

# Impact of Implementation of the HIPAA Privacy Rule on Research



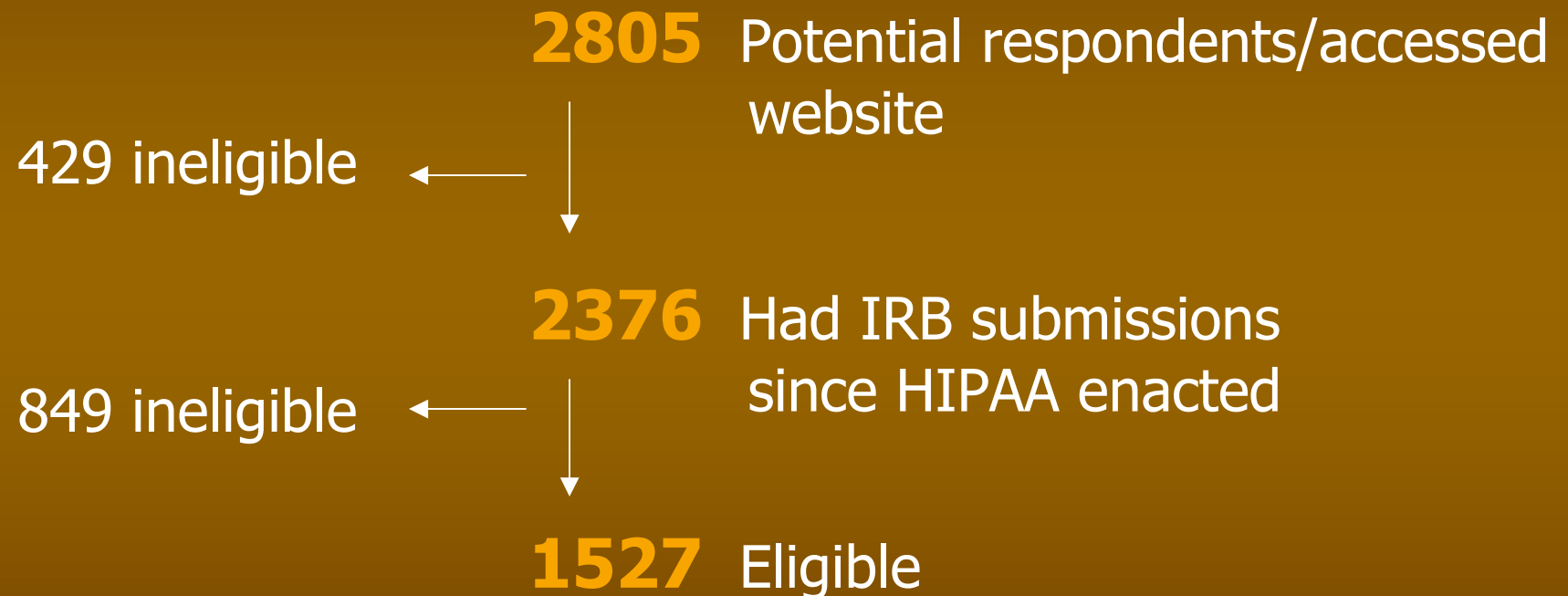
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# IOM – U. Pittsburgh National Survey of Epidemiologists

- ∇ 13 societies of epidemiology
- ∇ Web-based survey
- ∇ Anonymous responses



# IOM U. Pittsburgh Survey: Flow Diagram of Participants



# Survey Contents

## 1) Quantitative responses

- ∇ Types of data collection
- ∇ Pre- and post rule recruitment
- ∇ Experience obtaining waivers
- ∇ Experience obtaining de-identified data

## 2) Perceptions on 5-point Likert scale

- ∇ Ease and difficulty conducting research under rule
- ∇ Impact of rule on privacy/confidentiality

# Survey Contents (continued)

## 3) Case Studies

- ▽ Would your IRB approve?

## 4) Open-ended qualitative data collection



**Table 1. Demographics of survey respondents**

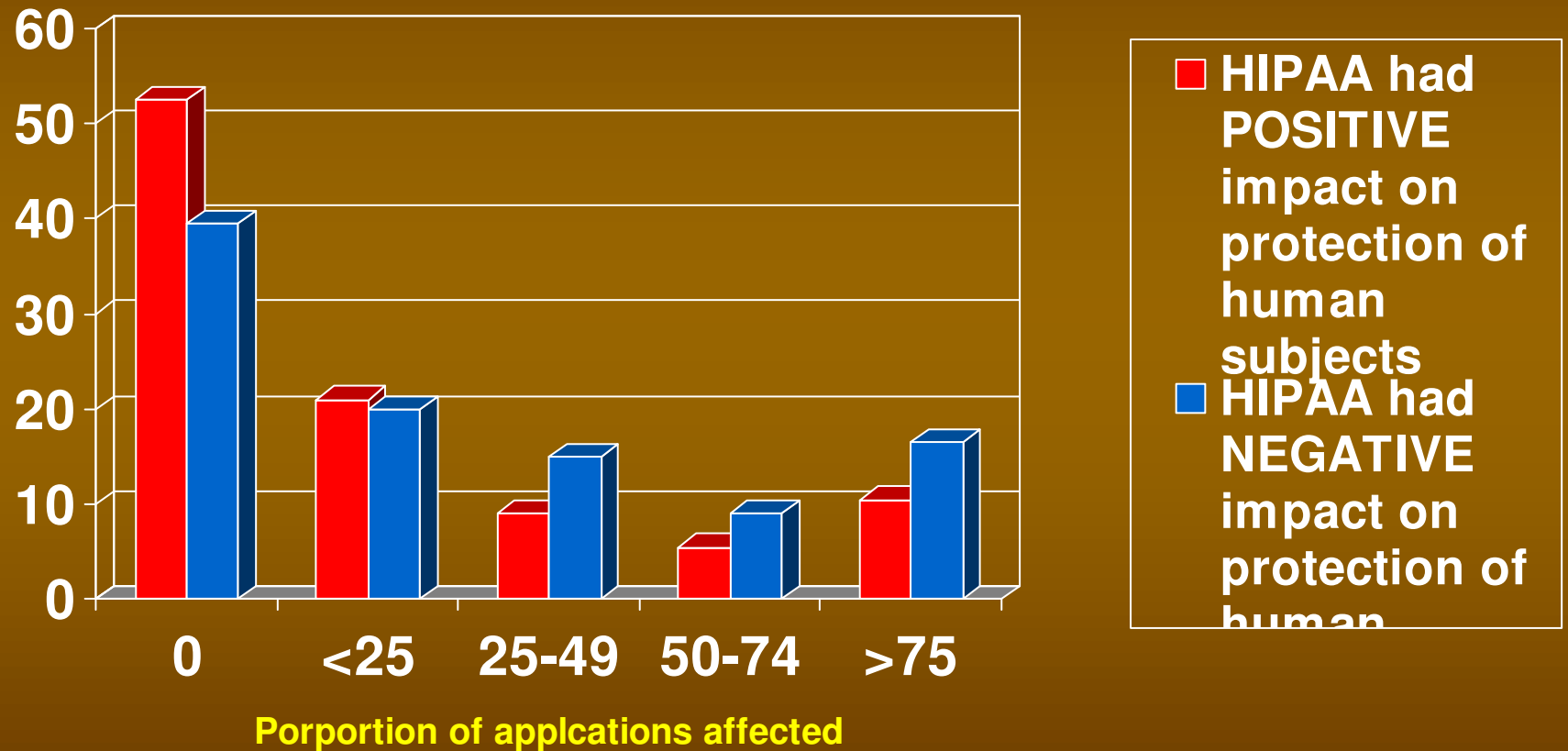
	N	%
<b>Gender</b>		
Male	492	41.0
Female	708	59.0
<b>Year of terminal degree</b>		
≤1977	151	12.4
1978-1987	266	21.8
1988-1997	332	27.2
1998-2007	470	38.6
<b>Employment</b>		
Academia	798	66.0
Industry	63	5.2
Government	176	14.5
NGO	74	6.1
Other	99	8.2
<b>Percent salary from extramural grants/contracts</b>		
0-24	406	34.3
25-49	141	11.9
50-74	169	14.3
75-100	469	39.6







**Figure. Percent of respondents indicating the proportion of IRB applications on which the Privacy Rule had an impact on human subjects' protection**



**Table 3. Impact of HIPAA Privacy Rule on specific provisions**

	N	%
<b>Attempted to access de-identified data</b>		
No	637	48.6
Yes	644	49.1
Don't Know	31	2.4
<b>Level of difficulty accessing de-identified data</b>		
1-2	246	38.2
3	129	20.0
4-5	259	40.2
Don't Know	10	1.6
<b>Attempted to obtain waiver</b>		
No	751	57.5
Yes	530	40.6
Don't Know	26	1.9
<b>Level of difficulty obtaining waiver</b>		
1-2	228	43.0
3	136	25.7
4-5	162	30.6
Don't Know	4	0.8

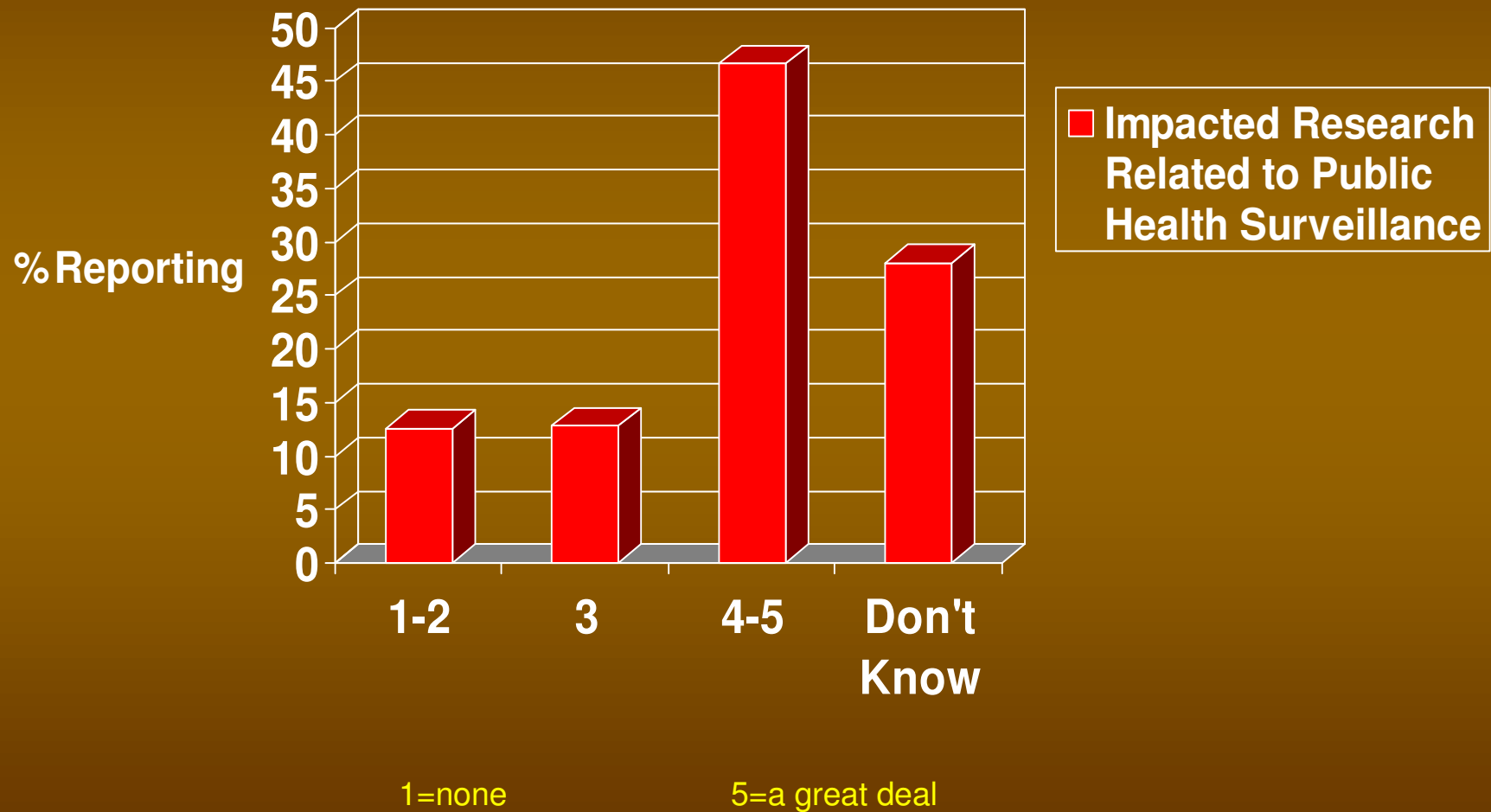
<b>Table 3. Impact of HIPAA Privacy Rule on specific provisions</b>		
	<b>N</b>	<b>%</b>
<b>Multicenter studies engendering Rule concerns**</b>		
No	180	18.8
Yes	734	76.8
Don't Know	42	4.4
<b>Rule concerns resulted in site-specific protocol differences</b>		
No	481	50.3
Yes	379	39.6
Don't Know	96	10.0

<b>Table 3. Impact of HIPAA Privacy Rule on specific provisions</b>		
	<b>N</b>	<b>%</b>
<b>Covered Entities unwilling to do clinical research due to Rule</b>		
No	932	70.0
Yes	230	17.3
Don't Know	170	12.8
<b>Studies approved by IRB but not honored due to Rule</b>		
No	1033	78.0
Yes	207	15.6
Don't Know	85	6.4
<b>Studies conceived but not IRB submitted because investigator thought couldn't get approval under Rule</b>		
No	1110	88.5
Yes	144	11.5

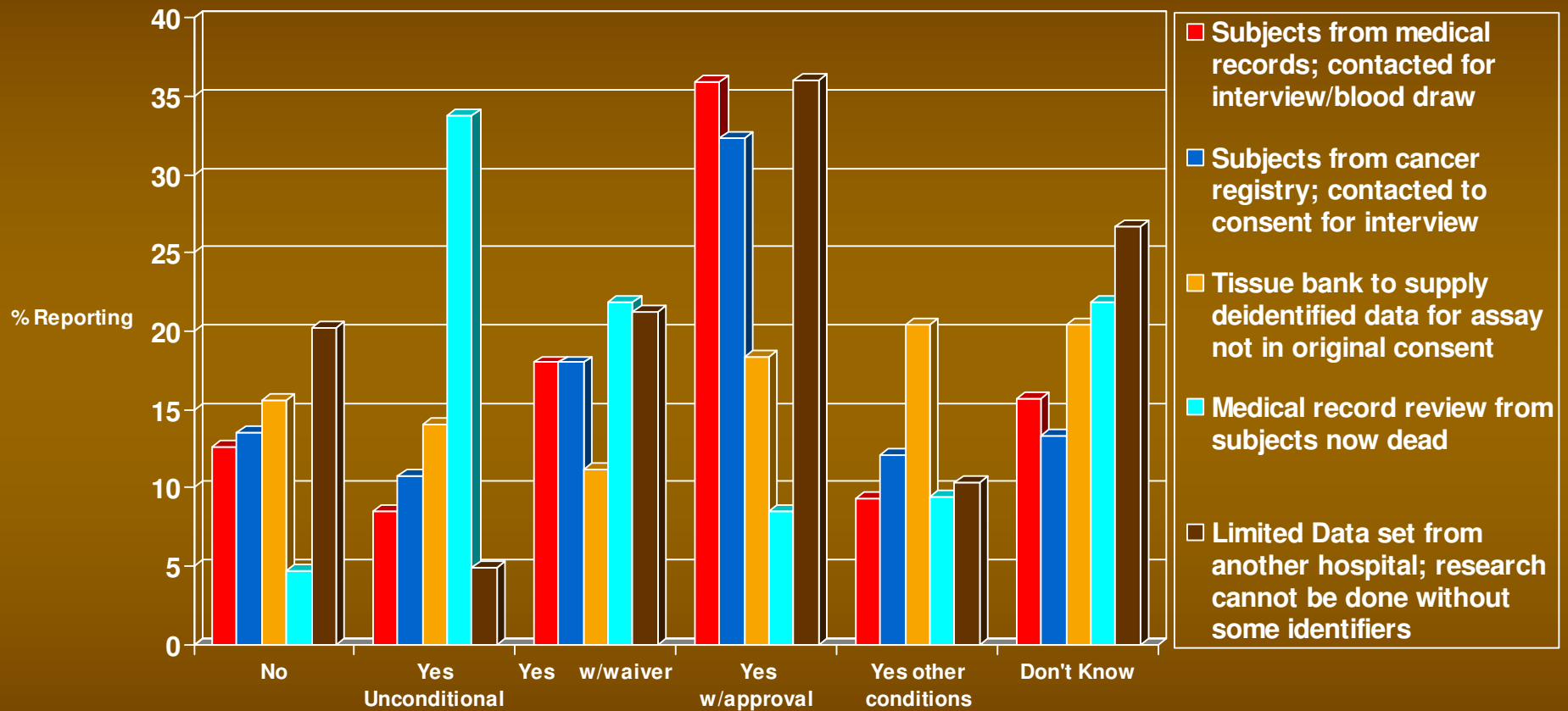
**Table 4. Description of IRB application most impacted by HIPAA Privacy Rule**

	N	(%)
<b>Most impacted application</b>		
None	628	47.9
At least one	684	52.1
<b>Year of most impacted application</b>		
2003	123	18.2
2004	155	22.9
2005	180	26.6
2006	165	24.4
2007	40	5.9
Don't Know	13	1.9

## Scaled perceptions of the impact of the HIPAA Privacy Rule

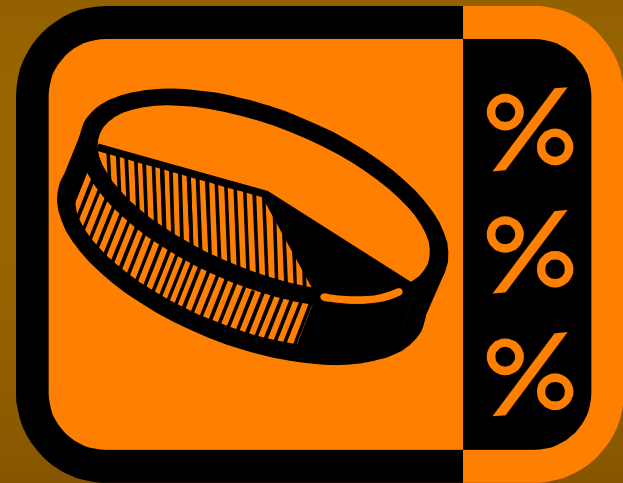


## Case Studies: Would your IRB Approve this Study?



# Tell Us Your HIPAA Stories

- ∇ 90% negative
- ∇ 5% neutral  
(researcher not impacted or exempt)
- ∇ 5% positive (HIPAA clarification helpful)



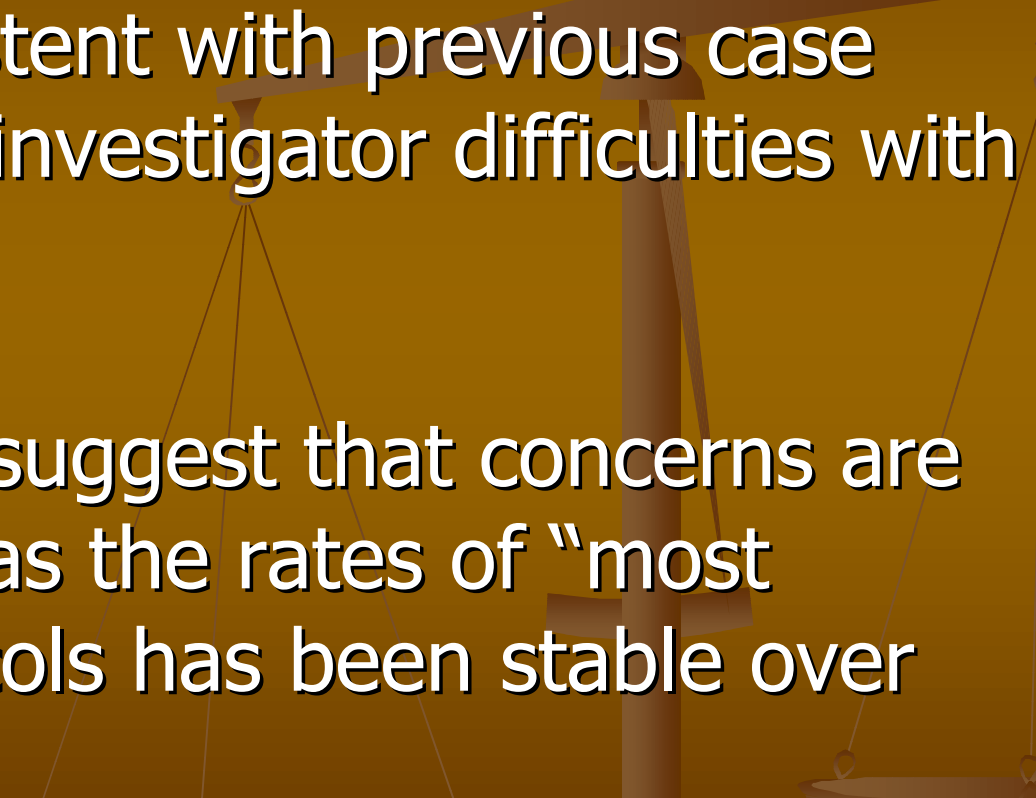
# Tell Us Your HIPAA Stories

- ∇ “An already cumbersome patient consent form now has an additional page-and-a-half explaining HIPAA restrictions. This detracts from the informed consent process pertaining to the more critical issue: the actual medical risks and benefits of participating.”
- ∇ “HIPAA is confusing for all stakeholders and generally serves as more of an impediment to clinical research than it should be. No one argues the merits of patient protection, only that the guidelines lend considerable variance in interpretation by IRB and other governing boards that may preclude a patient from participating in beneficial research.”


# Tell Us Your HIPAA Stories

- ∇ “In the main, HIPAA has not prevented any research that I have desired to pursue. What it has done is to slow the research enterprise through its training and compliance elements. I and my staff spend more and more time doing compliance related things and less and less time doing actual research.”
- ∇ “Besides research, HIPAA has affected basic public health surveillance for reportable diseases and has caused much confusion among healthcare providers that provide us with that information.”

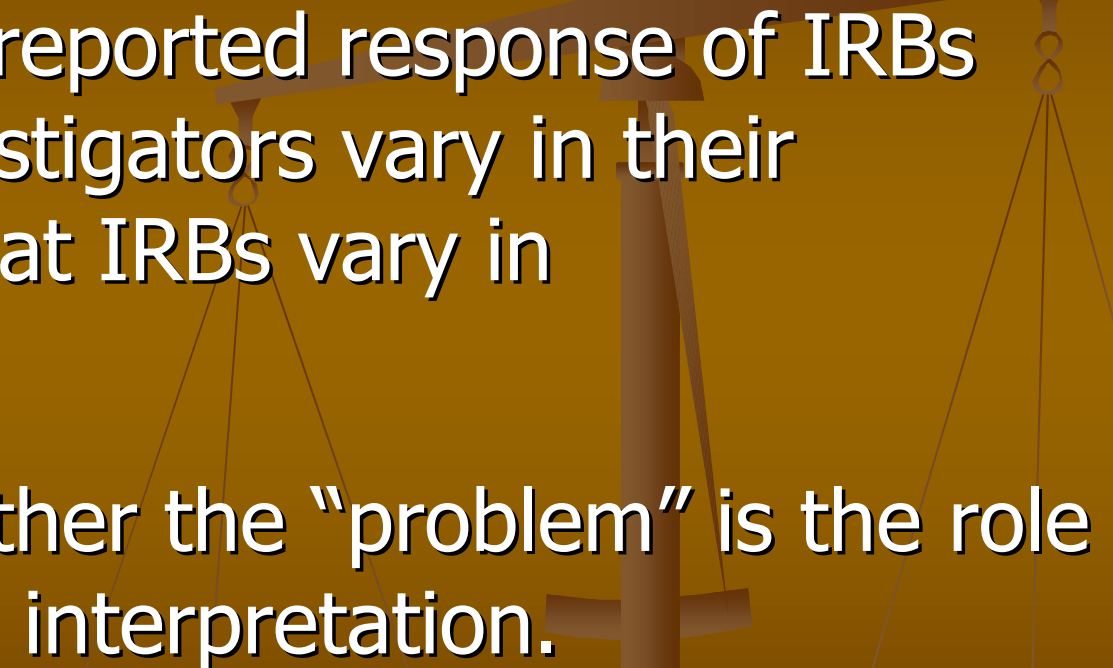
# Discussion

- ∇ Data were consistent with previous case reports showing investigator difficulties with HIPAA.
  - ∇ Our data do not suggest that concerns are “growing pains” as the rates of “most impacted” protocols has been stable over time.
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## Discussion (continued)

- ∇ Only one quarter of respondents indicated that the rule enhanced privacy.
  - ∇ Respondents perceived that the impact of HIPAA on human subjects' protection is more negative than positive.
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## Discussion (continued)

- ∇ Inconsistency in reported response of IRBs may be that investigators vary in their perceptions or that IRBs vary in interpretation.
  - ∇ It is unclear whether the “problem” is the role itself or local IRB interpretation.
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# Strengths

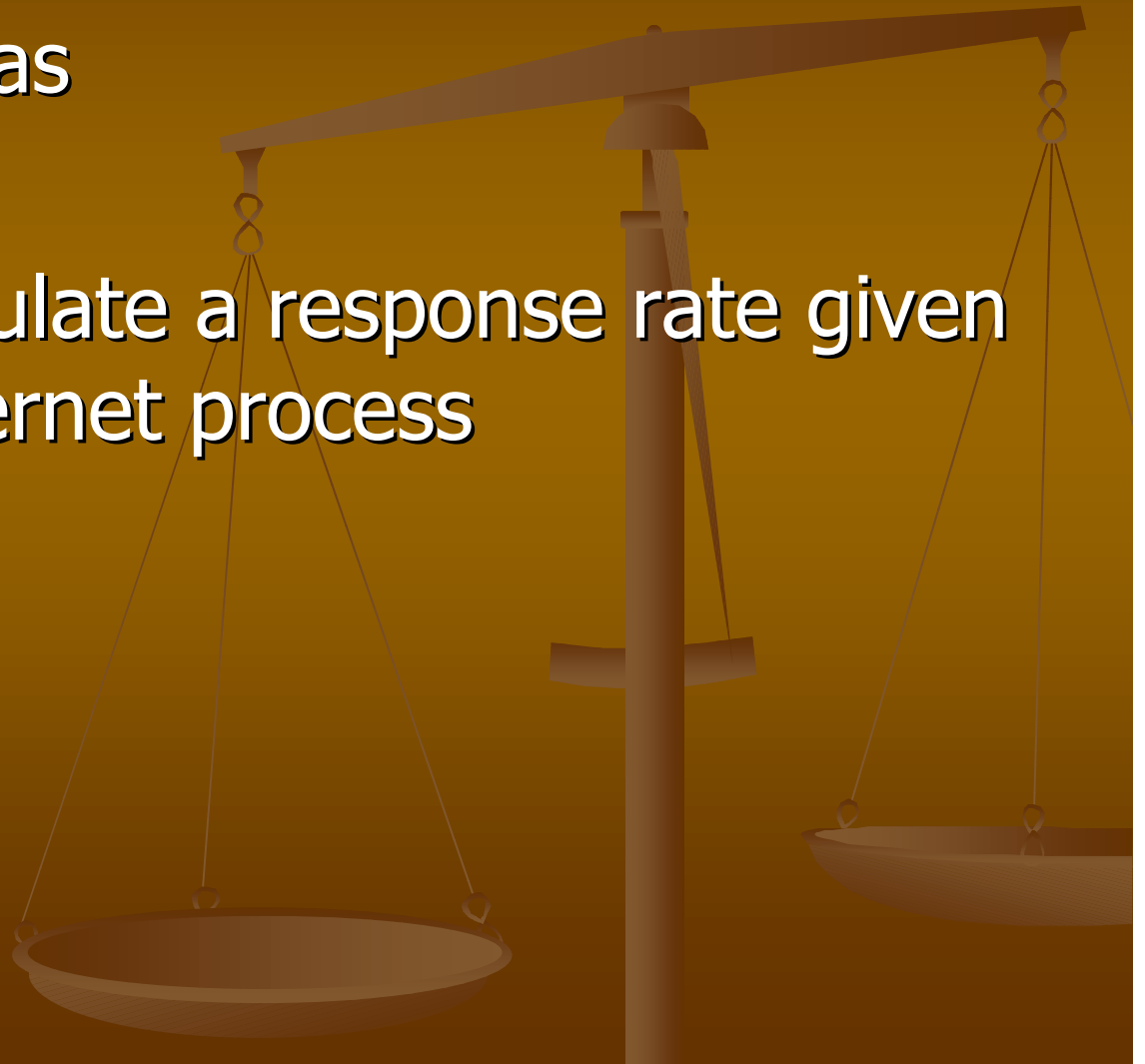
∇ National scope

∇ Composite of survey methods



# Weaknesses

- ∇ Respondents bias
- ∇ Inability to calculate a response rate given anonymous internet process



# Summary

- ∇ In this first national survey of epidemiologists, one quarter perceived that the HIPAA Privacy Rule has enhanced subject confidentiality/privacy.
  - ∇ The majority of respondents reported that the Privacy Rule has added uncertainty, cost, and delay to the conduct of U.S. research involving human subjects.
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