Information Sheet Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors

Clinical Investigator Administrative Actions – Disqualification

FDA is issuing this guidance document for immediate implementation in accordance with 21 CFR 10.115(g)(4)(i). If you choose to submit comments on this guidance document, submit your comments to the Division of Dockets Management (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Additional copies are available from:
Office of Good Clinical Practice
Office of Special Medical Programs, Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Ave., WO32-5129
Silver Spring, MD 20993-0002
(Tel) (301)-796-8340
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/default.htm

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NOTE: FDA made the following updates to the guidance in March 2014:

- In footnote 3, updated the website link.
- In Sections A.5. and D., updated the text to reflect publication of the final rule for Disqualification of a Clinical Investigator (77 Federal Register 25353, April 30, 2012).
- In Section C., updated the website link and simplified finding information about disqualification proceedings.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice

May 2010
(Updated March 2014)

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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 the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This Guidance document is intended to inform institutional review boards (IRBs), clinical investigators, and sponsors about the administrative action of disqualifying a clinical investigator from participating in studies involving investigational new drugs (including bio(ud)5s -1i,n2dtoiisBs), ing in stuttuict.T Y ou0n9g a45B46.8MCID 111( )5(a)-1(i)-2(ai)-2udingy 1(ap)5(p6abla

II. DISCUSSION

A. The Disqualification Process

1. Notice of Initiation of Disqualification Proceedings and Opportunity to Explain

FDA's field staff conduct on-site inspections of clinical investigators involved in the investigation of FDA-regulated products. FDA performs these inspections of clinical investigators to evaluate their practices and procedures to determine compliance with applicable regulations. FDA conducts many such routine (i.e., "surveillance") inspections each year. In addition, FDA may receive information about potential misconduct, and typically conducts an inspection of an investigator's site to determine the investigator's compliance.[3]

If, as a result of the inspection, FDA notes repeated or deliberate violations or potential repeated or deliberate violations, the FDA Center[4] having jurisdiction over the product used in the study may initiate the investigator disqualification process by issuing a Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE). Generally, the Center will consider issuing a NIDPOE when (1) subjects under the care of the investigator would be or have been exposed to an unreasonable and significant risk of illness or injury; or (2) subjects' rights would be or have been seriously compromised; or (3) data integrity or reliability is or has been compromised. The NIDPOE describes the alleged noncompliance and/or alleged submission of false information and offers the investigator an opportunity to explain in writing or, at the option of the investigator, at an informal conference with FDA. The NIDPOE specifies certain time frames for the investigator to respond to FDA.

If the investigator requests an informal conference, it will be held at the Center as soon as possible following the request. The investigator may bring an attorney. The informal conference may be transcribed, but the meeting is informal, and no prescribed format is required or suggested. After the meeting, the Center will review any new evidence or explanation and decide whether to proceed with the matter. In the event the Center accepts the investigator's explanation, the Center will notify the investigator in writing of this decision.

[3] See Information Sheet Guidance, "FDA Inspections of Clinical Investigators", at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf.

[4] Center for Drug Evaluation and Research, Center for Devices and Radiological Health, or Center for Biologics Evaluation and Research.

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administrative record along with the hearing transcript (see 21 CFR 16.80). The presiding officer's report includes a recommended decision and the reasons for the recommendation. When time permits, the parties are given the opportunity to review and comment on the presiding officer's report (21 CFR 16.60(e)).

The report and any comments of the parties are transmitted to the Commissioner who considers them as part of the administrative record to determine whether the investigator should be disqualified. The Commissioner then issues a written decision giving the basis for the final action taken. (See 21 CFR 16.95(b)).

5. Actions upon Disqualification

If the Commissioner or his or her designee determines that the investigator has repeatedly or deliberately failed to comply with the applicable regulatory requirements, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Commissioner will disqualify the investigator, and:

(a) Notify the investigator, the sponsor of any investigation in which the investigator has been named as a participant, and the reviewing IRBs that the investigator is not eligible to receive certain investigational products. The notification to the investigator, sponsor, and IRBs will provide a statement of the basis for this determination. The notification also will explain that an investigator determined to be ineligible to receive those investigational products will be ineligible to conduct any clinical investigation that supports tablon tr tha

requirements. This disclosure is necessary and appropriate for IRBs and sponsors to be aware of findings indicating violations or potential violations of the laws and regulations enforced by FDA.

In some cases, evidence of a violation or potential violation may implicate more than one of the clinical investigator's studies. If so, FDA may, where appropriate, share information concerning a violation or potential violation with the sponsors and IRBs of any of the clinical investigator's studies.

In accordance with the above, FDA posts on FDA's Web page[11] a listing of investigators who:

- are ineligible to receive FDA-regulated investigational products or have agreed to some restricted use of FDA regulated investigational products,
- have had restrictions removed,
- were issued NIDPOEs,
- were issued NOOH letters, and
- were the subject of presiding officer reports and Commissioner's decisions in clinical investigator disqualification proceedings.

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III. REFERENCES

1. FDA/ORA Compliance Program Guidance; Program 7348.811, Chapter 48 – Bioresearch Monitoring, Clinical Investigators and Sponsor-Investigators, issued December 8, 2008; available at http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/ucm133773.pdf.

2. Regulatory Procedures Manual, Chapter 5 – Administrative Actions, section 9 – Disqualification of Clinical Investigators; available at http://www.fda.gov/ora/compliance_ref/rpm/chapter5/ch5-9.html#toppage.

3. Staff Manual Guide, Volume IV – Agency Program Directives; Compliance Activities; SMG 7711 – Disqualification of a Clinical Investigator: The Hearing Process, effective June 20, 2008, available at http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm052928.htm.