

# EMERGING ISSUES IN RESEARCH COMPLIANCE

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# Agenda

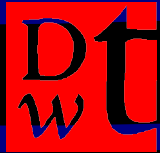
- **Background**
- **Research Compliance — Why Now?**
- **Lessons from Health Care Compliance**
- **Emerging Issues**
  - **Accreditation of Research Protection Programs (HRPPs)**
  - **The Challenge of HIPAA**



# Regulatory Scheme

## **Federal Policy for the Protection of Human Subjects (the “Common Rule”)**

- 45 CFR Part 46, Subpart A
- Applies to 17 federal agencies, including DHHS and SSA
- Each agency may also have its own rules (VA, Education)
- Applies to any research that is federally funded



# Regulatory Scheme

## **Food and Drug Administration (FDA)**

- 21 CFR Parts 50 and 56
- Applies to investigational drugs, biologics and devices, including privately funded clinical trials





# Allocation of Compliance Responsibilities

Institution or  
Medical Center  
*Facilities and Staff,  
Administrative Oversight*

Faculty Appointment  
Medical Staff  
Investigator Agreement

Investigator  
*Conduct of the Protocol  
Clinical Oversight*

Institutional Conflicts of Interest  
Billing & Coding for Services  
(False Claims)  
Financial Reporting (False  
Claims)  
Grant Management  
Patient Safety  
Insurance  
Unspent Funds  
Relationship with Investigators  
— Stark  
— Fraud and Abuse  
— Private Inurement  
Scientific Misconduct  
—As a medical staff issue  
—As an employment issue

IRB  
*Protection of Human Subjects  
Scientific Integrity*

Informed Consent  
Patient Safety  
Adverse Events  
Clinical and Scientific  
Reporting

Composition and Deliberation  
Conflicts of Interest  
▪ IRB Members  
▪ Investigator  
Review of Protocol  
Informed Consent and Other Protections  
Ongoing Monitoring  
Scientific Misconduct  
Financial Incentives for Recruitment  
Pre-Recruitment Activity Content  
Confidentiality & Privacy  
HIPAA and State Laws



# Research Compliance – Why Now?

- Highly publicized patient deaths since 1999
- Reshuffling of federal authorities
- Increased federal enforcement 2000-01
- Increase in law suits, including suits naming IRB members
- Qui Tam (Whistleblower) Statute applies to federally funded grants



# Research Compliance – Why Now?

- Increased use of non-academic trial sites
- Use of contract organizations adds more players seeking piece of research dollar (profit motive)
- Contraction of health care reimbursement leads to providers looking for other revenue sources
- Renewed interest in publicly funded research after 9/11 to respond to bioterrorism?



# Lessons from Health Care Compliance

- Laws are complex and overlapping
- Enforcement resources were limited and uncoordinated
- Operation Restore Trust (a successful pilot) led to increased funding for enforcement
- Prosecution of “poster child” cases
  - big names
  - big consequences (exclusion from program)



# Lessons from Health Care Compliance

- Increase in qui tam activity, including professional whistleblowers
- Promulgation of “compliance guidance” and voluntary disclosure protocols
- Now compliance programs are “unwritten condition of participation”
- Providers are bearing the cost



# Lessons from Health Care Compliance

As applied to research

- Also complex set of laws, limited and uncoordinated enforcement resources
- Many research institutions are also Medicare providers
- Poster child approach is appealing (e.g., Johns Hopkins)
- The government views the health care compliance/enforcement as successful



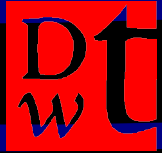
# IOM Report

- 2 phase study commissioned by DHHS
- 1st phase report: *“Preserving the Public Trust; Accreditation and Human Research” (August 2001)*
- Advocates a move from reliance on IRBs to broader human research protection programs (HRPP)
- Endorses accreditation standards developed by NCQA as a VA pilot



# NCQA v. AAHRPP

- NCQA incorporates methods familiar in health care compliance
- Emphasis on written policies, education, training, documentation
- Specificity of standards more likely to change behavior than AAHRPP's general statements, but does not address role of sponsors or CROs
- If VA adopts accreditation, it will affect academic medical centers that have affiliations with VA hospitals



# Benefits of Accreditation

- Uniformity of standards across institutions
- External independent validation of an institution's performance in protecting human research subjects
- Eventually a “seal of approval” or “standard of excellence”



# Challenges of Accreditation

- Expensive
- Favors large institutions
- Community hospitals may have to rely on outside IRBs
- Requires changes in behavior and practices of investigators as well as institutional staff
- Administrative burden



# OPEN QUESTIONS

- Will it be applied to proprietary IRBs, CROs, SMOs or non-biomedical research institutions?
- How will investigators be reviewed beyond the review of protocols by the IRB?
- Will research participants be involved in setting performance standards?



# OPEN QUESTIONS

- Are there sufficient mechanisms to hold institutions and sponsors accountable for funding, supporting and rewarding HRPP?
- Can quality improvement and self-assessment mechanisms of accreditation ensure subject safety?



# Limitations to HRPP Accreditation

- Does not address other research compliance issues, such as:
  - Financial accounting
  - Billing and coding
  - Use of unspent funds as a tax issue
  - Financial relationships with investigators that implicate Stark or Anti-Kickback
- Overlap with health care compliance



# IMPLEMENTATION

- Government has not decided whether accreditation should be mandated
- Might be effective way for government to shift costs of in the name of self-regulation to institutions and make effective use of its enforcement resources — the health care model
- Like fighting fraud, it's good PR



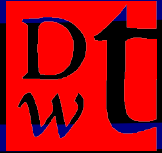
# IMPLEMENTATION

- Implementation is likely not to occur before NCQA and AAHRPP test programs wrap up
- Rulemaking process
- Deferred by war on terrorism or other events?



# IMPLEMENTATION

- Providers/Institutions with significant research \$\$ should:
  - Use proposed guidelines for baseline assessment of research compliance risks
- Providers/Institutions with limited research \$\$ should
  - Strengthen IRB compliance within budgetary constraints, pay attention to related issues



# National Bioethics Advisory Committee

- Recommends legislation to:
  - Create a single federal office to coordinate oversight of human research
  - Develop a unified comprehensive federal policy in a single set of regulations
  - Require certification of investigators, IRB members, IRB staff
  - Require accreditation of sponsors, institutions and independent IRBs



# Challenge of HIPAA

- Final privacy regulations effective 4/03
- Penalties: up to \$25,000 CMP per year; up to \$50,000 in criminal penalties and/or up to one year in prison for each violation
- Will affect how research is conducted
  - Existing databases
  - New databases



# HIPAA Definitions

- **PHI:** Protected Health Information that is or has been electronically transmitted or maintained.
- **TPO:** Treatment, Payment or Health Care Operations — does not include research
- **Consents:** Required for providers to disclose PHI for TPO
- **Authorizations:** Needed for disclosure of PHI outside of TPO



# HIPAA Definitions

- PHI includes demographic information, whether oral or recorded in any form or medium that is:
  - Created or received by a covered entity and
  - Relates to the past, present, or future physical or mental health or condition of an individual, or the past, present, or future payment for the provision of health care to an individual



# HIPAA Requirements for Research

- Permits use and disclosure of PHI for research either with
  - (1) Valid written authorization, OR
  - (2) Approval of IRB or privacy board on specified determinations



# Individual Authorization

- Effective authorization includes
  - Specific description of information to be used or disclosed
  - Person/entity to whom disclosure may be made
  - Purpose/use of disclosure
  - Expiration date
  - Revocation procedure
  - Disclosure that provider will receive remuneration from a third party for granting access to the information (if applicable)



# PHI Obtained in Research That Includes Treatment

- Authorization must
  - Describe extent to which health information will be used or disclosed for treatment, payment or administrative purposes.
  - Identify health information to be used or disclosed for hospital directories, public health purposes, etc.
  - Refer, if applicable, to provider's Consent for Treatment and Notice of Privacy Policies



# Waiver of Authorization

- IRB or privacy board may waive if:
  - Use or disclosure of PHI involves no more than minimal risk to individuals
  - Waiver does not adversely affect privacy rights or welfare of individuals
  - Research cannot practicably be done without waiver
  - Research cannot practicably be done without access to PHI



# Waiver of Authorization

- Privacy risks are reasonable in relation to anticipated benefits
- Plan exists for protection of personal identifiers from improper use and disclosures
- Plan exists to destroy identifiers at earliest opportunity consistent with research
- Adequate written assurance that PHI will not be reused or disclosed to a third party except as required or permitted by law



# Waiver of Authorization

- Documentation of waiver
  - Identify the IRB, date of action
  - State that IRB has made all determinations above
  - Describe PHI for which access is approved
  - State if IRB conformed with normal or expedited review regulations
  - Dated and signed by IRB Chair



# Exception for Preparatory Activities

- No authorization or waiver required if
  - PHI is used solely for review necessary to prepare a protocol or similar purposes
  - PHI is not removed from the covered entity
  - PHI is necessary for research
  - Covered entity obtains specified representations from the investigator/researcher



# Exception for De-Identified Information

- Remove all identifiers with respect to individual, his relatives, employers and household members, including
  - Names
  - All elements of date related to the individual (except year), including birth date, admission date, discharge date, date of death, all ages over 89, all elements (including year) indicative of age (except aggregated category 90 or over is OK)



# Exception for De-Identified Information

- Geographic subdivisions smaller than a state, including address, city, county, precinct, zip code or equivalent geocode
- SSN, phone, fax, e-mail, URL, IP address
- Medical record number, health plan number
- Account number, certificate or license number, vehicle identifiers, serial numbers, license plate number
- Biometric identifiers, voice and finger prints
- Full face photographs and images
- Any other unique number, characteristic, code



# Exception for De-Identified Information

- Covered entity cannot release de-identified information if it has actual knowledge that the information alone, or in combination with other information could identify a person
- Covered entity must control re-identification key



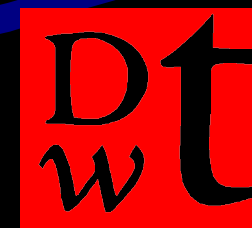
# Alternative to De-Identification

- A “Statistical Waiver”
- Expert opinion that disclosure of PHI would create minimal risk that recipient would be able to identify individual
- Expert must be a person with knowledge of accepted statistical and scientific principles and methods for de-identifying information
- Expert must document the method and results of analysis to justify a determination that the risk is minimal



# Issues

- Effect on existing research databases where not all have been removed, e.g., registries
- How to design an authorization specific enough yet broad enough for more than one use or purpose
- Scope of exception for research preparatory activity
- Effect on certain affiliates of covered entities



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