

Testimony of  
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Testimony Before the  
Committee on Ways and Means  
Subcommittee on Human Resources  
United States House of Representatives  
Hearing on Protections for Foster Children Enrolled in Clinical Trials  
May 18, 2005

Good afternoon. My name is Marjorie Speers. I am the Executive Director of the Association for the Accreditation of Human Research Protection Programs – an organization that accredits institutional review boards, or IRBs, as part of a broader human research protection program. I was invited to speak about the roles of IRBs and protections for children when they are research subjects.

IRBs have a broad responsibility to safeguard the rights and welfare of research subjects. Thus, they should be sufficiently qualified to review the research that comes before them and to ascertain the acceptability of proposed studies in terms of institutional commitments and requirements, applicable law, and standards of professional practice.

IRBs in institutions that receive funds from the Department of Health and Human Services or review research that the Food and Drug Administration regulates must abide by federal regulations to protect research subjects and Subpart D, which provides additional protections for children participating in research.

As stipulated in the regulations, IRBs must have “at least five members with varying backgrounds to promote complete and adequate review of research”, at least one member must have primary concerns in the scientific area, at least one member must have primary concerns in nonscientific areas, and at least one member must not be otherwise affiliated with the institution.

The primary role of the IRB is to determine whether a proposed study is ethically justifiable. The federal regulations lay out seven criteria for IRB approval of research. Briefly, they include: risks to subjects are minimized; risks to subjects are reasonable in relation to potential benefits, including direct benefits to subjects and the importance of the knowledge that might be gained; subjects are selected equitably; informed consent is

sought from each prospective subject or legally authorized representative and documented; and when appropriate, the research plan includes monitoring the data to ensure the safety of subjects and includes provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

IRBs use written procedures, checklists, and other tools to assist them in complying with the regulations. During IRB meetings, an IRB member usually describes the proposed study and all discuss and debate the ethical and scientific issues relating to the protection of prospective subjects. In the end, they come to a conclusion to approve or disapprove the study, request more information, or require modifications of the study in order to approve it.

Involving children in research poses special ethical dilemmas. Aside from state laws governing the age of majority and who may consent on behalf of the child to participate in research, children by nature of their developing cognitive abilities are unable to give voluntary informed consent to participate in a study. IRBs consider very carefully research involving children.

IRBs must make specific determinations regarding the level of risk involved in a proposed study and whether there is a prospect of direct benefit to the individual subjects. They may approve research only when it falls into one of four permitted categories. Research involving greater than minimal risk can only be approved when it meets certain regulatory criteria. These determinations are not easy to make because IRBs must interpret regulatory terms, such as “minimal risk” or “minor increase over minimal risk.”

One of the main protections for children is the requirement that IRBs approve research in which investigators solicit assent from the child and permission from the

parents or guardians – individuals who are authorized under law to consent on behalf of a child. Under the regulations, IRBs may approve research involving children who are wards. Depending on the level of risk and whether there is a possibility of direct benefit to the child-subject, a child advocate might be required. For example, in order to approve a study involving greater than minimal risk and no prospect of direct benefit to individual subjects, IRBs must find that the research is related to their status as wards or is conducted in settings, such as schools, where the majority of children involved as subjects are not wards. Further, IRBs must require the appointment of an advocate for each child who is a ward, in addition to anyone who is acting on behalf of the child as a guardian.

In summary, there are a number of regulatory requirements to ensure that children participating in research are adequately protected. When IRBs and investigators implement these additional protections, the system works well. Thank you for the opportunity to address the subcommittee.