Important Announcement from the Children’s National IRB/OPHS
May 13, 2016

The IRBear electronic submission system has been upgraded with two new processes:

1) The first upgrade enables investigators to request an IRB Congruence Review to certify that their grant application is congruent with their approved study.

2) The second upgrade creates a new process for investigators to request that Children’s National IRB rely on an external IRB or serve as the IRB of Record for an external site.

1) IRB Congruence Review

- The purpose of IRB congruence review is to certify that all the research activities included in the grant application are consistent (congruent) with the activities that were reviewed and approved by the IRB. This is required by federal regulations and NIH grants policy.

- The Office of Grants and Contracts will notify you when you should request an IRB Congruence Review.

- Use the “Request Congruence Review” activity on the study workspace in IRBear. Complete the brief electronic form and submit it to the IRB.

- Request a Congruence Review ONLY when instructed to by the Office of Grants and Contracts.

2) IRB of Record (IRB Reliance Agreements for Single IRB Review)

- Section 1.6 of the IRBear application is newly designed to make it easier to request single IRB review for studies that are conducted at multiple sites or with personnel from multiple sites. Single IRB review eliminates the need for a study to be reviewed by the IRBs at each site.

- There is now a short series of questions to answer in the IRBear application if you are a) requesting that Children’s National be the IRB of Record for an external site, or b) requesting that Children’s National rely on an external IRB.

- Children’s already has IRB reliance agreements in place for some industry-sponsored studies (Western IRB) and federally-funded multi-site projects (e.g., NCI, CASG, CPCCRN, and Pediatric Research Alliance). Other studies will require that a single-study IRB Assurance Agreement (IAA) be negotiated between the Children’s National IRB and the external site.

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).