

Research Compliance 101:

The Basics of Research Compliance
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Presentation Overview

- Your Position on the Team: Defining Your Role & Setting Up Shop
 - Source of Compliance Obligations
 - Operational Models
- Players on Other Teams: Knowing the Regulators
 - Applicable regulations defined by research subject matter and funding
 - The Line-up of “Players”
- Teammates: Working with Your Research Compliance Partners
 - Regulatory Committees – IRB, IACUC, etc.
 - Other Compliance Units
 - Legal Office
- Play-by-Play Analysis
 - Hot Topics: Plays to Watch
 - Case Scenarios for Discussion

Your Position on the Team: Defining Your Role

- **Wide variation in job descriptions for “Research Compliance Officer”:**
 - Duties may or may not include human subject research, animal research, export controls, conflict of interest, clinical trials, grant management, research misconduct, export controls, environmental health and safety, etc.
 - Duties driven by scope of research and size of organization.



Know Your Team's Research

- Know the research so you can know the regulations. Regulations drive compliance responsibilities.
- Get in the loop – Know what research projects are coming down the road so that you can be prepared in advance.
 - Avoid the “Compliance is always the last to know” syndrome.”
 - Be a “proactive resource,” not a “reactive process.”

Rulebooks: Source of Compliance Obligations

- Sentencing Guidelines – provides general compliance program structure, but more familiar in healthcare arena.
- OIG Foray – 2005, Notice of Proposed Rulemaking published on draft compliance program guidance from HHS OIG for recipient's of PHS funds. Later withdrawn.
- FARS Contract Requirements – Dec. 2008 Code of Business Ethics and Conduct for certain acquisition contracts.
- Subject matter regulations – source of requirements specific to particular areas.
 - Remember state and local regulations in addition to federal regulations.



The Front Office: Operational Models for Research Compliance Offices

- **Reporting:**
 - to Board of Directors.
 - to Chief Compliance Officer
 - to compliance committee
 - to high level research administrator
- **Multiple Compliance Units/Officers:**
 - E.g., healthcare compliance officer, research compliance officer, privacy officer
 - Multiple units require means for coordination of efforts and communication, formal and informal
- **Documentation – policies and procedures**
 - Overarching standards of conduct vs. subject matter specific standards
 - Mechanisms for reporting compliance concerns
 - Mechanisms for investigation of non-compliance
 - Sanctions

Knowing the Line-up of Regulators

- Broad scope of research activities and confluence of various activities in one research project mandates the need for expertise in multiple regulatory requirements and practice/guidance from multiple regulatory agencies.



Whose are the major players?
Get out your “agency trading cards.”

Note: Players not necessarily presented in the order that they may appear on your playing field.



DHHS Dept. of Health & Human Services

- **League:** DHHS is a league, as opposed to a team.
- **Teams in the DHHS League:** Office of Public Health & Science, Food & Drug Administration, Centers for Medicare & Medicaid Services, National Institutes of Health.
- **Major Stats:** Department of Health and Human Services (DHHS) is the federal agency regulating a large portion of federally supported human subject research.
 - Website: <http://www.hhs.gov/>
- **Watch for these Plays:**
 - Huge source of federal funding.
 - Debarment & suspension regulations.




HHS OIG
Dept. of Health & Human Services Office of Inspector General

- **League:** DHHS
- **Facts:** The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452 (as amended), is to protect the integrity of Department of Health and Human Services (HHS) programs, as well as the health and welfare of the beneficiaries of those programs.
 Website:
<http://oig.hhs.gov/index.asp>
- **Major Stats:** OIG has a responsibility to report both to the Secretary and to the Congress program and management problems and recommendations to correct them. OIG's duties are carried out through a nationwide network of audits, investigations, inspections and other mission-related functions performed by OIG components.
- **Plays to Watch for:**
 - Self-Disclosure Protocol
 - Corporate Integrity Agreements



CMS
Centers for Medicare & Medicaid Services

- League:** DHHS
- Facts:** The Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration, is the federal agency that administers the Medicare, Medicaid and Child Health Insurance programs.
- **Major Stats:** Clinical trial billing must follow CMS guidelines.
 Website:
<http://www.cms.hhs.gov/>
- **Watch for these Plays:**
 - Clinical Trial Policy
 - Recovery Audit Contractors



FDA
Food & Drug Administration

- **League:** DHHS
- **Facts:** One of the functions of the FDA is to evaluate clinical studies submitted in marketing applications for new human drugs and biological products and marketing applications and reclassification petitions for medical devices.
- **Major Stats:** Regulates, drugs; devices; biologicals and radiation emitting products; food, including dietary supplements; and combination products.
 Website:
<http://www.fda.gov/>
- **Plays to Watch for:**
 - New requirement for IRB registration.
 - Sponsored vs. Investigator Initiated Trials
 - FDA Inspections



NIH
National Institutes of Health

- **League:** DHHS.
- **Facts:** Primary federal agency for conducting and supporting medical research.
- **Major Stats:** Office of Extramural Research (OER) is NIH office that interfaces with the biomedical research community by guiding investigators through the

process of attaining grants funding and helping them understand and navigate through federal policies and procedures.

Website:
<http://www.nih.gov/>

Plays to Watch for:

- Possible expansion of conflict of interest regulations
- Clinical Translational Science Awards




OBA
Office of Biotechnology Activities

- **League:** DHHS. Part of the Office of Science Policy within NIH.
- **Facts:** Responsible for advisory committees that prescribe guidance for regulation of recombinant DNA. Also supports policy development in the area of "dual use" research.
- **Major Stats:** Works through Recombinant DNA Advisory Committee and Institutional Biosafety Committees.

Website:
<http://oba.od.nih.gov/oba/index.html>

• **Watch for these Plays:**

- NIH Guidelines for Research Involving Recombinant DNA Molecules




RAC
Recombinant DNA Advisory Committee

- **League:** DHHS. Committee of NIH's Office of Biotechnology Activities.
- **Facts:** The RAC is a panel of up to 21 national experts in various fields of science, medicine, genetics, ethics, and patient perspectives that considers the current state of knowledge and technology regarding recombinant DNA research. A key role of the RAC is to advise the NIH Director and the NIH Office of Biotechnology Activities (OBA),

which is the NIH locus of oversight for recombinant DNA research. RAC recommends changes to the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

Major Stats: The RAC reviews research proposals involving human gene transfer research, or "gene therapy" as it is often called. All human gene transfer trials occurring at or sponsored by institutions receiving NIH funds for recombinant DNA research must be submitted to OBA for review by the RAC.

Website:
http://oba.od.nih.gov/rdna_rac/rac_about.html



OHRP
Office of Human Research Protections

- **League:** DHHS.
- **Facts:** OHRP protects the rights and welfare of subjects involved in research conducted or supported by the Department of Health and Human Services (HHS) and helps ensure that such research is carried out in accordance with the regulations at 45 CFR part 46 (the "Common Rule").
- **Major Stats:** Provides oversight and guidance for Institutional Review Boards (IRBs). IRBs that review research funded by agencies that follow the Common Rule must have an OHRP approved Federalwide Assurance and register with OHRP.
 - Website: <http://www.hhs.gov/ohrp/>
- **Plays to Watch for:**
 - Determination Letters
 - Updated Guidance documents



ORI
Office of Research Integrity

- **League:** DHHS
- **Facts:** ORI promotes integrity in biomedical and behavioral research supported by the U.S. Public Health Service (PHS). It functions in accordance with 42 CFR Parts 50 and 93. ORI monitors institutional investigations of research misconduct and facilitates the responsible conduct of research (RCR) through educational, preventive, and regulatory activities.
- **Major Stats:** The responsible institutional official must assure on behalf of the institution that the institution-- (1) Has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) Complies with its own policies and procedures and the requirements of this part.
 - Website: <http://ori.dhhs.gov/>
- **Plays to Watch for:**
 - Filing of annual report.



DSMBs
Data Safety Monitoring Boards

- **League:** DSMBs serve as "referees" to ensure the safe conduct of regulated biomedical research.
- **Facts:** NIH requires that each Institute and Center have a plan for the appropriate oversight and monitoring of the conduct of clinical trials to ensure the safety of participants and the validity and integrity of the data for all NIH-supported or conducted clinical trials.
- **Major Stats:** The establishment of the data safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. The data and safety monitoring functions and oversight of such activities are distinct from the requirement for study review and approval by an Institutional Review Board (IRB). (See NIH Policy for Data and Safety Monitoring.)
- **Plays to Watch for:**
 - New FDA guidance regarding reporting of unanticipated problems.



OLAW
Office of Laboratory Animal Welfare

- **League:** DHHS
- **Facts:** Responsible for implementing *PHS Policy on Humane Care and Use of Laboratory Animals* & U.S. *Principles for Utilization and Care of Vertebrate Animals used in Testing Research and Training.*
- **Major Stats:** Provides oversight and guidance for Institutional Animal Care and Use Committees (IACUCs). Institutions that conduct animal research supported with PHS funding must file an Animal Welfare Assurance and Annual Reports.
 - Website: <http://grants1.nih.gov/grants/olaw/>
- **Watch for these Plays:**
 - New information regarding IACUC's use of designated member review.



BIS
U.S. Bureau of Industry & Security

- **League:** U.S. of the Department of Commerce
- **Facts:** Regulates export of items that have "dual use" – both commercial and military or proliferation applications.
 - Responsible for issuance of export licenses when required.
- **Major Stats:** Responsible for administering and enforcing application of the Export Administration Regulations (EAR, 15 CFR Parts 730-774).
 - Website: <http://www.bis.doc.gov/>
- **Watch for these Plays:**
 - Actual Exports & Deemed Exports
 - Fundamental Research Exemption



OFAC
Office of Foreign Assets Control

- **League:** Dept. of the Treasury
- **Facts:** Administers and enforces economic and trade sanctions in support of U.S. foreign policy and national security. Plays important role in U.S. export controls regulatory regime.
- **Major Stats:** Maintains "Specially Designated Nationals List" (SDNL) of persons to whom payments cannot be made. Maintains list of countries against which the U.S. has imposed sanctions (e.g., Cuba, North Korea).
 - Website: <http://www.treas.gov/>
- **Watch for these Plays:**
 - Be sure to check SDNL List for payments inside & outside of U.S.



NSF National Science Foundation

- **League:** Independent government agency.
- **Facts:** Provides funding support for fundamental science and engineering to advance health and welfare and secure the national's defense.
- **Major Stats:** Separate grant award requirements and policies.
 - Website: <http://www.nsf.gov/index.jsp>
- **Watch for these Plays:**
 - NSF has its own COI and research integrity/research misconduct requirements.



OSHA Occupational Health & Safety Administration

- **League:** Dept. of Labor
- **Facts:** Under the Occupational Safety and Health Act of 1970, employers are responsible for providing a safe and healthy workplace for their employees. OSHA's role is to promote the safety and health of America's working men and women by setting and enforcing standards; providing training, outreach and education; establishing partnerships; and encouraging continual process improvement in workplace safety and health.
- **Major Stats:** OSHA regulations that come into play in research arena include: Bloodborne Pathogens Standard; Personal Protective Equipment Standard; Hazard Communication Standard; and Occupational Exposure to Hazardous Chemicals in Laboratories.
 - Website: <http://www.osha.gov/>
- **Plays to Watch for:**
 - General Duty Clause



EPA Environmental Protection Agency

- **League:** EPA is an independent agency with cabinet representation.
- **Teams on EPA League:** Office of Prevention, Pesticides, and Toxic Substances; Office of Solid Waste and Emergency Response; Office of Air and Radiation; Office of Solid Waste and Emergency Response; and Office of Water.
- **Facts:** Regulates storage and disposal of many chemicals and materials used in health care and research laboratories.
 - Website: <http://www.epa.gov>
- **Watch for these Plays:**
 - Self-Disclosure Initiative



USDA
United States Dept. of Agriculture

- **League:**
- **Facts:** USDA Department of Agriculture (USDA) provides funds to researchers to address national problems and needs related to agriculture, the environment, human health and well being, and communities.
- **Major Stats:** USDA is responsible for implementation of Animal Welfare Act Regulations governing use of certain animals in research. USDA and Centers for Disease Control (CDC) are responsible for administering regulations regarding use of Select Agents in research.
 - Website: <http://www.usda.gov/wps/portal/usdahome>
- **Plays to Watch for:**
 - Annual inspection of animal facilities.



Examples: Multi-Agency Involvement

- NIH funded clinical trial with unapproved drug that is being conducted at multiple sites within the U.S. and at one site in Africa.
- National Science Foundation funded animal study of white-collared sooty mangabey in which these animals, which have natural resistance to SIV, are infected with HIV.

Examples: Multi-Agency Involvement

- Trial on unapproved drug for which the sponsor is intending to formally propose that the FDA approve the new drug for sale and marketing in the U.S. and for which the principal investigator, who holds an equity interest in the sponsor pharmaceutical company, must report serious and unexpected adverse events.

Your Teammates

- Working with your compliance partners.
 - Regulatory Oversight Committees
 - Auditors
 - Other Compliance Officers
 - Legal Counsel
 - Compliance Oversight and Enterprise Risk Management Committees



Regulatory Oversight Committees: DHHS Human Subject Protections

- 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:
- **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



Regulatory Oversight Committees: FDA Human Subjects Protections

- FDA regulations at 21 C.F.R. 56 govern Institutional Review Boards that review clinical investigations regulated by the FDA as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA.



Regulatory Oversight Committees: IRB Functions

- An **institutional review board** (IRB), is a group that has been formally designated by an entity where research is conducted to approve, monitor, and review research involving human subjects. Its aim is to protect the rights and welfare of these research subjects. FDA and HHS regulations have empowered IRBs to approve, require modifications in, or disapprove research.



Regulatory Committees: USDA and OLAW Requirements

- USDA: Animal Welfare Act and implementing regulations, 9 CFR Parts 1 to 4.
- OLAW:
 - Public Health Service Policy
<http://grants1.nih.gov/grants/olaw/references/phspol.htm>
 - Government Principles
<http://grants1.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples>
 - Guide for the Care and Use of Laboratory Animals
http://www.nap.edu/openbook.php?record_id=5140
 -



Regulatory Committees: IACUCs

- Both USDA and OLAW require functioning IACUCs to review animal research protocols.
- Specific membership requirements, including DVM, scientist experienced in animal research, and community member.
- IACUCs are also responsible for semi-annual inspection of facilities in which animal research and related activities occur.



Regulatory Committees: OBA Requirements

- NIH Guidelines at http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm must be followed for all NIH funded recombinant DNA research.
- Guidelines require establishment of Institutional Biosafety Committee and appointment of Biosafety Officer.



Regulatory Oversight Committees: IBC

- Institutional Biosafety Committee establishment is governed by NIH Guidelines. FAQ re. IBC establishment is at http://oba.od.nih.gov/rdna_ibc/ibc_faq.html#IBC_FAQ007
- Members must include two unaffiliated members who represent community.
- Annual report to NIH re. IBC membership is required.
- Minutes of IBC meeting must be provided to public upon request.



Regulatory Oversight Committees: COI Regulatory Authority

- Conflict of Interest (COI) is defined by DHHS for purposes related to PHS funded research or FDA marketing application procedures. 42 CFR Part 50, Subpart F (grants) and Part 94 (contracts) apply to institutions that apply for PHS grants, research contracts, or cooperative agreements.
- NSF COI regulations are in the NSF Grantee Standards at http://www.nsf.gov/pubs/policydocs/pappguide/nf09_1/aag_4.jsp#IVA.



Regulatory Committees: COI Compliance Mandate

- Grantees must certify on grant applications that they have a process to identify conflicting interests, and that existing conflicts will be reported to PHS awarding components prior to expenditure of any funds under the award, with assurance that conflicts have been managed, reduced or eliminated. Certification of compliance with NSF requirements also is required.



FDA Financial Disclosure Re. COI

- 21 CFR Part 54 regulates financial disclosure by clinical investigators so that the FDA can evaluate potential bias in the outcome of the study because of payments, proprietary interests, or equity interests held by the investigator. This information is used in the FDA's assessment of the reliability of the data. FDA requires completion of Forms 3454 or 3455.



Regulatory Committees: COI Committees

- Institutions frequently establish one or more internal COI committees to collect annual COI disclosures; to determine what "significant financial interests" constitute a financial conflict of interest; and to determine how financial conflicts of interest should be managed, reduced or eliminated.
- The IRB also must consider conflict of interest in its review of human subjects research.



COI and IRS Form 990

- Form 990, entitled "Return of Organization Exempt From Income Tax," is a report that must be filed each year with the Internal Revenue Service (IRS) by organizations exempt from Federal income taxes under section 501 of the Internal Revenue Code, and whose annual receipts are "normally" more than \$25,000 a year. It is an information return and not an income tax return since the organizations that file it do not pay income taxes (except, in certain cases an organization may have to pay an "unrelated business income tax").
- Line 75d asks whether the organization has a written conflict of interest policy.

Regulatory Committees: Research Misconduct Inquiry & Investigation Process

- PHS regulations regarding research misconduct are at 42 CFR Part 93. ORI policies are at <http://ori.dhhs.gov/policies/statutes.shtml>
- NSF policies and regulation regarding research misconduct are at 45 CFR Part 689.
- PHS regulations:
 - Sec. 93.307(c) states the purpose of an inquiry is to conduct an initial review of the evidence to determine if an investigation is warranted.
 - Sec. 93.307(d) states an Investigation is warranted if: (1) There is a reasonable basis for concluding that the allegation involves PHS supported research, research training, or activities related to that research or research training and falls within the definition of research misconduct, and (2) preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance.



Regulatory Committees: Inquiry and Investigation Committees

- Institutions may establish standing or ad hoc committees to conduct inquiries or investigations into allegations of research misconduct.
- Members with appropriate scientific expertise must be on committee.
- Members who conduct inquiry also may conduct investigation.
- Committee works with research integrity officer (RIO) and institution's administrative official



Other Compliance Officers

- Healthcare Compliance Officer
- Privacy Officer
- Information Security Officer
- Research Integrity Officer
- Environmental Health & Safety Officer
 - Radiation Safety Officer
 - Biosafety Officer

Internal & External Auditors

- Research compliance office should coordinate their compliance goals and efforts with internal audit offices.
- Internal audit may be able to provide help in determining success of compliance efforts by developing auditing programs to test compliance initiatives.
- External auditing expertise may be required to assist in review of complex compliance issues.
- Consult with legal counsel in developing audit plans and in retaining external auditors.

Legal Office

- Relation between Compliance Office and Legal Office is crucial.
- Issues of attorney client privilege and attorney work product require discussion and advance planning in carrying out audits and investigations.

Compliance Committee

- Board of Trustees or Directors may or may not have a special research compliance committee similar to Board of Trustee/Director “audit and compliance” committees in the healthcare arena.
- If Board of Trustees/Directors does not have a separate research compliance committee, consider an executive level compliance oversight committee that reports to Board or to highest level of administration.
 - Compliance committee should be involved in establishment of compliance goals and monitoring/auditing plans.

Risk Mgmt. Offices & Enterprise Risk Mgmt. Efforts

- Research Compliance Office should communicate regularly with risk management office concerning issues that are noted during compliance reviews.
- Research compliance issues should be addressed as part of enterprise risk management efforts through development of policies, procedures, training and monitoring.
- Adequacy of insurance coverage should be considered and extent of coverage should be considered when new lines of research are undertaken.

Lines of Responsibility

- When the fly ball comes, know who is supposed to make the catch!



Make sure Everyone Knows the Signals

- Develop a communications plan
- Develop standard forms and processes for internal reporting among units
- Determine which unit has responsibility for reporting to particular regulatory agencies
- Determine which unit has record keeping responsibility



Playbook

- Develop simple processes that everyone can follow for recurring matters.
 - Forms + Follow Through
- Make sure that policies and processes among units mesh and do not conflict.
- Consolidate when possible by involving multiple units from the beginning, e.g., a single fact-finding process in an investigation.
- Get clear on when and how legal counsel should be involved.



Play-by-Play Analysis

- Know how to “Issue Spot”
- Notify and involve appropriate personnel
- Identify relevant regulations and policies
- Send appropriate notifications and gather pertinent documents
- Identify gaps and develop corrective action
- Implement corrective action and document
- Monitor and review

Team Training

- Scarce training resources and trainee time.
- Coordinate training efforts.
- Tailor training approaches to subject matter and audience.
- Include appropriate training documentation
- Validate success of training efforts.
- Keep training fresh.

Look at the Instant Replay

- In the wake of a problem, review what was done and perform post-game analysis.
- Use results to develop corrective action.
- Coordinate overall compliance goals and compliance audit plans.
- Consult with legal counsel in developing audit plans and approaches.



Hot Topics: Plays to Watch

- Senators Grassley and Kohl introduced a revised version of the Physician Payments Sunshine Act of 2009 on Jan. 22, 2009.
- Drug, device, biologic, and medical supply manufacturers would be required to report annually certain payments or other transfers of value provided to physicians, or physician medical or group practices.

**Hot Topics: Plays to Watch
New PhRMA Guidelines**

- New voluntary Pharmaceutical Research & Manufacturers of America Code on Interactions with Health Professionals, effective Jan. 2009 at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>
- Prohibits provision of entertainment or recreational items (e.g., sport tickets, trips); permits “modest, occasional meals” in certain circumstances.
- Provides guidance for educational meetings.
- No more “non-educational” freebies.

**Hot Topics: Plays to Watch
CT Billing**

- Continuing debate on “therapeutic intent.”
- New Medicare guidance re. off-label use of drugs in cancer care and impact on CT billing.
- “Reversal” of Medicare Learning Network Guidance on pursuing patients for collection of denied claims in clinical trials.
- Making sure there is consistency among protocol, CT Agreement and informed consent.

Hot Topics: Subject Injury

- Medicare Secondary Payer Rule.
- Impact on Clinical Trial Agreements.
- Impact on non-Medicare participants and informed consents.

Hot Topics: International Trials

- Court clears way for lawsuits alleging Pfizer experimented on Nigerian children.
- The Washington Post (1/31, A7, Stephens) reports that the U.S. Court of Appeals for the 2nd Circuit in New York Friday "revived two lawsuits brought against Pfizer by Nigerian families who say the giant drugmaker used their children in an illegal test of an experimental antibiotic." The Post notes that the actions had been dismissed by a lower court judge "who said they should have been brought in Nigeria," adding that the move is being seen as "a precedent affecting other American companies accused of wrongdoing overseas. The lawsuits seek unspecified damages on behalf of the families, who say Pfizer violated international law by testing the drug, known as Trovan (trovafloxacin), on perilously ill children without their knowledge. Eleven children died during the 1996 clinical trial, carried out during a record meningitis epidemic. ...
- FROM AHLA Health and Life Sciences Daily, February 2, 2008

Hot Topics: Plays to Watch Animal Research and Animal Rights Activists

- Support of new administration for greater access to records requested by public through Freedom of Information Act.
- Animal rights activists frequently request information through FOIA.
- Impact on researchers and research.

Hot Topics: Plays to Watch Continuing Litigation

- Arizona court overturned the dismissal of a lawsuit by the Havasupai Indian tribe claiming that Arizona State University and the University of Arizona researchers misused blood samples taken from tribal members for diabetes research in the 1990's by using it for research into schizophrenia, inbreeding and ancient population migration without the tribe's permission. (Washington Post 11/29/08)

**Hot Topics: Plays to Watch
New FDA Guidance Regarding Adverse Event
Reporting**

- Adverse events vs. unanticipated problems.
- New guidance at <http://www.fda.gov/cder/guidance/OC2008150fnl.htm>
- Places more responsibility on sponsors for aggregating information in multisite trials and determining which adverse events are “unanticipated problems.”

**Hot Topics: Plays to Watch
Research Grants: Effort Reporting**

- Effort reporting is a method of verifying that the percentage of effort expended by research personnel on activities is commensurate with the percentage of salaries and wages charged to those activities or accounts. It is a requirement for all recipients of federal funds. Effort reports play a role in documenting cost sharing commitments.

**Hot Topics: Plays to Watch
Research Grant Accounting Oversight**

- Yale University agreed to pay \$7.6 million to settle issues arising from a federal research grant accounting investigation, including issues of cost transfers and effort reporting.
 - Yale University Office of Public Affairs press release, December 23, 2008.

**Hot Topics: Plays to Watch
Export Controls**

- Implementation of export controls regulations of deemed exports in research lab setting. Recent Univ. of TN case.
- Preservation of fundamental research exemption.
- Laptop and GPS rules.

**Hot Topics: Plays to Watch
HIPAA HIO Guidance**

- New guidance on application of HIPAA Privacy Rule to Health Information Organizations that use computer networking to electronically link PHI among separate covered entities.
- Guidance at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthit/index.html>



Hitting the Field

Case Scenarios for Discussion



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