Important Information for Investigators Initiating Clinical Trials
Using Investigational New Drugs (INDs):

Two new initiatives are being implemented to enhance the quality and compliance of our investigator-initiated clinical trials.

1) Beginning March 1, 2016, all new investigator-initiated IND protocols must undergo CRI scientific and feasibility review before being submitted to the IRB. In cases in which the protocol already underwent a formal scientific peer-review by a recognized authority, the Scientific Review Committee will focus on study feasibility. The committee’s recommendations will be forwarded to the IRB. Stephan Ladisch, MD., is the Chair of the Scientific Review Committee. The committee administrator is Dawn Griffiths.

2) The Clinical Research Quality Assurance Program has developed a Children’s National Clinical Trial Protocol Template to serve as an optimal resource to all clinical investigators. The document can be found on the IRBear website (Home > General Information > Forms and Templates).

The use of this template is mandated for all investigator-initiated IND trials when the IND holder is a Children’s National employee and a different protocol format is not required by an external sponsor. A similar template is currently being developed for medical device trials.

To ensure compliance with this policy, the Clinical Research Quality Assurance Program has been added to the IRB ancillary review process. Investigators must select the Clinical Research Quality Assurance Program as an ancillary reviewer for new protocols that fall under this policy. This is only required for the initial submission of the study for IRB approval.

Select ancillary reviews in section 2.0 (Required Reviews), item 3.0 of the IRBear SmartForm application.

If you have any questions regarding the protocol template please contact Mark Vetal, Clinical Research QA Program Lead, via email at mvetal@ChildrensNational.org or by phone at 202-476-1287.