Update on the OIG's Investigations Involving Clinical Research

Or, What is the OIG Worrying About Now and Why?

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Question #1: What is the OIG's Role?

- Independent oversight
- Assess effectiveness and efficiency

Question #2: What is the OIG's Track Record in this Field?

An extensive review of IRBS and human subject protections

Issuance of 10 reports (*www.oig.hhs.gov)*

Testimony at 3 Congressional hearings

Site visits to 25-30 IRBs

Presentations at 40-50 professional meetings

Question #3: Why has the OIG Become so Interested in Human Subject Protections?

1995 study on investigational devices raised questions about the continuing review role of IRBs

Led to broadly based inquiry of challenges facing IRBs

June 1998 issuance of high-profile reports on IRBs

June 1998 Report
IRBS: A Time for Reform

IRBs review too much, too quickly, with little expertise

They conduct minimal review of approved research

They face conflicts that threaten their independence

They provide little training for investigators and board members

Neither IRBs nor HHS devote much attention to evaluating the effectiveness of IRBs

Reactions to the Report

Raised much concern in the professional community

Helped spark some reform

Subsequent OIG Reports

Recruiting Human Subjects

Globalization of Clinical Trials

Clinical Trial Web Sites (*To be released this spring)*

With Respect to Human Subject Protections, What is the OIG Worrying About Now and Why?

Sustaining a capacity for independent review

Strengthening continuing review

Sustaining a Capacity for Independent Review

Enduring pressures on IRBs

Continuing resource constraints

Evolving emphasis on responsibility of investigators

Sustaining a Capacity for Independent Review (cont.)

Maintaining sufficient expertise

Limited organizational independence

Minimal outside representation

Strengthening Continuing Review

Looking to informed consent as a process, not just a form

Examining how the recruitment process really works

Strengthening Continuing Review (cont.)

Ensuring the continued safety of subjects

- making sense of adverse event reports
- determining the role of data safety monitoring boards

From “Trust” to “Trust but verify”