Instructions for Disclosing Study-Specific Financial Conflicts of Interest to the IRB/OPHS

Effective June 23, 2014, all Children’s National employees who are identified as Key Personnel on an IRBear study application are required to complete a Study Specific Conflict of Interest Disclosure Form. All completed disclosure forms must be submitted to the IRB/OPHS by uploading them into the appropriate IRBear SmartForm.

**Definition: Key Personnel** are 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 obtaining 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.

**New Studies.** The following are step-by-step instructions for submitting Study Specific Conflict of Interest Disclosure Forms to the IRB/OPHS for a new study. Numbers in red refer to the screenshots on the next page.

1. Go to section 1.4, Conflict of Interest, of the IRBear SmartForm application for a new study. COI Study Specific Disclosure Form is a link to the Study Specific Conflict of Interest Disclosure Form. This is a Word document and can be saved on your computer. The disclosure form is also available by visiting the IRBear Home page (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.”

   The PI and each Children’s National employee on the study meeting the definition of Key Personnel should complete a form. Each person with the ability to “edit” the SmartForm can upload his or her own disclosure form by following the directions below. Some study teams may prefer to designate one person (such as the study coordinator) to collect completed disclosure forms from all key personnel and submit the forms for them.

2. To submit a completed disclosure form, you must first select the person and identify him or her as Key Personnel. Click the Add button in item 1.0 to open a new window. Begin typing the person’s name in the Select Key Person box and click on his or her name in the pop-up list. (If the person’s name is not in the selection list, contact the OPHS for assistance.)

2a. The names of the PI, co-investigators, study coordinators, research nurse, and biostatistician that were entered on the first page of the IRBear application appear in the right margin to help remind you whom to include. **There may be other key personnel who are not listed in the margin. Be sure to add everyone in item 1.0 who meets the definition of key personnel above.**

3. After selecting a person’s name, you can now upload their completed disclosure form. Click on the Browse button to find the form in your files. Click OK to close the Add Study Personnel window, or click OK and Add Another to select more key personnel.

4. Item 1.0 now shows each of the key personnel you have identified. The symbols indicate whether the person’s disclosure form has been uploaded.

   ☑  COI form has been uploaded  ☞  COI form has not been uploaded

   Click on the person’s name and open the study personnel window to upload disclosure forms.
Conflict of Interest

The IRB requires all Children's National employees who are Key Personnel on this study to complete the Study-Specific Conflict of Interest Disclosure Form (link below). Key Personnel are 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:

- Designing or directing the research;
- Serving as co-investigator or study coordinator;
- Enrolling research subjects (including obtaining informed consent/parental permission and assent, if applicable);
- Making decisions related to research subjects' eligibility for enrollment in the research;
- Analyzing or reporting research data;
- Submitting manuscripts concerning the research for publication as a primary author or co-author.

Key Personnel who are not affiliated with Children's National are not required to complete the study-specific disclosure form for the IRB.

Add Key Personnel and upload completed COI disclosure forms below.

1. COI Study Specific Disclosure Form

Once this study is approved by the IRB, relevant changes in financial circumstances related to the research must be reported within 30 days, and new Key Personnel must complete the disclosure form.

Please note: The Grants and Contracts Office has its own requirements and process for submitting the Study Specific COI Disclosure Form. For further information, please contact that office at grantsandcontracts@childrensnational.org.

2. Key Personnel (click on the Key Person name to edit/upload the COI Disclosure form):

2.a. Principal Investigator:
Marie Curie, PhD

Responsible Investigator:

Co-Investigators:

Name
Virginia Aagar, MD
Albert Schweitzer, MD

PI Proxies:

Name
Clara Barton, RN

3. Study Coordinator:
Paul Meier, MD

Secondary Study Coordinator:

4. Once this study is approved by the IRB, relevant changes in financial circumstances related to the research must be reported within 30 days, and new Key Personnel must complete the disclosure form.

Please note: The Grants and Contracts Office has its own requirements and process for submitting the Study Specific COI Disclosure Form. For further information, please contact that office at grantsandcontracts@childrensnational.org.

Name
Virginia Aagar, MD
Albert Schweitzer, MD

PI Proxies:
**Change in Principal Investigator.** Add the new PI as Key Personnel on the Conflict of Interest Page of the Full Amendment SmartForm and upload his or her completed financial disclosure form.

**New Personnel.** When adding a new Children’s National employee to an approved study as key personnel, add the person on the Conflict of Interest Page of the Personnel Change Amendment SmartForm and upload his or her completed financial disclosure form.