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# **Information Sheet Guidance For Sponsors, Clinical Investigators, and IRBs**

## **Waiver of IRB Requirements for Drug and Biological Product Studies**

*Additional copies are available from:*

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*Contains Nonbinding Recommendations*

**Information Sheet Guidance  
For Sponsors, Clinical Investigators, and IRBs<sup>1</sup>  
Waiver of IRB Requirements for Drug and Biological Product  
Studies**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

**I. INTRODUCTION**

This guidance is intended to provide information for sponsors and sponsor-investigators<sup>2</sup> about requesting a waiver of Institutional Review Board (IRB) requirements for drug and biological product studies regulated by the Food and Drug Administration (FDA). This document supersedes *Waiver of IRB Requirements* (September 1998) Office of Health Affairs, Food and Drug Administration. That document has been revised to make it consistent with the Agency's good guidance practices regulations (21 CFR 10.115).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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<sup>1</sup> This guidance document was developed by the Good Clinical Practice Program in coordination with the Agency centers.

<sup>2</sup> For the purpose of this guidance, the term *sponsor* will be used to refer to both sponsors and sponsor-investigators. See 21 CFR 56.102 (j) and (k) for definitions.

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### **II. TO WHICH STUDIES DOES THIS GUIDANCE APPLY?**

This guidance applies to clinical investigations regulated by FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the Act).

### **III. WHEN CAN IRB REQUIREMENTS BE WAIVED?**

IRB review and approval is generally required before a study can be initiated under an Investigational New Drug Application (IND) (§56.103(a)). FDA may waive any of the IRB requirements for specific research activities or for classes of research activities otherwise covered by the IRB regulations (§56.105), but FDA believes that this waiver provision should be used only when alternative mechanisms for ensuring protection of the rights and welfare of human subjects are acceptable. The most common circumstance for which FDA receives a waiver request is when a sponsor wishes to conduct a foreign clinical study under an IND. In this case, typically sponsors utilize an Independent Ethics Committee (IEC) that operates in accordance with Good Clinical Practice (GCP).<sup>3</sup> Although its membership and functions for assuring human subject protection are comparable to those of an IRB, an IEC may not meet all the IRB requirements contained in Part 56.

### **IV. ARE THERE ANY REQUIREMENTS FOR WHICH A WAIVER IS NOT AVAILABLE?**

Because the waiver provision in 21 CFR 56.105 applies only to the requirements in Part 56, it does not apply to the informed consent requirements addressed in 21 CFR Part 50.<sup>4</sup>

### **V. WHEN IS IT UNNECESSARY TO REQUEST A WAIVER OF IRB REQUIREMENTS?**

A sponsor does not need to apply prospectively for a waiver of the IRB requirements for the *emergency use* of a test article<sup>5</sup>, provided that such use is reported to the IRB within 5 working days (§56.104(c)). Any subsequent use of the test article at the institution, however, is subject to IRB review. See the FDA Information Sheet Guidance: *Emergency Use of an Investigational Drug or Biologic* for more information.

A sponsor does not need to apply for a waiver of local IRB review when a centralized IRB review process is used. The IRB regulations expressly provide for joint or centralized IRB

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<sup>3</sup> Sponsors seeking additional guidance on GCP should consult "ICH E6 Good Clinical Practice: Consolidated Guideline," 62 FR 25692, May 9, 1997 (<http://www.fda.gov/cder/fda/guidance/index.html>).

<sup>4</sup> Please note that FDA will not waive the requirement of IRB review for investigations of medical devices conducted under section 520(g) of the Act because IRB review is a statutory requirement for such studies. See 520(g)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)(A)(i)).

<sup>5</sup> "Test article" is defined at 21 CFR 56.102(l).

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review for multi-institutional studies. (21 CFR 56.114). See the draft FDA Guidance: *Using a Centralized IRB Review Process in Multicenter Clinical Trials* for more information.

#### **V. WHAT SHOULD SPONSORS SUBMIT IN AN IRB WAIVER REQUEST?**

For domestic studies, an IRB waiver request should contain the following:

1. The specific requirement or requirements in the IRB regulations from which the sponsor is requesting a waiver and the reason the sponsor believes that the waiver is necessary
2. A description of the alternate mechanisms for assuring human subject protection that the sponsor intends to use

For foreign studies, an IRB waiver request should contain a description of the alternative mechanisms the sponsor intends to use to assure that the rights and welfare of the subjects are protected. As noted above, it would generally be acceptable for a waiver request to state that the sponsor intends to use an IEC that complies with GCP instead of an IRB that complies with 21 CFR Part 56.

The sponsor should submit the waiver request to the IND under which the study will be conducted in the appropriate review division in the Center for Drug Evaluation and Research (CDER) or in the Center for Biologics Evaluation and Research (CBER).

#### **VI. HOW WILL THE SPONSOR BE NOTIFIED?**

FDA [generally] will notify the sponsor in writing as to whether the waiver request is denied or granted. If a waiver is granted, sponsors should have investigators attach a copy of the letter granting the waiver to the signed investigator statement (Form FDA-1572) in the investigator's records.