Compliance Issues for Medical Research at Healthcare Systems

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Driving Forces for Compliance

- **Institutions**
- **Accreditation Agencies & Oversight**
- **Federal Government - Agencies/Offices**
- **State and local Government**
- **Private Sector**
- **Research Participants and Public**

The Government: Developing an Integrated Approach HHS/OIG 2004 Strategic Workplan

- Examine role of IRB's in overseeing clinical research involving children

- Determine if Medicare payments to clinical trials were made in accordance with program specification

- Determine if existing Medicare billing systems can accurately monitor the "appropriateness of these payments"

- Conflict of Interest (COI) regulations

The Government:
Developing an Integrated Approach
HHS/OIG 2004 Strategic Workplan

- **Audit of NIH practices to ensure that grantees are complying with adverse event reporting and monitoring in clinical trial regulations.**

- **Grant auditing to ascertain that indirect and direct cost awarded funds are appropriately allocated to their respective cost definitions.**

- **Compliance with HIPAA regulations on safeguarding participant records with respect to maintaining confidentiality of personal medical records.**

The Government:
Developing an Integrated Approach
HHS/OIG 2004 Strategic Workplan

- Oversight of Intramural Clinical Trials (FDA)

  - **inventory of clinical trials**

  - **develop quality control programs at each FDA center**

  - **ensure research is conducted under appropriate regulatory scheme for product being tested**

  - **initiating mandatory educational and certification program for all FDA clinical investigators on the scientific, regulatory and ethical issues regarding clinical research**

Health System Challenges

- **Multiple sites of care**
- **Geography and proximity of sites**
- **Private Practice Medical/Dental Staff**
- **Workforce Size**
- **Effective Communication to stakeholders**
- **Limited Resources across continuum**

Health System Challenges
Accreditation Agencies & Oversight

- **JCAHO**
- **CLIA**
- **OSHA**
- **FAA**
- **ICC**
- **DOT**
- **Health System multi-specialty Accreditations**

Health System Challenges
Federal, State and Local Government

- **Finance (Medicare, Medicaid, Third Party Insurers)**
- **OHRP**
- **FDA**
- **NIH**
- **HIPAA**
- **OIG**
- **Boards of Professional Practice**
- **IRS**

Research Enterprise

Education Programs

Adverse Event Management

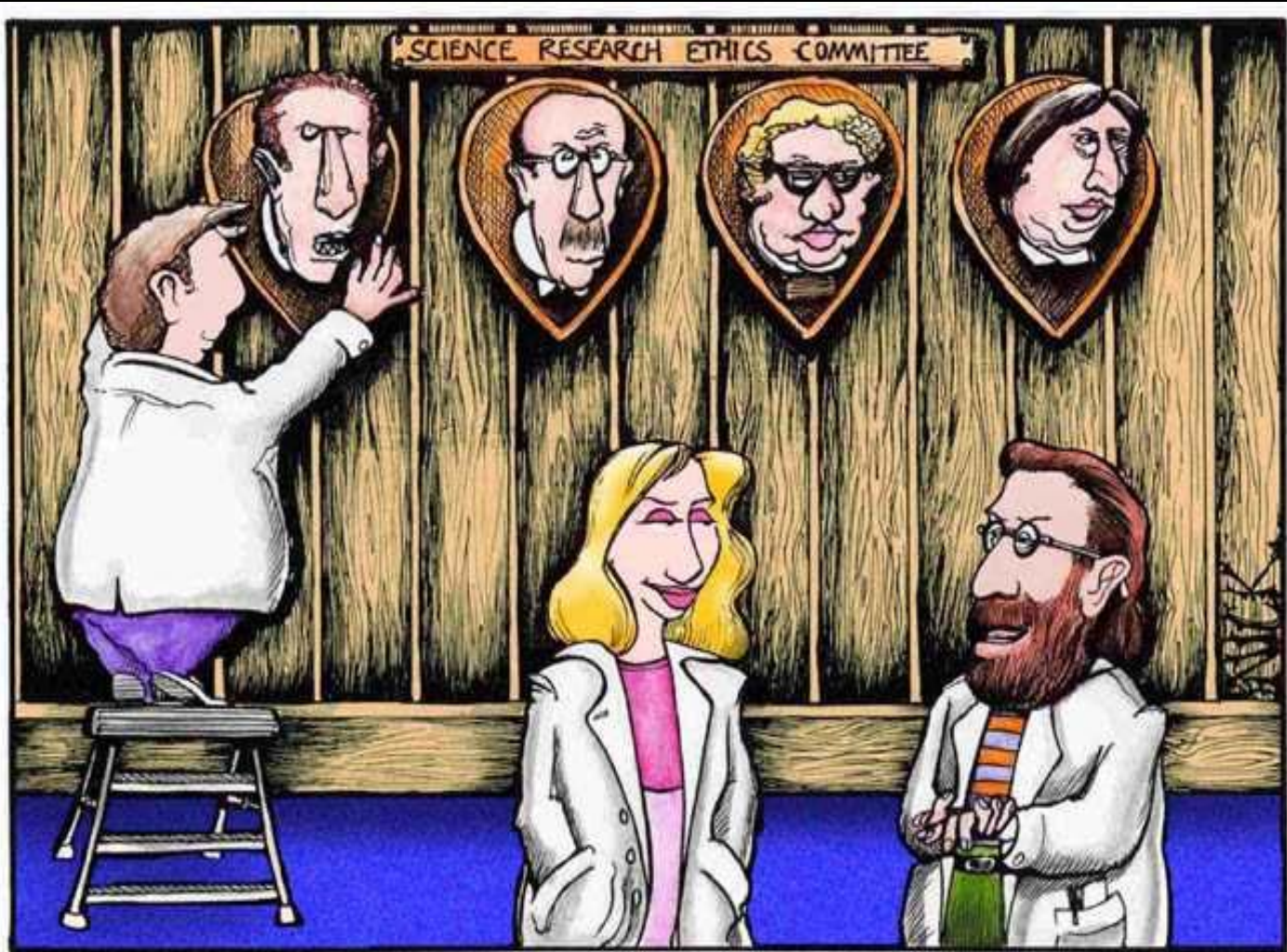**Conflict Management**

Compliance Oversight

IRB

Quality Management

Communications System

Administrative Staff

Information System

"There now. We get our wish of continuing our work unimpeded, and they get their wish of being in a position of direct oversight at all times."

Research Participants

Institutions

Sponsor

IRB

Investigator

Research Participants

Research Team

Advocates

Family

Government

Public

Compliance Stakeholders
Shared Responsibility

- Investigators/Research Team
- Sponsors
- Institutions
- IRBs
- Government
- Private Sector

Private Sector Initiatives

- Certification of Individuals
  - investigators
  - research Coordinators
  - IRB key staff and members
  - key study personnel

- Accreditation of Programs
  - Institution

Health System Perspectives

- **Primary focus is optimum patient care and outcomes**
- **Maintain economic viability in light of reduced reimbursements, increased competition and costs**
- **Reduce operating expenses and maximize revenues**
- **Retain and expand market share of key services**
- **Examine scope of services provided for potential realignment to meet strategic goals**
- **"Work smarter with less, to provide more, while maintaining positive patient outcomes and economic viability "**

Health System Initiatives

- **Key strategy is recognition that compliance is a health system responsibility**
- **Compliance must be viewed as an integral component of the corporate culture**
- **Requires the active involvement of all departments and personnel**
- **Transcends all boundaries**
- **Executive Management and Board of Director's support**
- **Recognition of the potential liabilities and costs of noncompliance**

Health System Existing Resources

- **Corporate Compliance**
- **Accreditation and Performance Improvement**
- **Research & Grants**
- **Institutional Review Board**
- **Executive Management**
- **Laboratory, Radiology, Ancillary Departments**
- **Medical Staff**
- **Finance & Internal Audit**
- **Information Services**
- **HIMS**
- **Organizational Development**

Health System Initiatives

- **Designation of a project leader**

- **Identification of the key stakeholders**

- **Preparation of a strategic plan or SWOT Analysis utilizing existing infrastructure and expertise**

- **Assignment of identified issues, required systems development and support, to an individual "champion"**

- **Formation of interdisciplinary workgroups to support each champion to provide practical solutions to achieving the assigned task with current resources**

Health System Initiatives

- **Clear, concise direction and tightly controlled time lines for each workgroup**

- **Open communication among working groups to assist in resolution of identified issues that may require expertise from one another**

- **Establish aggressive schedule for joint meetings of project champions to report on progress, issue identification and assistance that may be required to achieve assigned tasks**

Health System Initiatives

- **Develop an implementation plan with targeted milestones with emphasis on communication tactics to varied stakeholder audiences**

- **Identify key individuals to act as resources for each major area**

- **Establish in conjunction with the existing Health System Corporate Compliance Office, a formally recognized Committee to convene on a regularly scheduled basis to address new issues, develop methods of auditing compliance in the varying departments and establish a Continuous Process Improvement component**

Summary

- **Key strategy is recognition that compliance is a health system responsibility**

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