

**Pediatric Ethics Subcommittee
Open Meeting
November 15, 2005**

Overview

On September 10, 2004 the first meeting of the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee was held. This subcommittee was established to address various pediatric ethical issues, including Institutional Review Board (IRB) referrals under Food and Drug Administration's (FDA) Subpart D regulations, 21 CFR 50.51-50.54, as well as joint referral under both FDA and the Department of Health and Human Services (DHHS) Subpart D regulations, 45 CFR 46.401-409. This meeting is being held to address a referral from the University of Chicago IRB of the protocol entitled "*Gonadotropin-releasing Hormone (GnRH) Agonist Test in Disorders of Puberty.*" This referral was made by University of Chicago IRB

The University of Chicago IRB found that the protocol cannot be approved under § 50.51/46.404, § 50.52/46.405 or § 50.53/46.406 but presents a reasonable opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children. Therefore, the protocol was referred for consideration under 21 CFR 50.54 and 45 CFR 46.407.

After careful consideration of all supporting materials, public comments and views expressed during the expert panel meeting the Pediatric Ethics Subcommittee is to provide a recommendation to the Pediatric Advisory Committee regarding whether:

- (1) that the research in fact satisfies the conditions of § 50.51/46.404, § 50.52/46.405, or § 50.53/46.406, as applicable, or
- (2) the following:
 - a. the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
 - b. the research will be conducted in accordance with sound ethical principles; and
 - c. adequate provisions are made for soliciting the assent of children and the permission of their parents or guardian, as set forth in § 50.55/46.408.

To prepare you for these deliberations, you will receive a series of presentations. The agenda has been organized in the following manner: the Subpart D Expert panel process, charge to the committee, overview of the protocol, background by the Principal Investigator, comments from the IRB representative, scientific overview, and a summary of the public comments. The subcommittee will then discuss the protocol as it relates to its approvability under 21 CFR 50.54/45 CFR 46.407.

Introduction

In April 2001, the FDA published an interim rule to amend its regulations to provide additional safeguards for children enrolled in clinical investigations of FDA-regulated products. The interim rule was intended to bring FDA regulations into compliance with provisions of the Children's Health Act of 2000. This Act required that within 6 months of its enactment all research involving children that is conducted, supported, or regulated by the Department of Health and Human Services (DHHS) be in compliance with DHHS regulations providing additional protections for children involved as human subjects in research.

Both FDA and HHS regulations provide a process for an IRB to refer to FDA and/or DHHS under § 50.54/§ 46.407 any protocols which the IRB finds do not meet the requirements of § 50.51/ 46.404, § 50.52/46.405 or § 50.53/46.406, but which present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. Under the Subpart D regulations, a clinical investigation/research may proceed only if the Commissioner and the Secretary find, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following an opportunity for public comment that the conditions described above are met.

The Office for Human Research Protections (OHRP) and the FDA have been working to develop a unified, time-efficient and comprehensive process for Subpart D referrals under 21 CFR 50.54 and 45 CFR 46.407. We have agreed to utilize FDA's Pediatric Ethics Subcommittee and other experts designated by OHRP to review these referrals. The Pediatric Ethics Subcommittee will then present its deliberations to the full Pediatric Advisory Committee, which will then provide a recommendation to the Commissioner of the FDA and the Secretary of DHHS.

We appreciate you participating in this recently defined approach of dealing with complex and difficult pediatric issues. Your suggestions for improvements are welcome. If you have any procedural questions prior to the meeting please feel free to contact the Office of Pediatric Therapeutics at 301-827-1996.

We look forward to your participation on November 15, 2005, as we embark on this important activity in pediatric research.

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