Disclosure of Study-Specific Financial Conflicts of Interest (COI)
Frequently Asked Questions

**GENERAL FAQs**

Why are individuals being required to disclose study-specific financial conflicts of interest (COI)?
In order to comply with federal regulations, it is the policy of Children’s Research Institute (CRI) that all key research personnel must refrain from any real or potential financial conflicts of interest (COI) that may influence the design, conduct, or reporting of their research. By having key personnel disclosure financial COI related to their research, CRI can ensure that the integrity of investigators, the institution, and academic research, training and clinical activities are not compromised or perceived to be compromised by considerations of personal gain or financial benefit.

To whom must study-specific COI be disclosed?
Financial COI related to research must be disclosed to the following Children’s National departments:

- Grants and Contracts Administration
- Institutional Review Board (IRB) and Office for the Protection of Human Subjects (OPHS)

Conflicts of interest reported to Grants and Contracts or the IRB/OPHS are referred to the Children’s National Compliance Office for review and, when appropriate, development of a management plan.

If I submit a study-specific financial disclosure form to Grants and Contracts Administration, do I also have to submit one to the IRB/OPHS?
Yes. Grants and Contracts Administration and the IRB/OPHS use the same form, but they have different purposes. Also, your submissions to Grants and Contracts and to the IRB/OPHS may occur at different times, depending on when the research contract or funding agreement is processed and when you submit your application to the IRB.

Where do I find the Study-Specific Conflict of Interest (COI) Disclosure Form to complete?
Click on the link [COI Study Specific Disclosure Form](#) to open the study-specific disclosure form. This link is also available at the following locations:

- Grants and Contracts Administration Intranet page (click on “Forms, Policies, Procedures”)
- IRBear in Section 1.4 of the IRBear SmartForm application
- IRBear website Home page ([http://irbear.org/eResearch/](http://irbear.org/eResearch/); click on “General Information” in the far left column; select the sub-heading “Forms and Templates” and look for “Conflict of Interest”)

Who is required to complete a Study-Specific Financial Conflict of Interest Form?
The [Grants and Contracts Administration](#) requires that all Children’s National employees who are involved in the design, conduct, or reporting of the research and all Key Personnel (as identified in the study proposal) complete the study-specific COI.
This form is required to be completed when (i) submitting proposals to federal agencies requiring disclosures; (ii) entering into a contract agreement with an industry sponsor; (iii) requesting funding support from all other non-federal and non-industry sources (e.g., local government, foundation, intramural). Contact Grants and Contracts Administration at grantsandcontracts@childrensnational.org for more information.

Effective June 23, 2014, the Institutional Review Board (IRB) and Office for the Protection of Human Subject (OPHS) require that all Children’s National employees who are Key Personnel on a study must complete this form. The IRB/OPHS defines Key Personnel as members of the study staff who are responsible for the design, conduct, or reporting of the research, regardless of their title or position. This includes the PI and all individuals who conduct the following activities:

- Design or direct the research;
- Serve as co-investigator or study coordinator;
- Enroll research subjects (including obtain informed consent/parental permission and assent, if applicable);
- Make decisions related to research subjects’ eligibility for enrollment in the research;
- Analyze or report research data;
- Submit manuscripts concerning the research for publication as a primary author or co-author.

**What if someone on the study team is not a Children’s National employee? Should they also complete the form?**

Only employees of Children’s National are required to complete a study-specific COI disclosure form for the IRB/OPHS. Please contact the Grants and Contracts Administration regarding its requirements for non-Children’s National employees. Non-employees may be required to disclose financial COI at their home institution.

I am a Faculty member and previously submitted my annual COI disclosure to George Washington University (GWU). Do I also have to complete a study-specific COI form for each of my research projects?

Yes. It is important to know that:

1. Faculty will no longer submit annual COI forms to GWU beginning June 2014. All Faculty will submit through the RL system to Children’s National Health System (CNHS) Compliance Office.
2. The annual submission of COI to CNHS does not change the need for researchers to submit COI to the IRB/OPHS for new studies and to Grants & Contracts for new studies and annual reviews.
3. The financial disclosure of Outside Income that Faculty members submit annually to the Medical Staff Office or to their Division Chief does not satisfy the requirements for study-specific financial disclosure.

**What if my financial interests in the research change?**

You are required to submit an updated study-specific disclosure form to Grants and Contracts and to the IRB/OPHS within 30 days of a material change in your financial interests related to the research.
**FAQs about IRB/OPHS Requirements**

**When do the new IRB/OPHS requirements for disclosing financial conflicts of interest take effect?**

Study-specific financial conflict of interest disclosure forms are required by the IRB/OPHS beginning June 23, 2014.

**Why does the IRB want this information?**

Financial conflicts of interest have the potential to affect the conduct and integrity of a research study, which could in turn affect the rights and welfare of study participants. It is important for the IRB to be aware of any conflicts so that they can be eliminated or managed in a way that will still make it possible for the IRB to approve the study.

**Who must complete a study-specific disclosure form for the IRB/OPHS?**

The IRB/OPHS requires that study-specific disclosure forms must be completed by:

- All PIs and Children’s National employees who are key personnel on new IRB or study applications;
- Any PI who is replacing the original PI on a study that is already approved by the IRB; and
- Any Children’s National employees who are added as key personnel on study that is already approved by the IRB

**Are PIs and other key personnel required to complete a study-specific COI form for research that has already been approved by the IRB?**

It depends. Study-specific financial COI disclosure is not required for existing personnel on studies approved by the IRB before June 23, 2014. However, PIs and other Children’s National key personnel who are added after June 23, 2014, to the staff of a previously approved study must complete a disclosure form.

**Who on the study staff qualifies as “key personnel”?**

The IRB/OPHS defines key personnel as members of the study staff who are responsible for the design, conduct, or reporting of the research, regardless of their title or position. This includes the PI and all individuals who conduct the following activities:

- Design or direct the research;
- Serve as co-investigator or study coordinator;
- Enroll research subjects (including obtain informed consent/parental permission and assent, if applicable);
- Make decisions related to research subjects’ eligibility for enrollment in the research;
- Analyze or report research data;
- Submit manuscripts concerning the research for publication as a primary author or co-author.

**My study is not supported by external funding. Do I still have to submit a completed study-specific COI disclosure form to the IRB/OPHS?**

Yes.
I am requesting that my research be exempt from IRB review. Should I submit a COI disclose form?

Yes.

How do I submit study-specific COI disclosure forms to the IRB/OPHS?

- **New studies**: If you are preparing a new protocol submission, identify the PI and all other Children’s National key personnel and upload a completed disclosure form for each person in section 1.4, item 1.0 of the IRBear SmartForm application (see screenshot below).

- **Change in PI for an existing study**: The new PI must submit a completed disclosure form in the Full Amendment requesting the PI change in IRBear.

- **New study staff**: Completed disclosure forms for Children’s National employees being added to an IRB-approved study as new key personnel should be submitted in the Personnel Change Amendment SmartForm in IRBear.

For more details, see *Instructions for Disclosing Study-Specific Financial COI to the IRB/OPHS*.
What happens if I disclose a study-specific financial conflict of interest to the IRB/OPHS?

When the IRB/OPHS receives a disclosure form indicating that study-specific financial COI may exist, the IRB Analyst routes the protocol application (or amendment) to the Children’s National Compliance Office and the application transitions to the “Awaiting Ancillary Review” state in IRBear. The Compliance Office reviews the application and disclosure form and, in conjunction with the Conflict of Interest Committee, makes a determination whether a plan to manage or eliminate the conflict is warranted. When a determination has been made, the Compliance Office completes its review in IRBear and uploads any proposed management plan. This transitions the application (amendment) to “IRB Staff Review.” The IRB considers the proposed management plan as part of its review and determines if the study (amendment) can be approved with that plan in place. The IRB may require changes to the management plan before final approval is given to the protocol (amendment). Final management plans will be communicated to the PI by the OPHS.

Where can I find additional information about the IRB/OPHS conflict of interest disclosure requirements?

Additional information is available in our documents New IRB/OPHS Requirements for Disclosing Study-Specific Financial Conflicts of Interest and Instructions for Disclosing Study-Specific Financial COI to the IRB/OPHS or by contacting the OPHS at 301-565-8452.