

Department of Health and Human Services

Final Guidance Document

Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection

This document replaces the “HHS Draft Interim Guidance: Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subject Protection” dated January 10, 2001. This document is intended to provide guidance. It does not create or confer rights for or on any person and does not operate to bind the Department of Health and Human Services (HHS, or the Department), including the Food and Drug Administration (FDA), or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

I. Introduction

A. Purpose

In this guidance document, HHS raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects¹ and if so, what actions could be considered to protect those subjects. This guidance applies to human subjects research conducted or supported by HHS or regulated by the FDA. The consideration of financial relationships, as discussed in this document relates to human subject protection in research conducted under the HHS or FDA regulations (45 CFR part 46, 21 CFR parts 50, 56)²

¹ Under the Public Health Service Act and other applicable law, HHS has authority to regulate institutions engaged in HHS conducted or supported research involving human subjects. For a description of what is meant by institutions engaged in research see the Office for Human Research Protections (OHRP) engagement policy at <http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm>. Under the Federal Food, Drug, and Cosmetic Act, FDA has the authority to regulate Institutional Review Boards (IRBs) and investigators involved in the review or conduct of FDA-regulated research.

² This document does not address HHS Public Health Service regulatory requirements that cover institutional management of the financial interests of individual investigators who conduct Public Health Service (PHS) supported research (42 CFR part 50, subpart F, and 45 CFR part 94). This document also does not address FDA regulatory requirements that place responsibilities on sponsors to disclose certain financial interests of investigators to FDA in marketing applications (21 CFR part 54). Guidelines interpreting the application of the PHS regulations to research conducted or supported by the National Institutes of Health (NIH) that involve human subjects are available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-040.html>. Guidance interpreting the provisions

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Best regards,
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