

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

AcademyHealth Survey
Results
February 14, 2008

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As the professional society for health services researchers and health policy analysts, our mission is three-fold:

1. Strengthen the research infrastructure
2. Promote the use of the best available research
3. Assist health policy and practice leaders in addressing major health care challenges

We work to both “push” the production of research and promote the “pull” by decision makers

Health Services Research

“The multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to care, the cost and quality of health care, and ultimately, our health and wellbeing. Its research domains are individuals, families, organizations, institutions, communities, and populations.”^[1]

^[1] Lohr, K. and D. Steinwachs. “Health Services Research: An Evolving Definition of the Field.” *Health Services Research*, Vol. 37, No. 1, February 2002, pp. 15-17.



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Survey Methodology

Web-based survey of principal investigator (PI) experiences with HIPAA

Email invitation sent to all 3,461 AcademyHealth members to participate in a Web-based survey

5-week response period



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Survey Response

696 AcademyHealth members responded

396 responded they were a principal investigator and were included in the majority of survey questions



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Survey Respondent Demographics

55% female; 44% male

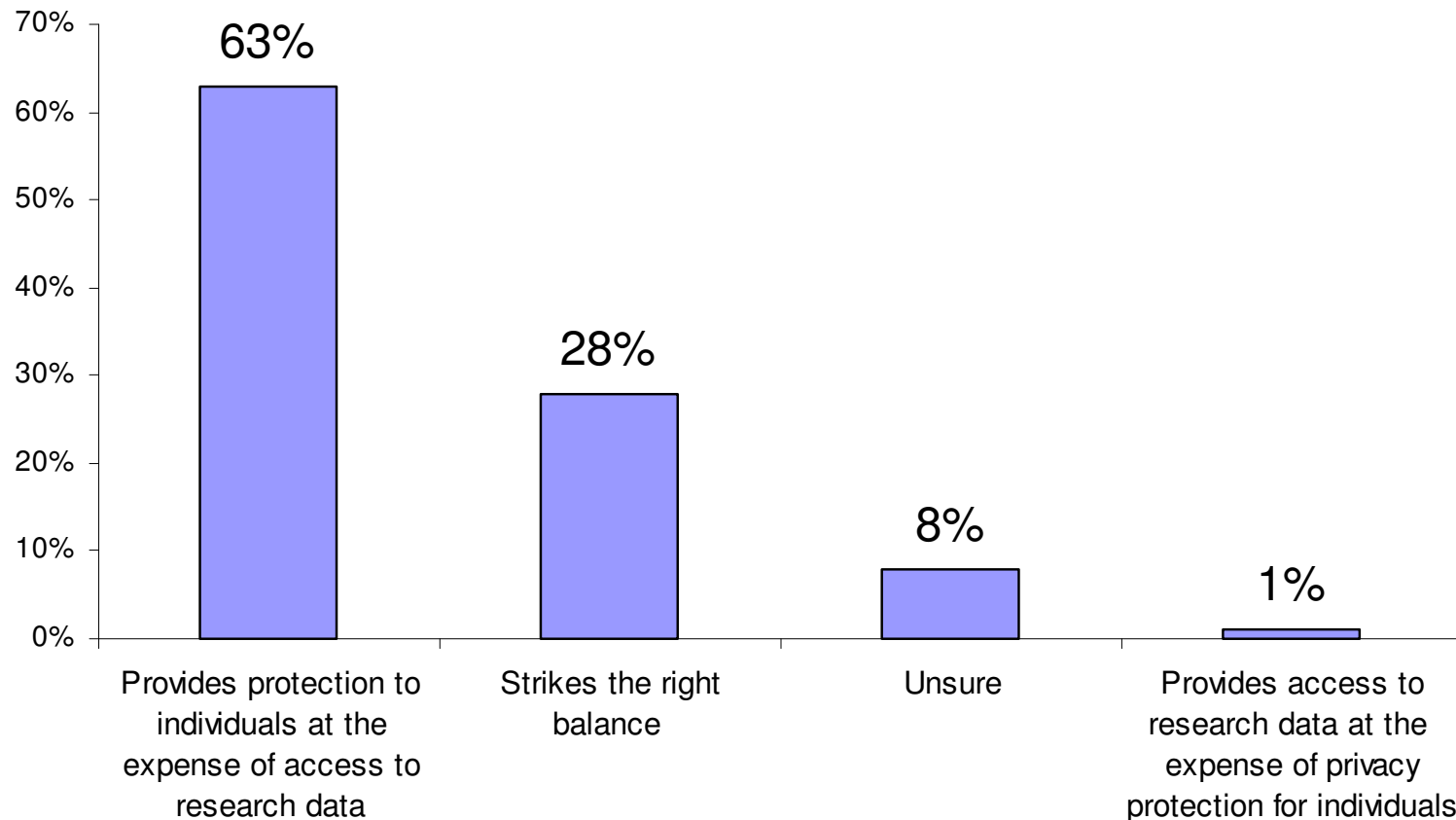
64% report HSR as their primary job function

Employment Setting:

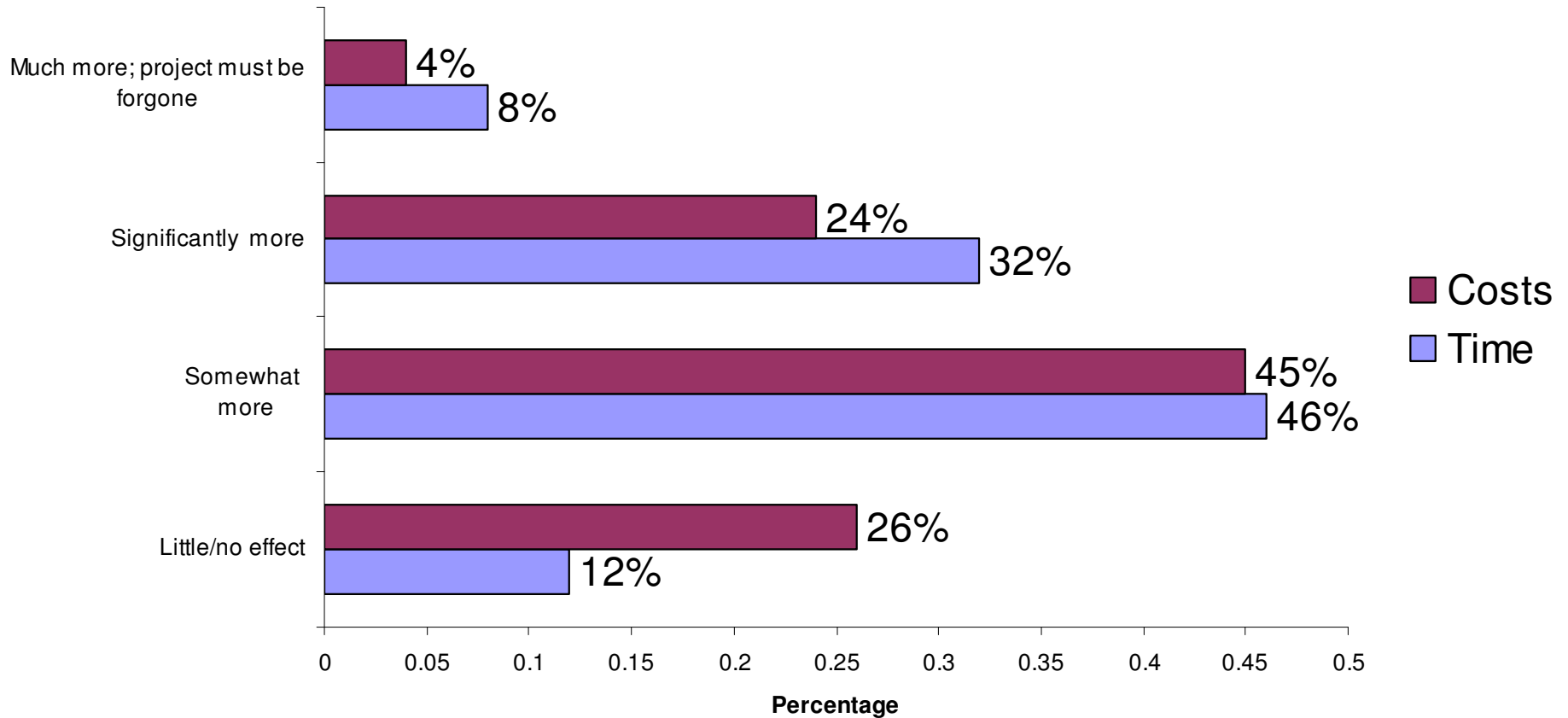
- 54% are employed at a college or university
- 25% are employed in the private sector
- 12% are employed in government



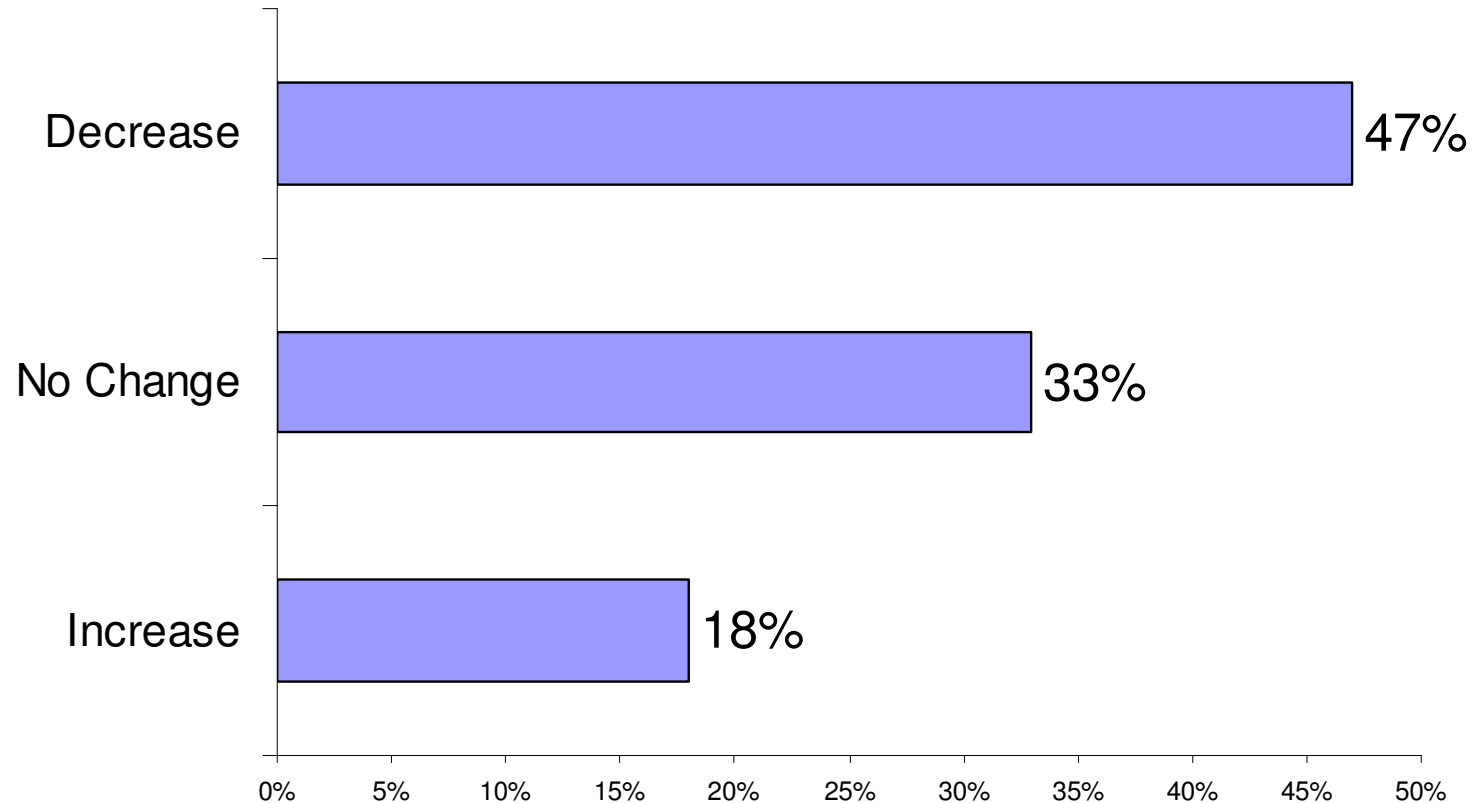
Perspective on the Balance of Individual Protections and Research Access



Impact on Costs and Time to Complete Research



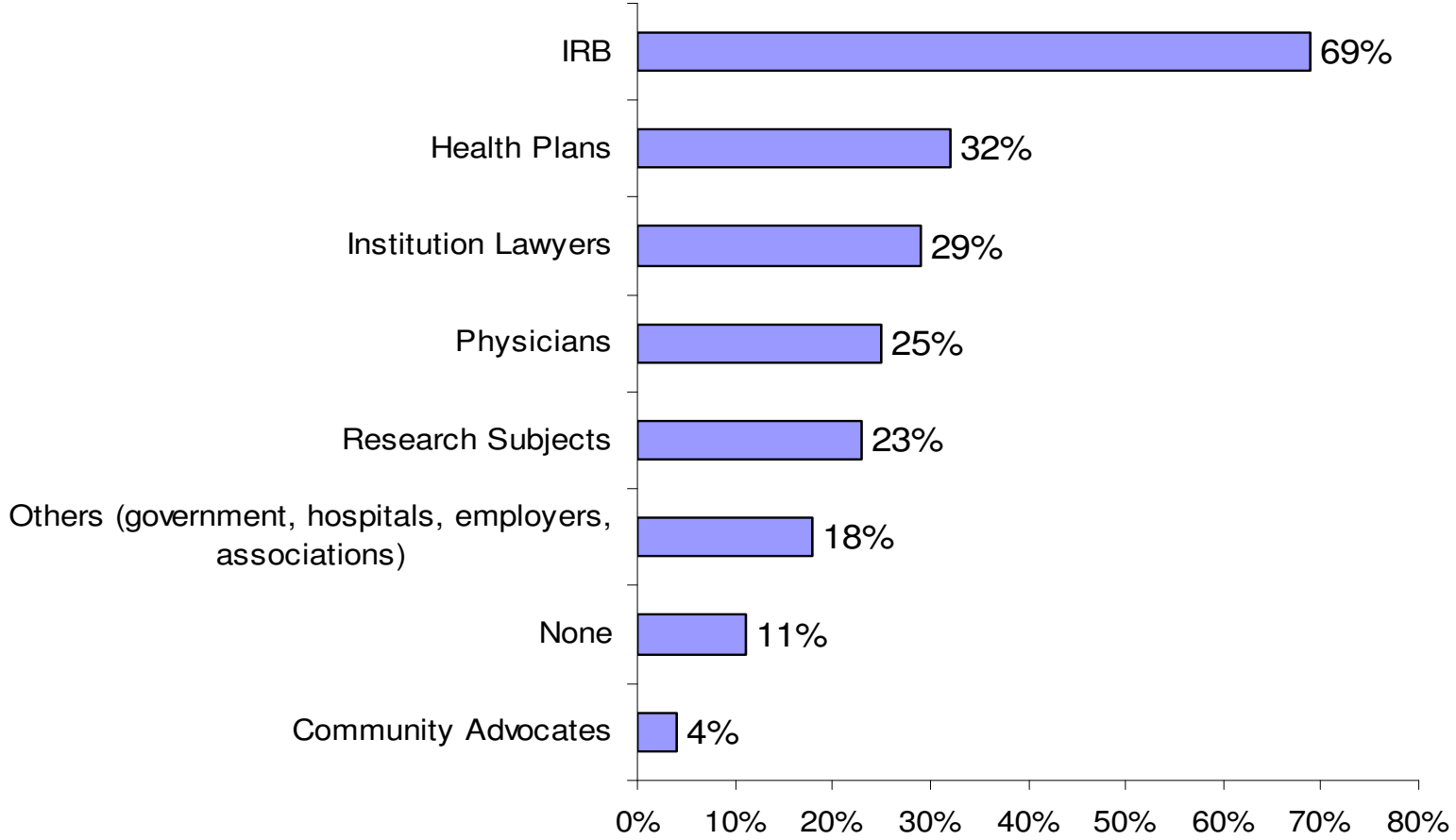
Change in Rate of Recruitment*



Among those who recruit subjects (n=260)

2% say the question is not applicable to their studies

Difficulty Gaining Approval to Collect Personal Health Information from the Following Groups:



* Response categories are not mutually exclusive



Use of Business Associates to Perform Activities on Behalf of a Covered Entity

22% used business associates in order to conduct research

- Of these, most report that [business associates] negatively impact research activities because they complicate the research process, make research more time consuming, and add more paperwork

10% are unsure if they have used business associates when conducting research



Impact of Penalties (or threat thereof) on Research

19% say penalties had no effect on efforts to obtain data from a covered entity

24% say penalties were considered by covered entities but ultimately did not impact researcher from obtaining data

26% say penalties have impeded access to data:

- 16% say penalties have caused covered entities not to provide data
- 10% say that covered entities' concerns about data privacy caused them not to pursue research

29% are unsure of what impact, if any, penalties have had



IRBs and Privacy Boards and Support for Researchers

The majority of respondents (76%) have IRBs at their institutions. 16% have both an IRB and a privacy board

48% say their institution provides support (staff/resources) to assist researchers with HIPAA compliance*

- Among respondents at institutions that offer support, most (77%) say they have used these resources

16% say they are not sure if their institution provides HIPAA support

•Among those who have requested waivers or alterations of Authorization from a IRB/privacy board (n=241)

Involvement in Studies Requiring IRB/Privacy Board Approval

62% say they have been involved in one or more studies requiring waivers or alterations of authorization requirement by an IRB/Privacy Board

- 65% have been involved in 2-5 studies*
- 3% have been involved in more than 20 studies

Health Services Researchers have submitted the following activities to IRB/Privacy Boards:

- Survey or questionnaire data (82%); medical record review (70%); or administrative data (66%)
- A small proportion of studies involve collection of specimens (9%) or use of existing specimens (5%)

* Among those who have requested waivers or alterations of authorization from a IRB/privacy board (n=241)

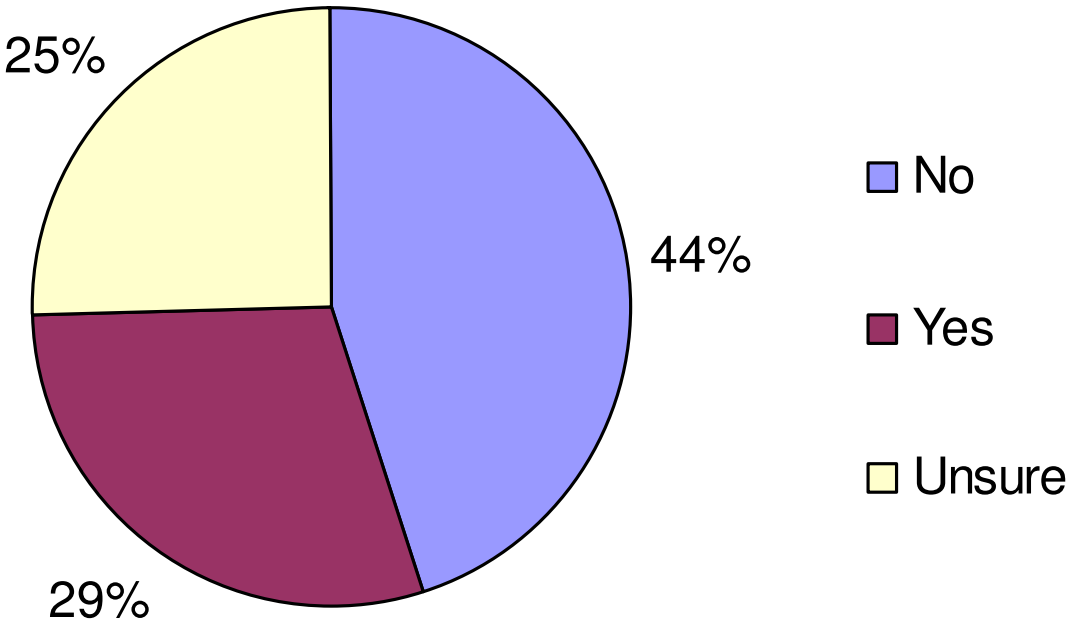
Studies Forgone Due to Concerns about IRB/Privacy Board or Privacy Rule Violation

13% say an IRB or Privacy Board has prevented a study in which they were involved from moving forward due to potential harms

10% say they considered or developed a study, but did not submit it to the IRB or Privacy Board because they thought it would not be approved*

* Among those who have requested waivers or alterations of Authorization from a IRB/privacy board (n=241)

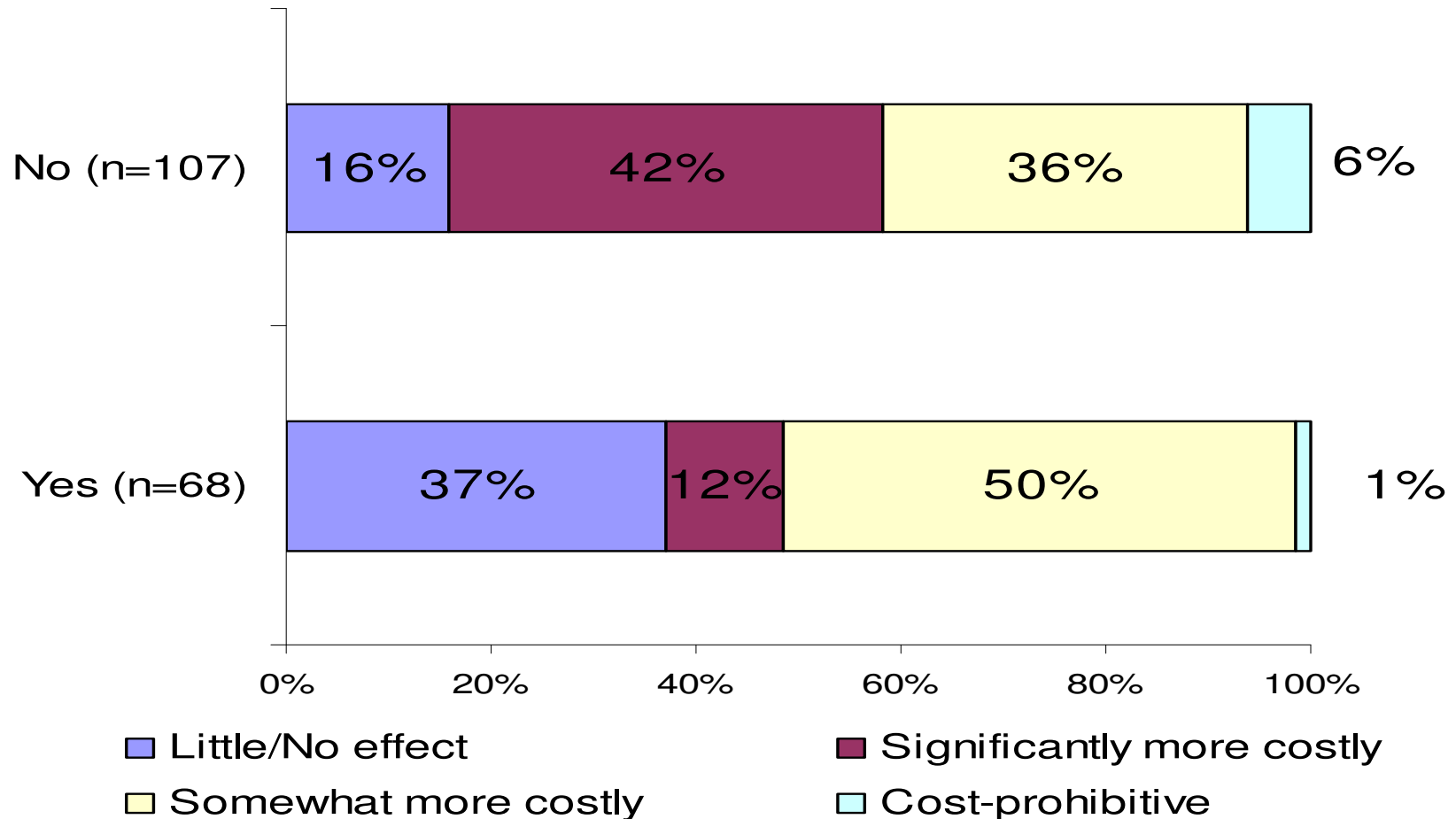
IRB/Privacy Board Correctly Differentiates Between Clinical Research and HSR



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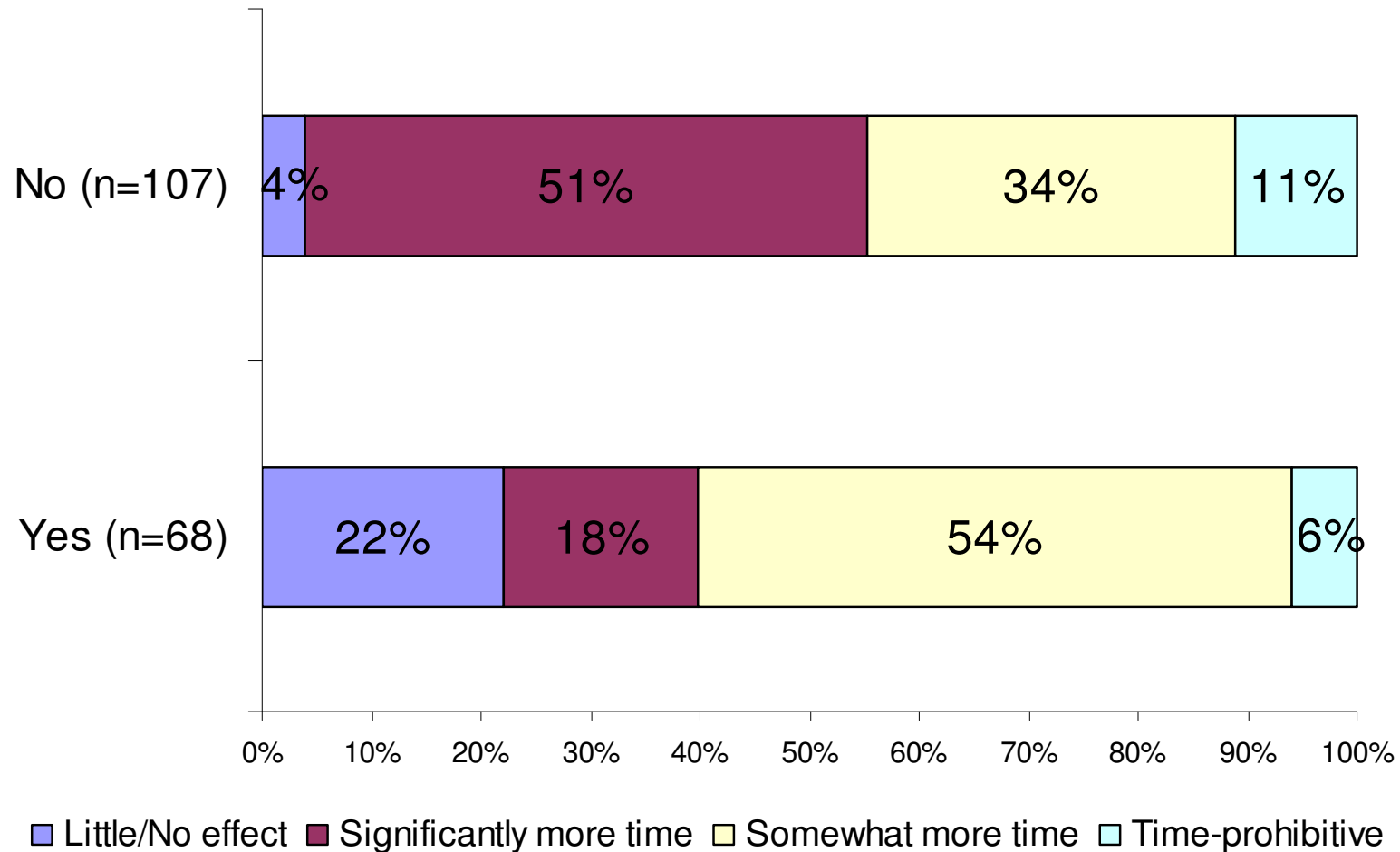


An IRBs Ability to Differentiate Between HSR and Clinical Research and the Cost of Conducting Research Studies



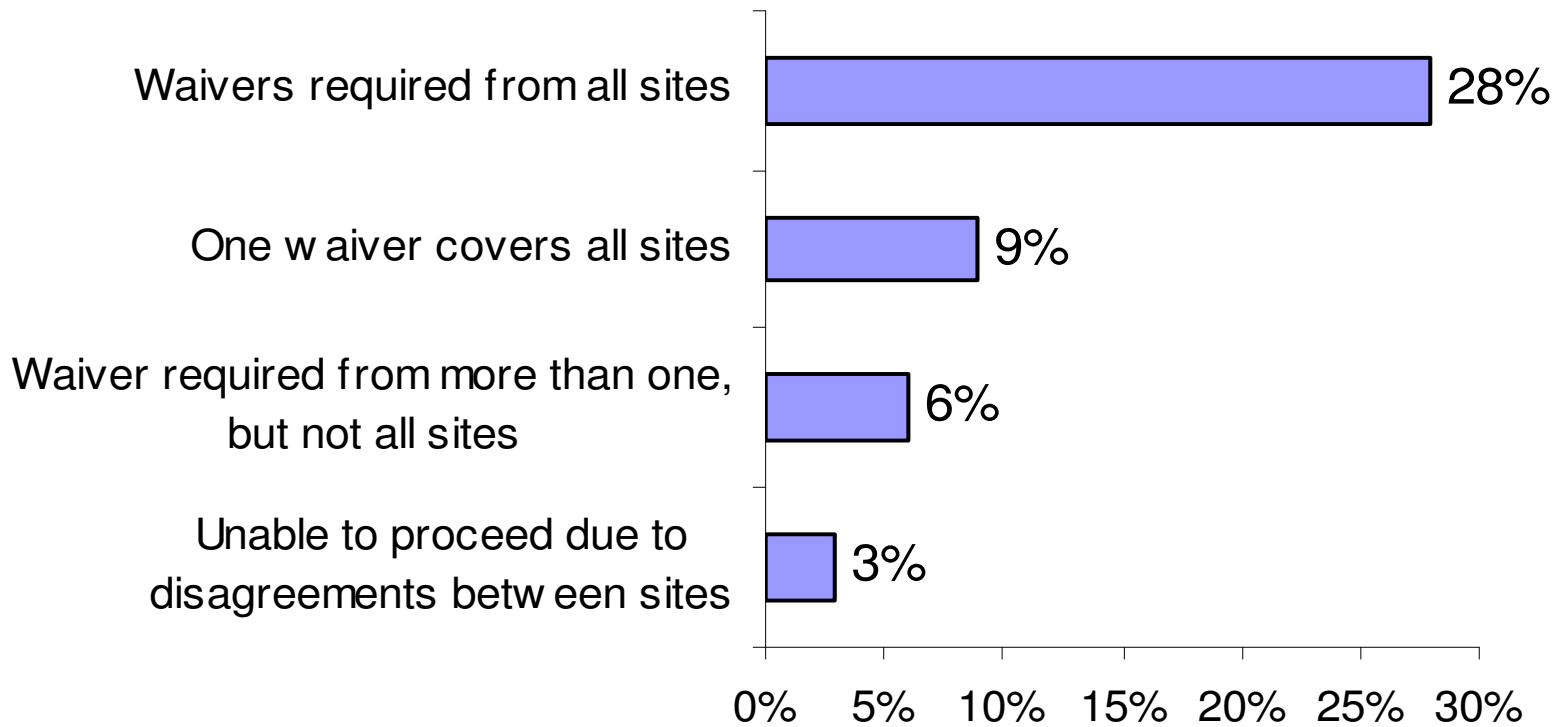
* Among those who have requested waivers or alterations of Authorization from a IRB/privacy board (n=241)

An IRBs Ability to Differentiate Between HSR and Clinical Research and the Time to Conduct Research Studies



* Among those who have requested waivers or alterations of Authorization from a IRB/privacy board (n=241)

Number of IRB/Privacy Board Waiver Requirements for Multi-Site Research*



*Among those who have requested waivers or alterations of Authorization from a IRB/privacy board (n=241)

**52% do not conduct multi-site research; **Does not include informed consent

Use of Existing Data Sets and Impact on Availability of Data*

92% say they have used existing datasets to conduct research

59% of researchers who use existing datasets say the availability of data has been impacted. Of these (n=134):

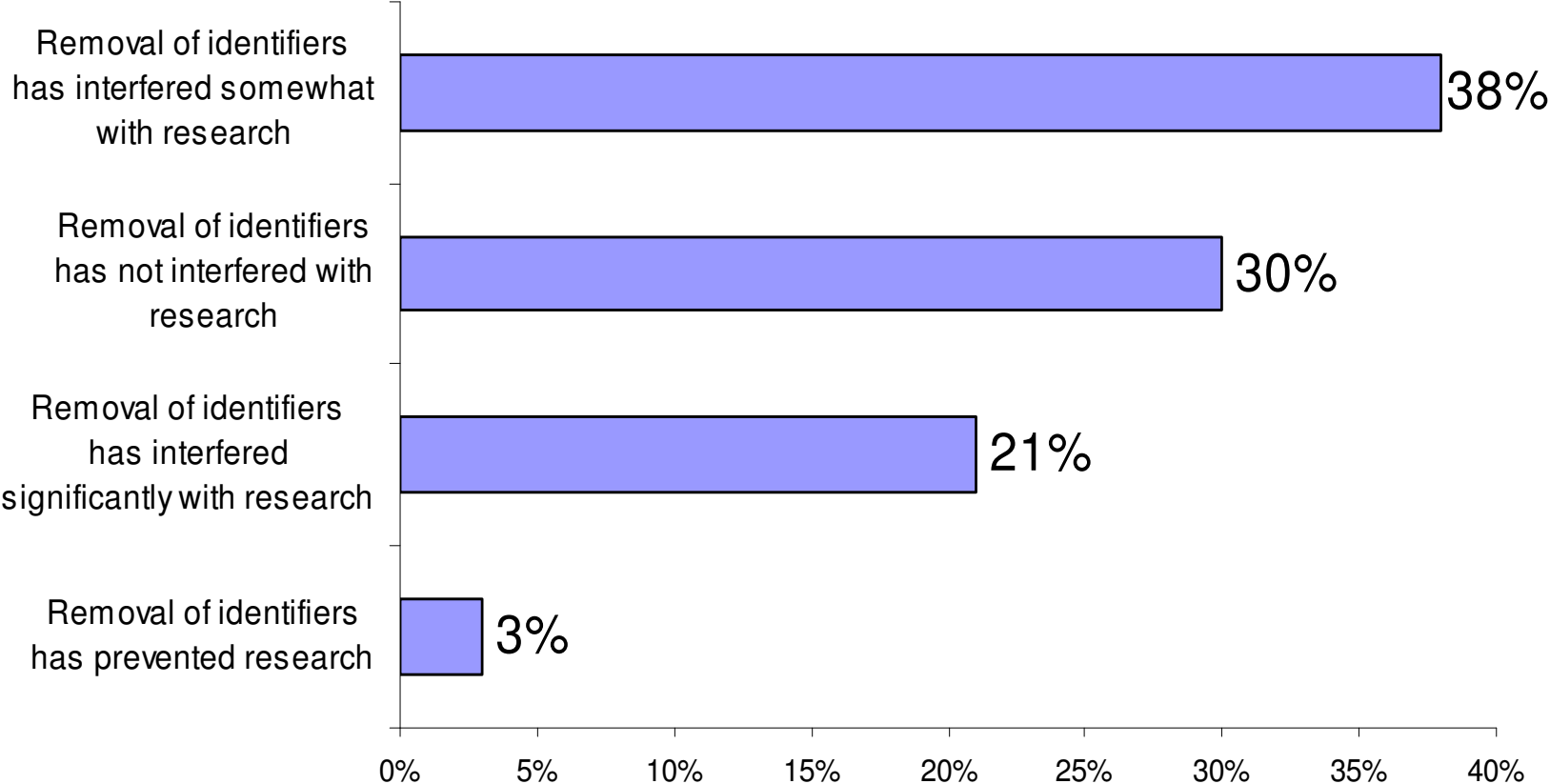
- 71% have gotten access to data after it has been stripped of all identifiers, making it a compliant de-identified dataset
- 40% have gotten access to data in mostly the same form under approved waivers of authorization and security
- 28% have gotten access to data because the respondent works for a covered entity that provides data to the respondent as an in-house researcher
- 26% have gotten access to data because of the development of a business associate relationship with the covered entity
- 14% have gotten access to data because of use of an intermediary organization that has a business associate relationship with the covered entity

*Among those who have requested waivers or alterations of Authorization from a IRB/privacy board (n=241)

**Response categories are not mutually exclusive



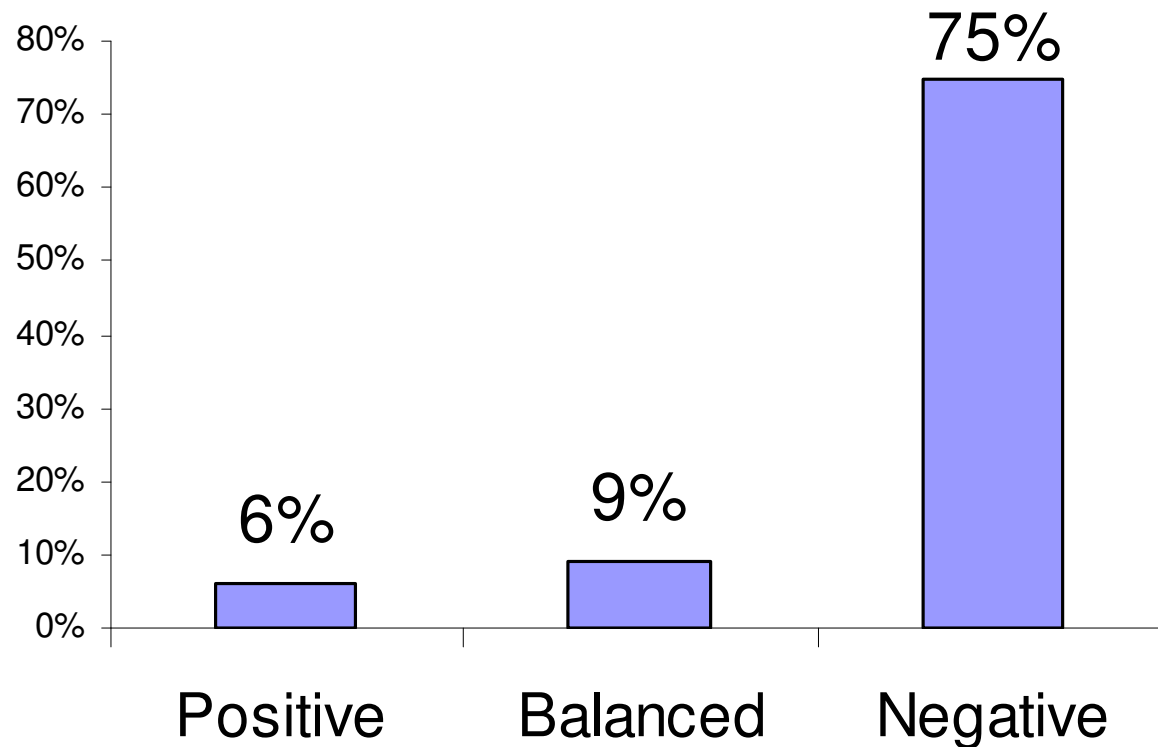
Impact of Removing Identifiers on HSR*



*Among those who have requested waivers, use existing datasets and report an impact on availability of data post-HIPAA (n=1344); 6% of respondents said they have not used limited datasets



Remarks on Experience the HIPAA Privacy Rule*



*273 people shared remarks about the HIPAA Privacy Rule.

Respondents' Comments: Positive View

“[HIPAA] has given more responsibility to providers in how they use private information that they control...It has serve[d] as dissuasive for the improper use of PHI that went unprotected on hospitals, providers office, etc.”

“HIPAA is necessary and was a long time in coming. The benefits outweigh the costs.”



Respondents' Comments: Balanced View

“HIPAA's privacy rule is important in safeguarding patient confidentiality information. However, the rule also makes it more difficult to access patient information for research purposes.”

“HIPAA itself creates few barriers to research. The barriers are created by overly cautious IRBs (and others) who do not understand HIPAA but believe that it says things it does not. There is an enormous need to clarify and eliminate the myths that have grown up around HIPAA in research and clinical settings”

“I believe that the spirit of the HIPAA Privacy Rule is noble, good, and necessary, But the problem is that...every institution is hyper-vigilant about releasing PHI due to possible liability.”



Respondents' Comments: Negative

“The main costs is that everyone is practicing ‘defensive medicine’ making sure that steps are taking to protect patients in cases when there is no risk for them. It slows down research, but more importantly, it makes studies more costly.”

“I’m not certain if HIPAA is so much the problem, as the tremendous variability in how IRBs interpret the rule.”

“The most significant problem is the level of general confusion about HIPAA. In many ways, it resembles the general confusion about TSA rules for airport security.”



Summary

63% say the HIPAA privacy rule protects privacy at the expense of access to data

70% say that compliance with the HIPAA privacy rule has made research 'somewhat' or 'significantly' more costly

75% say that compliance with the HIPAA privacy rule has resulted in taking 'somewhat' or 'significantly' longer to conduct research projects

44% do not think IRBs make correct distinctions between HSR and clinical research

28% report that they are required to obtain waivers from all IRBs/Privacy Boards involved in multi-site research studies

59% say that HIPAA has had an effect on the availability of datasets or the information they contain

