

IRBs – September 11, 2007

- Thank you for participating in this workshop. I'll begin by making a few comments and perspectives on IRBs.
- It may seem to most of you that IRBs have been around forever, but they haven't.
 - ✓ IRBs are man-made societal mechanisms developed by institutions to protect research enterprise, as well as to protect participants. They are intended to secure and retain support and trust of public for research by avoiding violations of basic human rights in its conduct, restore confidence of people participating in research that they are not being exploited by scientists.
- The Nuremberg trials and code of the late 1940s gave us the principle of informed consent for research, but not the process of group review to assure safety and the adequacy of information in the informed consent process. That came later.

- Gov't – New NIH Clinical Center 1953 “Group Considerations of Clinical Research Procedures”
 - ❖ Justify risks
 - ❖ Inform subjects
 - ❖ Group review of projects
 - ❖ This was IM only

- Extramural actions came in response to disclosures from Beecher and others in the 1960s that some research was being done that most people would consider unacceptable, and that relying on informed consent and investigators alone was not only not sufficient to protect research subjects, but jeopardized the whole research enterprise by eroding public confidence and support.

- To counter these concerns research institutions began processes of group review of research protocols by committees with various names – human subjects committees, research review committees, etc.

- First formalization of this process came from Surgeon General policy statement in 1966 – PHS funding contingent on “prior review by institutional associates”
- Required applicant institutions to have research involving people reviewed by a committee for its safety, acceptability, and adequacy of informed consent.
- Formalized in 1971-Institutional Guide to DHEW Policy on Protection of Human Research Subjects
- Disclosures of Tuskegee, fetal research involving decapitation, and other stories that shocked the public and again threatened the research enterprise led to Congressional passage of the National Research Act in 1974, authored mainly by Senator Ted Kennedy.
- This Act established the NCPHS, required DHEW to elevate its guidelines for research it supported to protect human subjects to regulation status, and required by law review by a local committee, an IRB, to assess safety and assure protection

including informed consent. One of the tasks of the NCPHS was to review the functioning of the IRB system that had sprung up in response to the 1966 and 1971 policies, and make recommendations for IRB operation as prescribed by regulations.

- The regulations developed for IRBs adopted certain principles:
 - ✓ local review and decision within context of regs to be developed.
 - ✓ rejected centralized review or appeal, but did provide option of central IRB for multi-site studies
 - ✓ government oversight for compliance with regs and procedures, but not decisions of individual IRBs
- Expected variance from one IRB to another – got more than we expected
- Investigators complaints about IRBs:
 - ✓ Take too long
 - ✓ Quibble over trivia of words (IC)

- ✓ Lack expertise in specialty or research topic
- ✓ Decisions vary from one place to another
 - ❖ Standard clinical practice in one site viewed as risky research by another (maybe it is, depending on expertise of performer)
 - ❖ Minimal risk definition varies
 - ❖ Risk averse IRB members
 - ❖ Protect institution rather than subjects
- NICHD has gotten appeals to convene conference on research versus practice in field, degree of risk, etc., to get consensus among IRBs
- Didn't do that – try to share information on process and thinking, reach more common ground (progression toward the mean) but no expectation of so much consensus that every IRB would make same decision

- Our hope - more concurrence on acceptable levels of risk for children. This workshop today can be viewed as a step in that process
- No question but that children need special consideration and protection in context of regs
- But it is also possible to be so protective that important, necessary, and acceptable research is prevented
- Must remember that it is possible to protect children to their harm if important research is prevented by excessively cautious IRB reviewers
- Protection is important, but so is research, and efforts need to be made to find ways to allow most research to proceed in an acceptable way.
- The greatest protection for children is knowledge, for which there is no substitute, and we must jointly resolve to find acceptable ways to acquire that knowledge through research.

- Your presence and participation in this conference is a sign of your commitment to this objective.
- The IRBs reflect the belief stated in the original Institutional Guide to Protection of Human Subjects that in a multitude of counselors there is safety. That concept must be married to the concept that ultimate safety comes from knowledge, and that gaining knowledge in ways that still protect individuals must be our overall goal. Thank you for investing your time and talents to launch a joint effort to promote and implement this objective.