

Pediatric Ethics Subcommittee Meeting Agenda Overview

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Pediatric Ethics Subcommittee meeting, June 9-10, 2008

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Charter - Pediatric Advisory Committee (PAC)

- The PAC advises and makes recommendations to the FDA Commissioner regarding... the ethics, design, and analysis of clinical trials related to pediatric therapeutics, and research involving children as subjects under 21 CFR 50.54 (and to the HHS Secretary under 45 CFR 46.407).
- A permanent Pediatric Ethics Subcommittee (PES) of the PAC advises and makes recommendations to the PAC on pediatric ethical issues, and IRB referrals related to clinical investigations involving children as subjects under 21 CFR 50.54 and 45 CFR 46.407.
- The PES will consist of two or more members of the PAC and additional experts (e.g., science, medicine, education, ethics and law) to address specific issues within their respective areas of expertise.



<http://www.fda.gov/oc/advisory/OCPedCharter2006.html>

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PES Meeting Agenda

- Overall Focus
 - Discuss the application of 21 CFR 50.52 (Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects) to FDA-regulated research.
- Monday, June 9, 2008
 - The discussion will be illustrated with hypothetical case examples of research involving HIV vaccines in adolescents (AM) and controlled trials of inhaled corticosteroids in children with asthma (PM).
- Tuesday, June 10, 2008
 - The discussion will be illustrated with a hypothetical case example of research using stem cells for treating neonatal hypoxic-ischemic injury.



Structure of Discussion

- For each hypothetical case description
 - Presentation of selected ethical concepts that may be pertinent to the case discussion
 - Presentation of the hypothetical case description and discussion questions
 - PES discussion of the ethical issues
- Time for “open public hearing” each day.
- General discussion of 21 CFR 50.52 at the end of the three case discussions.

