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# Research Data Sharing and Security: The Challenges We Face

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Senior Vice-Chair

Institutional Review Board

- “...start us off with your involvement with the IRB and the data security/privacy concerns and considerations that you address?”
- “What issues do you find to be most challenging or troublesome?”
- “What keeps you awake at night (if anything) regarding some of these things?”

# MedStar hackers exploited 9-year-old flaw to hold hospital data for ransom

## Veterans Affairs Data Theft

[Background](#) | [News Items](#) | [Resources](#) | [Documents](#)

### Latest News

■ **Stolen Veterans Affairs Laptop and Hard Drive Are Found.** The stolen laptop computer and hard drive containing sensitive data for up to 26.5 million veterans, their spouses and active-duty military personnel have been found, according to [Veterans Affairs](#) Secretary Jim Nicholson. This comes as newly discovered [documents](#) show that Veterans Affairs had given permission in 2002 for the analyst, from whom the equipment was stolen, to work from home with data that included millions of Social Security numbers, disability ratings and other personal information. Agency officials previously said the analyst was fired because he violated agency procedure by taking the data home. (Jun. 29)

■ **Scope of Veterans Affairs Data Theft Widens.** The personal information of about 1.1 million active-duty military personnel, 430,000 members of the National Guard and 645,000 members of the Reserves, was stolen in the recent theft of computer data from the [Department of Veterans Affairs](#), the agency [announced](#) Tuesday. The agency previously said ([pdf](#)) that all 26.5 million people affected by the data theft were veterans and their spouses. The data include Social Security numbers and disability ratings. [Privacy Rights Clearinghouse](#) offers ID theft prevention tips. (Jun. 7)

■ **Department of Veterans Affairs Reports Massive Data Theft.** The Department of Veterans Affairs [announced today](#) that an agency employee took home records on 26.5 million veterans that were subsequently stolen by a burglar. The data included names, Social Security numbers, and dates of birth, as well as some disability ratings. The FBI and the VA Inspector General's Office have launched "full-scale investigations." Information for those who are concerned about identity theft is available from the [Federal Trade Commission](#). (May 22)



A sign designates an entrance to the MedStar Georgetown University Hospital in Washington, Monday, March 28, 2016. Hackers crippled computer systems at a major hospital chain, MedStar Health Inc., on Monday, forcing records systems offline for thousands of patients and ... [more >](#)

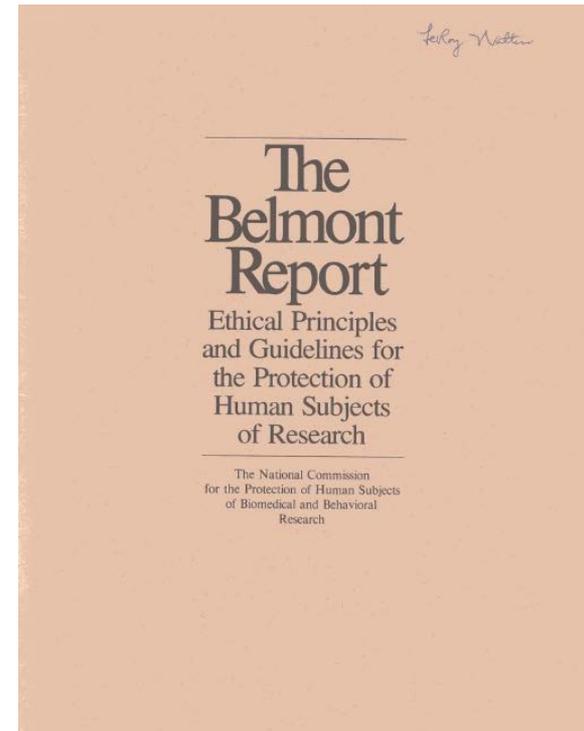


Posted: Mon 5:15 PM, Nov 23, 2015 | Updated: Mon 8:20 PM, Nov 23, 2015

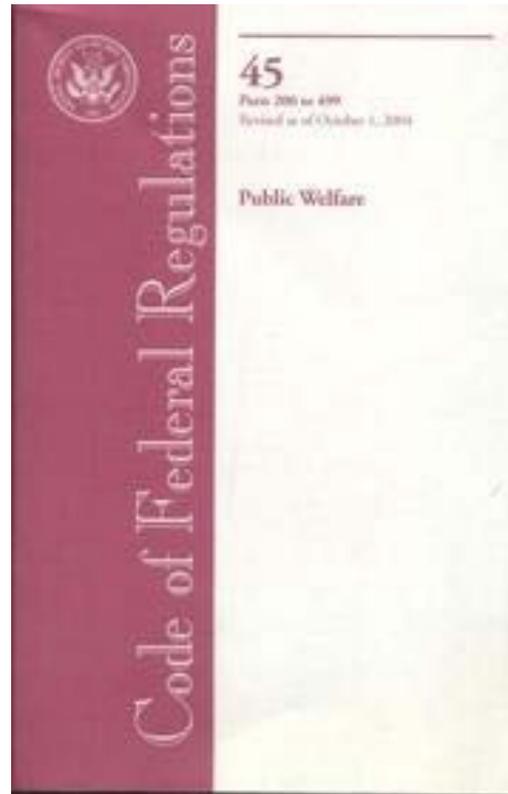
# The Belmont Report

April 18, 1979

- Basic ethical principles
  - Respect for Persons
    - Autonomy
  - Beneficence
    - Maximizing benefits while minimizing risks
  - Justice
    - Fair distribution of costs and benefits
- The Common Rule (1981)
  - No exceptions for emergencies



# FEDERAL REGULATIONS





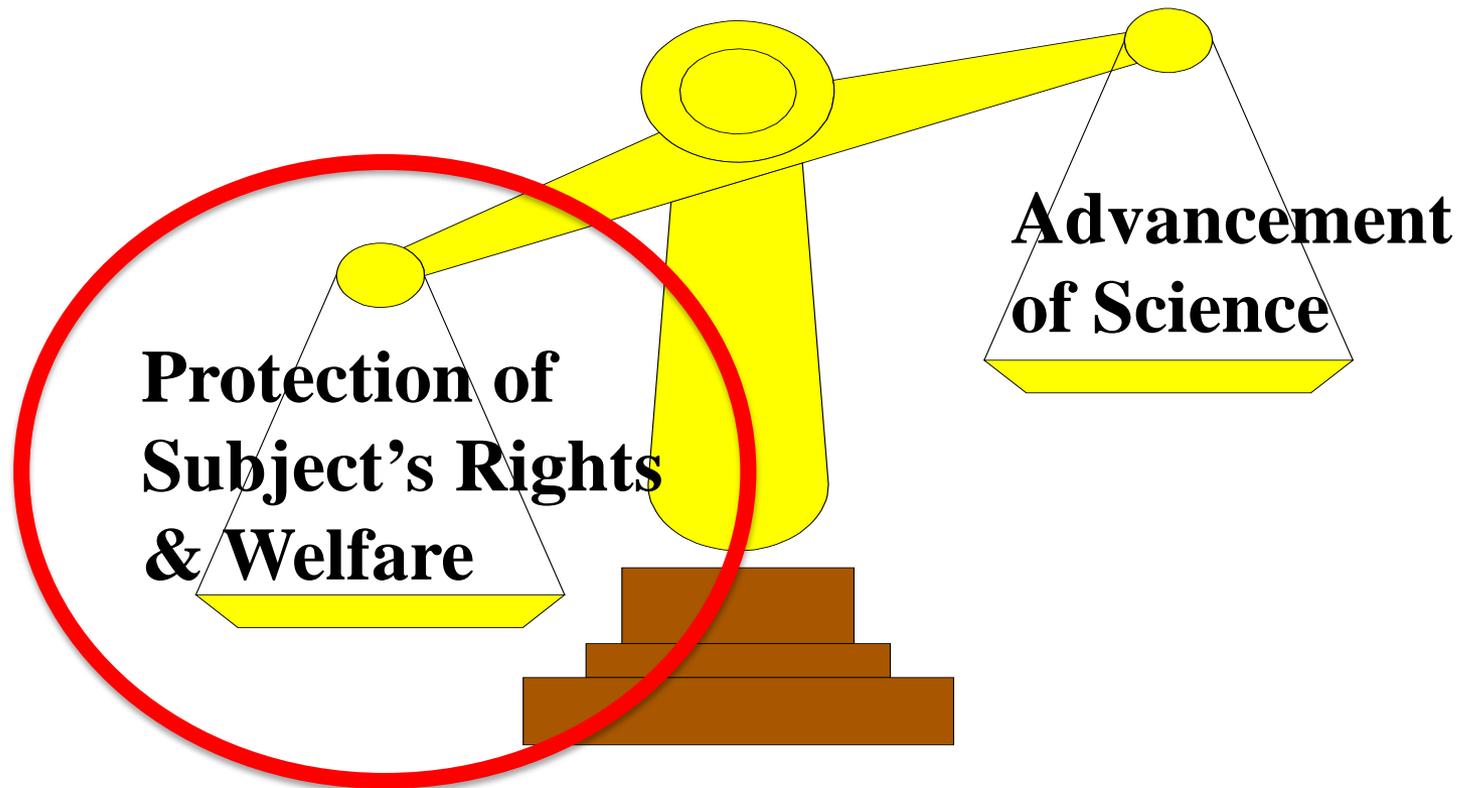
FDA	OHRP	ICH
<b>21 CFR (IND, IDE studies, but standards generally apply at UMB for all studies)</b>	<b>45 CFR 46(federal funding; if 21CFR silent, 45CFR46 usually applies – example children)</b>	<b>International (industry standard and often basis of NIH and other SOP's)</b>
<ul style="list-style-type: none"><li>• <b>Electronic docs (11)</b></li><li>• <b>Informed consent (50)</b></li><li>• <b>Financial disclosure (54)</b></li><li>• <b>IRBs (56)</b></li><li>• <b>IND regulations (312)</b></li><li>• <b>More re devices and biologics</b></li></ul>	<ul style="list-style-type: none"><li>• <b>IRBs (A)</b></li><li>• <b>Informed consent (A)</b></li><li>• <b>Women (B)</b></li><li>• <b>Prisoners (C)</b></li><li>• <b>Children (D)</b></li></ul>	<ul style="list-style-type: none"><li>• <b>Glossary (1)</b></li><li>• <b>Principles (2)</b></li><li>• <b>IRBs (3)</b></li><li>• <b>Investigator (4)</b></li><li>• <b>Sponsor (5)</b></li><li>• <b>Essential documents (8)</b></li></ul>

**BRACE YOURSELVES**

**AN NPRM JUST CAME OUT TO REVISE THE  
COMMON RULE**

memegenerator.net

# Balancing Two Goals



# DEFINITIONS

- ***“Medical Practice”*** (IRB is not involved)
  - Interventions designed solely to enhance the well-being of the patient.
  - Provides diagnosis, prevention or therapy with the expectation of a successful outcome.
- ***“Experimental”***
  - Defined as new, untested or different.
  - An experimental procedure is not automatically categorized as research.
    - A new "experimental" procedure should be formally researched (investigated) to determine if is safe and effective.

# DEFINITIONS

- ***“Research”*** (IRB is involved)
  - **Activities designed to contribute to generalizable knowledge.**
    - Tests a hypothesis and draws conclusions.
    - Research is described in a formal protocol and a set of procedures designed to reach an objective.
    - The line between practice and research is often blurred.
    - Research and practice can occur simultaneously

# What is a Human Subject?

- A “human subject” (participant, volunteer) is a living individual about whom an investigator conducting research obtains:
  - Data through intervention or interaction with the individual
  - or
  - Identifiable private information

From: 45 Code of Federal Regulations (CFR) 46.102

# CHALLENGE:

## Identifiable Private Information?

- DNA?
- Multiple linked data elements?
- Protected Health Information?
  - “Individually identifiable health information, held or maintained by a covered entity or its business associates acting for the covered entity, that is transmitted or maintained in any form or medium”

# Responsibilities of the IRB and Human Research Protections Program

- Protect the rights and welfare of human research subjects
- Determine if Benefit of the research (to the individual or society) *exceeds* the Risk to the participant (subject, volunteer, patient)

# CHALLENGE:

## Risks of “Big Data” and Biospecimens?

- Social?
- Financial?
- Employment?
- Insurance?
- How can it be shared and with whom?
- Special considerations
  - HIV, Substance Abuse

# What is Informed Consent (IC)?

- ***It is a process- not just a document!***
  - (1) disclosing to potential research subjects information needed to make an informed decision;
  - (2) facilitating the understanding of what has been disclosed; and
  - (3) promoting the voluntariness of the decision about whether or not to participate in the research

See: <http://answers.hhs.gov/ohrp/categories/1566>

# CHALLENGE:

## IC For “Big Data” and Biospecimens?

- Upon entry into the health system?
- Who obtains it?
- What form/process is used?
- What are the costs?
- What happens if the individual opts out?
  - How do we keep these data from the research data base?

# The “Baltimore Sun Test” ...

THE BALTIMORE SUN

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## Lead-paint lawsuits dog Kennedy Krieger

Study seeking cheaper abatement draws claims children still poisoned

June 07, 2014 | By Timothy B. Wheeler and Meredith Cohn, The Baltimore Sun

Kimberly Smith believed she was “in good hands” when she rented an East Baltimore rowhouse nearly 20 years ago that was part of a Kennedy Krieger Institute study of lead paint remediation techniques.

Kennedy Krieger takes care of children, Smith thought at the time. One of her children had suffered lead poisoning when the family had lived elsewhere, she recalled in a recent interview, and she was pregnant then with her fourth child, Cecil.

“I was told it was a great opportunity — it was lead-safe,” Smith said. “It was one less thing I had to worry about.”

But something went wrong while she and her children lived at 1110 Rutland Ave., according to a lawsuit filed in Baltimore Circuit Court. Though the house had undergone repairs intended to reduce lead-paint hazards, the suit alleges that her infant son was being poisoned from the time she brought him home from the hospital until she moved out of the house more than three years later. By then, Smith says, her son was showing signs of behavior problems, which she now sees as a symptom of brain damage that would plague him throughout his life.

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Kimberly Smith, mother of Cecil Harris, who has lead poisoning.... (Lloyd Fox, Baltimore Sun )