

# NCI's Support of an Evaluation of the Impact of the HIPAA Privacy Rule on Clinical Research

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# NCI Support of Research

- u **Cooperative Agreements**
- u Clinical Trials Networks
  - u Cooperative Groups
  - u Community Clinical Oncology Program (CCOP)
- u Research Project Grants
- u Contracts

# Accrual to Clinical Trials via Cooperative Groups & CCOPs in 2006

<u>Type of Clinical Trial</u>	<u># of pts.</u>
Disease Treatment	28,966
Prevention, Supportive Care	4,133
Total	33,099

# National Cancer Advisory Board's 2003 Survey

## u Goal:

- Assess potential impact of Rule on oncology research,
- Analyze issues & provide aggregate feedback to DHHS for further discussion or policy interpretation

# National Cancer Advisory Board's 2003 Survey

- u Letter sent to Cancer Center Directors and Cooperative Group Chairs
- u 226 Cancer Center & Cooperative Group individuals most familiar with HIPAA's potential impact on clinical, behavioral, & population based research

# National Cancer Advisory Board's 2003 Survey

- u Respondents noted:
  - a negative impact on research without significant additional privacy protection
  - variability in interpretation
- u But,
  - Survey was early after implementation
- u Do problems still persist?

# An Example: Study by Wolf et. al.<sup>1</sup>

- u Behavioral study to inform Veterans about Prostate Cancer Prevention trial (SELECT)
- u Implemented before HIPAA & continued afterwards
- u Described impact of HIPAA from 01/27/03 – 09/03/04

Wolf MS, Bennett CL. Local perspective of the impact of the HIPAA privacy rule on research. *Cancer*. 2006 Jan 15;106(2):474-9.

# An Example: Study by Wolf et. al.

## HIPAA's Required Changes:

- u Research Associates could no longer:
  - screen clinic logs
  - Directly approach patients w/out facilitated introduction by clinic staff

# An Example: Study by Wolf et. al.

## Results:

- u Evaluated 3 outcomes:
  1. Weekly patient accrual
  2. Hours per patient accrued
  3. Cost per patient accrued

# Wolf et. al. Study Results: Personnel Time & Costs

Outcome	Pre-HIPAA (2 mo.)	Post-HIPAA (3.8 mo.)	Post-HIPAA (4 mo.)
Wkly. Pt. Accrual	7.0	1.9	5.2
Hrs./pt. accrued	4.1	14.1	5.4
Cost/pt. accrued	\$49	\$169	\$65

# Calls for Further Study

- u President's Cancer Panel calls for an evaluation:
  - *Living Beyond Cancer: Finding a New Balance* (2003)
  - *Translating Research into Cancer Care: Delivering on the Promise* (2004-2005)
  - *Assessing Progress, Advancing Change* (2005-2006)

# Calls for Further Study

- u National Cancer Policy Forum, June 16, 2006
  - Input from researchers, lawyers, patient advocates, funding agencies, industry
  - Potential problematic areas:
    - u Accounting for disclosures
    - u De-identification standards
    - u Authorization for future research use
    - u Multi-site collaborative research
    - u Inconsistency among regulations
    - u Variability in interpretation

# Some of NCI's Questions Related to the Impact of HIPAA on Research

- u Has HIPAA increased awareness of privacy and confidentiality issues?
  - How to measure HIPAA impact on confidentiality & privacy in research setting?
- u Is there currently an impact on recruitment?
- u How has medical records research been affected?

# Some of NCI's Questions Related to the Impact of HIPAA on Research

- u What is the impact on:
  - Smaller, less seasoned research settings?
  - Epidemiologic/observational studies?
- u Has there been a greater impact on prevention research?
- u What is the impact in terms of costs and research not done?
- u How can more consistent interpretation of HIPAA be promoted?