EXAMINATION OF A RESEARCH COMPLIANCE PLAN: IS IT HEALTHY?

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HCCA Medical Research Summit

March 20, 2001

Washington, DC

Desk References Needed: Examples

- NIH-funded grants must comply with:
  - NIH Grants Policy Statement
    - http://grants.nih.gov/grants/policy/policy.htm
  - 45 C.F.R. Parts 74 & 92
    - HHS Grants Administration Rules
  - 42 C.F.R. Part 50, Subpart F, Financial Disclosure
  - 45 C.F.R. Part 46 - Human Subjects

Desk References Needed: Examples

- FDA-regulated grants must comply with:
  - 21 C.F.R. Part 54 - financial disclosure
  - 21 C.F.R. Part 50 - human subjects
  - 21 C.F.R. Part 56 - IRB

Desk References Needed: Examples

- All federally-funded grants must follow new OSTP policy on research misconduct: [65 Federal Register 76,260 (2000)]
- PHS funded grants - oversight by Office of Research Integrity (ORI)
  - 42 C.F.R. Part 50 - misconduct in science

Desk References Needed: Examples

- OHRP Guidebook for Human Subject Protections (on website)
- NIH education requirements in NIH Guide and pending PHS policy on Instruction in Responsible Conduct of Research (RCR Policy) published by PHS/ORI on 12/1/00
- NIH Internet Guide
  - http://grants.nih.gov/grants/internet_guide.htm

Diagnostic Examination

- How funds are spent
- How subjects are treated
- How researchers are protected
- How integrity is protected

Diagnostic Examination

- What representations have you already made. (Certifications & Assurances)
  - PHS form 398 (Standard Application)
  - PHS form 2950 (Continuation)
  - PHS form 6349 (Annual Report on Possible Misconduct)

Systems Review

- Follow Cost Principles for Government - Sponsored Grants
  - OMB Circular A-110 (45 C.F.R. Part 74)
    Uniform Administrative Requirements
  - Non-profit - OMB Circular A-122
  - University - OMB Circular A-21
  - Hospital - 45 C.F.R. Part 74, App. E
  - NIH Grants Policy Statement
  - Award Notice "Terms & Conditions" - Grant-Specific

Systems Review

- Review Grants Management Timeline
  - Program announcement
  - Application preparation and review
  - Submission
  - Peer review ⇩score
  - Award negotiation
  - Award issuance
  - Cost center ⇩ funds expended ⇩ reimbursement
  - Progress reports
  - Final report and close-out

Systems Review

- The award budget
  - Direct costs
  - Indirect costs

Systems Review

- Informed consent process
  - Recruitment
  - IRB approval
  - Documentation
  - Necessary disclosures
    - Clinical
    - Financial
  - Privacy and confidentiality
  - Federal Wide Assurance (FWA)

Systems Review

- Reporting requirements
  - Financial Status Report (FSR)
  - Audit Requirements: A-133 audit requirement
    - Reports of suspected misconduct:
      - PHS form 6349 (annual report to ORI)

Systems Review

- Conflict of interest
  - Are relationships affecting result?
  - Financial disclosure - NIH and FDA
  - Effect on physician - patient relationship

Medical Examiners: Who Will Make the Diagnosis?

- HHS Office of Grants and Acquisition Management - HHS wide policies
- NIH/Office of Policy for Extramural Programs (OPERA):
  - Establishes grant policies and oversees management and compliance issues for grants awarded by NIH institutes

Medical Examiners: Who Will Make the Diagnosis?

- PHS/OHRP - Human Subjects Protection
- NIH/Office of Lab Animal Welfare (OLAW)
- PHS/Office of Research Integrity - Scientific Misconduct

Medical Examiners: Who Will Make the Diagnosis?

- NIH/Office of Management Assessment (OMA)
  - Investigates individual cases of non-compliance with grant funding requirements
- FDA
  - IRB/Informed consent
  - Conflict of interest

Medical Examiners: Who Will Make the Diagnosis?

- Recombinant DNA Advisory Committee
- HHS Inspector General/Department of Justice

Some Signs of Infection

- IRB members not prevented from reviewing projects in which they have a potential interest
- Incomplete disclosure to IRB
- Incomplete review by IRB
- Consent forms significantly deviate from regulatory requirements

Some Signs of Infection

- Billing system doesn't clearly track patients who are subjects of clinical trials
- Physicians and nurses have financial relationships with sponsors that influence independent enrollment into trials or conduct of research

Acute Conditions

- Improper reporting of time and effort
- Unallowable costs
- Accelerated expenditures
- Improper cost allocation
- Misuse of funds

Acute Conditions

- False data or records
- Failure to keep adequate records
- Human subject violations
- Conflicts of Interest
- No Institutional Biosafety Committee (for recombinant DNA research)

Complication Creating Non-Compliance

- Decentralized system
- Conflicting goals
- Internal priorities v. external priorities
- Tradition of "laissez-faire" in a "big brother" world

Surgery May be Ordered

- Withhold of cash payments
- Suspend or terminate award
- Require corrective actions
- Impose special terms and conditions
- Withdraw approval of key personnel

Surgery May be Ordered

- Referral/Relator triggers False Claims Act
- Private law suits by subjects and their families

Post-Operative Order

- Institutional Integrity Agreements
- Debarment
- Monetary penalties and awards

Preventive Medicine

- Compliance standards
- Compliance monitoring
- Effective training
- Internal monitoring and auditing

Preventive Medicine

- Confidential disclosure mechanism
- Enforcement of standards
- Response to violations

Goals of Preventive Programs

- Proper management of funding
- Error reduction
- Protection of subjects
- Awareness of conflicts of interest

Goals of Preventive Programs

- Ethical science
- Limit negative exposure
  - Media
  - Congress
  - Insurance

Compliance Office: Wellness Clinic/Hospital/Morgue?

- Part of a bigger unit? - by expanding a billing compliance program - or standing alone?
- Who's in charge? - "high-level" personnel must have oversight responsibility

Compliance Office: Wellness Clinic/Hospital/Morgue?

University Board of Trustees

Oversight Committee

President
Vice President Academic Affairs
Compliance Officer
Counsel

V.P. for Research /Dean of Research/
V.P. Financial & Administration

Compliance Officer

Committees

Compliance Office: Wellness Clinic/Hospital/Morgue?

- Commitment is reflected in Academic Mission Statement and Letter from Chief Academic Officer endorsing the compliance plan - "Changing the Culture"

Compliance Office: Wellness Clinic/Hospital/Morgue?

- Who is responsible for the areas that will be come the elements of the compliance plan?
  - You may be asked:
    - Who monitors financial interest reporting?
    - Who reviews effort reporting?
    - Who knows what the IRB is doing?

Compliance Office: Wellness Clinic/Hospital/Morgue?

- An administrator should be providing support to the investigators
- Some duties cannot be passed off by investigators
  - Research conduct
  - Time and effort issues
  - Financial interest reporting
  - Following informed consent procedures

RX for Compliance

- Policies and procedures for
  - General compliance
  - Specific areas - see nine core areas of instruction listed in RCR Policy
- Dissemination
  - Format?
  - How to update?

RX for Compliance

- Training
  - Who gets mandatory training?
  - Will we certify?
  - Tools:
    - PHS/RCR Policy
    - NIH training modules
    - OHRP guidance
    - Websites (examples)
  - Who will train?

RX for Compliance

- Oversight
  - Research compliance committee with individuals representing areas covered in plan
  - Role of General Counsel
  - Communications
    - Hotline
    - Web
    - Integration into departments - conforming policies
      - IRB Chairs at each campus

RX for Compliance

- Audits
  - Following complaints
  - Proactive

Questions?

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