



FDA Informed Consent Waiver for Minimal Risk Investigations

FDA has issued [guidance](#) allowing IRBs to waive or alter the informed consent requirement for minimal risk investigations in which obtaining informed consent is not practicable. Up until now, the FDA regulations had no waiver provisions except for life-threatening Emergency Use or Planned Emergency Research. This hindered 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 an FDA-regulated product. The limitation was 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 real world evidence.

Since the guidance did not specify adults or reference children, we inquired and received confirmation from the FDA Office of Good Clinical Practice, that the waiver or alteration may apply to minimal risk clinical investigations involving children (i.e., 21 CFR 50.51 Category 1) if the waiver criteria are met. IRBs will consider the same four criteria provided in HHS regulations:

1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The clinical investigation could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The guidance will be withdrawn once they have revised the regulations to permit a waiver. The official announcement released earlier this week is below:

Subject: FDA issues guidance on IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects

The Food and Drug Administration has issued a guidance entitled "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects." This document provides guidance to sponsors, investigators, and institutional review boards (IRBs) on enforcement of FDA regulations governing informed consent requirements for clinical investigations that involve no more than minimal risk to human subjects.

The 21st Century Cures Act amended the Federal Food, Drug, and Cosmetic Act to provide authority for FDA to permit an exception from informed consent requirements when the

proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject. FDA intends to issue regulations to reflect this statutory change. Until FDA issues these regulations, this guidance informs sponsors, investigators, IRBs and other interested parties that FDA does not intend to object to an IRB waiving or altering informed consent requirements, as described in the guidance, for certain minimal risk clinical investigations. In addition, this guidance explains that FDA does not intend to object to a sponsor initiating, or an investigator conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements as described in the guidance.

The guidance is now available on FDA's website

at: <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM566948.pdf>