BENCHMARKING CLINICAL RESEARCH COMPLIANCE EFFORTS: IDENTIFYING AND AVOIDING KEY AREAS OF RISK

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Key Questions:

- What is “benchmarking?”
- Why evaluate your program?
- What are the benchmarks against which research compliance should be measured?
- Who should evaluate it?
- How do you perform a meaningful evaluation?
- What substantive and procedural areas should be covered?
- What is the “deliverable,” or work product?
- What are the keys to a successful evaluation?
- Practical issues: timing, costs, frequency?

Why Evaluate Your Program?

- Will it identify and help avoid or minimize risk of liability?
- Is it effective in preventing and detecting violations of law?
- Is it sufficiently comprehensive to avoid imposition of a CIA?

"The protocol review process is grossly inadequate and it does not conform to current standards. . . . The Hopkins system . . . results in never having anyone with the explicit responsibility to conduct a thorough review of a specific proposal. The Hopkins system limits, by its design, active discussion by the full committee, and loses the expertise that committee members bring to the review."

External Review Committee on Johns Hopkins IRB

“There has got to be a cultural change here . . . . We’re going to have to raise the bar higher. There can’t be any slippage. None.”

Edward Miller, CEO, Johns Hopkins Medicine

What Are the Benchmarks Against Which Research Compliance Should Be Measured?

- Your own compliance plan(s)/general or specific
- Your original and updated implementation plans
- Internal policies and procedures
- OHRP [OPRR] Institutional Review Board Guidebook
- FDA Information Sheets (Guidance for Institutional Review Boards and Clinical Investigators)
- Miscellaneous guidance (NHRPAC, OHRP, AAMC)
- State law

Who Should Evaluate It?

- Inside vs. outside
- Objectivity
- Legal vs. non-legal
- Privilege issues

How Do You Perform A Meaningful Evaluation?

- Document review (samples):
  - Compliance plan
  - Research-specific policies or procedures, manuals
  - Investigators' handbook
  - IRB minutes and other documentation
  - Forms (conflict of interest, informed consent, other)
  - Internal guidance on billing and coding
  - Training schedules and materials

How Do You Perform A Meaningful Evaluation? (Continued)

- Interviews
  - Director of research compliance
  - Director of research
  - IRB director (internal)
  - IRB chair/members
  - CCO/chair of compliance committee
  - CFO/billing and coding staff
  - CIO/CPO
  - Legal/other senior management

What Substantive and Procedural Areas Should Be Covered?

- Adequacy of all policies and procedures
- Organizational/practical relationship of research compliance to overall institutional compliance program
- Training for staff, IRB, PIs
- Informed consent/forms and practices
- Conflicts of interest
  - Institutional
  - Individual (PIs)
  - IRB
- Coding and billing
- Compliance with HIPAA privacy rule
- Overall adequacy of documentation

What Substantive and Procedural Areas Should Be Covered? (Continued)

- Functioning of the IRB(s) (sample issues per OHRP):
  - Individual presentation/review of protocol at duly convened meeting of full IRB?
  - Failure to perform annual continuing reviews
  - Lack of sufficient information required for approval
  - Inappropriate use of expedited review
  - Failure to review protocol changes
  - Deficient informed consent documents

What Substantive and Procedural Areas Should Be Covered? (Continued)

- Functioning of the IRB(s) (sample issues per OHRP)
  - Lack of race, gender, cultural diversity
  - Inadequate understanding of DHHS regulations
  - Inadequate IRB resources
  - Inadequate records
  - Inadequate minutes
  - Existence of handbook for investigators

What is the “Deliverable,” or Work Product?

- Privileged report to director of research/research compliance, CCO, legal
- Description of scope, process
- Synopsis of interviews
- Recommendations for remedial action
- Incorporating comments on draft report
- Presentation to senior management, compliance/audit committee

What Are the Keys To a Successful Evaluation?

- Organized process
- Simple, cost-effective
- Thorough and objective
- Clear recommendations for remedial action

Practical Issues: Timing, Costs, Frequency?

- Development of a realistic timeline
- Costs/order of magnitude
- Frequency
  - Size, complexity of your organization
  - Particular risk areas
  - Previous encounters with regulatory agencies
  - General guidelines

Conclusions

- Cost-effective, timely, concise
- Enormous potential benefits

Links:

http://www.jhu.edu/~jhumag/0202/web/trials.html

http://ohrp.osoqhs.dhhs.gov/references/findings.pdf