



American Heart Association® | American Stroke Association®

*Learn and Live.*

# **Institute of Medicine: Committee on Health Research and the Privacy of Health**

Penelope Solis, J.D.  
Senior Policy Manager  
American Heart Association



American Heart Association® | American Stroke Association®

*Learn and Live™*

# Organizational Mission

The American Heart Association is a national voluntary health agency whose mission is to build healthier lives, free of cardiovascular diseases and stroke.

**Impact Goal:** By 2010, to reduce coronary heart disease, stroke, and risk by 25%



# Commitment to Research

- Advocate for increased research funding for NIH and CDC
- Fund ~2,500 scientists through grants
- Invested over \$2.7 billion since 1949 and \$145 million in 2005-06 alone
- AHA funded breakthroughs include the first artificial heart valve, techniques and standards for CPR, implantable pacemakers, treatment for infant respiratory distress syndrome, cholesterol inhibitors, microsurgery, and drug-coated stents



## **Interest in HIPAA's Effect on Research**

- Recurring issue discussed by AHA councils and committees volunteers
- HIPAA has discouraged and/or made it more difficult to conduct research
- Believe need for modification/clarification but must retain the protections for patient privacy



# Survey Methodology

- Consulted with AHA epidemiologists experts in survey methodology
- Develop online version (15-20 minutes to complete)
- Pre-tested survey with 50 randomly selected Scientific Advisory Coordinating Committee
- 15,000 randomly selected AHA Council members
- Launch survey to AHA volunteers (April 19)
- Sent electronic reminders to volunteers who did not complete survey within a weeks time
- AHA survey closed (May 18)



# Survey Status

- 1037 surveys were completed (7% response rate)
  - § 624 respond that they had submitted a new applications involving Human Subjects to a U.S. Institutional Review Board (IRB)
- Currently reviewing all of data received from AHA survey
- Working with ACC to send survey to randomly selected members
- Have information to share at next IOM meeting



## **How steps to address HIPAA concerns increase the difficulty or complexity in recruiting participants and compliance with rule**

- Potential subjects were overwhelmed with minutiae to the point where the aim of the study was lost in "necessary text" making a full reading of the form nearly impossible for patients. This in turn discouraged many patients from participating in clinical research
- Some researchers noted that it is often difficult to get busy clinicians to make contact with families to ask them "permission" for a third party to contact them about research



## (Continued)

- HIPAA seem to have lead to more administrative costs including additional staff and/or increased number of meetings with legal, compliance, administration, to discuss roles, business relationships, and procedures that need to be followed
- Delays now inherent in IRB review and re-review nearly ensure delays unacceptable to funding agencies



## **(Continued)**

- One researcher commented that his institution had over 12,000 patients in the database of operations for his department. However, more than 20 surgeons had done the procedures, some of which now are out of state and other are retired or deceased, which has limited their ability to contact patients operated on by the surgeons who are no longer at the institution.



American Heart Association® | American Stroke Association®

*Learn and Live.*

Thank You