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# NEGATIVE IMPACT OF HIPAA ON POPULATION-BASED CANCER REGISTRY RESEARCH: UPDATE OF A BRIEF SURVEY

Institute of Medicine: Committee on Health Research and the  
Privacy of Health Information: the HIPAA Privacy Rule

June 14-15, 2007

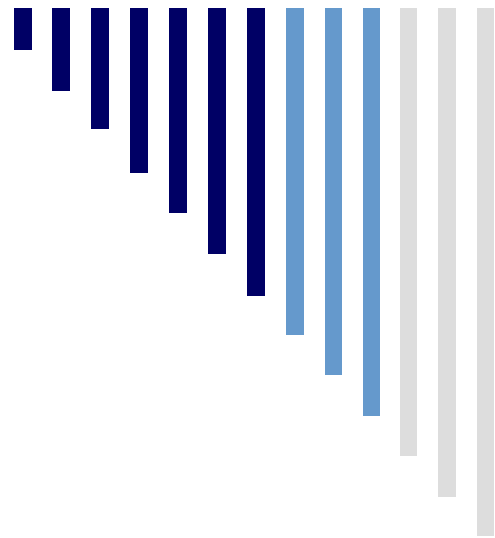
Washington, DC

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University of Southern California

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North American Association of Central Cancer Registries

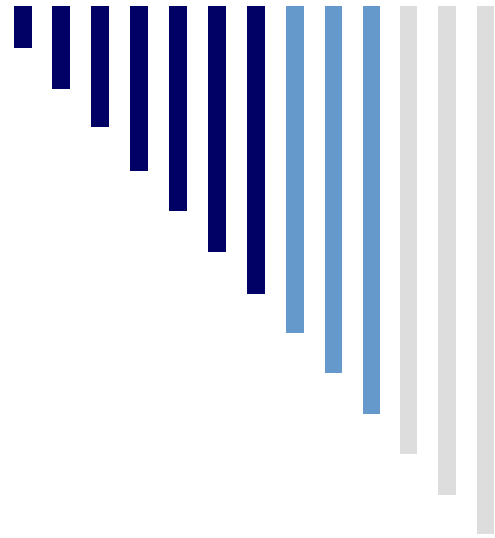
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HIPAA is fine as  
written...

**BUT**

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“The first thing we do,  
let’s kill all the  
lawyers.”

**William Shakespeare’s** *King Henry VI*, Part  
II, (Act IV), Scene 2,

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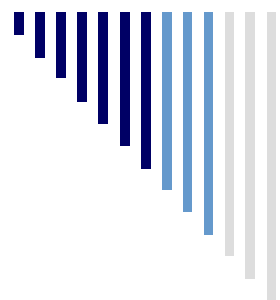


# Cancer Surveillance

- Reporting mandated by all US states
  - n Full patient identifiers
  - n Without patient consent
- “Exempt” from HIPAA\*
  - n Permits hospitals, physicians and other reporting facilities to comply without obtaining patient authorization

\*C.F.R 164.512

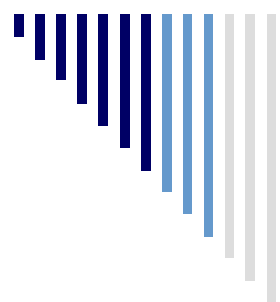
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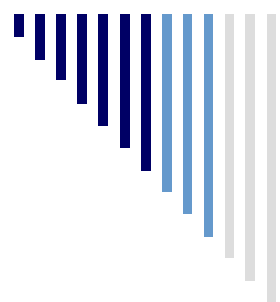
# Cancer Surveillance

- Most state-mandated cancer registries are not HIPAA “covered entities”
  - States’ use of the data is not covered by HIPAA



# 2006 Survey of US Cancer Registries

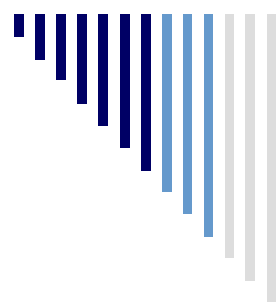
- On behalf of the Institute of Medicine's National Cancer Policy Forum
  - Presented at June 16, 2006 workshop.
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# 2006 Survey of US Cancer Registries

- North American Association of Central Cancer Registries (NAACCR)
  - In 2006, 78 members representing population-based state, regional and provincial cancer registries in Canada, the US and its territories
  - In 2006, 65 members were from U.S. registries, including 2 territories (P.R., Palau)
  - Internet-based survey of US registries (n=65) in May 2006
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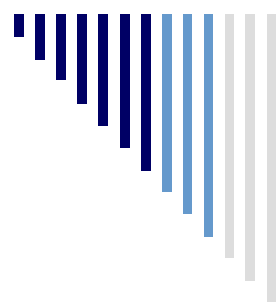


# 2006 Survey of US Cancer Registries

- 47 US registries responded (72% of surveyed)

“Has HIPAA been cited as the reason for actions that have interfered with **non-research operations** of your cancer registry?”

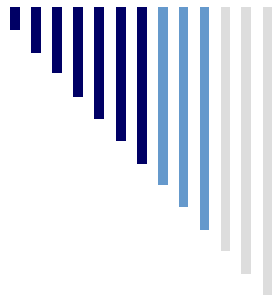
<u>No.</u>	<u>(%)</u>	<u>Response</u>
15	32	No
31	66	Yes
1	2	Don't know



# 2006 Survey of US Cancer Registries

“Has HIPAA been cited as the reason for actions that have interfered with **registry-based research**?  
(check all that apply)”

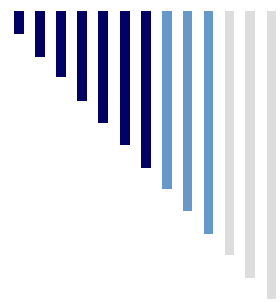
<u>No.</u>	<u>(%)</u>	<u>Response</u>
12	26	No
9	19	Yes, has stopped or prevented a research project
32	68	Yes, has delayed a research project or caused it to take longer
17	36	Yes, has possibly introduced bias into a research project, e.g., made data collection on some cases more difficult than others
5	11	Not applicable



# New Survey of US Cancer Registries: May 2007...

...of “yes” respondents to 2006 survey

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“Has HIPAA been cited as the reason for actions that have interfered with *non-research operations* of your cancer registry?” n=31

Yes, ceased cancer case reporting from at least one reporting source = 18

Was this problem resolved?

No = 3

Partially = 7

Yes = 8

Yes, prevented registry casefinding or auditing = 4

Was this problem resolved?

No = 2

Partially = 1

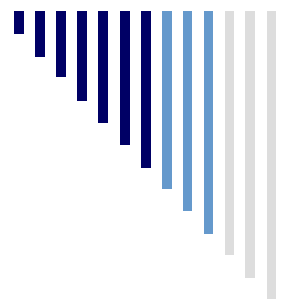
Yes = 1

Yes, interfered with registry collecting follow-up data = 1

Was this problem resolved?

No = 1

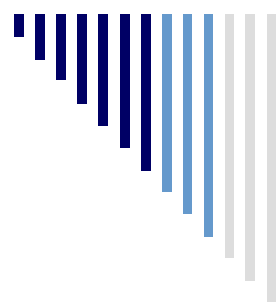
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## Issues Cited in Regards to Reporting

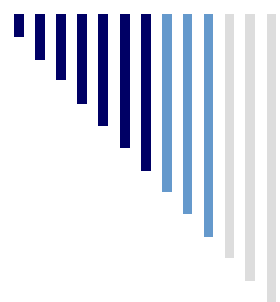
- Cancer incidence in some states has been under reported since 2004 due to misinterpretation of HIPAA
  - Other data, e.g., cancer patient survival, are missing
  - Delays in timeliness of reporting
  - Creates time/cost burden for registries
-



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## Issues Cited in Regards to Reporting

- Misunderstanding of HIPAA in relation to state-mandated cancer reporting by
    - n Hospital administrators, medical records directors
    - n Physicians
    - n IRBs
  - Continue to refuse, despite documentation
  - Re-explanation with personnel turnover
-

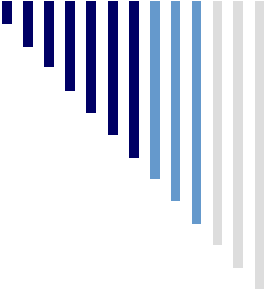


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# Summary/Opinion Regards to Reporting

- HIPAA continues to interfere with
    - n Collection of complete cancer incidence data in some state: data are either delayed or never collected
    - n Collection of other state-mandated cancer surveillance data in some states
  - The reasons are due to misinterpretation of HIPAA
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“Has HIPAA been cited as the reason for actions that have interfered with *registry-based-research*?” n=30

No = 1 (but introduced bias)

Yes, prevented a research project = 0

Yes, stopped a research project = 1

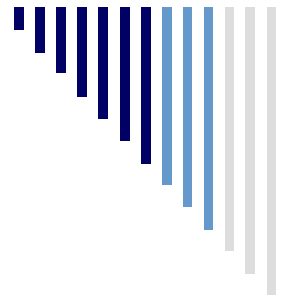
Yes, delayed a research project = 12

If yes, did this introduce possible bias?

No = 3

Yes = 10

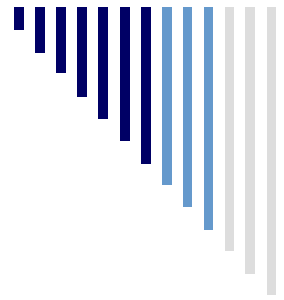
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## Issues Cited in Regards to Research

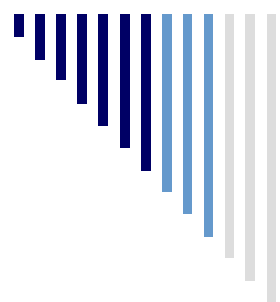
- Some patients think HIPAA prevents state disease reporting and believe that their HIPAA protections have been violated
  - Bias is introduced
    - Patients of some hospitals or physicians are excluded based on misunderstanding of HIPAA
-



# Issues Cited in Regards to Research

- Creates time/cost burden for registries and researchers

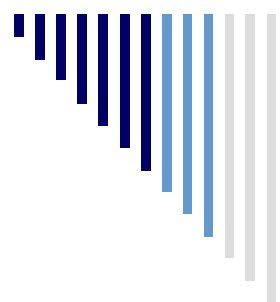




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# Summary/Opinion Regards to Research

- HIPAA continues to interfere with
    - n Access to registry-derived data
    - n Approvals of registry-based research
  - The reasons are due to misinterpretation of the HIPAA provisions for disclosure of data for research. Many facilities appear to be applying the provisions for disclosure of data for treatment and health care operations to research projects.
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## HIPAA Documentation, *for reference*

- Next 3 slides are citations from HIPAA documenting exemption of cancer reporting from patient authorization requirement
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# PERMITTED DISCLOSURES OF PHI WITHOUT CONSENT

Eleven “Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required” C.F.R 164.512

- a. Required by law
  - b. **Public health activities**
  - c. Victims of abuse, neglect or domestic violence
  - d. Health oversight
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## PERMITTED DISCLOSURES OF PHI WITHOUT CONSENT(cont.)

- e. Judicial and administrative proceedings
  - f. Law enforcement
  - g. About decedents
  - h. Organ donations
  - i. **Research purposes**
  - j. Avert a serious threat to health or safety
  - k. Specialized government functions (military, national security, public benefits)
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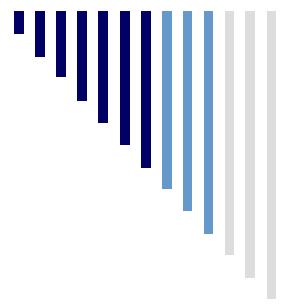
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# PERMITTED DISCLOSURES OF PHI: PUBLIC HEALTH

“b. Public health activities. Permitted disclosures. A covered entity may disclose PHI for the public health activities and purposes described in this paragraph to:

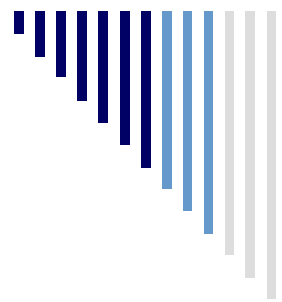
- (1) *A public health authority* that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease...and the conduct of public health surveillance....
  - (2) Permitted uses. If the covered entity also is a public health authority, the covered entity is permitted to use PHI in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.”
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## Examples Provided by Survey Respondents in regards to Reporting

- Registry and health care provided identities have been redacted

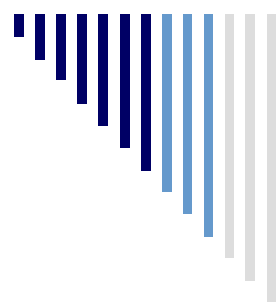




# Cancer Reporting

“Whenever new management staff are hired for a facility, they question our presence and we have to re-start negotiations with them to continue to do our work in their facility. Invariably, the documentation that we have sent their predecessor is "lost" so we have to re-send it and walk the new manager through it. Although this is not a problem, it does become time-consuming when we have 72+ facilities that we deal with in the area and those facilities have constant management staff turnover.”

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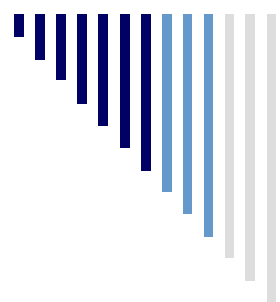


## Cancer Reporting

“If we want to audit a pathology lab for any missed cases, a pathology lab has taken the position, under HIPAA, that we cannot because we might see non-cancer reports. Some physician offices have invoked HIPAA to deny access to logs and records.”

“Whenever there is a major change of leadership in a reporting source, HIPAA issues are raised. Some hospitals and pathology labs have taken stronger positions and the issues are unresolved.”

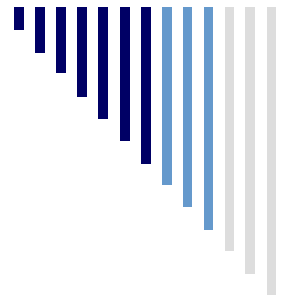
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## Cancer Reporting

“Hospitals and physician offices told [our] Hospitals and physician offices told [our] staff that we would have to go through release of information at their facility or wait until the patient gave consent to provide these data to us.”

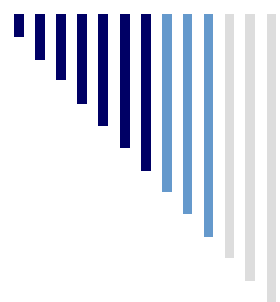
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# Cancer Reporting

“Some hospitals and other cancer reporting sources, such as physician's offices and oncology centers, believe that HIPAA prohibits or limits their ability to comply with state cancer reporting regulations. This has resulted in missed cases and increased costs.”

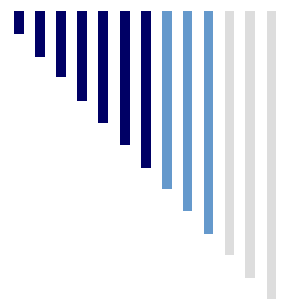
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# Cancer Reporting

“A number of non-hospital facilities (nursing homes, physician offices, free-standing cancer treatment centers, etc.) have been reluctant to comply with mandated reporting because they say that HIPAA prevents them from releasing confidential patient information without the patient's permission. We have had to spend time, effort and money to explain that state-mandated reporting of cancer cases is exempt from HIPAA requirements. While we have generally succeeded in getting cases reported by these facilities, delays in reporting have led to less timely reporting of cases and difficulties in meeting the standard of 95% of expected cases at 24 months and 90% of expected cases at 12 months. The impact has been greatest on the 12-month reporting.”

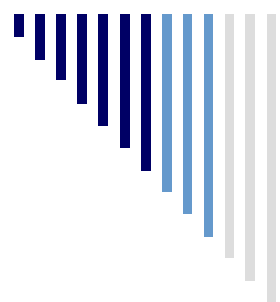
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# Cancer Reporting

“HIPAA has also been cited by physicians (and even a hospital, when we requested additional information) as a reason for their failure to comply with requests for patient diagnostic and treatment data. Responding to these challenges is time-consuming, which impacts on the timeliness of data collection and diverts staff from other tasks.”

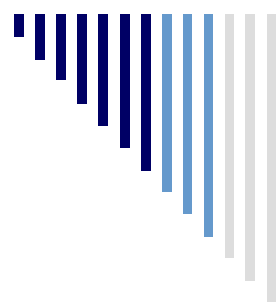
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## Cancer Reporting

“In 2005, we were told by ... Hospital in our region that we could not have our abstractor report cases from their facility. Consequently, we do not have complete case reporting for 2004 and we have zero cases for 2005/2006. This has and will continue to affect our completeness rate for NAACCR certification and CDC and SEER data submissions.”

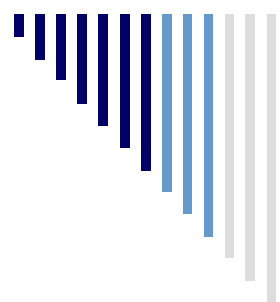
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## Cancer Reporting

“A small number of hospitals have tried not to release information to the Central Registry. This usually occurs when a new registrar starts in one of our registries. It is usually the new person's interpretation of the HIPAA directive.”

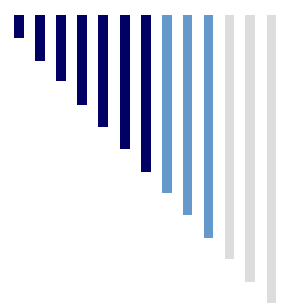
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# Cancer Reporting

“There are still occasions when physicians cite HIPAA as a reason for not responding to our requests for information on a known cancer case identified by a death certificate or pathology report.”

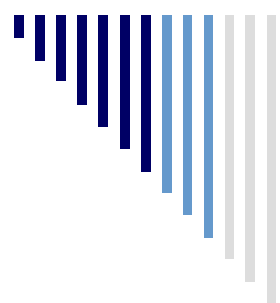
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## Examples Provided by Survey Respondents in regards to Research

“One of the facilities in the state cites HIPAA as the reason for requiring their IRB approve [of] all data release for rapid case ascertainment studies. This has certainly delayed studies and in some cases, possibly introduced bias, because researchers didn't want to spend the extra time and money on that facility's IRB.”

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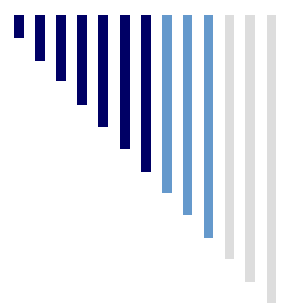


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## Examples Provided by Survey Respondents in regards to Research

“HIPAA authorization forms in use with this multi-site, long-term project were rejected last year by a consortium of hospitals across [our area]. Neither [our registry] nor the particular studies and their researchers are covered by the statute. Nevertheless, despite lengthy conversations about HIPAA regulations, [our state] law (and its exclusions), and the study at issue, the privacy officer insisted on revised authorizations, citing hospital policy in the alternative to HIPAA. Because the HIPAA authorizations were several years old, not all participants were available to sign new authorizations. Not all were necessarily willing. The position of the hospital threatened to compromise the sample of participants, and delayed access to information at a high administrative cost (having field-workers turned away at the front desks of 17 hospitals) to the study.”

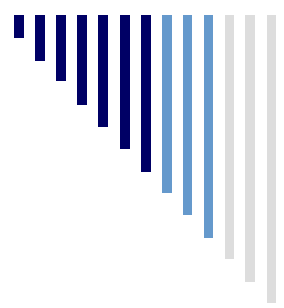
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## Examples Provided by Survey Respondents in regards to Research

“[We were performing a] study to link the registry data with service and follow up data that were collected by another agency. The problem happened when the registry was interacting with other programs covered under HIPAA. Data sharing and matching for research purpose became problematic when data could not be shared anymore or not in the format needed.”

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## Examples Provided by Survey Respondents in regards to Research


“Some hospitals refused to participate in the studies.”

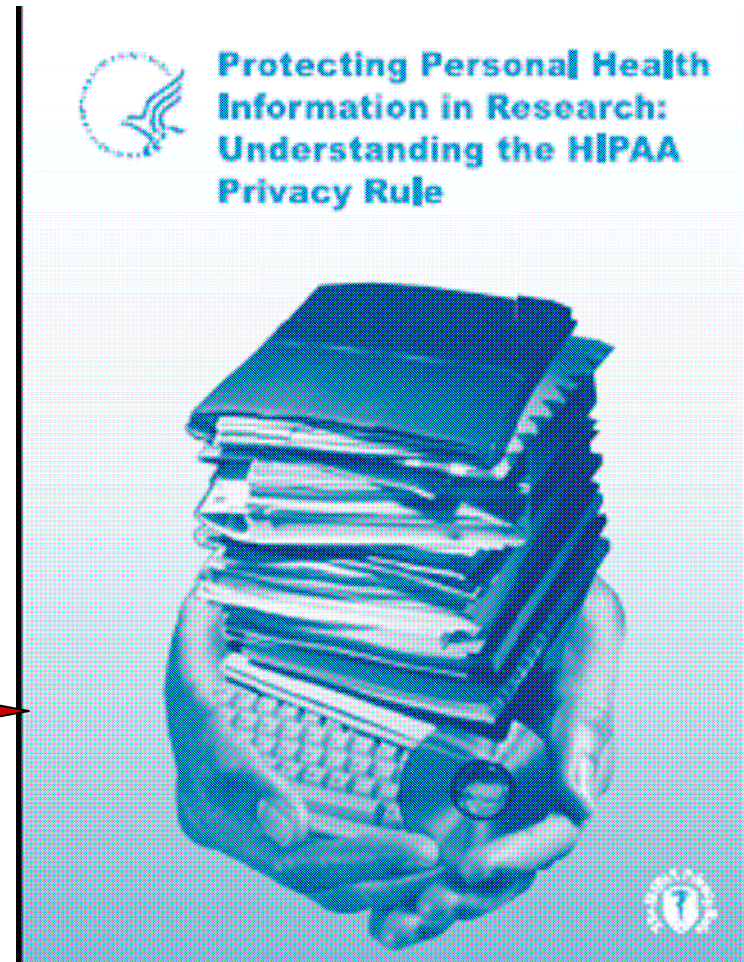
“Doctors were a lot more reluctant to give consent to contact their patients. Some physicians want their staff to do the subject recruitment which decreased the response rate and biased the results.”

“Pathology lab are less likely to release tissue blocks for studies.”

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# Recommendation

- Need unambiguous, detailed written guidance regarding the public health disease reporting provisions and procedures of HIPAA
- Similar to 
- NAACCR volunteers will help frame the issues



[http://privacyruleandresearch.nih.gov/pdf/HIPAA\\_Booklet\\_4-14-2003.pdf](http://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf) 