Research Privacy

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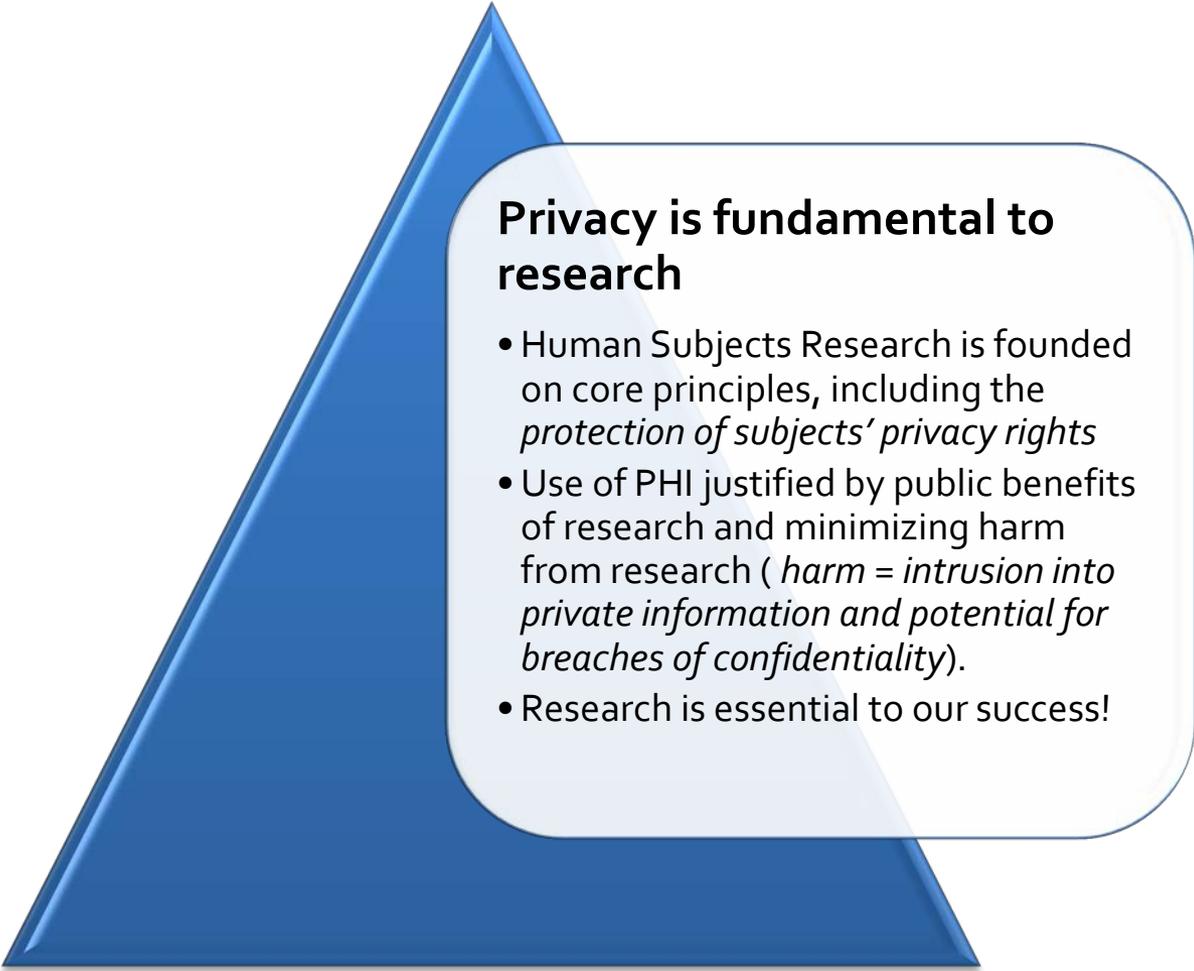University of Massachusetts Medical School

What is Privacy?

Privacy refers to the ability of a person to know when information is being collected about them and control the use and sharing of that information.

Key aspects of privacy:

- **Notice**
- **Choice**
- **Access**
- **Security**

Why is a Healthy Privacy Program Important for UMMS?

Privacy is fundamental to research

- Human Subjects Research is founded on core principles, including the *protection of subjects' privacy rights*
- Use of PHI justified by public benefits of research and minimizing harm from research (*harm = intrusion into private information and potential for breaches of confidentiality*).
- Research is essential to our success!

Research Privacy

Privacy rights of research subjects were already well established in existing research principles prior to HIPAA.

- Declaration of Helsinki (1964)
  - Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.
- Common Rule (1991)
  - Adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- Use of PHI justified by public benefits of research and minimizing harm from research (*harm = intrusion into private information and potential for breaches of confidentiality*).

HIPAA & Research

HIPAA:

- Researchers must actively protect subjects' privacy (HIPAA authorizations & waivers) and use appropriate privacy and security measures (access, use & disclosure controls and data security safeguards) to avoid breaching participant confidentiality.

Privacy Breaches (Criminal)

Increasing frequency of medical record thefts + Increasing value of medical records = **Significant increase in risk!**

Stolen patient health records earn $363 / record on average (Ponemon Institute Study – 2015)

Data that include Medicare #, birth date, SSN and insurance policy # sell for nearly $500 per record!

Children's information is most valuable (theft often goes undetected for years)

Criminals use this stolen information to:

•Open credit lines
•Commit tax fraud
•Create fake IDs
•Purchase medical equipment / drugs (paid for by insurance) and then resell at a profit
•Commit medical identity theft (free care) – costs victims $10K+ and erroneous info in medical records

Privacy Breaches

Criminal actions aren't the only cause of harm

- Any privacy breach can cause irreparable harm to the individual (personal life, career, community)

Government enforcement & organizational harm

- No harm needed to initiate government investigation
  - Under HIPAA, most significant liability stems from noncompliance, not consequential damages
- Significant fines result from government enforcement
- Settlements can negatively impact organization's reputation and ability to compete

Privacy Breach Example

On September 2, 2012, an unencrypted laptop computer containing 13,000 research participants' data was stolen from a Feinstein Institute for Medical Research employee's car.

The ePHI stored in the laptop included the names of research participants, dates of birth, addresses, social security numbers, diagnoses, laboratory results, medications, and medical information relating to participation in a research study.

On March 17, 2016, Feinstein entered into a **$3.9 million settlement** with OCR to resolve HIPAA violations and enter into a corrective action plan.
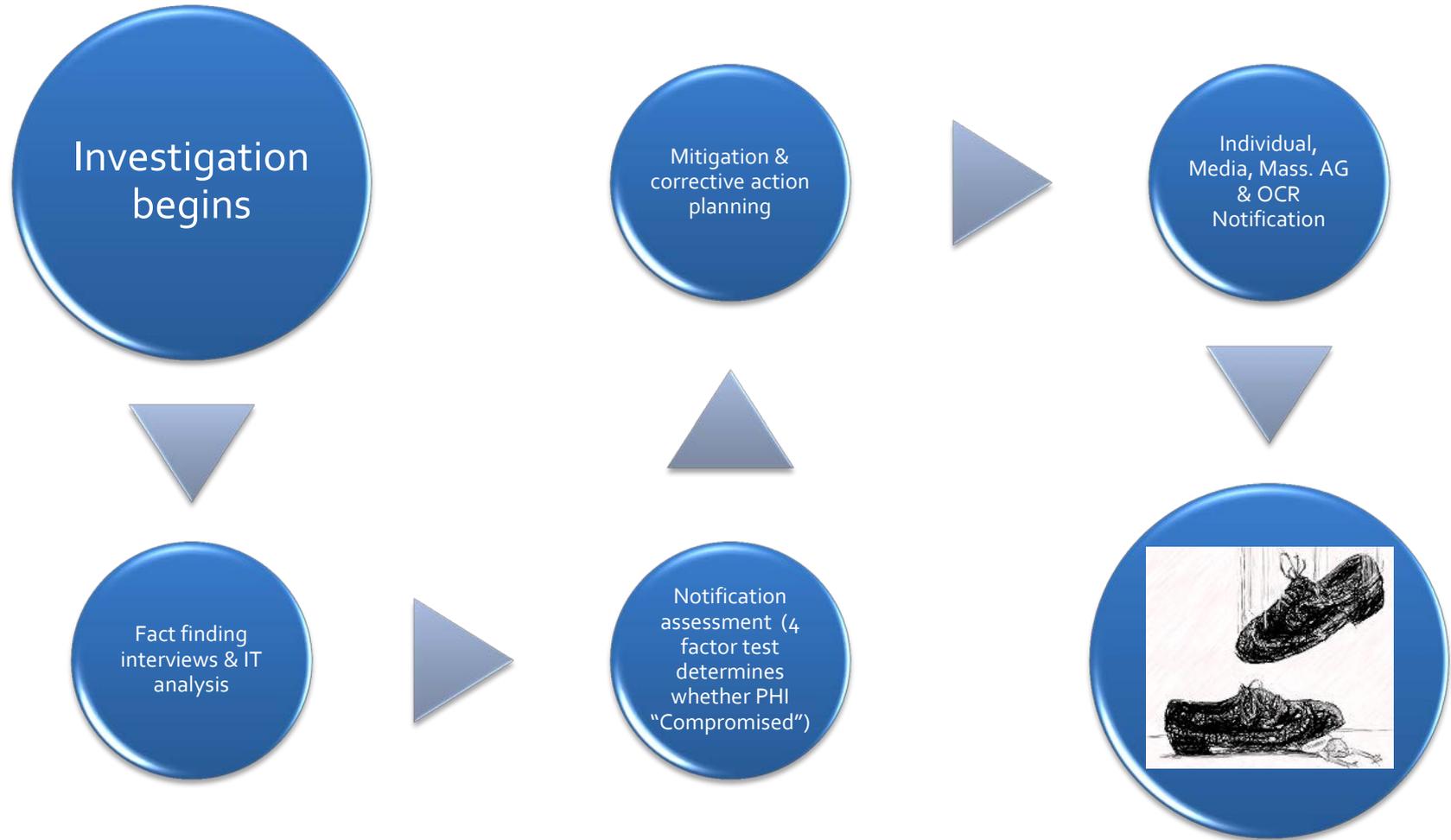
OCR Director Jocelyn Samuels offered this cautionary warning:

- "Research institutions subject to HIPAA must be held to the same compliance standards as all other HIPAA-covered entities… For individuals to trust in the research process, they must have some assurance that their information is kept private and secure."

- *OCR Press Release, March 17. 2016*

Anatomy of Privacy Breach

Investigation begins

Fact finding interviews & IT analysis

Notification assessment (4 factor test determines whether PHI "Compromised")

Mitigation & corrective action planning

Individual, Media, Mass. AG & OCR Notification

Conclusion

- Protecting subjects' privacy rights is essential to conducting research!
  - Given the importance of good privacy practices, always seek advice from research office, privacy office, IRB, etc.

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