

Quick Guide: iRIS Financial Disclosure Form

Research Development



Purpose

This guide has been drafted by the Saint Francis Hospital and Medical Center Research Development Office to use as a reference while completing the Trinity Health Of New England Financial Disclosure Form located in the electronic IRB system (iRIS).

Policy

Trinity Health Of New England requires that all Investigators promptly and fully disclose, in writing, any significant financial interest (including those of a spouse or dependent child) that reasonably relate to the Investigator's Institutional Responsibilities and, if applicable, comply with financial conflict of interest management or mitigation plans.

If a financial interest of greater than \$5,000 exists between the research sponsor and the Investigator, a management plan must be established by the Financial Conflict of Interest Committee (Review Committee), agreed to by the Investigator and monitored. Any individual with a financial interest with the research sponsor in excess of \$50,000 is precluded from participating in the research. The Review Committee shall recommend each management plan to the Trinity Health Of New England Institutional Review Board (IRB). The IRB shall be responsible for making the final determination with respect to the Investigator's role in the study to ensure participants are protected.

Any significant financial interest that could directly and significantly affect the design, conduct or reporting of research shall be managed by the Review Committee and the Investigator to reduce or eliminate any such effect.

Link to the Policy

<http://www.trinityhealthofne.org/documents/IRB/THOFNE-CCP4013-Investigator-Conflicts-of-Interest-Funded-Research.pdf>

Steps and Procedures

Note: A Financial Disclosure Form/Conflict of Interest Form is required to be completed for internally or externally sponsored or funded projects *only*.

1. Log on to iRIS (electronic IRB system)
 - iRIS website: <https://stfrancis.imedris.net> (Not compatible with Safari)
 - If you don't know your user ID, please contact the Trinity Health Of New England IRB: Telephone: (860) 714-4068 or Kathy Alexander (Kathryne.Alexander@TrinityHealthOfNE.Org)
2. Access the Financial Disclosure Forms/Conflict of Interest Forms by either method indicated below:



For New Studies choose New Study FDF

For Reapprovals choose Reapproval/Closure FDF

3. Click add a new form



4. Enter required information:

For a New Study FDF you will need the following information:

- Project Title
- Department
- Prime Sponsor
- Project Period

For a Reapproval FDF you will need the following information:

- Project Title
- IRB #
- Department
- Prime Sponsor

5. Appropriately complete sections as indicated below:

If you or your family do not have financial conflicts to disclose

- Click Agree for section 1.3 and 1.5
- Click Save and Continue to Next Section (*skip to step 6*)

If you or your family do have financial conflicts to disclosure

- Click Disagree for section 1.3
- For section 1.4 - check all boxes that apply
- Click agree for section 1.5
- Click Save and Continue to Next Section



New Study - FDF - (Version 6.0)

Print Friendly Save Section Save and Continue to Next Section

1.3 PART A. - FINANCIAL CERTIFICATION

I certify that:

1. I, or any member of my family (spouse, domestic partner, children, and any other person living in the same household), have not entered into any financial arrangement with the study sponsor(s) (e.g., bonus, royalty, or other financial incentive) whereby my compensation could be affected by the outcome of the research;
2. I, or any member of my family, do not have a proprietary interest (e.g., patent, trademark, copyright, licensing agreement, etc.) in the product tested in the clinical study;
3. I, or any member of my family, do not have any equity interest (i.e., ownership interest, stock option, or other financial interest whose value cannot be calculated with reference to publicly traded prices or other measure of fair market value) in the study sponsor(s);
4. I, or any member of my family, have not received any payment from the study sponsor(s), or manufacturer of the product or service being tested, having a total value in excess of \$0 when aggregated for the immediate family other than payments for conducting the research study. (Examples of such significant payments include, but are not limited to, grants or funding for ongoing research, compensation in the form of equipment, retainers for ongoing consultation and honoraria that are (a) paid directly to investigators or to the institution with which the investigators are affiliated, and (b) paid in support of investigator activities.);
5. I, or any member of my family, do not have a Board or executive relationship related to the research, regardless of compensation.

I have answered fully and to the best of my ability and will update this form promptly if my circumstances change.

Agree Disagree

1.4 PART B. - FINANCIAL DISCLOSURE

I disclose the following (check all that apply):

- I, or a member of my family, have entered into financial arrangement(s) with the study sponsor(s) (e.g., bonus, royalty, or other financial incentive) whereby my compensation could be affected by the outcome of the research;
- I, or a member of my family, have a proprietary interest (e.g., patent, trademark, copyright, licensing agreement, etc.) in the product tested in the clinical study;
- I, or a member of my family, have an equity interest (i.e., ownership interest, stock option, or other financial interest whose value cannot be calculated with reference to publicly traded prices or other measure of fair market value) in the study sponsor(s);
- I, or a member of my family, are receiving payments from the study sponsor or research entities other than the sponsor having a total value in excess of \$0 when aggregated for the immediate family, other than payments for conducting the research study. (Examples of such payments include, but are not limited to, grants or funding for ongoing research, compensation in the form of equipment, retainers for ongoing consultation and honoraria that are (a) paid directly to investigators or to the institution with which the investigators are affiliated, and (b) paid in support of investigator activities.);
- I, or a member of my family, have a Board or executive relationship related to the research, regardless of compensation;

1.5 I am aware of the Trinity Health Of New England policy on financial disclosure regarding amounts between \$5,000 and \$50,000 indicating I need a management plan and cannot serve as the PI. I am also aware that any amount over the threshold of \$50,000 will not allow me to be involved on the study at all. More information on this policy can be found on the Trinity Health Of New England IRB website (Investigator Conflicts of Interest in Funded Research Policy)

Agree

Check All Applicable Boxes

- Indicate all of the types of information you are disclosing Remunerations, Travel, Equity Interests, Royalties etc.

2.0 Required Disclosures

2.1 Remuneration Received From Other Entities

In the last 12-months, did you, your spouse or dependent children receive any remuneration from an entity other than Saint Francis Hospital and Medical Center, Saint Mary's Hospital, Mount Sinai Rehabilitation Hospital, Mercy Medical Center, or Johnson Memorial Hospital that reasonably appears to be related to your **institutional responsibilities**?

Yes No

2.2 Reimbursed or Sponsored Travel

Have you, your spouse or your dependent children received reimbursement or sponsorship for travel that reasonably appears to be related to your **institutional responsibilities**?

Yes No

2.3 Equity Interests

Do you, your spouse or your dependent children hold equity interest in a publicly traded or privately held entity that reasonably appears to be related to your **institutional responsibilities**? Equity interests include any stock, stock options or other ownership interests.

Yes No

2.4 Royalties/Income Related to Intellectual Property Rights and Interests

Have you, your spouse or dependent children received royalties or other income related to intellectual property rights and interests (e.g., patents, copyrights) that reasonably appear to be related to your **institutional responsibilities**?

Yes No

- Complete a new entry form for each disclosure

The screenshot shows the 'Entry 1' form with a green arrow pointing to a button labeled 'Click here to add another entry'. The form includes fields for Recipient Name, Relationship to you, Type of Remuneration (with a dropdown menu), Description of services provided, Paid By Name of Entity, and Amount Received in the last 12 months. A note at the bottom states: 'If amount received is \$5,000 or more from a single source (e.g., Pharma A), please describe the nature of the services in relation to this study.'

6. Click button to Electronically Sign the document:

The screenshot shows the 'Certification' section (3.0) with a yellow background. A green box highlights the 'Click here to sign the document' button. A callout box with a green border contains the text: 'Do not proceed without clicking this box'. The text below the button reads: 'I certify that the information is complete and true to the best of my knowledge and that I have read the Trinity Health Of New England Policy on Investigators Conflicts of Interest in Funded Research. I acknowledge that I am responsible for submitting updates to this information annually and within 30 days of discovering or acquiring any new financial interest.'

- Enter User ID and Password and click Save

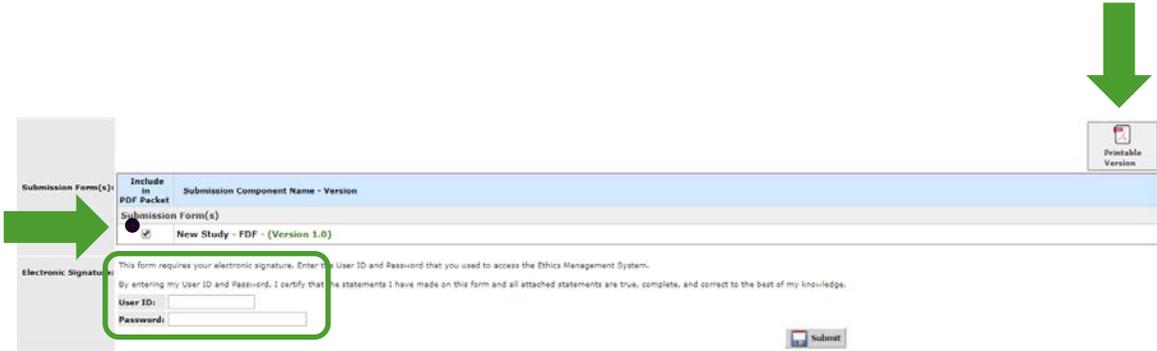
The screenshot shows the 'Electronic Signature' section. It includes a 'Back' button and a 'save' button with a green arrow pointing to it. The text reads: 'This form requires your electronic signature. Ms Kendra Williams please enter your User ID and Password below:'. There are input fields for 'User ID:' and 'Password:'.

- Click Signoff and Submit

The screenshot shows the 'Form has been Completed!' screen. It features a blue header with the text 'Form has been Completed!' and 'Instruction of Form has Been Completed Screen'. Below this, it says: 'You must submit a revised form within five (5) days of becoming aware that any of your answers have changed.' At the bottom, there are two buttons: 'Exit Form' (with a red X icon) and 'Signoff and Submit' (with a document icon). A green box highlights the 'Signoff and Submit' button.

Note: Remember to print a copy of the electronically signed FDF. Send a copy of the completed FDF to the staff member responsible for managing study documents.

- Check the box in front of the FDF and Click Printable Version (and save or print a signed copy)
- Enter User ID and Password and click Submit



7. Upload electronically signed copy of Financial Disclosure Form into the IRB Application and/or Reapproval Form.

- A new Financial Disclosure section will appear if the project is internally or externally funded
- Add each investigator’s saved Financial Disclosure Form (FDF) by clicking “Add a New Document”

6.3 Sponsor or funding source (Name):

INTERNAL
 EXTERNAL
 NONE

Name of Sponsor:

6.4 Please attach a completed New Study Financial Disclosure form for each investigator.

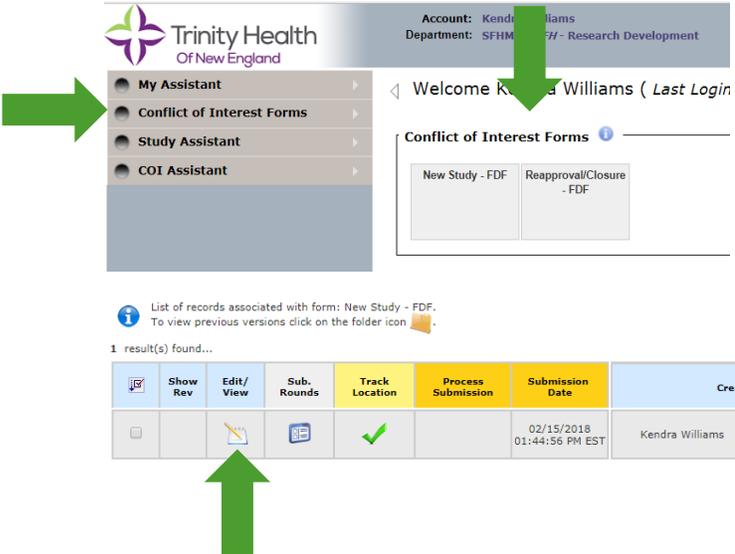
Refer to the link provided in the Help Tip to attach an updated Financial Disclosure Form with your submission.

Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
<input checked="" type="checkbox"/>	1.0	New Study - FDF_Vredenburgh	Financial Disclosure Form				33.50 KB

Note: The Conflict of Interest System is a separate system in iRIS; therefore all Financial Disclosure Forms need to be uploaded into the IRB Application and/or Reapproval Form. **Only attach copies of the Financial Disclosure Form which indicate that the electronic signature has been applied.**

Below is an alternative way to save/print the FDF after it has been signed and submitted:

- 1. Open the Conflict of Interest/FDF form by following the pictures below:



- 2. Click Print Friendly and select HTML



- 3. Click Print



- 4. Change Destination Printer to "Save as PDF"

