Conflicts of Interest in Research:
Industry Relationships with the IRB

PHARMACEUTICAL R&D IN THE NEW MILLENNIUM

OPPORTUNITY

• Scientific and Medical Breakthroughs
• Technology Breakthroughs

CHALLENGE

• Complexities of Scientific Environment/Regulatory Hurdles
• Cost Containment

SCIENCE:
A TRUTH-SEEKING PROCESS

BIAS IN RESEARCH:
Bias hinders the Search for the truth.

BIAS IN RESEARCH:
• Clinical Trials are Experiments—>Designed to Minimize Bias.
• Conflicts of Interest Induce Bias in Research.

BIAS IN CLINICAL TRIALS

• The Investigator
• The Nurse
• The Technician
• The Patient
• The Patient’s Relatives
• The Drug Company
BIAS IN RESEARCH:
• One Of The Major Efforts Of The Clinical Protocol Is To Minimize Bias.
• The IRB Should Be Sufficiently Sophisticated That It Can Recognize A Study With Potential Bias.

The Industry and the IRB
• Under what circumstances, for a clinical study, does the Industry interact with the IRB?
• What kinds of interactions occur?

The Industry and the IRB
• Two, curiously dichotomous circumstances govern contact by the Industry with the IRB.
• The path is determined by the identification of the principal investigator.

The Industry and the IRB
**First Path:**
In a Phase II or III study, the industry study manager (who might be a clinical scientist or might be a physician) works with a principal investigator (typically an academician) who, in turn, deals with the IRB.

The industry study manager would not even **think** about contacting the IRB.

The Industry and the IRB
**Second Path:**
In a Phase I study, the industry owns its own Clinical Research Unit. The director of the unit (typically a physician) **is** the principal investigator, and presents each study directly to the IRB.

The industry study manager is now the principal investigator; contact with the IRB is expected and natural.
The Industry and the IRB

Issues (I)

• The IRB needs to have some independence from the principal investigator, whether the IRB is academic, contract, or otherwise.
• The IRB should have some accountability for its actions.

Issues (II)

Should the IRB talk to the principal investigator?

OR

Should the protocol, etc, be mailed to the IRB for a decision?

Issues (III)

Accreditation is a good idea.

THE CHAIN OF TRUTH IN DRUG DISCOVERY AND DEVELOPMENT

• Molecular Development
• Synthesis Scale-Up
• Basic Pharmacology
• Early Toxicology
• Pharmaceutical Development
• Phase I in Humans
• Phase II in Humans
• Phase III in Humans
• Registration

FORCES WHICH MOTIVATE SCIENTISTS:

Altruism and Curiosity

Fame

Fortune

BACKUP SLIDES
FORCES WHICH MOTIVATE SCIENTISTS:

- Altruism and Curiosity
- Fame
- Fortune

FORCES WHICH MOTIVATE SCIENTISTS:

- Curiosity and Altruism
- Fame
- Fortune