

# **Ethical principles related to data protection and integrity**

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# Objectives

- Discuss privacy aspects of stored data
- Explore issues related to property interests tied to information
- Examine data integrity in light of principles of research safety

# Principles at stake when using stored human data

- Respect for persons
  - Informed consent, privacy, group identity
- Beneficence
  - Dignitary harm, maximizing benefits
- Justice
  - Fair distribution of resource
- Categorical imperative
  - Dignitary harm, no surprises rule

# Categorical imperative

"Treat each person as an end unto himself, and not merely as a means to an end."



# Data Management

- Systematic collection of data
- Adverse event monitoring
- Informed consent of research subject
- Statistical analysis of interim data
- Use of Data Safety Monitoring Boards
- Clear stopping rules
- Protection of research information

# Protection

- The act of keeping from being damaged, attacked, stolen, or injured.
- The act of guarding
- The act of assuring payment by setting aside funds
- *Pro* – in front; *tegere* – cover
- Note: Detect – to uncover; dis-cover

# Stored data: Questions to ask before collecting or using information

1. How do we ensure patient/subject understands what will happen to data?
2. How do we reduce (privacy/dignitary) harm?
3. How do we maximize benefits in using data?
4. How do we decide who gets to use data?
5. How do we show patient/subject we value him/her as an end and not a means?

# Privacy

# Privacy

- Inaccessibility or restricted access to a person, his/her body, or information about him/her
- "Right to be left alone"
- Granting access is an exercise of the right, not a waiver

# Confidentiality

- Obligation to protect information about person obtained in confidence/secret.
- Hippocratic Oath:
  - "...Whatever, in connection with my professional service, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret."

# HIPAA Mandate

- Covered entities and their business associates must implement "appropriate administrative, technical, and physical safeguards" for protected health information in all forms, non-electronic and electronic.
- Four categories:
  - Administrative procedures
  - Physical safeguards
  - Protection of data at rest
  - Protection of data in transit

# The Four A's of Information Security

- A**uthenticate the User - Passwords
- A**uthorize the User - Levels of clearance
- A**udit trail - Track users & uses
- A**ccountability - Discipline violators

Adapted from Rosenberg, Janice. *Medicine on the Net* 4(10):6-9, October 1998



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## Issues to Consider in the Research Use of Stored Data or Tissues

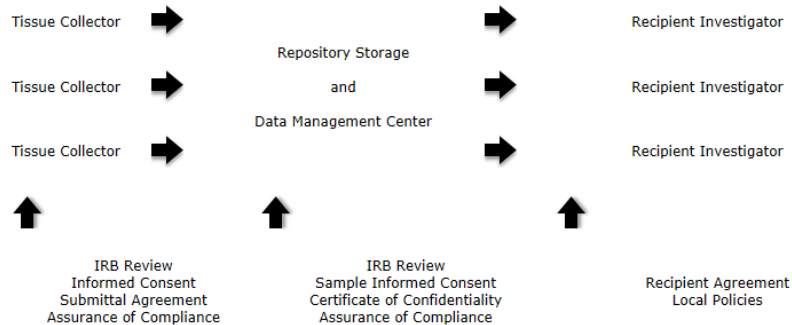


### OFFICE FOR PROTECTION FROM RESEARCH RISKS

#### Issues to Consider in the Research Use of Stored Data or Tissues

November 7, 1997

- **Human Tissue Repositories** collect, store, and distribute human tissue materials for research purposes. Repository activities involve three components: (i) the **collectors** of tissue samples; (ii) the **repository** storage and data management center; and (iii) the **recipient** investigators.
- If supported by the Department of Health and Human Services (HHS), each component must satisfy certain **regulatory requirements**.



- Operation of the Repository and its data management center should be subject to **oversight by an Institutional Review Board (IRB)**. The IRB should review and approve a protocol specifying the conditions under which data and specimens may be accepted and shared, and ensuring adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. The IRB should also review and approve a sample collection protocol and informed consent document for distribution to tissue collectors and their local IRBs. A **Certificate of Confidentiality** should be obtained to protect confidentiality of repository specimens and data.

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## OHRP - Guidance on Research Involving Coded Private Information or Biological Specimens

**NOTE: THIS GUIDANCE REPLACES OHRP'S AUGUST 10, 2004 GUIDANCE ENTITLED "GUIDANCE ON RESEARCH INVOLVING CODED PRIVATE INFORMATION OR BIOLOGICAL SPECIMENS." [CLICK HERE FOR THE AUGUST 10, 2004 GUIDANCE](#). THIS GUIDANCE HAS BEEN UPDATED TO BE CONSISTENT WITH THE CONTENT OF OHRP'S OCTOBER 16, 2008 "GUIDANCE ON ENGAGEMENT OF INSTITUTIONS IN HUMAN SUBJECTS RESEARCH."**

This guidance represents OHRP's current thinking on this topic and should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word *must* in OHRP guidance means that something is required under HHS regulations at 45 CFR part 46. The use of the word *should* in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of the HHS regulations at 45 CFR part 46. OHRP is available to discuss alternative approaches at 240-453-6900 or 866-447-4777.

**Date:** October 16, 2008

**Scope:** This document applies to research involving coded private information or human biological specimens (hereafter referred to as "specimens") that is conducted or supported by HHS. This document does the following:

1. Provides guidance as to when research involving coded private information or specimens is or is not research involving human subjects, as defined under HHS regulations for the protection of human research subjects (45 CFR part 46).
2. Reaffirms OHRP policy (see OHRP guidance on *repository activities* <http://www.hhs.gov/ohrp/policy/reposit.html> and *research on human embryonic stem cells* <http://www.hhs.gov/ohrp/archive/references/HESCGuidance.pdf>) that, under certain limited conditions, research involving **only** coded private information or specimens is not human subjects research.
3. Clarifies the distinction between (a) research involving coded private information or specimens that does not involve human subjects and (b) human subjects research that is exempt from the requirements of the HHS regulations.
4. (4) References pertinent requirements of the HIPAA Privacy Rule that may be applicable to research involving coded private information or specimens.

**NOTE:** Some HHS conducted or supported research involving coded private information or specimens may be subject to Food and Drug Administration (FDA) regulations. The FDA regulatory definitions of human subject (21 CFR 50.3(g), 21 CFR 56.102 (e)) and subject (21 CFR 312.3(b), 21 CFR 812.3(p)) differ from the definition of human subject under HHS regulations at 45 CFR 46.102(f). This guidance document does not apply to research regulated by FDA that involves coded private information or specimens. Anyone needing guidance on such FDA-regulated research should contact the FDA.

# Private information

- Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.
- Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

# Private information

- Private information must be **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects (bolding added for emphasis).



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## 111.12 Organization Policy on Privacy and Confidentiality

May 2005

It is the policy of the Organization that provisions for protecting the confidentiality of identifiable research data and patient health information must be reviewed by the JHM IRB as required by 45 CFR 46.111(a)(7) and 21 CFR 56.111(a)(7). The IRBs are authorized to ask the investigator to describe plans for protecting subject privacy and data confidentiality. The investigator's plan must preserve the subject's right to choose how and when his or her private information will be used, withheld, or disclosed. Potential risks of a breach of the subject's right to privacy must be disclosed to participants. The IRB may determine additional methods as needed to minimize the risk.

The Organization authorizes the JHM IRB to request that the PI secure a Certificate of Confidentiality to protect research data from legal process.

The JHM IRB must ensure that privacy and confidentiality are protected in accordance with all HIPAA Privacy Rule requirements, Organization policies, and State and local law.



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## Johns Hopkins HealthCare Data Sharing Committee Guidance

September 2006

### What is the JHHC Data Sharing Committee?

This committee is composed of the directors (or their delegates) of the principal departments within JHHC. The Committee will review the scientific merit, potential impact of the study and appropriateness of the study for the mission of JHHC. The Committee will assess the amount of JHHC resources that will be necessary to provide the data requested. It will also ensure that protected health information (PHI) in its custody is managed according to the HIPAA Privacy Rule and the data concerns of the individual plans with whom JHHC has contracted are respected.

### How should an investigator initiate a research project using clinical or administrative claims data (a.c.d.) residing at Johns Hopkins HealthCare LLC (JHHC)?

The first step is to obtain IRB approval for the study. In the course of completing the eIRB application, the investigator will be prompted to complete the JHHC Data Request Application. The JHHC will be notified when a new application involving its clinical or a.c.d. has been submitted. When IRB approval for the study is granted, an automatic notification from eIRB will be sent to the Chair of the JHHC Data Sharing Committee. Approval to obtain/access the clinical or a.c.d. must then be granted by the JHHC Data Sharing Committee.

### What are the steps of the review process at JHHC?

**Step 1** The Committee will review the Data Request Application and documentation. Generally, the investigator requesting the data will be asked to present the study to the JHHC Data Sharing Committee before a final decision is made. Based upon the assessment of the study's scientific merit, potential impact and correspondence to the JHHC mission, one of following three actions may be taken: 1) Approve; 2) Pending – further information required, and the PI will be contacted; or 3) deny. If the DSC denies access to the data, the IRB will be notified of this action.

**Step 2** When approved, the request will be forwarded to the Director(s) of the health plans whose enrollee data is requested: Priority Partners, Employers Health Program (EHP), and/or Uniform

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## Research Databases

March 2006

A research database is any collection of patient -level data, whether identifiable or not, that is maintained for use in future research. Federal regulations and JHM policies that protect the privacy of patients and research subjects apply to both the *creation* and *use* of research databases, as described below.

The information in this guidance is also summarized in the table at [Attachment A](#).

### Getting Started

First, determine whether the database will contain *identifiers*. Identifiers include not only information (e.g., name, address, SSN, or medical record number) that can be used to identify someone directly, but also any of the other 18 data elements listed in the HIPAA privacy rule (see [Attachment B](#)), such as dates of birth or treatment.

A code number that is linked to an identifier is itself an identifier, unless

- The code is unique and not used for any other purpose (and is not derived from another identifier, such as SSN); **and**
- The database user will not have access to the code key and will not be permitted to re-identify any of the information.

Second, determine how information will be obtained for the database. Will the source be existing clinical or research information, or will patients/subjects be interviewed, tested, or otherwise contacted for the purpose of obtaining research data? A researcher who will interact with subjects for the purpose of collecting identifiable data for a database should ask for the subject's consent and HIPAA authorization, as described below.

A physician-investigator may also ask his or her patients to give their consent/HIPAA authorization to permit clinical data (and associated specimens) to be included in a research database. Procedures for obtaining consent and authorization are described below.

### Creating and Using the "De-Identified" Database

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## Research Databases

### Creating and Using the "De-Identified" Database

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# Research Databases

**De-identified Data:** De-identified data are not considered to be Protected Health Information (PHI). The Safe Harbor under HIPAA permits a covered entity to consider data "de-identified" if all of the following identifiers removed:

- Names
- Geographic subdivisions smaller than a state except first three digits of the zip code;
- All elements of dates (except year) for individuals under 90 years old; all elements of dates (including year) for those 90 years old or older;
- Telephone numbers;
- Fax numbers;
- E-mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet protocol address numbers;
- Biometric identifiers, including voice and finger prints;
- Full face photographic images and any comparable images;
- Any other unique, identifying number characteristic, or code, except for unique codes, provided that the persons who receive or use the data do not have access to the code keys or any means of re-identifying data subjects.

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http://www.hopkinsmedicine.org/institutional\_review\_board/guidelines\_policies/guidelines/research\_databases.html

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- Guidelines
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Resources

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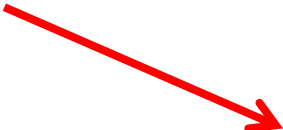
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2. Data Source?



Where did data/tissue come from?

Clinical

Research

Existing

Prospective

Existing

Prospective

Non-  
Identifiable

Identifiable

Repository



# Identifiers That Must Be Removed to Make Health Information De-Identified

- (i) The following identifiers of the individual or of relatives, employers or household members of the individual must be removed:
  - (A) Names;
  - (B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, **except for the initial three digits of a zip code if**, according to the current publicly available data from the Bureau of the Census:
    - (1) The geographic unit formed by combining all zip codes with the same three initial digits **contains more than 20,000 people**; and
    - (2) The initial three digits of a zip code for all such **geographic units containing 20,000 or fewer people is changed to 000**.
  - (C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, **except that such ages and elements may be aggregated into a single category of age 90 or older**;

# Identifiers That Must Be Removed to Make Health Information De-Identified

- (D) Telephone numbers;
- (E) Fax numbers;
- (F) Electronic mail addresses;
- (G) Social security numbers;
- (H) Medical record numbers;
- (I) Health plan beneficiary numbers;
- (J) Account numbers;
- (K) Certificate/license numbers;
- (L) Vehicle identifiers and serial numbers, including license plate numbers;
- (M) Device identifiers and serial numbers;
- (N) Web Universal Resource Locators (URLs);
- (O) Internet Protocol (IP) address numbers;

# Identifiers That Must Be Removed to Make Health Information De-Identified

- (P) Biometric identifiers, including finger and voice prints;
  - (Q) Full face photographic images and any comparable images; and
  - (R) Any other unique identifying number, characteristic, or code [except for unique codes provided that data user does not have access to code key or means of re-identifying data subjects]; and
- 
- (ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

# Health information that may remain in a limited data set under HIPAA

- Dates such as admission, discharge, service, DOB, DOD;
- City, state, five digit or more zip code; and
- Ages in years, months or days or hours.



# HHS regulations at 45 CFR 46.101(b)(4):

- "Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."

Where did data/tissue come from?

Clinical

Research

Existing

Prospective

Existing

Prospective

What is Nature of Informed Consent?  
Risk Assessment, Identifiers, Future Contact

Existing Clinical Data/Tissue

Non-  
Identifiable

Identifiable

Not Private

Private

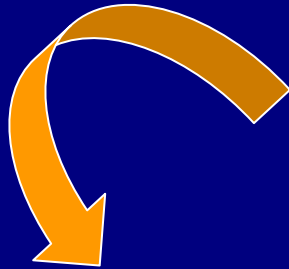
Public

Not Public

Exempt

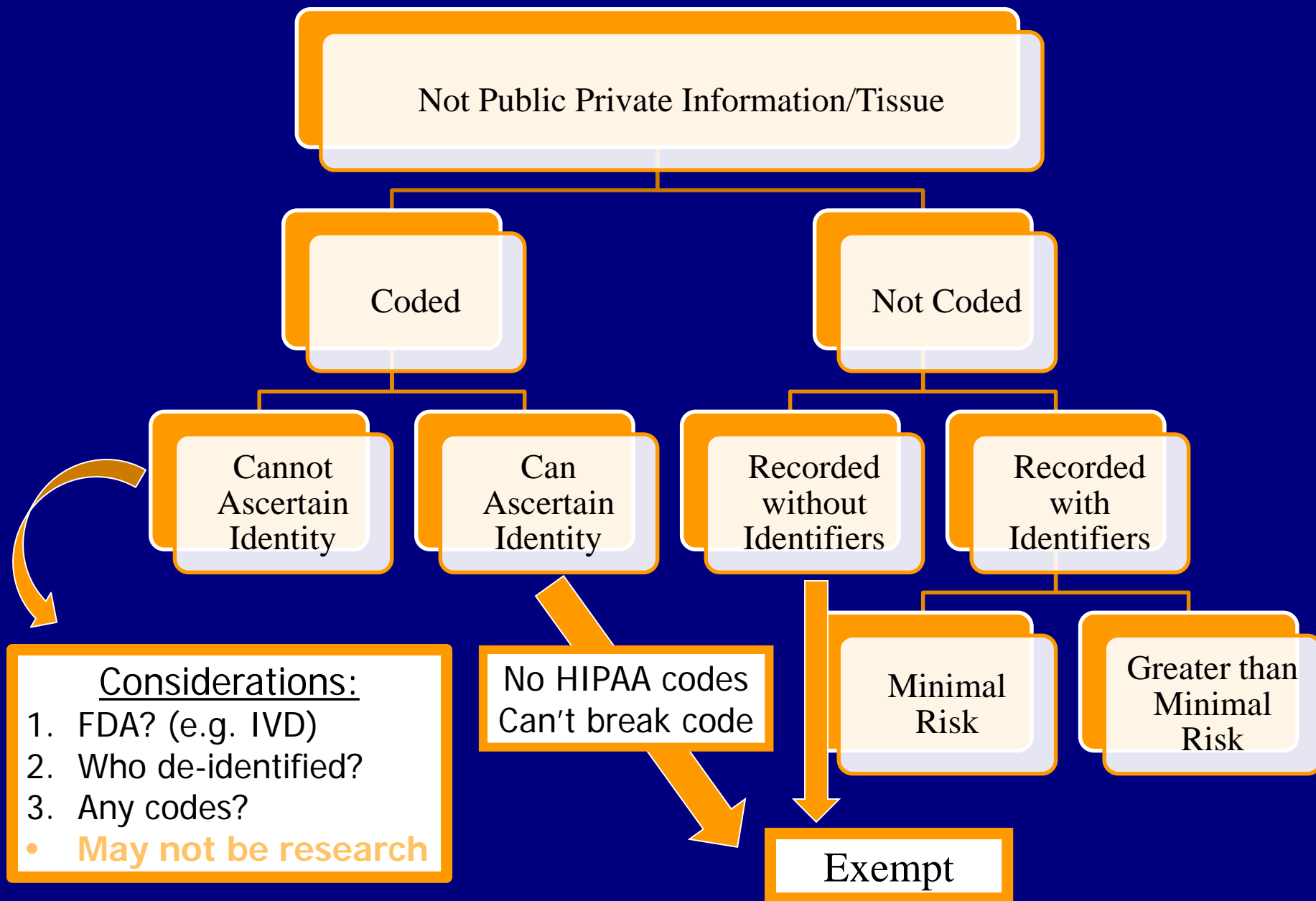
Considerations:

1. FDA? (e.g. In Vitro Diagnostic)
  2. Who de-identified?
  3. Any codes?
- **May not be research**



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## Risk Assessment Matrix

### Probability of harm

### Severity of harm

Catastrophic

Critical

Marginal

Negligible

Impossible

Improbable

Remote

Occasional

Probable

Frequent


1

2

3

1

**High Risk**

2

**Medium Risk**

3

**Low Risk**

# **Office for Human Research Protections (OHRP)**

Secretary's Advisory Committee on Human Research Protections (SACHRP)

SACHRP Letter to HHS Secretary

January 31, 2008

## **Recommendations Related to the Interpretation of Minimal Risk**

“... While the harms and discomforts ordinarily encountered differ widely among individuals and individual populations, an ethically meaningful notion of "harms and discomforts ordinarily encountered" should reflect "background risks" that are familiar and part of the routine experience of life for "the average person" in the "general population." It should not be based on those ordinarily encountered in the daily lives of the proposed subjects of the research or any specific population.”

# Archived Data

- Relationship to informed consent
  1. Is *research* intended or anticipated?
  2. How was information obtained?
  3. How is subject identity protected?
  4. What are the risks to research subject?



# Property

# Privacy and Property Rights

## ■ Whose information is it?

1. Study subject
2. Researcher
3. Institution
4. Funding organization
5. Community/society

# Hopkins boilerplate

Scientists at Johns Hopkins work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to both this study and to future research.

If you join this study:

- You will not own the data, or the tissue, blood, or other specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research may study your data and the tissue, blood or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea."

# Hopkins boilerplate

Scientists at Johns Hopkins work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to both this study and to future research.

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- You will not own the data, or the tissue, blood, or other specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research may study your data and the tissue, blood or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea."

# For Sale: The Framingham Heart Study

When US government scientists began recruiting residents of a Boston suburb for the Framingham Heart Study, the Cold War was just beginning, the personal computer was a fantasy and Watson and Crick had yet to reveal the structure of DNA. Since then, data collected from more than 10,000 Framingham residents have helped shape the modern idea of a 'healthy heart' by drawing clear links between diet, smoking, exercise and heart disease.

Today, biomedical research technology has surpassed all expectations. The Framingham researchers have moved beyond heart-rate monitoring and cholesterol tests and into genetic screening. And the potential of generating genetic data from such a closely monitored clinical cohort has not escaped the notice of technology transfer staff at Boston University (BU)—the institutional home of the 52-year-old project,

of a contract, not a grant. Therefore, it is technically an intramural NIH project run by BU, an arrangement that promises to give the government more leverage. However, BU has subsidized the research since the 1970s.

Both BU scientists and administrators say they share Lenfant's concerns and will be able to address them. Ledley described the discussions between BU and NHLBI as non-confrontational.



sion. This is the type of data that FGM is most interested in. "Companies have an urgent need to know which genes matter to disease," says Ledley.

There will be no conflicts of interest since none of the researchers will hold stock in the company, Ledley says. And, FGM is offering to fund an ethical oversight committee run by a group of study participants known as the Friends of the Framingham Heart Study. The Framingham community may also benefit from a trust fund established from a portion of company stock, which could be used for scholarships or medical care.

At present, any researcher who wants it can get raw data from the study. But, "it's always required a little effort on the part of the investigator to pull particular data from a study," Ledley says. The company plans clean up the raw data so that it will be compatible with "modern information systems" and sell it to in-

# Framingham Genomic Medicine

- Boston University venture capital group
- \$20 million funding for spin-off company
- Repackage data into digitalized database to sell to drug companies
- Researchers would still have access to raw data
- Should a publicly funded database be proprietary?

# Framingham Heart Study: Not For Sale

- One participant wrote to the local newspaper stating that he felt "betrayed" by the plan to sell the data:

*"While many of us hoped that our contributions would lead to life-saving research and discovery, none of us anticipated that our contributions would be sold as a commodity for possible future profits."*



# Hopkins boilerplate

Scientists at Johns Hopkins work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to both this study and to future research.

If you join this study:

- You will not own the data, or the tissue, blood, or other specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research may study your data and the tissue, blood or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea."



# Intellectual Property (IP)

- Generic legal term used to protect ideas
- 3 forms: copyrights, trademarks, patents
- Similar characteristics to real property:
  - Can be bought and sold (assigned)
  - Can be rented (licensed)
  - Owner can prevent trespass (infringement)

Intellectual Property Law: a primer for scientists.

Brown WM. *Mol Biotechnol.* 2003 Mar;23(3):213-24

# Who owns IP?

- Inventors (Faculty, students, staff) disclose their inventions to the University (Report of Invention - ROI)
- University (may) obtain patent in name of Inventors. Inventors assign their patent rights to the University (\$1) that then licenses it to companies
- University (may) license but doesn't sell its IP
- Proceeds from license distributed to Inventors, Inventors laboratory, Inventors Department, School and University according to a formula

# Property

- Something owned, a possession
- Something tangible or intangible to which its owner has a legal right
- The right of ownership; title

# Possession

- Property interest in which one has actual control over an object, and intends to possess it to the exclusion of others.
- Actual holding or occupancy with or without rightful ownership

# ***The Icelandic Database***

# ***The Icelandic Database***

- 1998 Icelandic Parliament enacted the Health Sector Database Act (HSDA)
- Exclusive 12 year contract with for-profit, Delaware-based deCODE Genetics for electronic database
- All medical records of Icelanders dating back to 1915

# ***The Icelandic Database***

- Database to be linked to genealogical records dating back to 9<sup>th</sup> century
- Also linkage to genetic information from blood samples donated voluntarily by 110K Icelanders
- deCODE has sole right:  
*“during the period of the license to use the data on the database for purposes of financial profit.”*

# *The Icelandic Database*

- No affirmative consent by patients before deCODE accesses records
  - Patients have to opt out if they do not want their medical records in database

- According to deCODE:

*"Presumed consent is a nebulous concept, but... we regard it as the consent of society to the use of health care information according to the norms of society."*



# ***The Icelandic Database***

- *Ragnhildur Gudmundsdottir vs. Iceland*
- Woman sued, objecting to inclusion of her dead father's medical information in database
  - Claimed it violated her right to privacy
- April 2004 Icelandic Supreme Court found HSDA unconstitutional
  - Fails to protect personal privacy adequately
  - Plaintiff could prohibit transfer of father's information into database

# Genetic privacy

Who gets to know your genetic test results?

- Family?
- Employer?
- Insurance companies?
- Mortgage lender?

# Genetic discrimination

- Concerns about stigmatization
- Can decisions (employment, insurance, etc.) be made based on this information?
- Genetic Information Nondiscrimination Act (GINA; more later)

ASH > OHRP Home > Policy & Guidance

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## Office for Human Research Protections (OHRP)

### Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards

This guidance represents OHRP's current thinking on this topic and should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word must in OHRP guidance means that something is required under HHS regulations at 45 CFR part 46. The use of the word should in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of the HHS regulations at 45 CFR part 46. OHRP is available to discuss alternative approaches at 240-453-6900 or 866-447-4777.

**Date:** March 24, 2009

**Scope:** This document applies to non-exempt human subjects research conducted or supported by HHS. It provides background information regarding the Genetic Information Nondiscrimination Act of 2008 (GINA) and discusses some of the implications of GINA for investigators who conduct, and institutional review boards (IRBs) that review, non-exempt human subjects research involving genetic testing or the collection of genetic information (hereinafter referred to as "genetic research"), particularly with respect to the criteria for IRB approval of research and the requirements for obtaining informed consent.

The information presented in the background section of this document is intended for general information purposes only. While the background section does not cover all of the specifics of GINA, it does provide an explanation of the statute to assist those involved in the conduct or oversight of research to understand the law and its prohibitions related to discrimination based on genetic information in (a) coverage provided either by health insurers or by employment-based group health plans (hereinafter referred to as "health coverage"), and (b) employment. This information should not be considered legal advice. In addition, some of the provisions of GINA discussed involve issues for which the rules have not been finalized, and this information is subject to revision based on publication of regulations.

**Target Audience:** Investigators who conduct, and IRBs that review, genetic research involving human subjects that is conducted or supported by HHS.

#### Background on GINA:

GINA is a Federal law that prohibits discrimination in health coverage and employment based on genetic information. GINA, together with already existing nondiscrimination provisions of the Health Insurance Portability and Accountability Act, generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or an individual's family members, or using such information for decisions regarding coverage, rates, or preexisting conditions. GINA also prohibits employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. The parts of the law relating to health coverage (Title I) generally will take effect between May 22, 2009, and May 21, 2010, and those relating to employment (Title II) will take effect on November 21, 2009.<sup>(1)</sup> GINA requires regulations pertaining to both titles to be completed by May 2009. Once GINA takes effect, it generally will prohibit discrimination based on genetic information in connection with health coverage and employment, no matter when the information was collected.

GINA provides a baseline level of protection against genetic discrimination for all Americans. Many states already have laws that protect against genetic discrimination in health insurance and employment situations. However, the degree of protection they provide varies widely, and while most provisions are less protective than GINA, some are more protective. All entities that are subject to GINA must, at a minimum, comply with all applicable GINA requirements, and may also need to comply with more protective State laws.

GINA defines *genetic information* as information about:

- An individual's genetic tests (including genetic tests done as part of a research study);

# Genetic Exceptionalism

- Are genetic test results different from other medical information?
  - Possible implications for family members
  - Intrinsic
  - Predictive
  - Probabilistic

# *The PXE Contract*

# *The PXE Contract*

- Pseudoxanthoma elasticum (PXE)
  - Rare ( $<1/25,000$  births) genetic disorder
- 1994 Sharon and Patrick Terry discovered their 2 children had PXE
- Formed PXE International in 1995
  - Network with 2000 individuals with gene
  - Retains ownership of blood/tissue bank

# *The PXE Contract*

- Sharon Terry realized:  
*"the research community was not set up to work together."*
- Up until that time only 4-5 families had been studied
- Needed to create network to have more research participants to facilitate research



# Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?

**Rao R**

*J Law, Medicine, Ethics* Fall 2007; 35(3):371-82

- Before researchers can access the blood and tissue, they must sign a contract saying that they will share with PXE International the ownership and profits on any research from the samples.

# Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?

**Rao R**

*J Law, Medicine, Ethics* Fall 2007; 35(3):371-82

- February 2000, Charles Boyd at University of Hawaii isolated gene responsible for PXE
  - Listed Sharon Terry as co-inventor
- University of Hawaii required him to relinquish all future intellectual property rights to the university

# Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?

**Rao R**

*J Law, Medicine, Ethics* Fall 2007; 35(3):371-82

- University of Hawaii initially refused to give up licensing rights
  - Recoup costs of patent application
  - Collect royalties from licensing deals
- Agreement reached in 2001
  - PXE given rights over licensing decisions
  - Equal share of royalties derived from any diagnostic test or marketable product

# Stored Data/Tissue: Privacy, Contract, Property?

- As a matter of policy, what is the best way to view the use of stored data in biomedical research?
  - Is it a privacy matter?
  - Is it an issue for contractual negotiation?
  - Is it a property interest?



# Integrity

# Integrity

1. Steadfast adherence to a strict ethical code.
2. When one is unimpaired.
3. Soundness or completeness.
4. The state or quality of being whole.

# Protecting the integrity of data

SCIENTIFIC MISCONDUCT: Researcher Faces Prison for Fraud in NIH Grant Applications and Papers - Microsoft Internet Explorer

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Address <http://www.sciencemag.org/cgi/content/full/307/5717/1851a?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=poehlman&searchid=1&FIRSTINDEX=1> Go Links

Home > [Science Magazine](#) > [25 March 2005](#) > [Kintisch](#), pp. 1851

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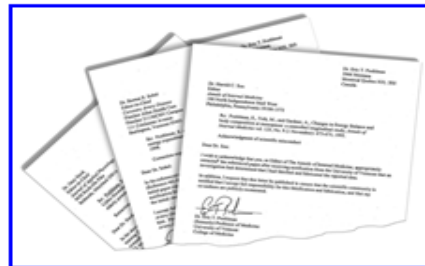
*Science* 25 March 2005:  
Vol. 307, no. 5717, p. 1851  
DOI: 10.1126/science.307.5717.1851a

## NEWS OF THE WEEK

### SCIENTIFIC MISCONDUCT: Researcher Faces Prison for Fraud in NIH Grant Applications and Papers Eli Kintisch

In the most extensive scientific misconduct case the National Institutes of Health (NIH) has seen in decades, a researcher formerly at the University of Vermont College of Medicine in Burlington has admitted in court documents to falsifying data in 15 federal grant applications and numerous published articles. Eric Poehlman, an expert on menopause, aging, and metabolism, faces up to 5 years in jail and a \$250,000 fine and has been barred for life from receiving any U.S. research funding.

Scientists say the falsified data—including work in 10 papers for which Poehlman has requested retractions or corrections—have had relatively little impact on core assumptions or research directions. But experts say the number and scope of falsifications discovered, along with the stature of the investigator, are quite remarkable. "This is probably one of the biggest misconduct cases ever," says Fredrick Grinnell, former director of the Program in Ethics in Science at the University of Texas Southwestern Medical Center in Dallas. "Very often [in misconduct cases], it's a young investigator, under pressure, who needs funding. This guy was a very successful scientist." Neither Poehlman nor his attorney returned calls from *Science*.



**Retractions.** Eric Poehlman (shown in 1991 photo) has notified journals about 10 papers that required retractions.

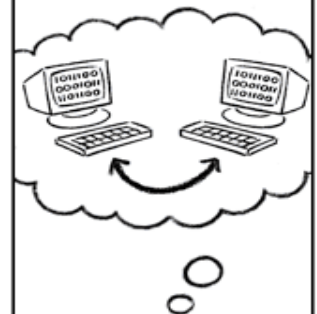
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## An Unwelcome Discovery

By JENEEN INTERLANDI  
Published: October 22, 2006

On a rainy afternoon in June, Eric Poehlman stood before a federal judge in the United States District Court in downtown Burlington, Vt. His sentencing hearing had dragged on for more than four hours, and Poehlman, dressed in a black suit, remained silent while the lawyers argued over the appropriate sentence for his transgressions. Now was his chance to speak. A year earlier, in the same courthouse, Poehlman pleaded guilty to lying on a federal grant application and admitted to fabricating more than a decade's worth of scientific data on obesity, menopause and aging, much of it while conducting clinical research as a tenured faculty member at the University of Vermont. He presented fraudulent data in lectures and in published papers, and he used this data to obtain millions of dollars in federal grants from the National Institutes of Health — a crime subject to as many as five years in federal prison. Poehlman's admission of guilt came after more than five years during which he denied the charges against him, lied under oath and tried to discredit his accusers. By the time Poehlman came clean, his case had grown into one of the most expansive cases of scientific fraud in U.S. history.



Illustration by Misprinted Type

"I need to start out by apologizing," Poehlman said now, standing at the lectern before the judge. Speaking quickly and stammering occasionally, he apologized to friends and former colleagues, some of whom were listening in the back of the courtroom. He apologized to his mother, who sat in the front row, crying. And he apologized to Walter DeNino, the former protégé who turned him in, who was also sitting in the courtroom, several rows back on the prosecution's side.

"I have wanted to say I'm sorry for five years," Poehlman said, without turning around to face DeNino. "I want to make it very clear I am remorseful. I accept the

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# The Poehlman case

- Gave Excel spreadsheets to research staff member for statistical analysis in preparation for publication.
- Laboratory test results and physiologic measurements in longitudinal study on aging
- Poehlman denied performing data entry himself

# The Poehlman case

- Poehlman had control of 678 datasets maintained/updated by staff member
- Staff member kept file on Poehlman's desktop computer, maintaining single copy of most updated version
  - Would perform file transfer protocol (FTP) when creating current version
- 9 spreadsheets in existence

# July 16, 2000 e-mail

"Finally found the corrected TEE file. We need to do the following

1) I have entered additional TEE's and corrected the misentries...

Don't fool with these numbers... I spent a lot of time over the weekend working on them. I want them pasted into the most current longitudinal worksheet. We will then proceed to do statistical analysis...

This will be an excellent paper."

# The Poehlman case

- Staff member was puzzled by dramatic increase in numbers but trusted Poehlman
- In December 2000, staff member suspected misconduct, and re-entered data based on one value for each subject from T1 and T2, and saw discrepancy

# The Poehlman case

- Whistleblower submitted database from April 1999 and August 22, 2000
- Showed that Poehlman had entered large number of non-existent values to enhance results
  - Fabricated results
  - Altered actual results (e.g. T1 and T2)
- Other protocols also proved suspect

# Fabrication

*Making up data or results and recording or reporting them*

Forgery (old nomenclature)

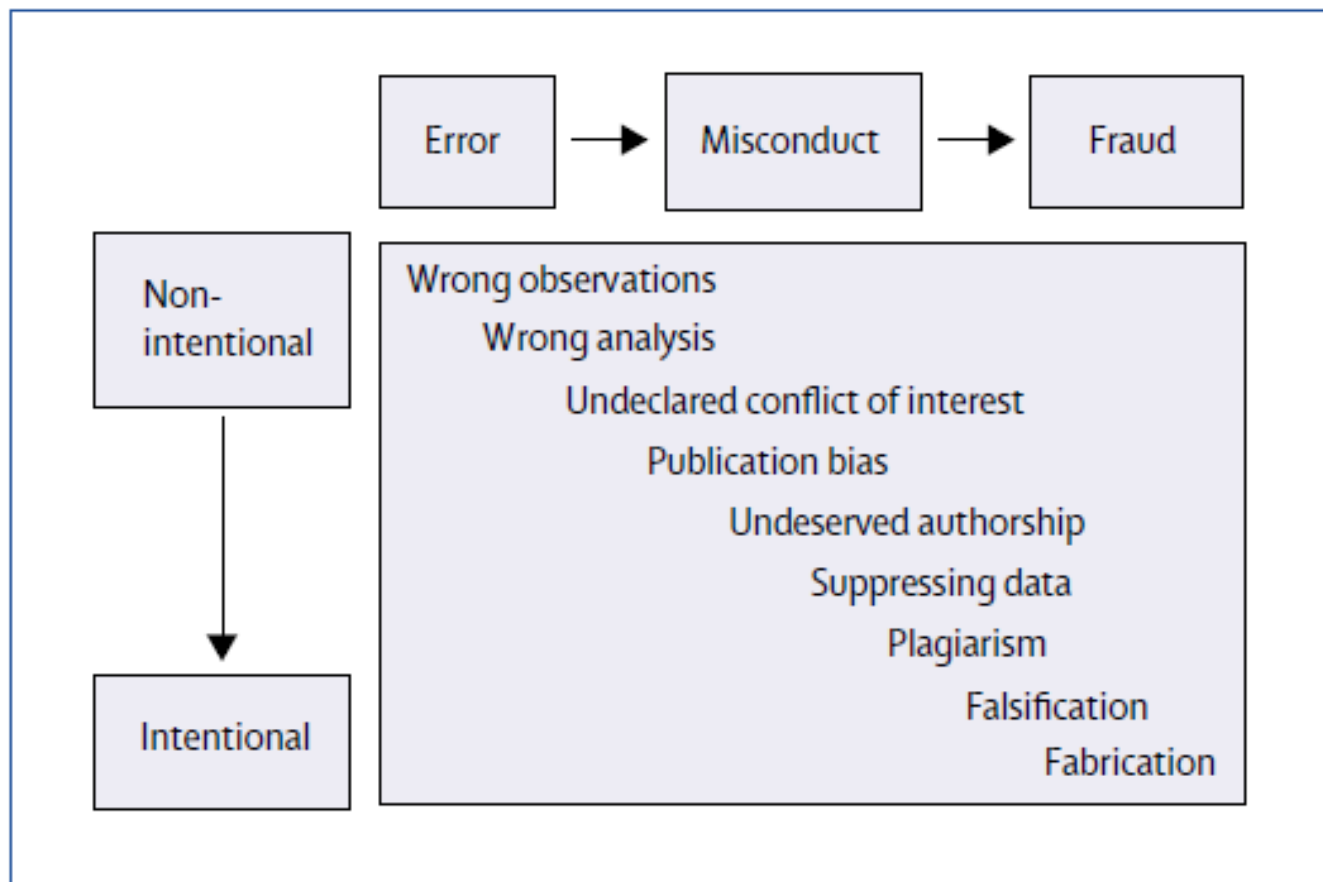
*Reporting of data when the experiment was not even done.*

# Falsification

*Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record*

Fraud (old nomenclature)

*Deliberate reporting of "facts" that the reporter knows are unsubstantiated.*



**Figure: Slippery slope between honest errors and intentional fraud, with examples in the middle**

Horizontal axis represents extent of deviation from acceptable scientific behaviour. Vertical axis represents extent of blame, from excusable errors, via non-intentional but still blameable deviance, to wilful actions.

Nylennaa M, Simonsena S. Scientific misconduct: a new approach to prevention  
Lancet 367(9526):1882-1884





## JHM Office of Human Subjects Research - Institutional Review Boards

### About IRB

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## 103.7 Organization Policy on Investigator Non-Compliance

August 2013

The Organization has granted the responsibility for review of all human subjects research to the JHM IRBs. The JHM IRBs may approve applications that meet the criteria set forth in government regulations, Organization policies, and other federal, state, and local laws and regulations. IRB approval notices to the Principal Investigator (PI) detail any special conditions or requirements for conduct of the research and provide a time limit on the approval period. The PI is responsible for conducting the approved research in accord with the IRB's requirements, as well as in accord with all ethical standards, Organization policies, and federal or state laws or regulations applicable to the research study. It is the obligation of the PI and study team to submit a written report to the IRB if non-compliance occurs during the conduct of the research.

The Organization defines non-compliance to be:

- Failure on the part of the PI, any member of the study team, or any other individual involved in research's review or oversight to follow the terms of the JHM IRB's approval; or
- Failure of the PI, any member of the study team, or any other individual involved in research's review or oversight to abide by applicable laws or regulations or Organization policies, including failure to submit human subjects research or changes to the approved research for IRB review and approval prior to commencing the research or changes to it.

Non-compliance varies in nature, severity, and frequency. The IRB must review written reports of non-compliance. The IRB will determine whether each report represents either: a) an instance of minor non-compliance with the IRB's approval determinations; b) an instance that is serious non-compliance; or c) a pattern of continuing non-compliance with the IRBs' determinations.

Minor non-compliance is defined by the Organization to be reported incidents, or events, which are not serious or continuing non-compliance.

Serious non-compliance is defined by the Organization to be failure to comply with laws or regulations, Organization policies, or the requirements or determinations of the IRB when that failure actually or potentially increases risk to participants or adversely affects the rights and welfare of the participants. A single instance of non-compliance may be determined by the IRB to be serious non-

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# JHU Responsible Conduct of Research Policy (for faculty and senior administrative staff)

Standing Committee on Discipline's recommendations may include, but are not limited to, the following sanctions:

- A letter of reprimand (with stipulations as appropriate) from the Dean to be placed in the accused person's personnel file;
- Suspension for a specified period of time, or other alteration in employment status;
- Remedial training or counseling;
- Restitution of misappropriated funds;
- Termination, whether the faculty member or senior staff member is appointed under a fixed term contract, or has a contract to retirement.

Safety

# Culture of Safety in Research – April 12, 2011

Dear Colleagues:

I am writing to remind all faculty, students and staff who are involved in human subject research at JHM that it is the responsibility and duty of all individuals on research teams to ensure the safety of research participants. An essential element of the conduct of research is the commitment of all individuals to a culture of safety.

When we examine problems in research protocols, we frequently find that someone on the team had concerns but decided to defer to the judgment of the physicians or principal investigators on the protocols. I want to emphasize that anyone who has questions about whether an individual participant should continue to have research interventions has a responsibility to pursue these concerns to the extent necessary to protect the rights and welfare of human research subjects.

Any member of a research team, even someone who is new to the research team or to clinical research, may raise concerns about the continued participation of an individual enrolled in a study and request a discussion to examine safety issues or stop research procedures for safety concerns. In addition, any concerns about safety may be brought to my attention or to the attention of the compliance team in the Office of Human Subjects Research.

Please use this e-mail as an opportunity to discuss with your research teams the need to create a culture where it is acceptable to question and improve the implementation of our research protocols.

Daniel E. Ford, M.D., M.P.H.

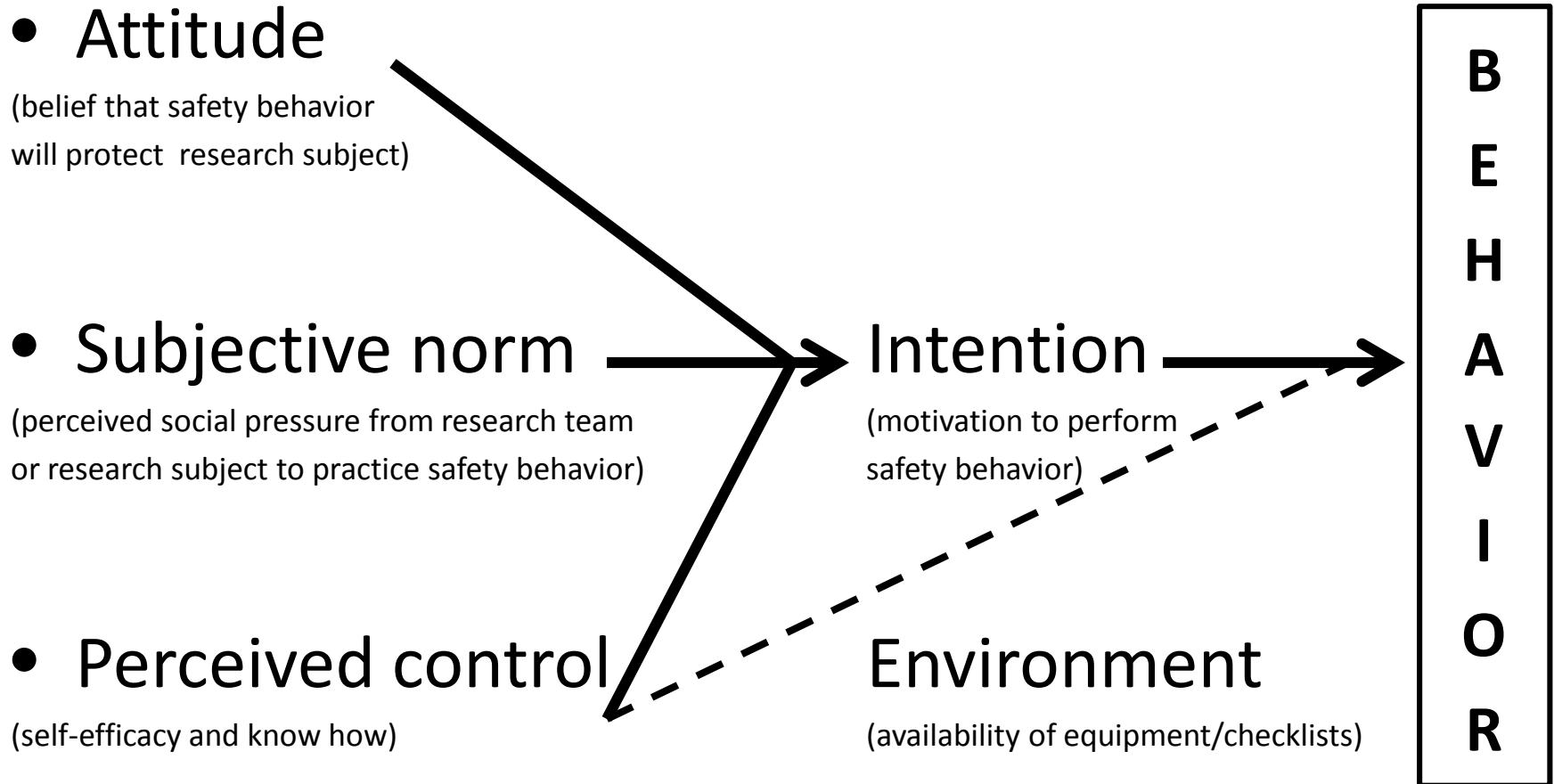
Vice Dean for Clinical Investigation

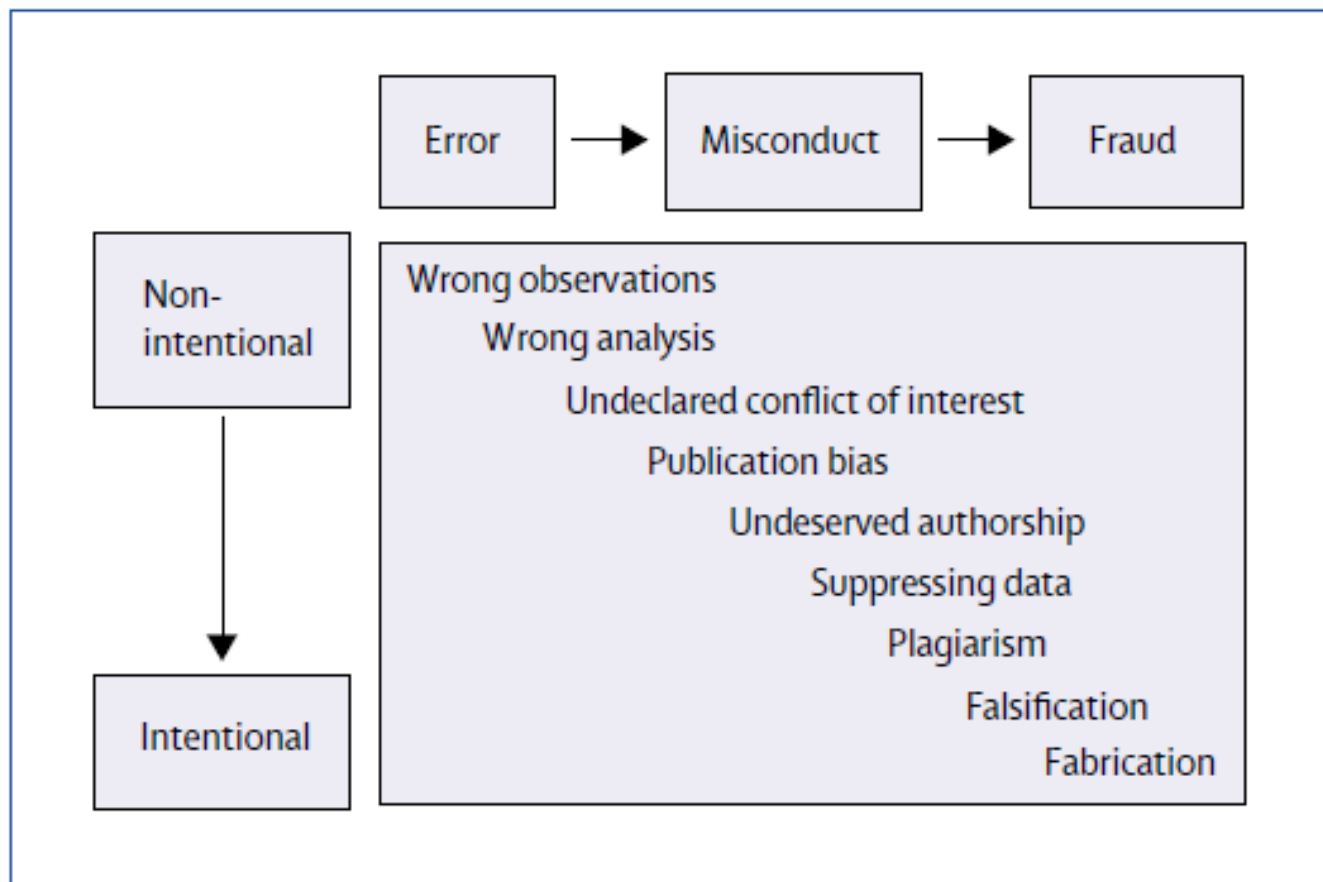
# The Role of Context in Safety Culture

- “Characteristics of the organization and its environment that influence the implementation and effectiveness of the... safety practice.” [Ann Intern Med 2011;154:693-696]
  1. External factors – regulatory requirements
  2. Organizational structure – size, complexity
  3. Teamwork, leadership, and safety culture
  4. Management tools – audit, feedback, training

# Theory of Planned Behavior

Adapted from Foy R et al. *BMJ Qual Saf* 2011;20:453-459





**Figure: Slippery slope between honest errors and intentional fraud, with examples in the middle**

Horizontal axis represents extent of deviation from acceptable scientific behaviour. Vertical axis represents extent of blame, from excusable errors, via non-intentional but still blameable deviance, to wilful actions.

Nylennaa M, Simonsena S. Scientific misconduct: a new approach to prevention  
Lancet 367(9526):1882-1884

Thanks for coming!