



Conflict of Interest Committee Submission Guide

Training materials for using IRBNet are available at:
<http://www.irbnetresources.org/> (userID: kettering, password: training)

Guides and submission forms are posted on the
Forms and Templates page in IRBNet

Contents

Account Creation and Verification	2
Conflict of Interest Training.....	2
Submitting Conflict of Interest (COI) Training Certificates	3
First Time Submission	3
Updating	3
Submitting Financial Disclosures.....	4
First Time Submission	4
Annual update or revision	5
Submitting a <i>Project Personnel and Funding Report</i>	6
First Time Submission	6
Annual update or revision	7
Track the COI Review and Determination.....	7
Reviewing and Acknowledging a Management Plan.....	8
Subsequent Submissions	8
After review	8



Account Creation and Verification

Create a user account and password in IRBNet at www.irbnet.org. Each researcher needs his or her own IRBNet user account.

- Click “New User Registration” in the upper right hand corner.
- Follow the prompts to affiliate with Kettering Health Network and complete registration.
- Activate your account through the email used to register.

Provide a signed *Electronic Signature Attestation* form to the Conflict of Interest administrator.

- Login to IRBNet.
- Click “Forms and Templates”
- Click the *Electronic Signature Attestation* title or paper icon. Select “Save” and select a location to save the document on your computer.
- Click “Open”, complete the document, “Save” after completion, and “Print”.
- Sign and date the completed document. Mail to:

Conflict of Interest Administrator
Kettering Medical Center – 4 NW
3535 Southern Blvd.
Kettering, Ohio 45429



Conflict of Interest Training

Conflict of Interest training for Kettering Health Network is completed through the Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org. Each individual needs his or her own CITI training account with Kettering Health Network.

If you have **not** previously created a CITI user account for any institution:

- Click “Register Here” in the body of the page and follow the prompts.
- Affiliate with Kettering Health Network in your registration.
- Follow the prompts to complete your registration.
- In the *Select Curriculum – Kettering Health Network* page, select Conflicts of Interest Course under question 2. Optional Modules. Click “Submit”.

If you have previously created a CITI user account, but have not affiliated with Kettering Health Network:

- Login to CITI.
- From the *Main Menu* page, select the [Affiliate with another Institution](#) link.
- Follow the prompts to affiliate with Kettering Health Network.
- In the *Select Curriculum – Kettering Health Network* page, select Conflicts of Interest Course under question 2. Optional Modules. Click “Submit”.

If you already have a Kettering Health Network user account:

- Login to CITI.
- From the *Main Menu* page, below the My Courses list, select [Add a course or update your learner groups for Kettering Health Network](#).
- In the *Select Curriculum – Kettering Health Network* page, select Conflicts of Interest Course under question 2. Optional Modules. Click “Submit”.

Complete KHN conflict of interest educational requirements:

- Login to CITI.
- From the *Main Menu* page, below Kettering Health Network and under “My Courses”, select the “[Enter](#)” or “[Re-enter](#)” link next to the Conflicts of Interest course. Follow the prompts to complete the three modules in the course. You may complete different modules at different times.
- After completion, print your completion report to a PDF and save it to your computer. Contact the Conflict of Interest support staff with any questions.

Upload your training certificate (see below) to your user profile (see below)



Submitting Conflict of Interest (COI) Training Certificates

First Time Submission of a COI training certificate in IRBNet:

- Login to IRBNet.
- Click “User Profile” toward the top right of the screen. The *User Profile* screen will appear. **Note: Follow this submission process only to submit your first COI training certificate to the KHN COI Committee. To update a previously submitted COI training certificate, skip to the **Update** section below.**
- Click “Add New Record” at the bottom of the *Training and Credentials* section. The *Training and Credentials Record* screen will appear. Skip to *Training and Credentials Record* screen below.

Updating your COI training certificate in IRBNet:

- Login to IRBNet.
- Click “User Profile”. The *User Profile* screen will appear.
- In the *Training and Credentials* section, click the pencil to the right of the previously submitted certificate to be updated. The *Training and Credentials Record* screen will appear.

Training and Credentials Record screen (**First Time Submission** and **Updates**):

- Select the Conflict of Interest Course as the *Document Type* from the drop-down list.
- *Description*: enter description, for example, “CITI COI Course”.
- *Effective Date*: enter the date the course was completed
- *Expiration Date*: Skip this field. It will be completed by administrators.

- *File*: Click “Browse”. Locate the saved completion report on your computer, select the file and click “Open”
- Click “Attach” to add the document to your IRBNet Training and Credentials. This will return you to the *User Profile* screen. Your new document will now be listed.
- Submit the CITI certificate to the Conflict of Interest Committee. Click the [Submit](#) link near the bottom right of the row containing the new document.
 - Select “Kettering Health Network Conflict of Interest Committee, Kettering, OH” (locate quickly by entering “Kettering” in the “Search for a Board” text box and clicking “Search”)
 - Click “Continue”.
 - Enter a subject and message (optional) and click “Submit”.

Training and Credentials will be processed administratively after which the status of the submission will be updated. An email notification will be issued in the unlikely event questions exist concerning the submission.



Submitting Financial Disclosures

First Time Submission of a financial disclosure:

- Login to IRBNet.
- Click *New Project* to create a new project in IRBNet. Title the project **Financial Disclosure**. This will be used for the first financial disclosure submission.
- Locate the *Financial Disclosure Form* (available from both the *Designer* page and the *Forms and Templates* page). Download (see Download Tips) and complete the *Financial Disclosure Form* and related attachments.

Download Tips:

To download a **new** document from the *Forms and Templates* page, select the *Kettering Health Network Conflict of Interest Committee* library. Click the document title or the paper icon at the right of the column, select “save”, and choose a location on your computer to save the document.

To download a **new** document from the *Designer* page, select the *Kettering Health Network Conflict of Interest Committee* library under **Step 1**. Select the document title, click “Download”, select “save” and choose a location on your computer to save the document.

To download a **previously submitted** document, from the *Designer* page, locate the previously submitted document under **Step 2**. Click the title or the paper icon at the right of the column, select “save”, and choose a location on your computer to save the document.

IRBNet ID: 369561-1 USER PROFILE LOGOUT

IRBNet

Welcome to IRBNet **Designer**

[369561-1] Financial Disclosure

Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: Kettering Health Network Institutional Review Board, Kettering, OH

Select a Document: **Financial Disclosure Form** Download

Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.

Documents in this Package:

Submission Manager
Agendas and Minutes
My Projects
Create New Project
My Reminders

Project Administration
Project Overview
Designer
Share this Project
Sign this Package

Select the Kettering Health Network Conflict of Interest Committee

Select the appropriate document and download

- Upload the completed *Financial Disclosure Form* as a document type: Conflict of Interest – declaration from the *Designer* page.

Upload Tips:

To upload a **new** completed document, from the *Designer* page, click “Add New Document” at the bottom of the page. Select the document type. Add a description (optional) and click “Browse” to locate the completed document on your computer. Click “Open”, then “Attach”.

To **update** a previously submitted document with a new version, from the *Designer* page, click the pencil icon to the right of the document to be updated. Add a description (optional) and click “Browse” to locate the updated document on your computer. Click “Open”, then “Attach”.


- Click *Sign this Package* in the left column under **Project Administration**. Select “Other Signatory” from the drop down list, then click “Sign”. Note: all materials for review must be uploaded before the project is signed.
- Click *Submit this Package* in the left column under **Project Administration** and follow the prompts. Select the Kettering Health Network Conflict of Interest Committee as the Board to which the disclosure will be submitted.

Annual update or revision to a previously submitted financial disclosure:

- Login to IRBNet.
- Click the ***Financial Disclosure*** project title.
- If the *Project Overview* page indicates the project has been submitted to the Kettering Health Network Conflict of Interest Committee, click the *Project History*

button in the left column under **Project Administration**, and click “Create New Package”.at the bottom of the screen.

- Click *Designer* in the left column under **Project Administration**.
- Download the document to be updated (see Download Tips above).
- Update the desired document using the pencil icon (see Upload Tips above).
- If needed, add any new documents not previously provided (see Upload Tips above).
- Click *Sign this Package* in the left column under **Project Administration**. Select “Other Signatory” from the drop down list, then click “Sign”. Note: all materials for review must be uploaded before the project is signed.
- Click *Submit this Package* in the left column under **Project Administration** and follow the prompts. Select the Kettering Health Network Conflict of Interest Committee as the Board to which the disclosure will be submitted.

Tip: If the status of the IRBNet project package is “Work in Progress” or the package is unlocked  to provide required / missing materials, it has not been submitted / processed for review. After the submission has been processed and assigned for review, the “Project Overview” page will specify the submission date and the “Review Details” page will list an agenda date.

Contact the Conflict of Interest support staff with any questions.




Submitting a *Project Personnel and Funding Report*

First Time Submission of a *Project Personnel and Funding Report*.

- Login to IRBNet.
- Click *New Project* to create a new project in IRBNet. This will be used for the first submission of the project. Share the project in IRBNet with your project personnel:
 - Co-Investigators: full access
 - Submission support staff: write access
 - Sub-investigators and others involved in the project: read access
- Locate the *Project Personnel and Funding Report* form (available from both the *Designer* page and the *Forms and Templates* page). Download (see Download Tips above) and prepare the form and attachments (as needed).
- Upload the completed forms to IRBNet from the *Designer* page (see Upload Tips above).
- Link the key personnel’s* Conflict of Interest training credentials to the project. Click [Link/Unlink Records](#) and click the “Link” box next to the CITI Conflict of Interest Training.

- When the package is ready for submission, all key personnel involved in the project must review and sign the submission. Each individual should login to IRBNet, select the project title, review the materials in the submission, and click *Sign this Package* in the left column under **Project Administration**. Select the appropriate project role from the drop down list, then click “Sign”. Note: all materials for review must be uploaded before the project is signed.
- Click *Submit this Package* in the left column under **Project Administration** and follow the prompts. Select the Kettering Health Network Conflict of Interest Committee as the Board to which the disclosure will be submitted. Individuals with “full access” to the project will receive an email notifying them that the package has been submitted.

Tip: If the status of the IRBNet project package is “Work in Progress” or the package is unlocked  to provide required / missing materials, it has not been submitted / processed for review. After the submission has been processed and assigned for review, the “Project Overview” page will specify the submission date and the “Review Details” page will list an agenda date.

Contact the Conflict of Interest support staff with any questions.

Annual update or revision to a *Project Personnel and Funding Report*.

- Login to IRBNet.
- Click the project title.
- If the *Project Overview* page indicates the project has been submitted to the Kettering Health Network Conflict of Interest Committee, click *Project History* in the left column under **Project Administration**, and click “Create New Package” at the bottom of the screen.
- Click *Designer* in the left column under **Project Administration**.
- Download the document to be updated (see Download Tips above).
- Update the desired document using the pencil icon (see Upload Tips above).
- If needed, add any new documents not previously provided (see Upload Tips above).
- Click *Sign this Package* in the left column under **Project Administration**. Select “Other Signatory” from the drop down list, then click “Sign”. Note: all materials for review must be uploaded before the project is signed.
- Click *Submit this Package* in the left column under **Project Administration** and follow the prompts. Select the Kettering Health Network Conflict of Interest Committee as the Board to which the disclosure will be submitted.



Track the COI Review and Determination




Track the review status and the COI Committee’s determination from the *Project Overview* page in IRBNet through the *Review Details* link. The Principal Investigator (and other “full access” personnel) will be notified by email of the determination. All official communications are available as a permanent part of the study record on the *Review Details* page. This can be

downloaded or printed to be provided to the IRB of Record for the project, when applicable. Any modifications or revisions requested by the COI Committee must be completed and notification of approval to proceed must be received before the research can commence. No enrollment of subjects, collection of data, or conduct of the research may be initiated before receiving IRB approval.



Reviewing and Acknowledging a Management Plan

Management Plans established by the COI Committee will be posted in IRBNet. When applicable, you will receive email notifications to review and acknowledge the management plans for specific projects. To document your review and acknowledgement of a management plan in IRBNet:

- Login to IRBNet.
- Click the applicable project title.
- Click *Reviews* in the left hand column. Look for the Management Plan to be reviewed in the list of Board Documents (tip: the most recent documents are at the top of the list).
- Click the document title or the paper icon to open and review the document.
- Click “Messages and Alerts”  **Messages & Alerts (1)** in the left hand column.  A red flag identifies your pending messages or alerts.
- Click the *Message Type*: “Committee Message...” concerning the management plan to open the message. Click “Reply” to create your response. Suggested wording: “I have reviewed, and agree to comply with, the management plan for this project.” Click “Send” to send the message and document your acknowledgement and agreement.
- After responding to the message, click the flag to silence the message. 



Subsequent Submissions

Create a new package for each subsequent submission (see **Update or Revise** in the applicable section above). Sign and submit new packages as described above.



After review

- Individuals are responsible for acknowledging and complying with any conflict of interest management plans established.
- Email notifications will be provided to individuals with full access to each project when an annual report is due, either to a financial disclosure form, or to the project personnel and funding report. Annual reports must be provided **at least 45 days before expiration** to

provide sufficient time for COI review prior to expiration of the IRB approval or submission of required funding reports to federal agencies.

- Individuals are responsible for providing an updated financial disclosure *within 30 days* of any changes to their financial interests according to the Kettering Health Network *Conflicts of Interest in Research and Funded Projects* policy.
- An updated *Project Personnel and Funding Report* is due before proposed changes to funding, sponsorship, or project personnel.
- Non-compliance is subject to retrospective reviews and institutional sanctions.



Please contact the Conflict of Interest support staff (937) 395-8309 with any questions.

*Key Personnel - Anyone involved in the development, execution and reporting of research.