Limited to Review of Existing Data, Quality Improvement, and Case Reports

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

Changes to the IRBear application form described in this document apply only 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 upgrade.

What’s different?

The second page of the IRBear application for new studies (section 1.01) now asks the user to select the type of project being submitted. The response to this item determines which set of questions will follow. The application now has separate branches for reviews of existing data, QI projects, and case reports.

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1. Human subjects research

Most submissions will involve human subjects research. These applications will continue to have the standard questions with branching based on whether the research is biomedical or social/behavioral, and the type of review (full board, expedited, exempt, or facilitated).
2. **Review of existing data ONLY**

Select this type of submission if the human subjects research is limited to *retrospective* review of records, charts, databases, or biospecimens. All of the information that will be collected or received must be in existence before the date the application is submitted or the study is not a retrospective review.

Features of the updated application for studies limited to the review of existing data include:

- The financial conflict of interest disclosure is not required.
- Answers to some application questions pre-populate.
  - Requested Review Type (application section 2.0) defaults to Expedited.
  - Medical Records is a default Ancillary Review (section 2.0).
  - Expedited Qualification (section 2.01) pre-populates with category 5, *research that involves materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes.*

  These default answers can be changed by the user.
- The standard Summary of the Research (application section 2.1) is replaced by new items that are tailored specifically to reviews of existing data, including questions about the location, type, and date range of records to be reviewed, and how the information will be collected or received.
- The application branches automatically to section 8.21, *Request for Waiver of Informed Consent or Parental Permission.* (The waiver of consent request is now embedded in the IRBear application. It is no longer necessary to complete the form in Word and upload it for submission.)
- The application branches automatically to section 9.1a, *Waiver of HIPAA Authorization Request.*

The result of these changes is a more streamlined application that is designed specifically for retrospective data or biospecimen review studies.

3. **Quality Improvement (QI) Project**

The aim of a Quality Improvement (QI) project is to improve the process or delivery of care with established/accepted quality standards, or to implement change according to the Children’s National Quality Improvement Plan. QI does not constitute human subjects research. Final determination whether a project is QI or meets the definition of human research is made by the IRB/OPHS. A series of specific questions in the application (section 1.02) has been created to assist with this determination.

There are three possible review pathways for a QI submission in IRBear:

a) **QI project, no additional information needed.** If the user’s responses in section 1.02 indicate that the submission clearly meets the criteria for a QI project and no additional information is needed, the OPHS will issue an acknowledgement through IRBear documenting that the activity is a QI project and does not require IRB review and approval.

b) **Additional information needed, determined to be QI.** When section 1.02 is completed, additional information may be required (if, for example, the project is multi-site or federally funded) to determine for certain whether the activity is a QI project. Application questions on funding, location(s) of the project, objectives and design, and participants must also be completed by the user. An IRB analyst will review the submission and, if the activity is a QI project, issue an acknowledgement to document that IRB review and approval is not required.
c) **Additional information needed, determined not to be QI.** When section 1.02 is completed, additional information may be required (if, for example, the project is federally funded) to determine for certain that activity is a QI project. Application questions on funding, location(s) of the project, objectives and design, and participants must be completed by the user. An IRB analyst will review the submission and, if the activity does not meet the criteria for a QI project, instruct the user to revise the application by returning to section 1.01, selecting “Human subjects research study” as the type of submission, and completing the standard application.

Please also note:

- The financial conflict of interest disclosure is not required for projects which are determined to be QI activities.
- Division approval is not required. Projects which are determined to be QI activities will bypass the review by the PI’s Division Chief/Center Director.
- Children’s National employees who are engaged only in Quality Improvement projects are required to complete online CITI training in the Responsible Conduct of Research (RCR) for Social and Behavioral Research at [www.citiprogram.org](http://www.citiprogram.org).
- Employees who are engaged only in Quality Improvement projects are not required to complete CITI training in Human Subjects Research or Conflict of Interest.

With these changes to IRBear, the criteria for QI projects are more clearly defined and users are not required to answer questions that are not applicable to their proposed activities.

4. **Case reports**

A case report is typically developed as a way to share clinical information for medical and educational purposes. Reports of three (3) or fewer clinical cases are generally considered anecdotal rather than systematic investigations and so do not constitute human subjects research. Final determination whether a project is a case report or meets the definition of human research is made by the IRB/OPHS. A series of specific questions in the application (section 1.03) has been created to assist with this determination.

- If the user’s responses in section 1.03 indicate that the submission clearly meets the criteria for a case report, the OPHS will issue an acknowledgement through IRBear documenting that the activity is a case report and does not require IRB review and approval.
  - The financial conflict of interest disclosure is not required for projects which are determined to be case reports.
  - Division approval is not required. Projects which are determined to be case reports will bypass the review by the PI’s Division Chief/Center Director.
  - If Protected Health Information will be disclosed when the case report is published or presented, be sure to upload the HIPAA authorization form in the IRBear application.

- If responses to section 1.03 indicate that the submission is not a case report, the user is automatically directed back to section 1.01 to select a different type of submission.

The addition of a brief case report application in IRBear standardizes the process by which clinicians obtain a formal determination that their proposed activity does not constitute human subjects research. It also ensures that they receive the documentation needed to verify for journal editors that IRB review and approval is not required.

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).