Important Announcement from the IRB and Office for the Protection of Human Subjects (OPHS)


The Office for the Protection of Human Subjects (OPHS) is committed to the ongoing development of the IRBear platform to improve the research community’s experience and satisfaction with the IRB’s electronic submission process.

The latest upgrade on July 31, 2015, launched new application workflows designed to simplify and shorten the application process for three types of submissions to the IRB:

- Reviews of existing data ONLY (for example, retrospective chart reviews)
- Quality Improvement (QI) projects
- Case reports

The IRBear application has a series of new questions designed specifically for studies limited to retrospective chart/database reviews. Users submitting this type of study are now able to bypass some sections of the standard application, making it shorter and more streamlined and saving time for both researchers and reviewers.

QI projects and most case reports do not meet the federal definition of human subjects research. According to Children’s National policy, only the IRB/OPHS can make the determination that an activity does not constitute human subjects research. To increase the speed and consistency of these determinations, the IRBear application form now branches to questions specifically designed to distinguish QI projects and case reports from human subjects research. After processing, OPHS will issue an acknowledgement through IRBear that the submission is a QI project or case report and does not require IRB approval.

**IMPORTANT**: The updated version of the IRBear application form will only apply to new study submissions created after 6 p.m. on Friday, July 31, 2015. Applications that were approved or already in progress (including in the Pre Submission state) at 6 p.m. that day will not be affected by the changes.

For additional information, please refer to the reference sheet accompanying this announcement and also available on the IRBear Home page at [www.IRBear.org](http://www.IRBear.org).

Still have questions? Please contact the Office for the Protection of Human Subjects at 301-565-8452; or visit or call our office in the Main building, floor 3.5, room 232, Monday through Thursday (202-476-3472).