

IRB REGULATORY REMINDER

Risks to Research Subjects

July 11, 2001

- Assessment of risks is a critical element of ethical review.
- Possible risks should be minimized/Possible benefits should be maximized

STAY ON THE RIGHT TRACK

Help the IRB stay on the right track by ensuring that Risks to Research Subjects:

- are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.

In addition, the IRB should:

- recognize the requirement for consultation with appropriate experts prior to initiation of research with prisoners;
- scrutinize assignment of prisoners to a placebo control group which will not benefit from the research;
- consider the education level of expected subject populations, especially prisoners, in approving consent form language.

Applicability: **Initial and Continuing Reviews** Questions? Call Office of Research Integrity:
257-3138 257-8315 257-3038 323-2446 257-9425

Ride the Regulatory Reminder Railroad

Stay on the right track when assessing
Risks to Research Subjects