Research Compliance Conference

Research Compliance 101

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Presentation Objectives

- **How research fits in to compliance objectives.**
- **Outline some of the ways that a provider organization can feel the impact of non-compliance in research.**
- **Detail the fundamentals and events that serve as the underpinnings for research compliance**
- **What are the top 10 major risks that compliance officers must address in the research area?**
- **What you need to know in order to fine tune your research compliance program.**

Compliance & Research

Compliance & Research
Introduction

- **Compliance Officers focus on reducing risks.**
- **Day-to-day activity is informed by various external and internal drivers.**
  - OIG Work Plan
  - Internal compliance work plan
  - HIPAA guidance
  - Data security
  - Results of internal and external audits
  - Adherence to the Seven Fundamental Elements of an Effective Compliance Program

Compliance Officers function to protect their institutions from risk, preserve the integrity of their clinical programs, and enhance the safety of their institution's facilities, data, patients, staff, and physicians.

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Compliance & Research
Introduction

- Achieving such a broad objective requires careful review and ongoing assessment of key functions.
- For many provider organizations, research represents an area that is often targeted as high risk.
- Many health care systems and hospitals have active research programs while many others have research occurring on their premises which they may not be as involved in as they would like or should be.
- Research compliance is seen as a specialty area but the risks in this space are considerable.

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Compliance & Research
Overview of Pressures

Volume of Activity	↑
Complexity	↑
Competition	↑
Scrutiny	↑
Demand for Accountability	↑
Large investments in facilities	↑
Pressure to maintain / reduce admin costs	↑
Funding levels	→

During a time where many of these growth factors occurring simultaneously, many organizations have failed to make an associated *and proportionate* investment in the compliance infrastructure necessary to keep risks in check.

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Compliance & Research
Overview of Complexities

- **Primary Risk Areas:**
  - Faculty start-ups
  - Conflicts of Interest
  - Equity interests of institution
  - International collaboration
  - Sub-recipient monitoring
  - Human subjects protections
  - Researcher misconduct
  - OMB circular A-21
  - Cost accounting standards
  - Tech transfer
  - Clinical trials billing
  - Stem cells and other scientific controversy
  - grants.gov and clinicaltrials.gov
  - HIPAA / Privacy
  - Investigator Salary and Effort
- **Competing or Misaligned Interests:**
  - Principal investigators ("PIs")
  - Research support (research asst., CRCs, RRNs, etc.)
  - Students
  - Board members
  - Tax payers
  - Federal agencies
  - Commercial sponsors
  - Suppliers and procurement specialists
  - Foundations
  - Donors and investors
  - Human subjects
  - Advocacy groups
  - Institutional, Departmental, and Divisional administrators

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Compliance & Research
Rationale for Having a Research Compliance Program

- **Oversight, management, and mitigation of the risks cited on prior slide.**
- **Leadership and guidance for the various constituents and stakeholders with a role in preserving institutional integrity and compliance.**
- **Need for experts who understand that health care research is fundamentally different from other operational activities of a health care organization.**
  - Activities "look" the same as other key practices and processes, but the nuance and dynamics are often mistaken or incorrectly applied.
  - This can exacerbate risks.

It is imperative that organizations seeking to grow (or nurture) research, at a minimum, should have the following:

1. ***Sufficient compliance and administrative leadership over research***
2. ***Effective policies & SOPs***
3. ***Solid internal controls (both pre- and post-award)***

The absence of such items may result in additional pressures and the realization of the risks referenced in this presentation.

Compliance & Research

Rationale for Having a Research Compliance Program

- **There are multiple financial, operational compliance challenges that underscore the need for research expertise among compliance professionals.**
  - Informed consent.
  - Medicare as a secondary payer.
  - Researcher misconduct and COI in research.
  - Financial research administration, grants accounting, award monitoring.
  - Credentialing of research coordinators who perform tests, do basic clinical diagnostic procedures, access secure floors or review the eHR.
  - Budgeting and contracting for services associated with clinical trials.
  - Fair Market Value for physician services rendered in connection with clinical trials.

Huge Issue that is Often Left to Internal Audit to Monitor

Institutions that are "performance sites" for health care research need a research compliance program that can manage compliance risks, preserve regulatory integrity yet allow scientists to pursue innovative research opportunities that can lead to breakthroughs and advancements.

Implications of Non-Action

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Implications of Non-Action
What Happens When Oversight is Insufficient?

- **Reputational Impact**
  - No organization wants to become the "poster child" for wrongdoing.
    - Northwestern ($5.5MM), Hopkins ($2.6MM) & Harvard ($2.4MM) – effort
    - Penn – informed consent & COI
    - Mayo Clinic ($6.5 MM) & Yale ($7.6MM) – cost transfers, effort, cost sharing
    - Rush ($1MM) – clinical trial billing
    - Vermont – research misconduct
    - U. of Oklahoma – informed consent
  - These cases, and many others, have brought considerable unwanted attention to research institutions.
- **Regulatory Consequences**
  - Corporate Integrity Agreements and Certification of Compliance Agreements
  - Loss of letter of credit funding authorization
  - Suspension, debarment, and exclusion of individuals (or even entire programs or institutions) engaged in research
  - Additional monitoring

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Implications of Non-Action
What Happens When Oversight is Insufficient?

- **Operational Changes**
  - In the absence of effective controls, the impact on operations is often significant. It can result in many of the following outcomes:
    - Additional training
    - New policies and SOPs
    - New work flow
    - Re-organization of personnel
    - Additional approvals and review periods from superiors
    - Heightened credentialing
- **Financial Repercussions**
  - Fines and penalties
  - Cost to enhance operations
  - Litigation and legal defense costs – considerable liability risk
  - Funding loss
  - Financial impact of reputational consequences cited on prior slide

Implications of Non-Action
What Happens When Oversight is Insufficient?

- **Risk reduction and avoidance of these undesirable outcomes is a priority for Compliance Officers.**
- **There are no shortage of reasons why a Compliance Officer may view their responsibilities as particularly challenged when they work in an organization with research programs.**
  - Multiple stakeholders
  - Major funding
  - Opportunity for abuse
  - Physician and/or Principal Investigators' objectives not always aligned with institutional objectives
- **These challenges are often exacerbated by the prevailing mindset of a PI and the pressures they are under to bring in funding.**

Given the issues, Compliance Officers have unique points of view on how to fulfill their responsibilities and ensure that risks are reduced for the "research enterprises" that they support.

Major Risk Areas Affecting Research Compliance

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Major Risk Areas Affecting Research Compliance
Introduction

- **A Compliance Officer has many resources at its disposal to help mitigate risks associated with research administration.**
  - Policies and SOPs
  - Training
  - Audits / investigations
  - Threat of regulatory intervention
  - Law
  - Culture
- **Among the most compelling allies that Compliance Officers have are PIs.**
  - Tone at the top
  - Given resources to "follow the rules" most will do the right thing
- **All research stakeholders are accountable for assisting the organization with fulfilling its compliance imperatives.**

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Major Risk Areas Affecting Research Compliance
Introduction

- **There are a number of risks to mitigate and deserve the focus for your research compliance program. The top ten (in no particular order) are the following.**
  1. **Effort Reporting**
  2. **Clinical Trial Billing**
  3. **Financial Management of Federal Awards** (*sub-recipient monitoring, charging practices, cost transfers*)
  4. **Export Controls**
  5. **Animal Research**
  6. **Human Research Protections** (*informed consent, IRB, ethics, meeting inclusion/exclusion requirements*)
  7. **FDA Regulations** (*sponsor-investigators, GMPs, etc.*)
  8. **Conflicts of Interest** (*including fraud and abuse*)
  9. **Research Integrity and Research Misconduct**
  10. **Privacy and Security**

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Effort Reporting

Effort reports must reflect all compensated activities, including those efforts not federally funded such as instruction, governance, and academic advising. Labor related charges generally comprise the majority of direct research costs.

How Do You Know If Your Organization Is at Risk?

- **Are Effort Reports certified by an individual with full knowledge of all aspects of the employee's effort?**
- **Are Effort Reports certified by the employee?**
- **Does effort reasonably reflect the activity for which an individual is paid by their institution?**
- **Do the Reports reflect all of these activities performed by the individuals?**
- **Is there after the fact confirmation to ensure that charges reasonably approximate estimates of effort?**

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Effort Reporting

Strategies To Reduce the Risk

- **Determine if payroll posted to research projects exceeds yearly salary cap set by the sponsor.**
  - Review a test sample of research projects to ensure the salary posted per person doesn't exceed (e.g. NIH salary cap from Oct 1, 2008 - Dec 31, 2009 $191,300).
    - Likely the PI or Co-PI
    - Likely a long-term and large federally sponsored grant
- **Ensure salary posted to research projects agrees with corresponding expected salary based on percentage effort listed on effort report.**

Old Issues, New Focus

- **$5.5 million settlement - Northwestern University**
  - Qui tam lawsuit
  - False Claims Act
  - "Knowingly or recklessly overstated salary rates for faculty"
  - University lacked system to reconcile proposed effort and actual effort
- **$2.6 million settlement – Johns Hopkins University**
  - Flaws in committed effort
  - Overcharging for fringe benefit
- **$2.4 million settlement - Harvard Medical School**
  - Internal review reported to NIH
  - Grew into DOJ investigation

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Effort Reporting

Strategies To Reduce the Risk

- **Ensure effort reports are certified within the institutional time period for certification and are not out of compliance.**
  - Review a test sample of effort reports and determine if they were signed in the appropriate time period.
- **Obtain list of salary transfers to determine if there are problems and other systemic risks associated with effort reporting.**
- **Review vacation days, sick days, PTO, bonuses and overtime payments to ensure they are properly recorded to the research project and not skewing total salary posted to the research project.**

Oversight of Effort Report depends on finely tuned work flow and an appreciation of roles and responsibilities. Training is key as the regs are complex and dynamic. Periodic reviews and selective monitoring is essential.

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Clinical Trial Billing

Medicare "double billing" has been the subject of numerous OIG/DOJ investigations and settlements. To avoid running afoul of the regs, it is important to track clinical/standard of care vs. "research only". Non-compliance can result in considerable penalties and the risk of PHS funding cuts.

How Do You Know If Your Organization Is at Risk?

- **Are processes highly manual or do you have a CTMS?**
- **Are the often multiple competing interests and agendas understood? Roles and responsibilities are clear?**
- **Is there annual training activity on billing, study accounts, coverage, etc?**
- **Is there a research compliance curriculum for PIs? Coordinators? Billing personnel? Those who develop coverage analyses?**
- **Do sponsor contracts/agreements clearly state which patient care costs are covered?**
- **Are sponsors being billed and payments being collected (and credited to study accounts) in a timely manner?**

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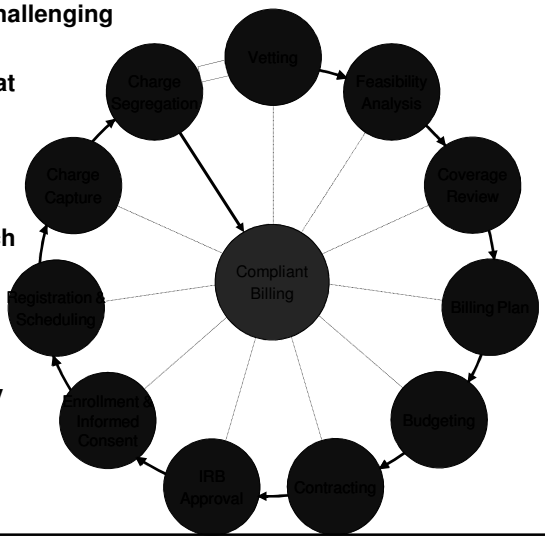
Clinical Trial Billing

Synchronous Work Flow is Key

- **From the standpoint of optimizing process, it is vital to spend time early on to plan for potentially challenging billing issues.**
- **Effective internal controls at the outset of a study initiation can help reduce risk.**
- **Oversight, tools, IT, and dedicated personnel at each step in the process continuum are essential.**
- **While this illustration highlights each step as its own process activity, many of these can be done simultaneously.**



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Clinical Trial Billing

<u>What Are Some Strategies To Reduce the Risk?</u>

- **Standardization and Central Support Services**
  - Decentralization leads to disparate, fragmented work flow.
  - Many organizations have created a "fee for service" model to perform these services.
- **Implementation of clinical trials management systems (CTMS)**
- **Realigning organizational designs**
- **Training**
- **Requiring development and use of a Medicare Coverage Analysis at the outset of the planning for any trial to be hosted by your organization**
- **Pre-Study Planning, Vetting, and Financial Evaluation**
- **Periodic Study Account Review and Monitoring**
- **Compliance Oversight**
- **Close Out**
- **Strategic Review**

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Financial Management of Federal Awards

Managing a research portfolio that includes federally sponsored awards implies additional oversight. Effort reporting, sub-recipient monitoring, cost transfers, cost sharing, and dealing direct & indirect cost accounting concerns create considerable challenges which must be addressed by a compliance program.

How Do You Know If Your Organization Is at Risk?

Effort

- **Is committed effort on awards greater than 100 percent?**
- **Who is certifying effort? Suitable means of verification?**
- **Are faculty members with "other" duties charging 100 percent to sponsored projects?**
- **Is committed cost sharing being reported?**

Cost Transfers

- **Does your organization have an irregularly high number of cost transfers? Are too many of them greater than 90-120 days after original charge?**
- **Is documentation on cost transfers adequate?**

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Financial Management of Federal Awards

How Do You Know If Your Organization Is at Risk?

Sub-Awards

- **Are internal controls in place to perform monitoring on sub-awards?**
- **Are there unallowable costs or lack of cost sharing documentation on sub-awards?**

Charging & Accounting Practices

- **Are there charges for routine admin support inappropriately charged as direct costs?**
- **Are departmental/institutional business managers allocated to multiple awards?**
- **Have audits been performed to review expenditure allowability?**
- **Are close outs revealing irregular accounting or billing practices?**
- **Are policies routinely followed for closing out accounts or do a number of accounts for dormant research remain open?**

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Financial Management of Federal Awards
Strategies to Reduce the Risk

All Areas

- **Roles & responsibilities**
- **Policies & SOPs**
- **IT solutions rather than paper-based work flow**
- **Include these areas in monitoring plans**
- **Update and enforce training for PIs and other relevant stakeholders**

Effort

- **Update processes and systems and assign a "champion" to monitor**
  - Timely payroll adjustments
  - Track total committed effort
  - Use cost share accounts
- **Review NOGAs to identify greater than 100% committed effort**
- **Review actual IBS relative to proposed IBS**
- **Ensure that cost sharing implications are understood**

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Financial Management of Federal Awards
Strategies to Reduce the Risk

Cost Transfers

- **Require documentation (reason/nature of error, explanation of how the cost benefits the project it is being moved to, etc.)**
- **Faster account set up…consider pre-award accounts**
- **Standardize forms**

Sub-recipient Monitoring

- **Develop sub-contracting templates (meeting A-133 requirement)**
- **Develop process to pre-qualify sub-recipients**
- **Monitoring protocols (PI-approval for invoices, etc.)**

The complexity of the regulations for federal awards and the implications of non-compliance are severe. AMCs, in particular, depend on federal funds so ensuring that research compliance efforts include ample understanding of the difference between federal and commercial awards is critical.

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Export Controls

Export Controls are important federal regs that define the compliant manner with which foreign nations and foreign countries are to be dealt with in terms of technology, IP, services, and data associated with research activities.

What is Affected by Export Controls?

- **Foreign students and researchers participation in research associated with a controlled technology**
- **Ability to provide services to foreign nationals**
- **Ability to send controlled equipment internationally**
- **Disclosure of proprietary information**

Oversight of Export Controls

1. **Dept. of State: Military technology**
2. **Dept. of Commerce: "Dual use" technology**
3. **Dept. of Treasury: Prohibits transactions with adverse countries**

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Export Controls

What Are Some Strategies To Reduce the Risk?

- **Does the information being disseminated meet any of the eligible exclusions?**
  - Employment
  - Laptop
  - Education
  - Fundamental Research Exclusion
- **Review documentation of export control SOPs and license determinations.**
- **Review transactions to ensure that no controlled chemicals, bio-agents or toxins are being shipped internationally.**
- **Review transactions to ensure that no actual or potential military applications or economic protections issues are possible.**

The internationalization of the research community demands that those in positions to oversee compliance are aware of these risks, appreciate export controls risk, and take steps to educate constituents.

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Animal Research

Institutions that perform research on animals are required to obtain the review and approval of the institution's IACUC. Animal research hinges on compliant purchasing, supplying, and care of animals. Financial management is challenging given usage, per diem and surgical procedures involved.

How Do You Know If Your Organization Is at Risk?

- **Has the IACUC's membership, structure, effectiveness, and approval process been reviewed?**
- **Are policies and procedures sufficient for outlining expectations and work flow?**
- **Are animal per diem rates representative of the actual costs?**
- **Are animal charges properly allocated to the benefiting research projects?**
- **Are all protocols for continuing research reviewed and approved (when required)?**

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Animal Research

What Are Some Strategies To Reduce the Risk?

- **Craft a policy and SOP that details animal subject protocols, including the calculation for per diem.**
- **Enhance and update training of administrative personnel related to animal subject policy and procedures.**
- **Include additional monitoring of animal research:**
  - Periodically review selection of awards to ensure that protocols are active
  - Review calculation of per diem billing rates

Human Research Protections

Significant HRPP failures have resulted in patient injury and death, government enforcement including prosecutions, and career-ending sanctions. HRPPs must be designed to assure prospective IRB review and institutional oversight, and conduct of trials in compliance with applicable regulatory mandates.

How Do You Know If Your Organization Is at Risk?

- **Are HRPP leaders, IRB members, researchers, and research staff all *well-informed* about their respective roles and obligations?**
- **Is the *HRPP perceived* as a barrier to scientific progress or as a partner in assuring research quality?**
- **Do IRB *operating procedures* meet standards established by OHRP and FDA – and are they actually operationalized?**
- **Does the IRB clearly *document* its basis for approving proposals, including compliance with special requirements for research involving vulnerable populations?**

Human Research Protections

How Do You Know If Your Organization Is at Risk? (continued)

- **Are sample *consent and authorization* documents thoroughly reviewed?**
- **Is there a *"speak up" culture* or do staff self-censor?**
- **What is the *history* of institutional and investigator inspections?**
- **Are risks to the HRPP generally and to individual participants adequately analyzed and is institutional focus concentrated on *higher risk activities?***

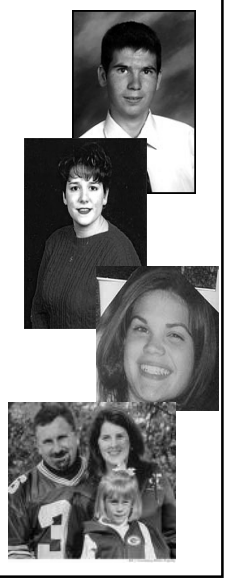
What Are Some Strategies To Evaluate the Risk?

- **Review Audit sources**
  - OHRP Self-Assessment Tool: http://www.hhs.gov/ohrp/qi/; and FDA Self-Evaluation Checklist for IRBs: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm118063.htm
  - OHRP Determination Letters: http://www.hhs.gov/ohrp/compliance/letters/index.html and FDA Warning Letters: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

Human Research Protections

Other Strategies To Evaluate the Risk?

- **Review IRB rosters to assure IRB membership appropriately reflects the types of studies reviewed.**
- **Review IRB minutes to assure conflicted members were excused from all meetings during deliberations and votes.**
- **Review sample publications against IRB approval records to determine whether studies actually received prior approval.**
- **Review documentation of researcher training/certifications to assure compliance with grant or other applicable mandates.**
- **Review IRB minutes and interview staff to assure that problems are promptly identified and addressed and that any mandatory reporting is promptly completed … don't delay for overwrought investigation.**



Human Research Protections

What are Some Strategies to Reduce Risk?

- **Accreditation ... but note limitations**
- **Tracer Audits**
  - Document consistency?
  - IRB files and minutes indicative of appropriate and thorough reviews?
  - Has the study been re-approved at least annually and were the necessary findings made?
  - Does the informed consent form comply with applicable requirements?
  - Do investigator files include copies of signed consent forms for all subjects, including screen failures?
  - Timely reporting of events (i.e., AEs and SAEs), protocol deviations, etc.
- **SOPs for managing instances of non-compliance**

Audited protocols are rarely error-free, and multiple levels of controls exist to avoid major problems (IRB, institution, and sponsor oversight; investigator supervision). But controls cannot be relied upon until tested and systematic deficiencies must be continuously identified and addressed to avoid future recurrence.

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FDA Regulations

The U.S. Food and Drug Administration has been under fire for perceived regulatory failures thought to have played a role in approval or failure to timely remove dangerous products from the market. The current administration has prioritized compliance and enforcement.

How Do You Know If Your Organization Is at Risk?

- **Do the IRB or HRPP leaders consistently and accurately identify the need for an *investigational new drug* application or *investigational device exemption?***
- **Do *sponsor*-investigators understand their *additional responsibilities*?**
- **Are key functions on research studies *delegated to staff? Documented?***
- **What mechanisms are in place to assure appropriate *qualifications* of investigators, research staff, and others responsible for research activities?**
- **To what extent does the institution *rely on industry monitoring*?**
- **Does "*manufacturing*" occur in-house? Properly, consistently *monitored?***

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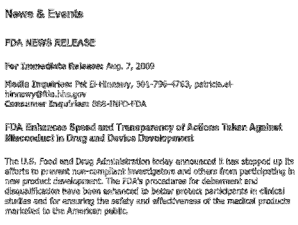
FDA Regulations

What Are Some Strategies To Evaluate and Reduce the Risk?

- **Review a sample of research studies involving any drug or device**
  - Is the sponsor clearly identified in the research agreement and/or protocol?
  - Have the appropriate permits been secured?
  - If a NSR study, has the IRB made and documented the necessary determinations?
  - If the drug or device is manufactured in-house, are GMP/QSR requirements followed?
  - Is product accountability appropriately handled?
- **What are other organizations doing?**
  - IND/IDE support units (voluntary, mandatory)
  - Centralized regulatory support
  - Specialized education and training unique to FDA-regulated studies. "Professionalizing" study support staff



News & Events

FDA NEWS RELEASE

For Immediate Release: Aug. 7, 2009

Media Inquiries: Pat El-Hinnawy, 301-796-4763, patricia.el-hinnawy@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA Enhances Speed and Transparency of Actions Taken Against Misconduct in Drug and Device Development

The U.S. Food and Drug Administration today announced it has stepped up its efforts to prevent non-compliant investigators and others from participating in new product development. The FDA's procedures for debarment and disqualification have been enhanced to better protect participants in clinical studies and for ensuring the safety and effectiveness of the medical products marketed to the American public.

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Conflicts of Interest

Conflicts of interest must be systematically identified and appropriately managed to assure the integrity of research programs and avoid legal, regulatory, and reputational risk.

How Do You Know If Your Organization Is at Risk?

- **Do policies *identify who* is subject to conflict disclosure/management?**
- **Do policies define which conflicts must be disclosed, when, and to whom?**
- **Are potential conflicts *consistently, accurately, and timely identified*?**
- **Are data consistently collected *prior to submission* of grant applications and reported *prior to expenditures*?**
- **Are *new conflicts* tracked following initial disclosure prior to grant award?**
- **How do you recognize, address *non-financial conflicts* (i.e., IRB or staff)?**
- **What kind of *monitoring and controls* are in place to assure compliance?**
- **Do *sponsor-investigators* in FDA-regulated studies collect required data or rely on the institution to do so?**

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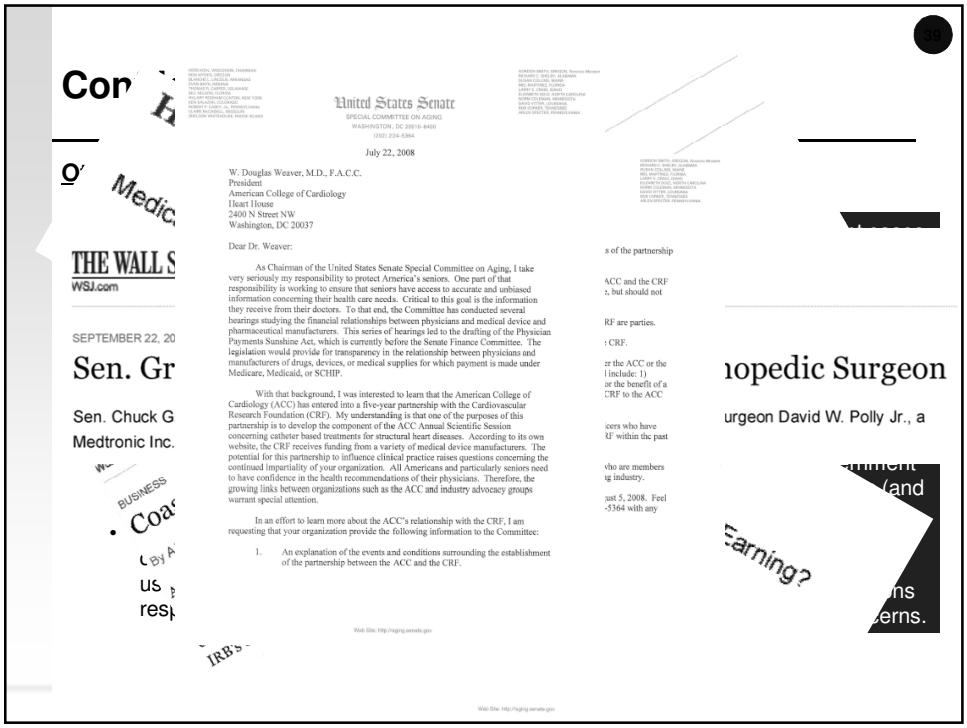
Conflicts of Interest

What Are Some Strategies To Evaluate and Reduce the Risk?

- **Perform a *policy audit*: do current SOPs actually comply with regulatory mandates?**
  - Work plan sources should include at least NIH grants policy statement (and 2007 OPERA findings), and AAHRPP accreditation requirements (if applicable)
- **Review research and related agreements with sponsors**
  - Are services rendered necessary and appropriately documented
  - Do payments for services of researchers/consultants accurately reflect the fair market value of the services provided



United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510-6400
(202) 224-5364

July 22, 2008

W. Douglas Weaver, M.D., F.A.C.C.
President
American College of Cardiology
Heart House
2400 N Street NW
Washington, DC 20037

Dear Dr. Weaver:

As Chairman of the United States Senate Special Committee on Aging, I take very seriously my responsibility to protect America's seniors. One part of that responsibility is working to ensure that seniors have access to accurate and unbiased information concerning their health care needs. Critical to this goal is the information they receive from their doctors. To that end, the Committee has conducted several hearings studying the financial relationships between physicians and medical device and pharmaceutical manufacturers. This series of hearings led to the drafting of the Physician Payments Sunshine Act, which is currently before the Senate Finance Committee. The legislation would provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

With that background, I was interested to learn that the American College of Cardiology (ACC) has entered into a five-year partnership with the Cardiovascular Research Foundation (CRF). My understanding is that one of the purposes of this partnership is to develop the component of the ACC Annual Scientific Session concerning catheter based treatments for structural heart diseases. According to its own website, the CRF receives funding from a variety of medical device manufacturers. The potential for this partnership to influence clinical practice raises questions concerning the continued impartiality of your organization. All Americans and particularly seniors need to have confidence in the health recommendations of their physicians. Therefore, the growing links between organizations such as the ACC and industry advocacy groups warrant special attention.

In an effort to learn more about the ACC's relationship with the CRF, I am requesting that your organization provide the following information to the Committee:

1. An explanation of the events and conditions surrounding the establishment of the partnership between the ACC and the CRF.

Web Site: http://aging.senate.gov

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Conflicts of Interest

Model Programs, Best Practices and Other Trends

- **"Zero tolerance" policies**
- **Transparency policies – voluntary public reporting**
- **Centralized electronic data capture and reporting annually and concurrent with any changes**
- **Standardized management approaches to facilitate consistency and appropriateness of management plans**
- **PR response plans in the event of unanticipated attention**
- **Proposals, model programs, etc.**
  - AAMC/AAU
  - IOM

Although the regulatory and industry "best practices" landscape is in flux, steps can and should be taken now to evaluate program strengths and weaknesses and prepare for what lies ahead.

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Research Integrity & Research Misconduct

"Misconduct" is a term of art that refers to fabrication, falsification, and plagiarism ("FFP") in connection with PHS-sponsored research. Research integrity programs and policies seek to prevent, identify, and address misconduct and other similar problems that can undermine research.

How Do You Know If Your Organization Is at Risk?

- **Who is the research integrity officer? Deciding official?**
- **Are there written policies and procedures that address the requirements of the PHS regulations? Assurance? Annual reports?**
- **Are PIs and staff knowledgeable on standards, reporting requirements?**
- **Do policies clearly identify and distinguish among preliminary assessments, inquiries, and investigations?**
- **What systems have been implemented to assure confidentiality? Protection of whistleblowers?**
- **Do policies clearly distinguish between misconduct and the following:**
  - "Honest error"/non-compliance that is not FFP?
  - Differences in opinion, authorship disputes, etc.

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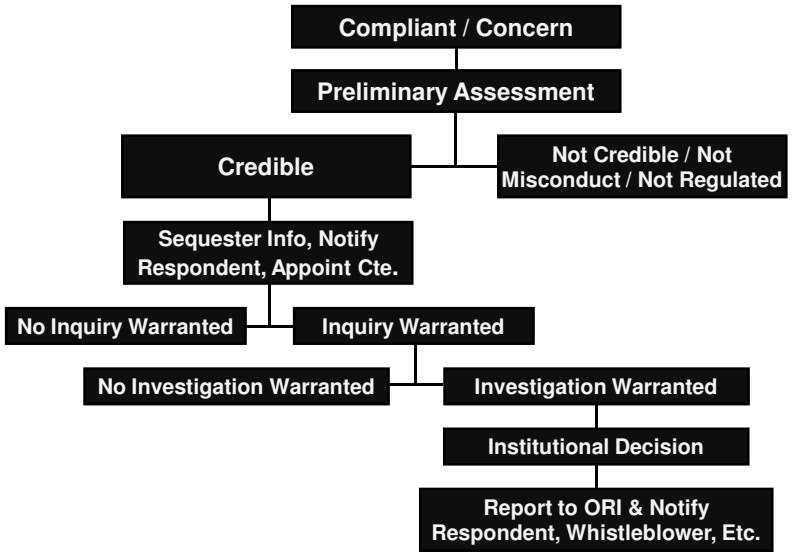
Research Integrity & Research Misconduct
Assessment and Action



Research Integrity & Research Misconduct

What Are Some Strategies To Reduce the Risk?

- **Education**
- **Triage and Consults**
- **Clearly define roles of all involved**
- **Consider lessons learned**
  - Purpose of investigation (substantiate or refute allegations, not root causes; questions for panel)
  - Communications with whistleblowers and respondents
  - Insulation of review panels from external influence

Additional Resources: http://ori.dhhs.gov/

Research misconduct allegations must be taken seriously and carefully addressed. Even an investigation that fully exonerates a respondent may have lasting negative consequences for the respondent if not handled appropriately.

Privacy and Security

HIPAA/HITECH and other laws and regulations impose obligations on health professionals who control records necessary for research to maintain their confidentiality and privacy. HITECH has substantially increased potential penalties for non-compliance.

How Do You Know If Your Organization Is at Risk?

- **Do HIPAA training focus *education* relevant to related obligations, including Common Rule/FDA privacy and confidentiality requirements, FDA data integrity mandates, and applicable state laws?**
- **Is a single person (or two) *accountable* for privacy and security compliance across the institution, regardless of use of the data?**
- **If researchers function within the boundaries of a covered entity (or business associate), do research staff understand their *record retention* obligations?**

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Privacy and Security

How Do You Know If Your Organization Is at Risk? ***(Continued)***

- **If the researcher is a covered entity, have applicable *business associates* been identified? If a potential BA, have covered entities been identified?**
- **How are participant complaints handled? Who manages OCR inquiries? What *SOPs* have been developed to address potential *security breaches*?**
- **How is *recruiting* handled?**
- **How are privacy and security considerations addressed in *unregulated research?***
- **Are *research computers/systems* appropriately protected? Are there SOPs to prevent, identify, and address security breaches?**

Strong health information privacy and security practices can help assure necessary access to health records and avoid exposure to enhanced penalties that may be imposed under HITECH.

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Privacy and Security

What Audits May Be Appropriate?

- **Consents, authorizations and waivers**
  - Do consents describe how data will be handled and what the risks are?
  - Are authorizations or waivers documented for approved research activities and are they stored to assure sufficient retention?
  - Is the waiver appropriately documented?
  - Who is accounting for disclosures made pursuant to the waiver? Is the necessary information being reported to HIM or the privacy office, as applicable?
- **Limited data sets**
  - Are the necessary elements omitted from data exchanged in the project?
  - Is a data use agreement on file?
- **Security**
  - Include the research program in any information security audits
- **Other exceptions**
  - Have state privacy laws and regs been integrated into research policies and SOPs?

Privacy and Security

What are Some Strategies to Reduce Risk?

- **Educate PIs, research staff, and IRBs about available mechanisms to improve privacy protections, including certificates of confidentiality**
- **Consider standardization opportunities**
  - IRB applications
  - Informed consent and authorization documents
  - Registry policies
  - Computer systems and policies, particularly relating to information security
    - What happens when computers are purchased using grant funds?
- **Determine whether research facilities and staff are adequate to address privacy and security requirements**
  - Is there sufficient storage space to assure appropriate documentation retention?
  - What electronic systems are used to support the research enterprise?
    - Do they comply with HIPAA security requirements
    - 21 CFR part 11 (if FDA-regulated research is conducted)?

Challenges & Opportunities:
How To Deal with the Complexity of Research Compliance Issues

Challenges

- **Conducting an effective research compliance program requires specialized expertise**
  - HCCA and other organizations offer comprehensive training programs tailored to the needs of different HRPP participants
    - Investigators
    - Research staff
    - Compliance officers

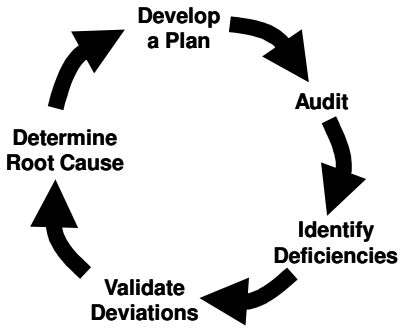
- **Research programs present special challenges, as described above, sometimes exacerbated by decentralized or siloed management and oversight functions**
- **But … research compliance can be facilitated effectively within any structure**
  - Culture of compliance
  - Program support

Lessons Learned

- **Engage investigators and research staff proactively**
- **Catalog mechanisms to identify potential deviations from legal/regulatory standards**
  - Adverse event/deviation reports
  - Sponsor/CRO monitoring visits
  - Regulatory inspections – OHRP, FDA, etc.
  - Regulatory/guidance notices – determination letters, warning letters, etc.
  - Compliance reviews
  - Internal audits
- **Require reporting to HRPP and Compliance Officer of observed deviations**
  - Research agreements
  - Institutional SOPs

CQI

- **Develop a standard SOP for receiving and responding to deviation reports, regardless of source**
  - Validate deviation occurred as reported
  - Determine cause of deviation
  - Develop corrective and preventive action ("CAPA") plan
  - Audit to assure CAPA plan is appropriately implemented and effectively avoids future recurrence
- **Use experience to ensure that research support is both**
- **(1) sufficient; and**
- **(2) appropriately allocated**



Opportunities

Strong Research Compliance Programs

- **Facilitate efficient conduct of research**
- **Can result in stronger, more consistent external support**
- **Encourage participation (research volunteers)**
- **Reduce individual and institutional risk**
  - Regulatory
  - Financial
  - Reputational
  - Etc.
- **Result in more satisfied researchers, participants, administrators, and regulators**

Questions and Discussion