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# Impact of HIPAA Privacy Rule on Scientists & IRBs in the HMO Research Network: *Progress Report*

Sarah Greene, MPH

Group Health Center for Health Studies

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# In service to key stakeholders— research participants



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Unscientific *n of 1* sample

“Can’t you just aggregate the data?”

“Can’t you just use anonymous data?”

Implications and nuances of research are far more elemental – notion of future research, outcomes research, difference between anonymous & confidential, and myriad other distinctions we’ve discussed may be lost on our constituents

Think about how we would explain this project, its outcomes, and its impact in lay terms—presume fairly limited knowledge of the research enterprise

§ *Literacy & health literacy are important contextual considerations*

# Components of Our Project



## Phase I:

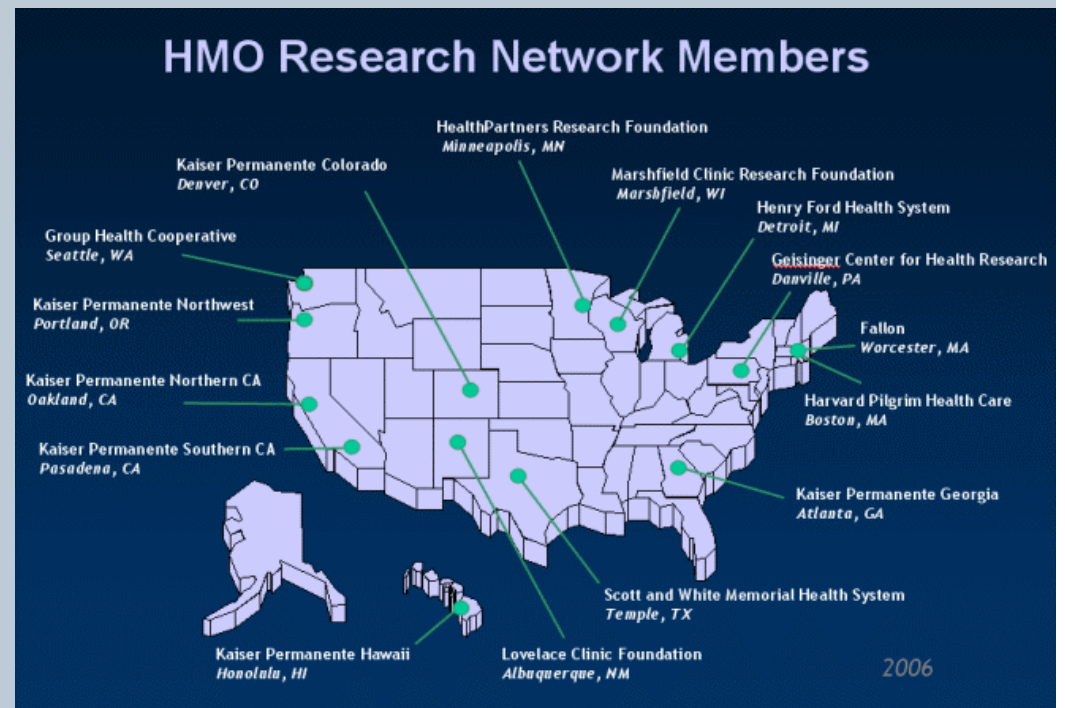
### Survey of HMO Research Network (HMORN) Scientists

Broad disciplinary representation: epidemiology, health services, clinical researchers

N ~ 250 researchers

Web-based survey, followed by interviews for researchers who report having a study “affected” by HIPAA Privacy Rule

***Launched October 1, 2007***



# Components of Our Project (cont'd)



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## **Phase II: Survey of IRB administrators at HMORN sites (*n* = 15)**

**All are established research centers that are part of covered entities**

**May have different perspective than academic IRBs, since research participants are typically health plan members**

### **Questions focus on:**

- § Attitudes, roles, practices, desired guidance from Feds
- § Occurrence of privacy breaches, and subsequent effect on research climate
- § Extent of interaction with health plan's privacy officer/board

# Opportunity to address Committee's specific questions



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**What else would be crucial/helpful to know from these IRB administrators?**

**Per yesterday's discussion, we can try to elicit:**

- § **Extent of variability of implementation, interpretation**
- § **Self-assessment of whether their IRB is more or less conservative than other IRBs they have worked with on multi-site studies**

**Can be addressed via brief conference with subcommittee  
(for efficiency)**