

## **FDA Guidance Allows IRBs to Waive or Alter Consent for Minimal Risk Research**

While the FDA works on revising its regulations to add an exception from informed consent requirements when clinical studies pose no more than minimal risk to human subjects as required by the 21<sup>st</sup> Century Cures Act, the agency issued guidance July 24 allowing IRBs to waive or alter consent for minimal risk research.

"This guidance informs sponsors, investigators and IRBs that, until FDA issues these regulations, we do not intend to object to an IRB approving a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 21 C.F.R. §50.25, or waiving the requirements to obtain informed consent," the FDA said in announcing the guidance.

However, in order to waive or alter the elements, the IRB must find and document:

- The clinical investigation involves no more than minimal risk (as defined in 21 C.F.R. §50.3(k) or 21 C.F.R. §56.102(i)) to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The clinical investigation 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.

"In addition, we do 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," the agency added. "We believe that this guidance will facilitate investigators' ability to conduct studies that may contribute substantially to the development of products to diagnose or treat diseases or conditions, or address unmet medical needs, without compromising the rights, safety or welfare of human subjects."

The FDA defines "minimal risk" as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

The agency noted its regulations and the Common Rule "share the same definition for minimal risk, but the Common Rule allows a waiver of informed consent for minimal risk research if specific criteria are met." The FDA added that its present regulations "allow exception from the general requirements for informed consent only in life-threatening situations when certain conditions are met (21 C.F.R. §50.23) or when the requirements for emergency research are met (21 C.F.R. §50.24)."

The Common Rule, which "has been adopted and successfully employed for decades by numerous other federal agencies," permits an IRB to waive the requirements to obtain informed consent, or to allow changes to, or omission of, some or all elements of informed consent if the IRB finds and documents that:

- 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 (45 C.F.R §46.116(d)).

The FDA noted that the recent revision of the Common Rule adds a fifth criterion: if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. "As FDA revises its regulations to harmonize to the extent appropriate and permissible with the Common Rule, we will consider including this new criterion in any waiver provision," the guidance said.

The FDA issued the guidance for immediate implementation, without prior public comment, because the agency determined prior public participation was not feasible or appropriate. However, public comments sent to Docket No. FDA-2017-D-3235 will be considered and the FDA "will revise this guidance when appropriate."

However, the FDA noted that the agency "intends to withdraw this guidance after we promulgate regulations to permit a waiver or alteration of informed consent."

The FDA added that sponsors, investigators and IRBs may contact the agency with questions about implementing the guidance's recommendations for a specific clinical investigation; however, the questions should be directed to the appropriate product center:

- Center for Drug Evaluation and Research – Ebla Ali Ibrahim, Office of Medical Policy Initiatives, Office of Medical Policy, 301-796-2500 or 301-796-3691, Ebla.Ali-Ibrahim@fda.hhs.gov.
- Center for Biologics Evaluation and Research – Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010, ocod@fda.hhs.gov.
- Center for Devices and Radiological Health – Office of Device Evaluation, Office of the Director Clinical Trials Program, 301-796-5640, CDRHClinicalEvidence@fda.hhs.gov.

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