



## Developing a Research Compliance Program in the Context of Corrective Actions to an OHRP Investigation

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## Agenda

1. Background
2. First steps
3. IRB issues
4. Investigator issues
5. Institution issues

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## Background

Chief Compliance Officer for Spectrum  
Health starting January 2010

Is your compliance department involved  
with research compliance?

Different laws

Different jargon

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Background (cont.)

Working with OHRP

Culture of compliance within the institution

It's not just about the 10 studies

First steps

Assemble team

- Compliance Officer
- PI
- Lead Study Coordinator
- Business Administrator
- Head of Cancer Center
- Outside counsel
- (New) HPA

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First steps (cont.)

Role of IRB?

External IRB

Not member of team

Coordinate/cooperate

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First steps (cont.)

Initial Meetings

- Meetings to respond to OHRP
- Meetings with oncology physicians
- Meetings with IO/SO
- Meetings with executive leadership
- Compliance Committee

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## First steps (cont.)

### New Meetings

- Meetings to implement corrective action
- Meetings with affiliates
- Meetings with NCI/NIH/CCOPs
- Meetings with IRBs

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## **IRB ISSUES**

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## Initial Review

### Lacking sufficient information to make determination

- Informed consent
- Subject recruitment and enrollment
- Privacy and confidentiality

### Vulnerable populations

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## Continuing Review

### Not conducting continuing review

- Transitioning IRB review to another external IRB
- Electronic protocol tracking system
- Dedicated secretary
- Double check system
- 11 to 10 month approval cycle
- Policies on closure, lapsed studies, continuing review and affiliates
- Training
- Internal audit

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## IRB SOPs

Documentation management

Continuing review

Renewal

Distribution of materials

Expedited review

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## Use of External IRBs

Transferring studies to another IRB

Cooperation between IRBs

Who determines whether a study could be transferred?

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## Pros/Cons of External IRB

Adopting policies

Auditing

Minutes

Site visits

Maintaining documentation

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## IRB documentation

External IRB

Who is responsible?

Contract with IRB

Who keeps documentation

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## INVESTIGATOR ISSUES

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### Prompt reporting

Reporting to the IRB, appropriate institutional officials, any department or agency head and OHRP

- Unanticipated problems involving to subjects or others
- Serious or continuous non-compliance
- Suspension/termination of IRB approval

### Internal policies

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## Prompt reporting (cont.)

What was reported?

IRB procedures?

Informal reporting needed to become more formal

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## Protocol deviations

Changing protocols without prior review

Intentional versus unintentional

Initially, not seen as useful

Taken off study

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## Investigator/staff training

Internal policies and procedures

Policies and procedures of external IRBs

Common Rule/FDA regulations

CITI training

Online OHRP Assurance Training

NIH Protecting Human Research Participants

Every 2 years

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## PI Restructuring

Identifying potential PIs by disease site

Training newly identified PIs prior to  
assuming PI responsibilities

Allocating studies on a go-forward basis

Reassigning current studies to different  
PIs

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PI Restructuring (cont.)

Developing or redesigning reporting mechanisms

Developing and maintaining adequate support structures for PIs

Impact on affiliates

Auditing and monitoring

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PI Restructuring (cont.)

Study Intensity = relative burden

Inspired from NIST methodology

Subject Status: active tx, active FU, LTFU

Study Complexity: 1 (least) – 5 (most)

Aggregate the product of all subjects in a particular study

PI Restructuring (cont.)

Open/Active Subjects – significant shift

Closed/Active Subjects – 80/20 rule

Open/No Active Subjects – case-by-case

Closed/No Active Subjects – permanently  
close study

**INSTITUTIONAL ISSUES**

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## Institutional Official and HPA

Change Human Protections Administrator

Change the Institutional/Signatory Official

- Training
- All audit findings to IRB and OHRP

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## Affiliates

Separate institutions under Common Rule

Responsibility under NCI/NIH

Consortium Agreements

Quality assurance

IRB Authorization Agreements

Patients “off study” or transferred

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## Verification Policy

Questions about getting the information  
the IRB requests

Internal (institutional) policy

Versus external IRB policy

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## Auditing

Human Subject Research Audit Policy

Annual Research Audit Plan

- Continuing Review
- Lapsed Studies
- Unauthorized research activity  
performed prior to IRB approval

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## Auditing (cont.)

### Annual Research Audit Plan (cont.)

- Reporting unanticipated problems
- Planned protocol changes
- Timely filing of amendments
- Informed consent – Obtained and submitted

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## Auditing (cont.)

### Annual Research Audit Plan (cont.)

- IRB minutes
- Expedited review
- IRB records
- Affiliate studies
- Training for investigators, key personnel, HPA and IO/SO
- Contracts

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## Compliance Involvement

Is your compliance department involved  
with research compliance?

Different laws

Different jargon

Same solutions

## Contact Information

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