Study Group Working Notes #15: Equivalent Protections

Study Group: NA

Background: In 2003, the Department of Health and Human Services published the *Report of the Equivalent Protection Working Group*. This report concluded that equivalent protections is a feasible strategy for ensuring the protection of human subjects in research conducted in, or through, foreign research institutions.

To clarify the scope of the equivalent protections provision, the authors attempted to characterize the protections they believe may be reasonably inferred from the content of 45 CFR 46. Two general conclusions were drawn from this analysis: (1) that the primary focus of the policy is the accountability of the research institution for the welfare and rights of research subjects; and (2) that the overarching goal of the specific accountability mechanisms and procedures described in the policy is to establish expectations of ethical conduct within the research institution. The analysis also suggests that the protection of the welfare and rights of human subjects of research is achieved as much through the proper promotion and conscientious execution of standard practices and procedures within the institution, as through competent reasoned application of ethical principles in research ethics review. It also requires that three main levels of responsibility are recognized and met: (a) responsibilities of the institution; (b) responsibilities of the IRB; and (c) discretion on the part of the appropriate U.S. Department or Agency head to take action, where necessary, to ensure that the responsibilities are appropriately exercised.

A five step process is proposed, the first 4 of which are steps in determining the equivalence of the protections offered by procedures employed in foreign research institutions, and the last of which involves an assurance that these procedures will be followed within the institution:

Steps in determining equivalence

(1) Articulation of the specific protections embodied in 45 CFR 46
(2) Assessment of the protections provided by the institution's procedures
(3) Comparison of the protections provided by the institution's procedures with those provided by 45 CFR 46 and determination of equivalence, or not
(4) Approval of the relevant department or agency head for the substitution of the institutional procedures in lieu of the procedures of 45 CFR 46

Mechanism of assurance

(5) Assurance from the institution that the substituted procedures will be followed in the conduct of human subjects research funded by the U.S. Department of Health and Human Services (DHHS).

The analysis identified 7 specific protections afforded by 45 CFR 46 that should figure in the determination of equivalence:

- Establish expectations of ethical conduct and due diligence in review and performance of research within the institution.
- Ensure adequate authority and independence of the IRB/Research Ethics Committee
- Protection from biased and arbitrary decisions in research ethics review
- Ensure sufficient quality and comprehensiveness of research ethics review
- Ensure review and oversight are commensurate with risk and vulnerability of study population
- Protection from unnecessary or unjustified risk throughout the course of the study
- Protection from inadequate disclosure and non-voluntary participation