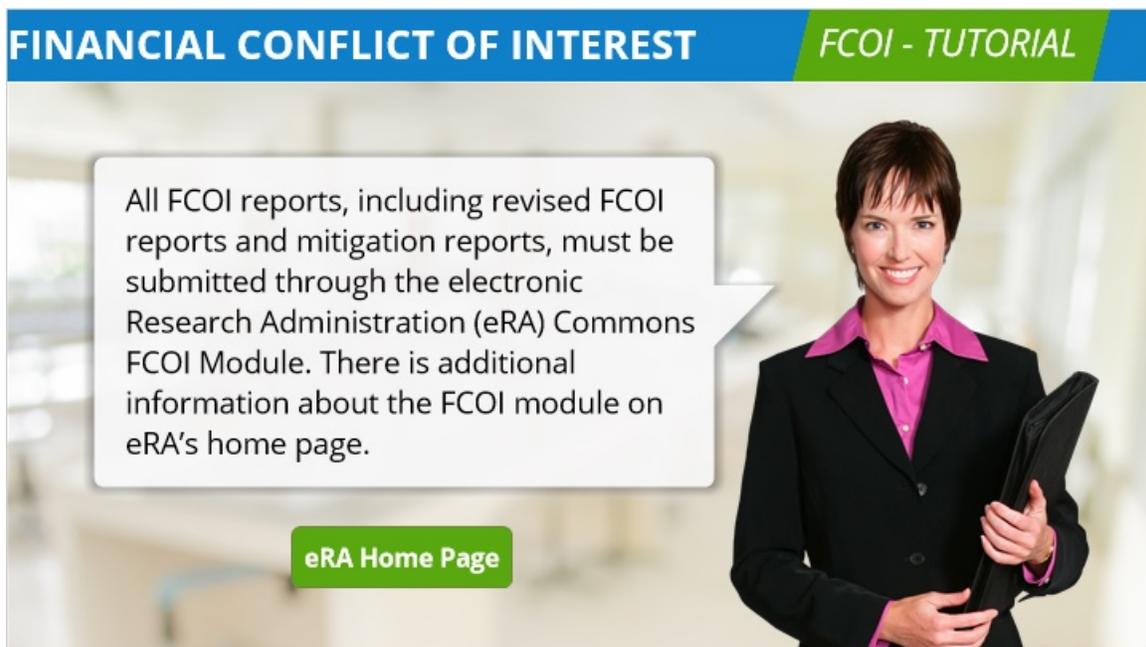
Ok, so I understand that in many circumstances the institution must provide the NIH with reports. **How does the institution submit this information to the NIH?**

The slide features a woman, Mary, standing in a laboratory setting. She is wearing a patterned sleeveless top. A speech bubble points to her with the text above. The background is a blurred laboratory with blue lighting.

Notes:

Ok, so I understand that in many circumstances the institution must provide the NIH with reports. How does the institution submit this information to the NIH?

1.88 Sue Talking



FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

All FCOI reports, including revised FCOI reports and mitigation reports, must be submitted through the electronic Research Administration (eRA) Commons FCOI Module. There is additional information about the FCOI module on eRA's home page.

[eRA Home Page](#)

The slide features a woman, Sue, standing in an office setting. She is wearing a black blazer over a pink shirt and holding a black folder. A speech bubble points to her with the text above. The background is a blurred office with warm lighting.

Notes:

All FCOI reports, including revised FCOI reports and mitigation reports, must be submitted through the electronic Research Administration (eRA) Commons FCOI Module. There is additional information about the FCOI module on eRA's home page.

1.89 Mary Talking

FINANCIAL CONFLICT OF INTEREST **FCOI - TUTORIAL**

Ok, so far I know when to submit reports to NIH and how to submit them.
What about the content of the report?
What information must be included in an FCOI report to the NIH?

Notes:

Ok, so far I know when to submit reports to NIH and how to submit them. What about the content of the report? What information must be included in an FCOI report to the NIH?

1.90 Untitled Slide

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

What to Include in an FCOI Report:

1. The project number;
2. The PD/PI or Contact PD/PI if there are multiple PD/PIs;
 - a. When the value of the financial interest is given, the following dollar ranges are permissible: \$0 to \$4,999 dollars; \$5,000 to \$9,999 dollars; \$10,000 to \$19,999 dollars. For amounts higher than \$19,999 dollars, amounts between \$20,000 and \$100,000 can be given in increments of \$20,000, and amounts above \$100,000 can be given by increments of \$50,000.
3. The name of the investigator with the FCOI;
4. The name of the entity with which the investigator has an FCOI;
5. The nature of the financial interest, for example, equity interest, consulting fee, travel reimbursement, honorarium;
6. The value of the financial interest 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. When the value of the financial interest is given, the following dollar ranges are permissible: \$0 to \$4,999 dollars; \$5,000 to \$9,999 dollars; \$10,000 to \$19,999 dollars. For amounts higher than \$19,999 dollars, amounts between \$20,000 and \$100,000 can be given in increments of \$20,000, and amounts above \$100,000 can be given by increments of \$50,000.
7. A description of how the financial interest relates to the NIH-funded research and the basis for the institution's determination that the financial interest conflicts with such research;
8. And lastly, the report must have a description of the key elements of the institution's management plan, including:
 - a. The role and principal duties of the conflicted investigator in the research project;

Notes:

Good question. There's a few things that must be included in an FCOI report.

1. The project number;
2. The PD/PI or Contact PD/PI if there are multiple PD/PIs;
3. The name of the investigator with the FCOI;
4. The name of the entity with which the investigator has an FCOI;
5. The nature of the financial interest, for example, equity interest, consulting fee, travel reimbursement, honorarium;
6. The value of the financial interest 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. When the value of the financial interest is given, the following dollar ranges are permissible: \$0 to \$4,999 dollars; \$5,000 to \$9,999 dollars; \$10,000 to \$19,999 dollars. For amounts higher than \$19,999 dollars, amounts between \$20,000 and \$100,000 can be given in increments of \$20,000, and amounts above \$100,000 can be given by increments of \$50,000.
7. A description of how the financial interest relates to the NIH-funded research and the basis for the institution's determination that the financial interest conflicts with such research;
8. And lastly, the report must have a description of the key elements of the institution's management plan, including:
 - a. The role and principal duties of the conflicted investigator in the research project;

- b. The 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.

1.91 Mary Talking

FINANCIAL CONFLICT OF INTEREST **FCOI - TUTORIAL**

All right, got it. But I think we've been assuming, up until now, that everyone is going to be cooperating. **What if an investigator fails to comply with the institution's FCOI policy or management plan?**

Notes:

All right, got it. But I think we've been assuming, up until now, that everyone is going to be cooperating. What if an investigator fails to comply with the institution's FCOI policy or management plan?

1.92 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*



and document the institution's determination as to whether any NIH-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. This review and documentation must be completed within 120 days of when the institution determines noncompliance.

Notes:

Each institution must establish adequate enforcement mechanisms, provide for employee sanctions, and other administrative action, where appropriate. The institution may determine the nature of the enforcement mechanisms and sanctions.

If an investigator fails to comply with an institution's FCOI policy or FCOI management plan, the institution will complete a retrospective review of the investigator's activities and the NIH-funded research project, document the institution's methodology of reviewing the SFI(s), and document the institution's determination as to whether any NIH-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. This review and documentation must be completed within 120 days of when the institution determines noncompliance.

1.93 Mary Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman with dark hair, wearing a patterned sleeveless top, stands in a laboratory setting. A speech bubble points to her from the left.

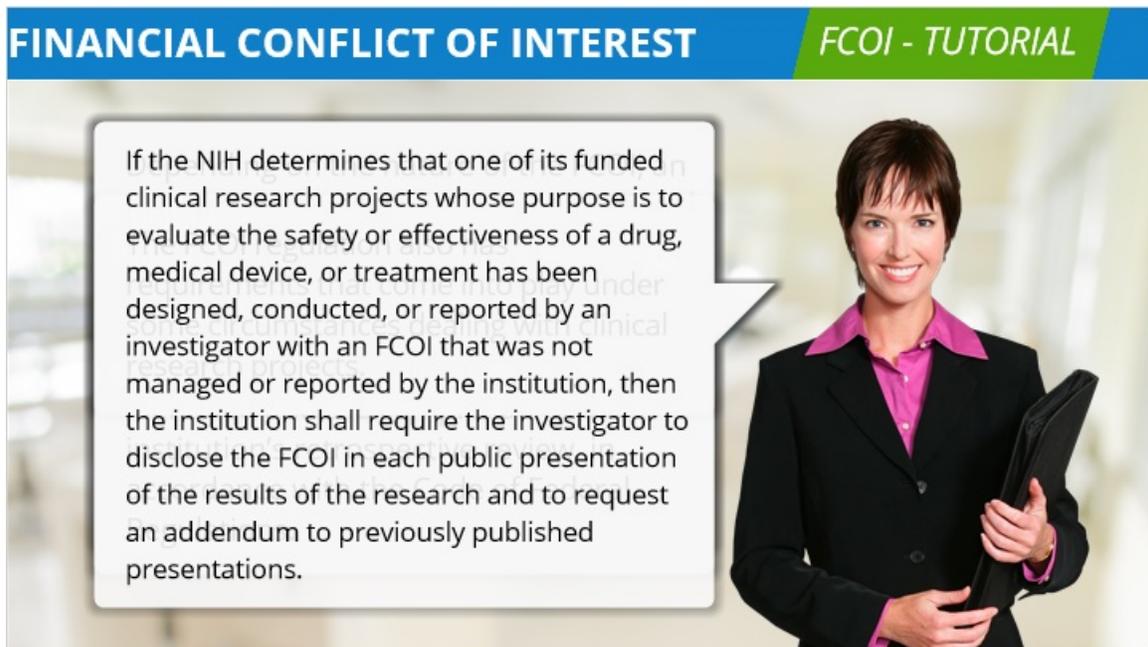
So when the institution does their review, they may or may not find bias. **What happens if they find bias?**

Notes:

So when the institution does their review, they may or may not find bias. What happens if they find bias?

1.94 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

A woman with short brown hair, wearing a black blazer over a pink shirt, stands in a laboratory setting. She is holding a black folder. A speech bubble points to her from the left.

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 an FCOI that was not managed or reported by the institution, then the institution shall require the investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Notes:

Right, a review can end with a finding of bias or not. If bias is found, the institution must submit a mitigation report to the NIH, in accordance with the Code of Federal Regulations, that addresses the impact of the bias on the research project and the actions the institution has taken to mitigate the bias. Depending on the nature of the FCOI, 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 FCOI is identified and the completion of the institution's retrospective review, in accordance with the Code of Federal Regulations.

The FCOI regulation also has requirements that come into play under some circumstances dealing with clinical research projects. 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 an FCOI that was not managed or reported by the institution, then the institution shall require the investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

1.95 Mary Talking

FINANCIAL CONFLICT OF INTEREST FCOI - TUTORIAL

What should be done in the event an investigator's non-compliance with the institution's FCOI policy or management plan results in bias?

Notes:

What should be done in the event an Investigator's non-compliance with the Institution's FCOI policy or management plan results in bias?

1.96 Sue Talking

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

The NIH will consider the situation. The NIH will also take appropriate action or refer the matter to the institution for further action. If the NIH recommends the action be taken by the institution, this action may include directions to the institution on how to promote and maintain appropriate objectivity in the NIH-funded research project.



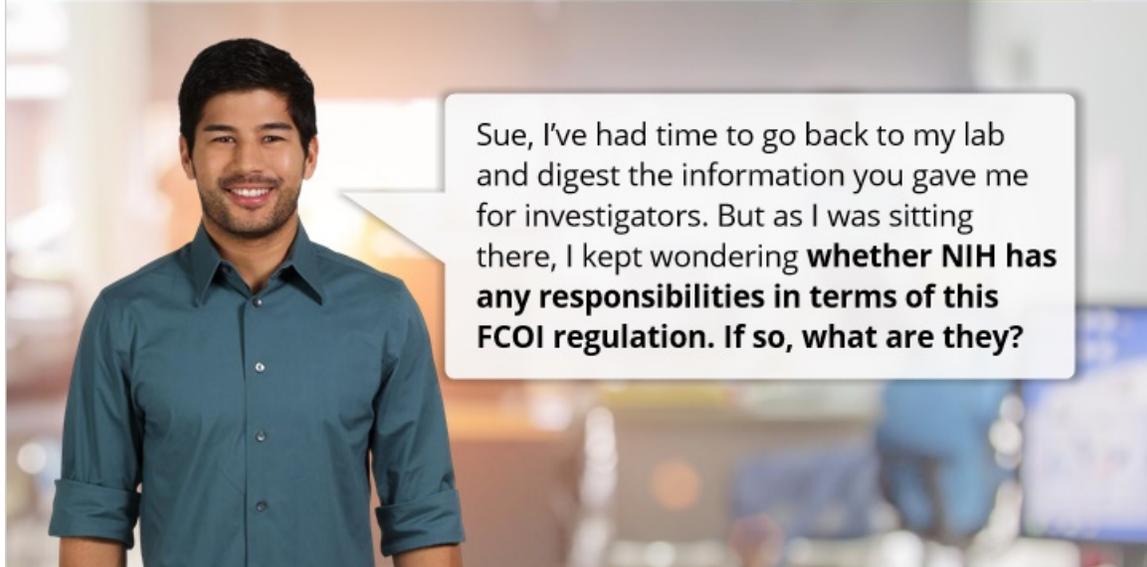
Notes:

Consistent with the Code of Federal Regulations, If the failure of an investigator to comply with an institution's FCOI policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the institution shall promptly notify the NIH of the corrective action taken or to be taken.

The NIH will consider the situation. The NIH will also take appropriate action or refer the matter to the institution for further action. If the NIH recommends the action be taken by the institution, this action may include directions to the Institution on how to promote and maintain appropriate objectivity in the NIH-funded research project.

1.97 Kirby Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*



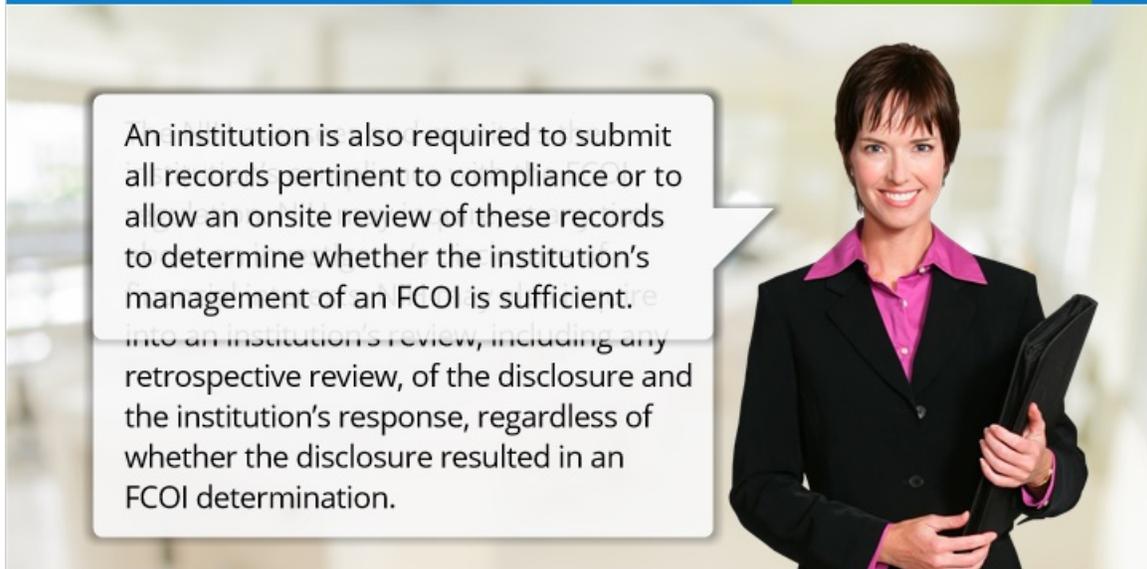
Sue, I've had time to go back to my lab and digest the information you gave me for investigators. But as I was sitting there, I kept wondering **whether NIH has any responsibilities in terms of this FCOI regulation. If so, what are they?**

Notes:

Sue, I've had time to go back to my lab and digest the information you gave me for investigators. But as I was sitting there, I kept wondering whether NIH has any responsibilities in terms of this FCOI regulation. If so, what are they?

1.98 Sue Talking

FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

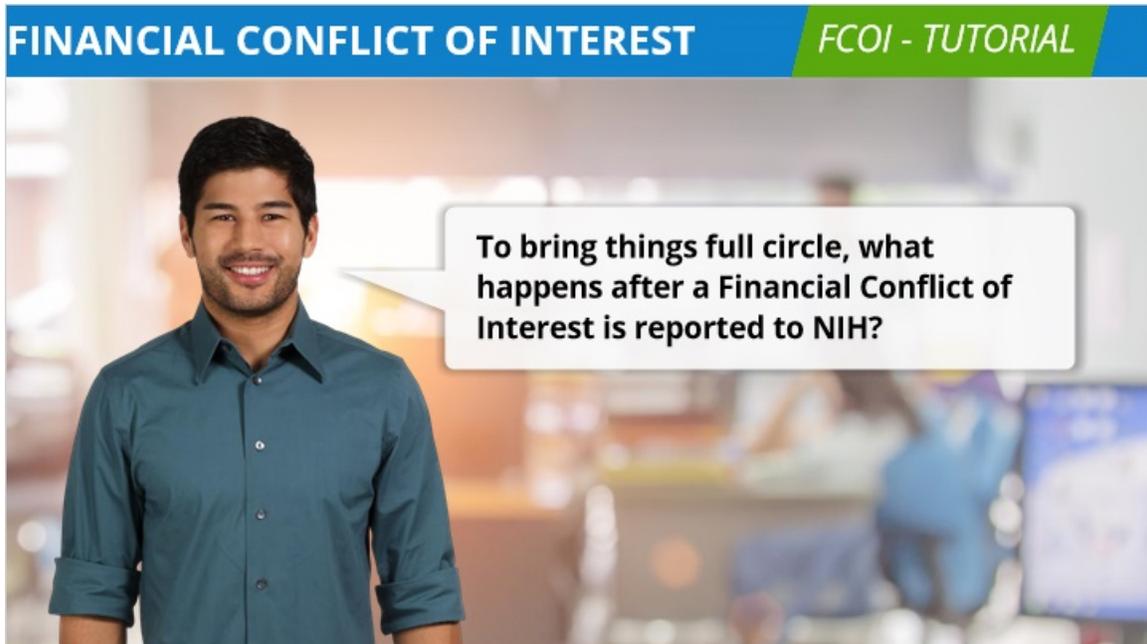


An institution is also required to submit all records pertinent to compliance or to allow an onsite review of these records to determine whether the institution's management of an FCOI is sufficient. **re into an institution's review, including any retrospective review, of the disclosure and the institution's response, regardless of whether the disclosure resulted in an FCOI determination.**

Notes:

The NIH oversees and monitors the institution's compliance with the FCOI regulation. NIH may inquire, at any time, about an investigator's disclosure of financial interests. NIH may also inquire into an institution's review, including any retrospective review, of the disclosure and the institution's response, regardless of whether the disclosure resulted in an FCOI determination

1.99 Kirby Talking



Notes:

To bring things full circle, what happens after a Financial Conflict of Interest is reported to NIH?

1.100 Sue Talking

FINANCIAL CONFLICT OF INTEREST

FCOI - TUTORIAL

If NIH decides that a particular FCOI will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or if NIH decides that the institution has not managed the FCOI in accordance with the regulation, NIH may determine that imposition of specific award conditions or suspension of funding or other enforcement action is necessary until the matter is resolved. NIH will make these decisions consistent with 45 CFR Part 75 and the [NIH Grants Policy Statement](#).

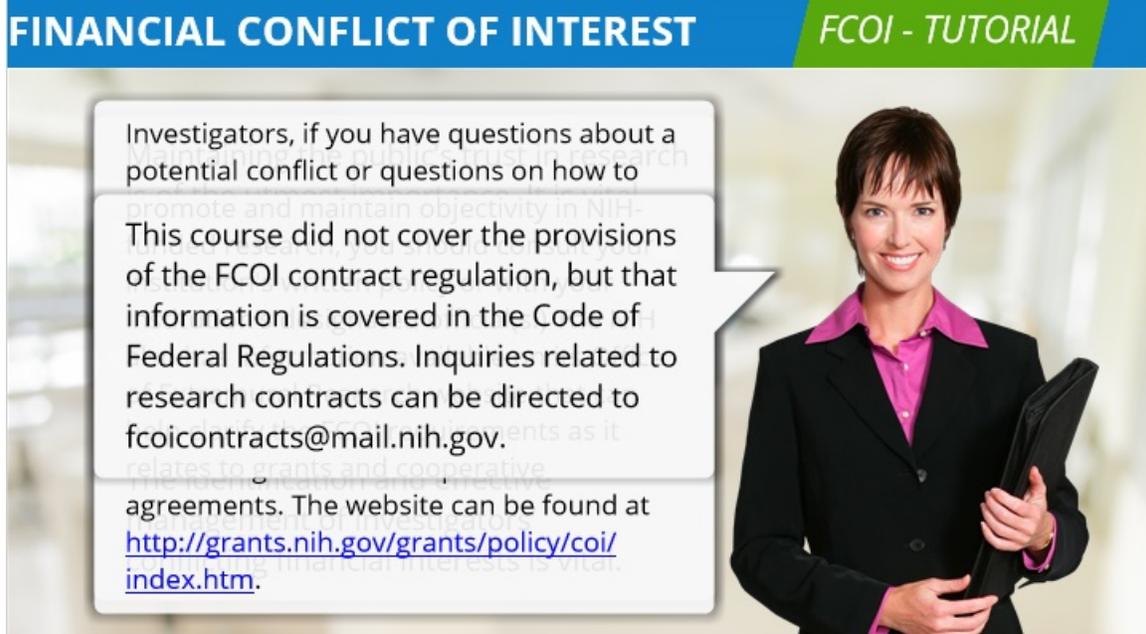


Notes:

We've covered the responsibilities of investigators, institutions, and the NIH, but this whole process is a two-way street. So, after NIH receives information from an institution, NIH professional and scientific staff will evaluate the information received in FCOI reports to determine whether additional information is needed and whether an institution's actions are sufficient. This information is also used to monitor compliance. After considering the information provided in the FCOI report, the NIH may request additional information from the institution. Once that information is considered, the NIH may decide that further action is needed to ensure the objectivity of the research or that the institution has not managed the FCOI in accordance with the regulation.

If NIH decides that a particular FCOI will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or if NIH decides that the institution has not managed the FCOI in accordance with the regulation, NIH may determine that imposition of specific award conditions or suspension of funding or other enforcement action is necessary until the matter is resolved. NIH will make these decisions consistent with 45 CFR part 75 and the NIH Grants Policy Statement.

1.101 Sue Talking



FINANCIAL CONFLICT OF INTEREST *FCOI - TUTORIAL*

Investigators, if you have questions about a potential conflict or questions on how to promote and maintain objectivity in NIH-funded research, you should consult your institution's written policy or with your institution's designated official(s.) The NIH also has information available on its Office of Extramural Research website that can help clarify the FCOI requirements as it relates to grants and cooperative agreements. The website can be found at <http://grants.nih.gov/grants/policy/coi/index.htm>.

This course did not cover the provisions of the FCOI contract regulation, but that information is covered in the Code of Federal Regulations. Inquiries related to research contracts can be directed to fcoicontracts@mail.nih.gov.

Notes:

We've covered a lot of material. Remember that you can refer back to this course at any time.

Maintaining the public's trust in research is of the utmost importance. It is vital that investigators, institutions, and the NIH-work together to promote and maintain objectivity in research. Responsibilities should be thoughtfully fulfilled and in compliance with all Federal and institutional requirements. The identification and effective management of investigators' conflicting financial interests is vital.

Investigators, if you have questions about a potential conflict or questions on how to promote and maintain objectivity in NIH-funded research, you should consult your institution's written policy or with your institution's designated official(s.) The NIH also has information available on its Office of Extramural Research website that can help clarify the FCOI requirements as it relates to grants and cooperative agreements. The website can be found at <http://grants.nih.gov/grants/policy/coi/index.htm>.

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