

Conflict of Interest, Scientific Misconduct and Other Thorny Research Issues

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Overview

- Human Subject Protections
- Scientific Misconduct
- Conflict of Interest
- Clinical Research Billing
- Scenarios

Human Subject Protection: Historical Context

- Primum non nocere
- WWII Experimentation
- Nuremberg Code, Declaration of Helsinki
- Belmont Report

Primum non nocere

- Human Subjects Protections = ethics
- Ethical human subjects research is practical
- Ethical humans subjects research is the law

Twentieth Century Experimentation

- Nazi Experimentation
 - High altitude/low pressure simulation
 - Pathogenesis of diseases (malaria, typhus, etc.)
 - Bone, muscle, nerve regeneration and transplantation
 - Rendering sea water drinkable
 - others
- Japanese Experimentation
 - Exposure to mustard gas, black plague, anthrax
 - Live vivisection (w/o anesthesia)
 - others
- USA's Experimentation
 - Experiments on servicemen
 - Tuskegee Syphilis Study
 - others

Nuremberg Code, Declaration of Helsinki

- Nuremberg Doctor's Trial 1946-47
 - 23 defendants, 15 found guilty, 7 executed
 - Nuremberg court provided standards for conducting human medical research, known as the Nuremberg Code
 - Nuremberg Code has 10 principles regarding human experimentation- ***The voluntary consent of the human subject is absolutely essential.***
 - Adopted by the World Medical Association 1948
- Declaration of Helsinki
 - Expansion of the ethical guidelines (12 basic principles)
 - Distinction between therapeutic and non-therapeutic human subjects research

Belmont Report

- Belmont Report- 1979
 - Congress formed the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research as a direct reaction to the Tuskegee Syphilis Study incident
 - Foundation of Federal Regulations for Human Subjects Research
 - Three main principles, Respect for Persons, Beneficence, Justice

Regulatory Overview

- Regulations
 - 21 CFR 50 (Food and Drugs – Protection of Human Subjects)
 - 21 CFR 56 (Food and Drugs - IRBs)
 - 45 CFR 46 (Public Welfare – Protection of Human Subjects)

Funding Agency / Regulatory Agencies	Regulations/Policies/ Guidance
<p>DHHS</p> <p>The Department of Health and Human Services (DHHS) is the federal agency regulating a large portion of federally supported human subject research..</p>	<p>The DHHS 45 Code of Federal Regulations (CFR) Part 46 applies to all human research supported or funded by the DHHS and is applied to all human research by most large institutions. Subparts include:</p> <ul style="list-style-type: none"> •Subpart A: Basic Federal Policy for the Protection of Human Subjects •Subpart B: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research •Subpart C: Additional Protections for Prisoners Subpart D: Additional Protections for Children
<p>NIH</p> <p>The National Institutes of Health provides federal funding for biomedical research.</p>	<p>NIH Grants Policy Statement</p>
<p>OHRP</p> <p>The Office for Human Research Protections is the DHHS oversight body that provides guidance to IRBs and investigators conducting human subject research.</p>	<p>OHRP Policy and Assurances guidelines, regulations, ethical principles, IRB Guide Book, OHRP/OPRR Reports, FAQs, and other materials relevant to the protection of human research subjects are available from the OHRP Website.</p>

Funding Agency / Regulatory Agencies	General Regulations
<p>FDA The Food and Drug Administration (FDA) oversees the use of drugs, devices, biologics, etc. including their use in research with human subjects.</p>	<p>The FDA has numerous regulation, guidance documents, and information sheets directly impacting human subject research, available on their website..</p>
<p>Department of Defense</p>	<p>Research that is funded by the Department of Defense must meet its funding and oversight requirements.</p>
<p>Department of Education.</p>	<p>Research that is funded by the federal Department of Education may have additional requirements that must be met.</p>
<p>Department of Veterans Affairs (VA).</p>	<p>Research involving human subjects recruited from or conducted in a VA facility must also meet the VA requirements.</p>
<p>Other Federal Agencies.</p>	<p>Other federal agencies may have additional policies, procedures, requirements, etc. that must be applied to research involving human subjects.</p>

An IRB...

- Is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.
- Has authority to approve, require modification of, disapprove, and conduct continuing review of research
 - IRBs can observe the consent process
 - IRB can suspend or terminate ongoing research
 - DHHS and FDA- two main agencies that provide IRB oversight
- Must have at least five (5) voting members, must reflect the diversity of the community; one member must be from outside of the home institution, one member have non-scientific expertise

HOWEVER, AN IRB....

- Is not a data analysis body
- Does not have the authority to freeze/withhold research funds
- Is not an institutional feasibility body

Functions of an IRB

- At least annually
- Monitor consent process
- IRBs assist and educate investigators and research staff
- IRBs conduct initial and continuing review of research
 - Full Board Review
 - Exempt Research
 - Expedited Review
- IRBs must keep good records
 - Minutes with sufficient detail
 - Records for 3 years
- IRBs review of device/drug trials may have special considerations
 - Approved or investigational?
 - IND, IDE?
 - Emergency Use?
- IRBs conduct continuing review of research
 - Management of Unanticipated Problems/Adverse Events

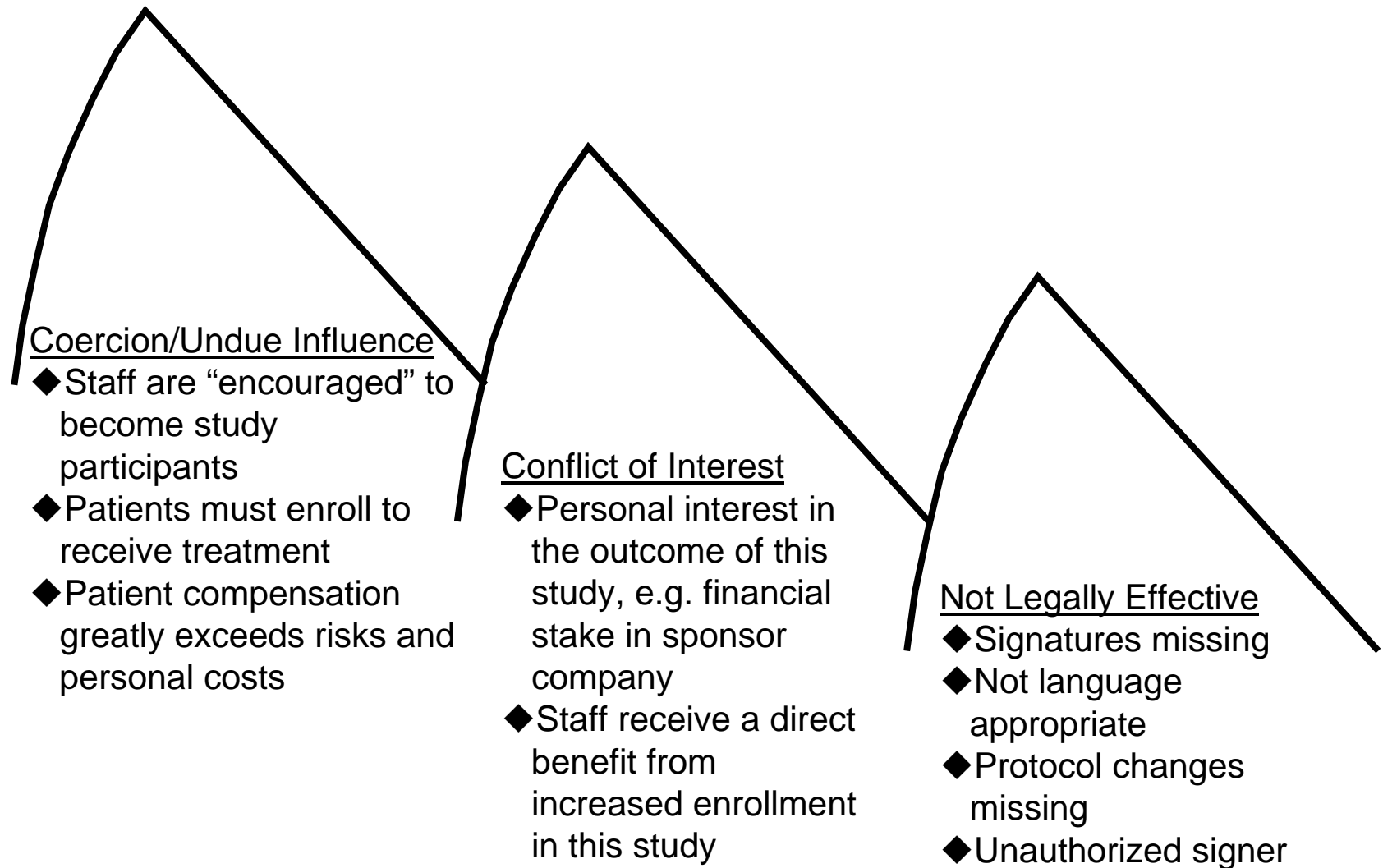
Hot Topics in IRB

- Informed Consent
 - Genetic Studies and Tissue Banking
- Expedited Review
 - Less than Minimal risk?
- Review of Social/Psychological and Behavioral Research
 - Many IRBs less familiar with non-medical human subjects research
- Appeal of IRB Decisions

IRB Assessment Tips

- **Membership**
 - Check for diversity, non-institutional and non-scientific members
 - Quorum
 - Check documents for management of COI
- **PIs are responsible, but Coordinators know best**
 - Coordinators usually responsible for all documentation
 - Office assistants have relationships with IRB staff
- **Regulations are Good, Guidance is Better**
 - Difficult to change the laws of the land. Regulatory agencies issue guidance that carry weight.
 - Good/Best clinical practice documents

There are potential pitfalls in the Informed Consent process.



Case Review :

Gelsinger v. University of Pennsylvania (C.P. Phila. Co., 2000)

- 18 year old with OTC, a rare metabolic disorder, entered a gene transfer clinical trial as a volunteer
- Principal investigator at Penn's Institute for Human Gene Therapy was also founder of Genovo, Inc., which had a business arrangement with Penn
- Information given during consent process did not mention:
 - monkey deaths
 - previous adverse events
 - relationship between principal investigator, University of Pennsylvania, and Genovo, Inc.
- After injection of adenovirus vector, subject died
- Confidential settlement reached

Case Review :

John Hopkins University

In 2001, A healthy volunteer, who was also an employee, died one month after inhaling hexamethonium bromide (an irritant). She was the third participant in an asthma study that analyzed of the effects of irritants on the lungs.

Issues and allegations

- After initial submission, the PI did not notify the IRB of significant changes to the protocol, including modifications to the dosing conditions
- The informed consent was deficient, as it did not mention the potential dangers of the substance
- No potential adverse events were listed on the informed consent, and no amendments were made after adverse events occurred on the first two participants
- The PI did not notify the IRB when the first two subjects experienced adverse events.

Results

OHRP suspended all federally funded research involving human subjects at nearly all Hopkins divisions, nearly 2,400 protocols. This suspension was partially lifted after 5 days. Afterwards, the institution was forced to undergo a re-review of every research protocol to ensure human subjects protections.

Additional guidances to review.

- Informed Consent for Non-English Speaking Participants:
<http://www.hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm>
- Informed Consent Requirements for Emergency Research:
<http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc97-01.htm>
- Informed Consent Guidelines for Exculpatory Language:
<http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm>
- Informed Consent--Legally Effective and Prospectively Obtained:
<http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc93-03.htm>

Research misconduct – a topical issue

- A former staff physician and principal investigator at Saint Vincent Hospital (SVH) in Indianapolis entered into a three-year voluntary exclusion agreement to settle findings of scientific misconduct against him. SVH and the Office of Research Integrity (ORI) found that Hans E. Geisler "**engaged in scientific misconduct by soliciting a pathologist to falsify" a pathology report and then submitting the falsified report to a colleague at the University of Iowa in order to justify enrollment of a patient in an oncology clinical protocol funded by the National Institutes of Health.** Geisler disagreed with the ORI finding but wanted to "avoid further proceedings and bring this matter to a close." (Report on Research Compliance – January 12, 2006)

Research misconduct – a topical issue

- The Department of Health and Human Services (HHS) debarred a University of Pittsburgh research project coordinator from participation in federally funded research for three years for fabricating data. According to an announcement published in the *Federal Register* on December 19, 2005, Jessica Lee Grol was debarred following investigations by the University of Pittsburgh and the Office of Research Integrity. Investigators found that she fabricated research records for 15 subjects, including patient interview data, forms tracking data, and the medical record extraction data in a study on the management of cerebral aneurysms.
(Report on Research Compliance – January 5, 2006)

Research misconduct – a topical issue

- Stem cell researcher Gerald Schatten was cleared of research misconduct by a University of Pittsburgh panel. Schatten was listed as co-author of a *Science* article with South Korean stem cell researcher Hwang Woo Suk. The data used for the magazine article were found to be fraudulent. The Pitt panel decided that Schatten, "Likely did not intentionally falsify or fabricate experimental data, and there is no evidence that he was aware of the misconduct." The panel decided that Schatten's activities were considered "research misbehavior" and recommended that university administrators "implement whatever corrective or disciplinary actions are commensurate with this finding of research misbehavior." (Report on Research Compliance – February 16, 2006)

Research misconduct – a topical issue

- Researcher Eric Poelman was sentenced in June 2006 to a year and a day in federal prison for making a false statement on a federal grant application in 1999. He was a scientist at the University of Vermont College of Medicine in Burlington and before that at the University of Maryland, Baltimore. (ScienceNOW Daily News, June 28,2006) He had already paid a \$180,000 in a related civil settlement. The allegations in that civil action included falsifying and fabricating research data in several federal grant applications from 1992 to 2000.

Research misconduct –the definition

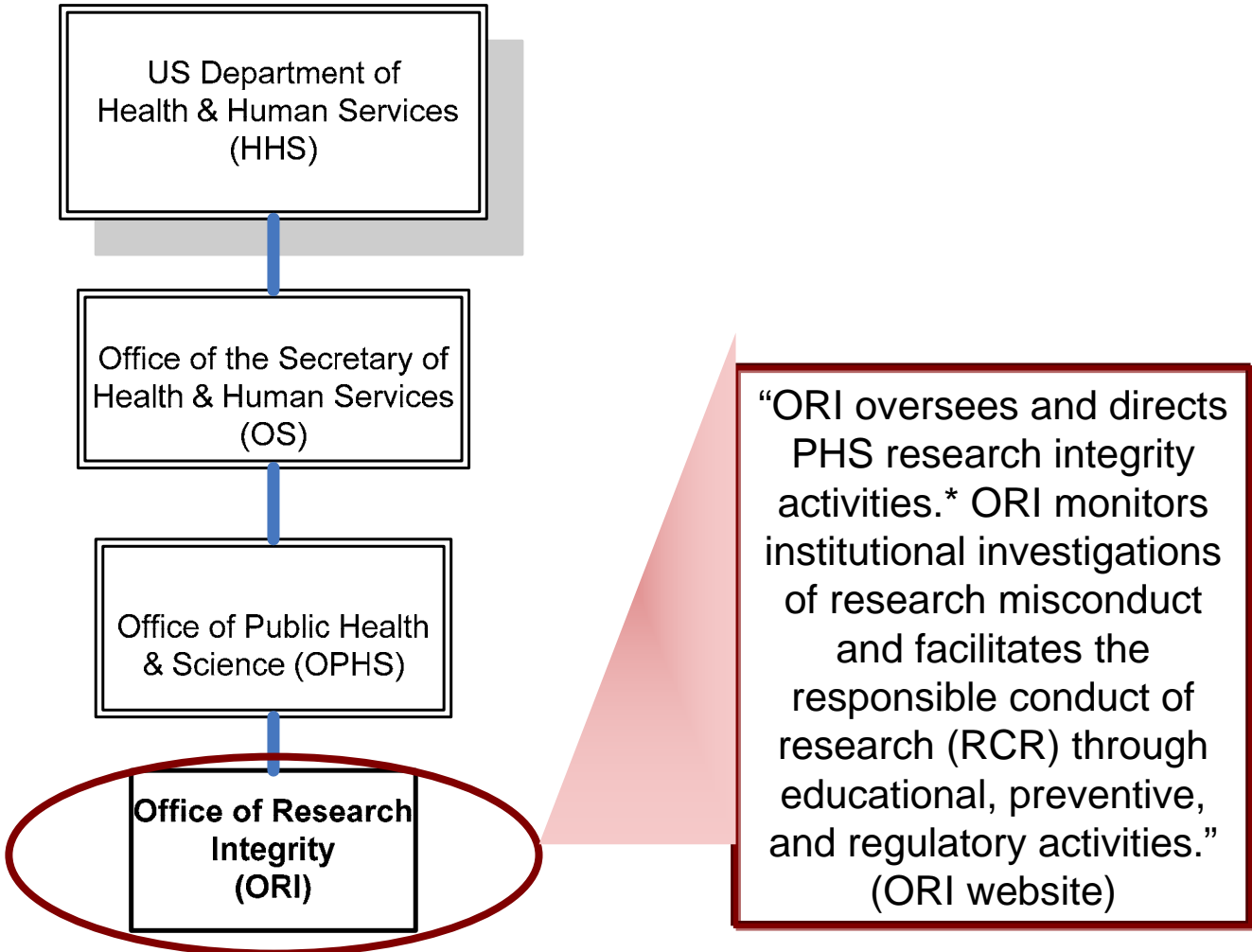
- 42 CFR 93* - Public Health Service Policies on Research Misconduct; Final Rule defines Research Misconduct as:
 - Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research , or in reporting research results
 - **Fabrication:** making up data or results and recording or reporting them
 - **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
 - **Plagiarism:** the appropriation of another person's ideas, processes, results, or words without giving appropriate credit
- Research misconduct does not include honest error or differences of opinion

* Final rule effective June 16, 2005 – Part 93 replaces part 50.

Applicability of the rule

- The rule applies to all recipients of Public Health Service (PHS) support
 - Biomedical research, behavioral research, research training or activities related to that research
- PHS agencies include:
 - National Institutes of Health
 - The Centers for Disease Control and Prevention
 - The Substance Abuse and Mental Health Services Administration
 - The Food and Drug Administration
 - The Health Resources and Services Administration
 - The Agency for Healthcare Research and Quality
 - The Agency for Toxic Substances and Disease Registry
 - The Indian Health Service

Authorities and governance



* With the exception of regulatory research integrity activities of the FDA.

An institution's responsibility to ORI – compliance and assurance

- **Compliance**

- Have *written* policies and procedures for addressing allegations of research misconduct
- Respond to allegations of research misconduct in a thorough, competent, objective and fair manner
- Foster an environment that promotes the responsible conduct of research
- Protect the positions and reputations of good faith complainants, witnesses and committee members
- Ensure the cooperation of respondents; Cooperate with HHS during the research misconduct hearing or compliance review
- Assist in administering and enforcing any HHS administrative actions
- Have an active assurance of compliance

- **Assurance**

- Institutions are required to have an assurance on file with ORI that states that the institution has written policies and procedures for responding to allegations of research misconduct and complies with its own policies and procedures. If the institution is too small to handle research misconduct process, ORI will work with the institution to implement a process for handling misconduct proceedings

An institution's responsibility to ORI – records

- Maintenance and custody of research records
 - Take reasonable steps to secure research records and evidence needed to conduct the proceedings
 - Give the respondents copies and/or supervised access to research records
 - Maintain records for 7 years of research misconduct proceedings

Research misconduct proceedings – the players

- Research Integrity Officer (institutional official with primary responsibility for assessing allegations of scientific misconduct)
 - Implement procedures for assessing scientific misconduct
 - Appointing the inquiry & investigation committee
 - Reporting to ORI
- Complainant – the person bringing forth a good faith allegation of research misconduct
- Respondent – the person subject to the research misconduct proceedings
- Inquiry committee – committee charged with conducting the inquiry phase of a research misconduct proceeding
- Investigation committee – committee charged with conducting the investigation phase of a research misconduct proceeding

Requirements for findings of research misconduct

- Three criteria for findings of research misconduct
 - There is a significant departure from accepted practices of the relevant research community; and
 - The alleged misconduct is committed intentionally, knowingly or recklessly; and
 - The allegation is proven by a preponderance of evidence
- If the institution's procedures include an appeal process, the appeal must be completed within 120 days
 - Applies to appeals that could result in reversal or modification of the findings of research misconduct

ORI reporting requirements

- Decision to initiate an investigation
 - Name of respondent and nature of allegation
 - PHS applications or grants involved
 - Basis for recommending that investigation is warranted
 - Any comments on the report from respondent or complainant
- Documentation of decision not to proceed with conducting an investigation
- Final outcome of the investigation
 - Copy of the final investigation report
 - Notice of final decision/action and institutional administrative actions
- Notice of planned termination of investigation
- At any stage under the following circumstances:
 - Immediate health hazard
 - Criminal violation
 - Need to protect federal funds or equipment
 - Probable that alleged incident could be reported publicly
 - Allegations involve public health sensitive issue
 - Need to protect persons involved

HHS responsibilities

- ORI review - ORI may respond to an institution's allegation of research misconduct at anytime
 - Conducting allegation assessments
 - Does allegation fall within the definition of research misconduct?
 - Does it involve PHS support?
 - Reviewing an institution's findings and process
 - Make a finding of research misconduct
- HHS administrative actions
 - ORI may propose administrative actions to the HHS
 - Notifies the respondent in a charge letter which includes ORI's findings of research misconduct
 - Suspension, debarment (from receiving Federal funds)
 - HHS debarment official issues a notice of proposed debarment or suspension as a part of the charge letter
- ORI assistance to institutions
 - Provide information, technical assistance, procedural advice regarding misconduct proceedings

HHS administrative actions

- Clarification, correction or retraction of research record
- Letter of reprimand
- Suspension or termination of PHS grant, contract or cooperative agreement
- Imposition of supervision requirements on a PHS grant, contract or cooperative agreement
- Special review of all requests for PHS funding
- No participation in any advisory capacity to PHS
- Suspension or debarment

Institutional standards

- The rule clearly states that institutions may have internal standards of conduct that are different from HHS standards
- Furthermore, it states that the rule does not limit how an institution handles allegations or misconduct that are not within the definition or do not involve PHS support
- What are other behaviors / practices that may be considered misconduct that institutions may want to address?
 - Coercion

Sources – for detailed information

- 42 CFR Part 93 – “Public Health Service Policies on Research Misconduct; Final Rule”
- Office of Research Integrity – www.ori.hhs.gov

CONFLICTS OF INTEREST

Conflict of interest concerns for Board Members, executives, faculty and staff have become more prominent in recent years due to intermediate sanctions, Sarbanes-Oxley, and anti-kickback laws.

Definition of Conflicts of Interest

- A Conflict of Interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.
- Conflicts of Interest involve the use of a person's authority for personal and/or financial gain.
- Conflicts may involve both individuals and institutions

Why Are Conflicts of Interest a problem?

- May endanger human subjects' safety
- May jeopardize public's faith in findings and/or lead them to question whether the investigator is acting in their best interest or merely using them as a vehicle for conducting research
- May reduce the public's willingness to participate in studies
- May inhibit future discoveries if less support for research

Who Can Have a Conflict of Interest?

- **Individuals**
 - Clinical Investigators
 - Study Coordinators
 - Research technicians
 - IRB members
 - Anyone else involved in technology transfer
- **Institutions**
 - Financial holdings of the institution
 - Allocation of resources for research

Examples of COI Headlines

Gelsinger v. University of Pennsylvania (2000)

- University sued after 18 year old with rare metabolic disorder died while volunteering for a gene transfer clinical trial. The principal investigator failed to disclose the relationship between the investigator, the University of Pennsylvania and Genovo, Inc., maker of the therapy.

Examples of COI Headlines (cont'd)

Wright v. Fred Hutchinson Cancer Center (March 2001)

- Patients in two separate studies brought suit against the Center for alleged research improprieties, much of which were argued to be related to the researchers' and the institution's failure to disclose their financial interests in a collaborating research company.

Examples of COI Headlines (cont'd)

House of Representatives Investigation

- Rep. Billy Tauzin (R-La.) and James Greenwood (R-Pa.) launched a broad investigation into NIH grant-making decisions after discovering alleged improprieties in how grants were distributed by former NCI Director. House Committee sought full accounting of industry payment to NIH employees.

Institutional Conflicts of Interest

- Institutional Conflicts of Interest can occur in a variety of ways. This includes when interests of the institution might affect or appear to affect institutional processes including the conduct, review, or oversight of human research. If an institution owns a financial interest in a company that holds a patent to a new drug or device, a conflict and/or a perception of a conflict can arise.

Above all, conflicts arise when career and personal advancement desires interfere, or appear to interfere, with research objectives.



Public Health Service Regulations

- Regulations are found in: 42 CFR Part 50, Subpart F
- Under the regulations, an investigator must disclose to the institution:
 - Any “significant financial interest” in entities whose financial interests might be affected by the research;
 - the institution must designate an “institutional official(s)” to solicit and review the financial disclosure statements made by investigators
 - Applies to any institution who has signed a Federal Wide Assurance with the Department of Health and Human Services.

PHS Definition

- **PHS regulations define a significant financial interest as:**
 - **Income (salary, royalties and other payments) which when aggregated for the investigator, an investigator's spouse or dependent children exceeds \$10,000 over twelve months OR**
 - **An equity interest (including spouse and dependent children) in excess of \$10,000 or 5% ownership in a single entity**

NIH Grants Policy Statement

- Applies to any entity that gets funding from the NIH
- States that COIs might be handled by:
 - Public disclosure of significant financial interests
 - Monitoring of research by independent reviewers
 - Modification of the research plan
 - Disqualification from participation in all or part of the research
 - Divestiture of significant financial interests
 - Severance of relationships that create actual or potential conflicts

Limits to Disclosure

- **PHS regulations demand reporting of financial interests only.**
- **They do not require recusal by the researchers with a conflict of interest**
- **There is no requirement for notification to research subjects**

IRBs and Conflict of Interest

- **IRB conflict of interest issues are regulated under:**
 - **45 CFR 46.107(e)**
 - **21 CFR 56.107(e)**
- **Under these regulations, “No IRB member may participate in initial or continuing research in which they have a conflicting interest except to provide information requested by the IRB.”**
- **If a conflict is found, an IRB member must recuse him or herself.**

How Should An Institution Respond to the Problem of COIs?

Objective:

The goal of an institution's conflict of interest/conflict of commitment policy should be to:

- Protect the institution
- Protect those who volunteer to participate in the research by **Managing** financial relationships that create the potential for conflicts of interest

Management of COIs

- **The Institution, not PHS, selects the method for gathering information from investigators, determining if a COI exists, and if any COI that exists is properly managed**
- **If an institution determines that an investigator has a conflict, it must report that conflict to the PHS awarding component and explain whether the conflict has been managed, reduced or eliminated**

Management Techniques

- 1) Create a precise definition as to what constitutes a financial COI
 - Determine what standard will be used in evaluating what should be done with a conflict (i.e., “rebuttable presumption of not doing the research vs. “compelling circumstances”)
 - Articulate what is allowed in terms of investments, fees and honoraria, consulting fees, intellectual property rights, enrollment bonuses, payments coupled to results, and spouse/dependent finances
 - Establish enforcement mechanisms/sanctions

Management Techniques (continued)

- 2) Establish a standing COI committee. The committee should be responsible for:**
 - Reviewing any financial interests that may pose a conflict and determine whether disclosure, management, elimination, or another course of action is appropriate.**
 - Documenting the committee's decisions**
 - Monitoring procedures and conditions surrounding research involving a financially interested individual.**
 - Communicating, on a regular basis with the IRB**
 - Developing a process by which COI committee or IRB decisions may be appealed by investigator**

Management Techniques (continued)

- 3) Designate an institutional official(s) to solicit and review financial disclosure statements from investigators, and a separate body to review institutional disclosure statements**
- 4) Allocate space and personnel for maintaining records of investigator and institution disclosures and COI and IRB committee decisions**
- 5) Require that all faculty, key employees, and board members of the Institution should annually complete and submit a Conflict of Interest Disclosure Form.**

Management Techniques (continued)

- 6) Other important methods for dealing with COIs:
- **Ensure representation of public on COI committee**
 - **Design educational programs for all researchers, data managers, IRB members, institutional officials with research and finance decision-making responsibilities**
 - **Establish a firewall between offices responsible for financial decisions and those responsible for research decisions**
 - **Ensure that that scientists and other institutional personnel never accept gifts or favors of more than nominal value from a company with which the Institution has or may have a sponsored-research, licensing or other relationship without the express permission of the Vice President of Research Administration or other member of Senior Management.**

Other Issues to Consider

Points to Consider When Evaluating Financial Interests:

- **How is the research supported or financed?**
- **Where and by whom was the study designed?**
- **Where and by whom will the resulting data be analyzed?**
- **Do individuals or institutions involved:**
 - **Have any proprietary interests in the product including patents, trademarks, copyrights, and licensing agreements?**
 - **Have an equity interest in the research sponsor and is it a publicly held or closely held company?**
 - **Receive significant payments of other sorts (grants, equipment, honoraria, retainers, etc.)**
 - **Receive payment per participant or incentive payments**
- **Given the financial relationships involved, is the institution an appropriate site for the research?**

Where is the Issue of Conflict of Interest Going From Here?

- **Greater focus on the issue from Congress**
- **Increased regulation and guidance**
- **Institutions will need more precise policies and procedures which lay out not only a definition of conflict of interest, but also structures, policies and procedures for identifying, eliminating, disclosing, and managing conflicts of interest, such as:**
 - **Clear recognition of institutional conflicts**
 - **Clear separation of research administration and financial administration (e.g., technology licensing) within the institution**
 - **More detailed reporting**
 - **Disclosure of conflicts on informed consent**
 - **Delegation of conflicts review function to IRB or a separate conflicts committee**

How do you support institutions dealing with COI issues?

A Conflict of Interest review includes:

- **Assessing an institution's compliance with related regulatory requirements on reporting financial interests**
- **Identifying potential individual conflicts of interest (board members, executives, faculty, staff)**
- **Identifying potential institutional conflicts of interest**
- **Identifying potential Institutional Review Board conflicts of interest**
- **Evaluating procedures to manage or eliminate conflict of interest scenarios**
- **Recommending changes to internal policies and procedures relating to conflicts of interest**
- **Providing training to board members, executives, faculty, and/or staff on current conflict of interest issues, regulatory requirements, and industry best practices**

Conflict of Interest Case Study

Case Study 1

Dr. Smith is an investigator in several studies testing drugs in human subjects. The sponsors of each individual study are large pharmaceutical companies such as Pfizer, Merck, and Aventis.

During the trial period, Dr. Smith agrees to be a consultant for Merck to evaluate and assess their current protocols as well as give insight on recent research developments with other pharmaceutical companies. For these services she has been paid \$10,000 in the past 12 months.

Is this a potential conflict of interest?

If so, how should this potential conflict of interest be addressed?

Conflict of Interest Case Study (cont.)

Discussion

Assume that the investigator would do nothing that would compromise the integrity of the research but is willing to take steps to manage the potential conflict anyway in order to reduce the risk? If so, what would you choose?

- 1. Require that the investigator disclose his/her financial interest in publications or in public discussions of the research?**
- 2. Require that the investigator terminate all consulting activities during the course of the study?**
- 3. Remove the investigator from any or all of the following: patient recruitment and selection, treatment, data analysis?**
- 4. Require the investigator be removed from the study?**

Financial Management Considerations

Treatment of Residual Balances—Could be viewed as a kickback

Finders fees or other incentives—is this an inducement to investigators to cram subjects into studies?--
Could be viewed as a kickback

Double Dip—payments from grants/trials and insurers

Preventing Allegations of Double Billing and Kickbacks

- Prepare a Billing Plan
- Knowing the costs of the study is not enough—Need to know who will pay which costs and have a plan to promote timely and appropriate billing of trial costs
- Develop a billing plan that clearly differentiates between costs borne by sponsor and costs borne by other parties
- Establish bright line methods of dealing with residual balances
- Educate investigators on the danger of incentives and finders fees being regarded as a payment to induce enrollment of patients into trials

National Coverage Decision

- NCD (9/19/00) Defines requirements and procedures for submitting “routine costs” associated with “qualifying” clinical trials
- Available at <http://www.cms.gov/quality/8d2.htm>

Medicare Basics of Billing:

Medicare generally does not reimburse for purely experimental medical care, even if there is no other source of payment

If a service/item is provided or reimbursed by another payor (including industry-sponsored, federally sponsored clinical trials and or by private insurance), Medicare cannot be billed. Need to prevent the “double dip”!

Recent government enforcement

- Rush University Medical Center in Chicago agreed to pay one million dollars and make program changes after a voluntary disclosure in a federal fraud settlement. (December 2005) concerning billing Medicare for routine clinical trial costs.
- Allegations that:
 - Medicare was billed for services paid for by study sponsors
 - Medicare was billed for services indicated as free to subjects in the consent document
- Some Rush departments were apparently over-billing, some billing correctly, some not billing for trial costs.

Government enforcement

- Independent coverage analysis of every study was needed to determine who pays for what services and which studies qualify for coverage under the NCD.
- Database of all trials was created and training on charge capture process and coding was performed.

QUESTIONS? COMMENTS?