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Evolution of an IRB Quality
Improvement Program

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Purpose

- To Describe the Evolution of an IRB Quality Improvement Program (QIP) at the University of Kentucky
- To Discuss Lessons Learned in Developing the Quality Improvement Program (QIP)

Lessons Learned

Key Issues to
Consider In Setting
Up Program

What Are Your Objectives?

- Quality Assurance
- Quality Improvement
- QA and QI

What Standards Will You Use?

- 45 CFR 46
- OHRP Policies
- 21 CFR 50 & 56
- 21 CFR 312, 314
- ICH GCP
- IRB Policy

Who Oversees the Program?

- Internal to IRB Office
- External to IRB
- Combination

Who Assesses Findings?

- IRB
- QI – QA Staff
- PI
- ?

What Shapes Decisions?

- Objectives
- Existing Organization
- Resources

IRB QA – QI at UK

'96-'97 UK Objectives

1. Determine if Study Implemented as Approved
2. Evaluate IRB/ORI Procedures/Ethical Decisions
3. Identify Issues for Education
4. Examine Informed Consent Process

'96-'97 Program

- Staffed Internal to IRB
- Standards: 45 CFR 46
- IRB Made Determination of Additional Action on Protocol Finding
- ORI Director Took Action on ORI/IRB Findings

'96-'97 Program

- Random Selection Protocol
- On-Site Review/Chair/Staff
- Inspect Corresponding IRB Files/Minutes Etc.
- Compare with Sponsored Project File

Lessons Learned

- Labor Intensive
- Necessary Expertise

'98-2002 UK

- Used 3 of 4
Original Objectives
- Hired 1 Full Time Staff
- Broadened Standards

Goal

Improve Programs

Good News/Bad News

- IRB Loved the Program
- IRB Loved the Program

Lessons Learned

- QI vs. QA
- Set Policy Through Noncompliance
- Labor Intensive
- Necessary Expertise

2003-? Objectives

1. To Assess Individual Protocol Compliance as Directed by IRB or ORI
2. To Evaluate ORI/IRB Procedures for Compliance and Efficiency
3. To Assist Investigator/Staff in Complying, Monitoring and Responding to External Reviews

2003-? Components

- Objective 1: IRB Directed On-Site Reviews
- Objective 2: Administrative IRB/ORI Reviews
- Objective 3: Routine On-Site Reviews
- Objective 3: PI Self-Assessment/Subject Survey

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References

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References

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