

New FDA Guidance allows IRBs to Waive Informed Consent Requirements for Qualifying Minimal-Risk Research

FDA has issued [guidance](#) allowing IRBs to waive or alter the informed consent requirement for qualifying minimal risk research in which obtaining informed consent is not practicable.

The FDA regulations have waiver provisions that apply only to life-threatening Emergency Use or Planned Emergency Research. This limitation hinders the ability for an IRB to waive the consent requirement for studies, such as [cluster randomized trials](#) or large retrospective record reviews collecting outcomes data about FDA-regulated products. The limitation is also counter to FDA's current emphasis on use of "[real world evidence](#)" (RWE) in making regulatory marketing/labeling determinations. The new guidance will help facilitate the conduct of minimal risk observational and outcomes investigations collecting RWE.



Since the guidance did not specify adults or reference children, the UK ORI inquired and received a response from the FDA Office of Good Clinical Practice, indicating that the waiver or alteration may apply to minimal risk clinical investigations involving children if the waiver criteria are met. Investigators describe how their research meets the above criteria in the IRB application.

The IRB will consider the same criteria that is currently used to waive or alter informed consent for research conducted according to the common rule regulations:

- ◆ the research involves no more than minimal risk to the subjects;
- ◆ the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- ◆ the research could not practicably be carried out without the waiver or alteration; and
- ◆ whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Generally, the IRB would not consider a request to waive or alter informed consent for convenience purposes or in cases where the researcher has reasonable opportunity to obtain informed consent.



Sample IRB Application and Protocol Development Resources

www.research.uky.edu/ori/human/SampleIRBapplication.html

In response to a faculty member's suggestion, ORI has developed a webpage resource posting sample IRB submission materials and links to protocol templates, tools, and other resources. The sample research descriptions and forms are provided as examples for education purposes. They have not been reviewed or endorsed by the IRB. Each research proposal is unique with varying regulatory and ethical issues; descriptions should be customized to the protocol, processes, and procedures the investigator will implement in the conduct of the research.

In addition, the page provides links to several protocol development toolkits including the *National Institutes of Health (NIH) e-Protocol (Electronic Protocol) Writing Tool*, the *TransCelerate Common Protocol Template Tool*, and the *Connected and Open Research Ethics (CORE) Resource Library* which includes resources pertinent to research involving mobile technologies, internet, and social media.

Data Management: Balancing Confidentiality & Reproducibility

Data management plans include methods for securely archiving and/or de-identifying raw data upon completion of research to ensure confidentiality of human subjects. However, since science is validated by reproducibility and corroboration, destruction of raw data can be counterproductive.



Journals and funding agencies have reproducibility requirements that dictate either primary and/or aggregate data be retained, in some cases beyond the University minimum. The ability to access data and replicate research results builds confidence in published findings.

The following are University of Kentucky resources on data management, security, sharing, and preservation for reproducibility.

The UK Libraries Data Management Research Guide is the “go-to” resource for data management, data preservation, and data sharing. Includes metadata standards and a Data Management Planning Tool that provides templates for all of the major funding agencies. <http://libguides.uky.edu/c.php?g=223382&p=1478751>

Research Data Management: Basics & Best Practices Training, January 2017
Christie Peters, Head, Science Library & eScience Initiatives
http://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1000&context=rdsc_workshops

UK Good Research Practice (GRP) Resource Center

The GRP Resource Center assists researchers who are seeking to strengthen their research programs and meet NIH/NSF or regulatory (FDA/EPA) standards by supporting data quality, integrity and reproducibility.

UK GRP Website Excerpt:

Data Sharing and Record Retention

It is recommended that data and reports are maintained in a durable format using a consistent filing and retrieval system that ensures records can be readily provided if requested during consideration for publication and upon reasonable request upon publication as per ‘data and material sharing’ guidelines¹ and expected policy changes requiring ‘on-line access to methods, protocols, original data, data reductions and analysis protocols’².

¹ Principles and Guidelines for Reporting Preclinical Research. Data and material sharing.

² NSF Reproducibility Framework. (2014).

E-IRB Progress

Effective June 21, 2017, new Exemption Applications must be submitted via the web-based application system, E-IRB. The E-IRB Pilot Phase continues for Initial Full and Initial Expedited reviews with mandatory participation by the Departments of Surgery, Neurology, and the College of Communication and Information.

Online video tutorials provide specific instruction for various components of the E-IRB system and can be accessed via a link on the [E-IRB Log-in page](#). If you would like to participate in an online “E-IRB Basics” training session (strongly recommended for anyone participating in the Pilot), please [review the schedule](#) for a session convenient for you.

For updates, frequently asked questions, general info, and E-IRB tips see the [E-IRB Information web page](#).

Education Events

The Office of Research Integrity is pleased to present Mary L. Gray, PhD, Senior Researcher at Microsoft Research and Fellow at Harvard University’s Berkman Klein Center for Internet and Society.

Dr. Gray will present, [*“When Human Subjects, Science and Consumer Rights Collide”*](#) on October 12, 2017 at the University of Kentucky Chandler Hospital Pavilion A Auditorium.



Full program details at www.research.uky.edu/ori/upcoming_events/MaryGray2.pdf
[Click to Register](#)

The educational seminar will explore the link between “big data” and human subject protection, access to social data, and accountability in data sharing.

Target audience includes biomedical or social-behavioral researchers, student researchers, and Institutional Review Board (IRB) members.

There is no fee to attend; however, registration is required and attendance is limited to auditorium capacity.



Visit the forum website at www.cincinnatichildrens.org/research/cincinnati/support/clinical-translational-research/ohrp to view the full conference schedule, session descriptions, and register for the event.