Important Information from the Children’s National IRB/OPHS:
New Module in IRBear for Submitting Reportable Events to the IRB

The IRBear electronic submission system has been expanded to allow for electronic reporting to the IRB of the following:

- Unanticipated problems (including those that are internal adverse events)
- Protocol deviations
- Compliance issues
- External serious adverse events (SAEs) when reporting is required by the study sponsor
- IND safety reports
- Data and safety monitoring reports (when received outside of the Continuing Review cycle)
- Changes to product information (investigator brochures, device manuals, package inserts)
- Action letters
- Study suspensions and terminations

Effective June 1, 2015, all reportable events must be submitted to the IRB electronically using the IRBear system. Paper submission forms will not be accepted after May 31.

Advantages to the new Reportable Events module include:

- Investigators reporting adverse events do not need to submit a Serious Adverse Event Summary Table.
- Investigators can submit an updated investigator brochure, package insert or device manual, IND safety report, data and safety monitoring report, or action letter WITHOUT creating an amendment.
- Investigators can track the progress of their submission in IRBear.
- Investigators will receive email notification when further action is required and when IRB review has been completed.
- If IRB review is not required, investigators will receive written acknowledgment that the IRB has received the report.

Instructions and guidance for using the new Reportable Events module are available on the IRBear Home page and from the Office for the Protection of Human Subjects (OPHS). Resources include:

- Examples of events that qualify as unanticipated problems, protocol deviations, and compliance issues and the timelines for reporting them to the IRB.
- Quick-Steps, illustrated with screen shots, for using the Reportable Events module.

Questions? Please contact the OPHS during office hours in the Main Building, Floor 3.5, Room 232, or by calling 301-565-8452 (Silver Spring office) or 202-476-3472 (Sheik Zayed Campus satellite office).