PRACTICAL
CONSIDERATIONS FOR
DEVELOPING A NEW QA/QI
PROGRAM FROM SCRATCH

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OUTLINE

- What is a QA/QI program
- Why do we need a QA/QI program
- Scope of authority
- Overall responsibility
- Getting started
WHAT IS A QA/QI PROGRAM

• Many definitions, only some consensus

• One possible working definition: QA/QI Program is an important part of a Human Research Protection Program (HRPP) that ensures regulatory compliance, improves investigator, as well as IRB performance through auditing and education, and measures the overall quality, effectiveness, and efficiency of the HRPP
WHY DO WE NEED QA/QI

• Ensuring compliance – Quality Assurance
  • Identifying potential and/or actual non-compliance
  • Recommending appropriate corrective actions
  • Assisting in implementing corrections

• Improving performance – Quality Improvement
  • Facilitating communication between IRB and the research community
  • Promoting best practice beyond mere compliance
  • Increasing overall efficiency of IRB operations and study site management
SCOPE OF AUTHORITY

• Conducting review/audit of all IRB-approved studies
• Conducting review/audit of IRB records
• Ensuring proper reporting of all reportable events
• Requiring corrective actions and mandatory follow-up review/audit
• Reporting potential serious or continuing non-compliance to IRB and/or institutional officials
• Providing education to IRB and research community
OVERALL RESPONSIBILITIES

- Ensuring regulatory compliance
- Improving investigator/IRB performance
- Providing education
- Supporting study sites (investigators and study staff)
- Measuring HRPP’s quality, effectiveness, and efficiency
ENSURING COMPLIANCE

• Conducting on-site review/audit
  • Routine/regular
  • For-cause/direct

• Assisting self-assessment
  • Not reviewed by QA/QI staff with general corrective actions and/or recommendations
  • Reviewed by QA/QI Program with specific corrective actions and/or recommendations

• Providing corrective actions plan

• Ensuring proper reporting
Improving Performance

- IRB
  - Data gathering - turnaround time
  - Streamlining review process

- Individual study site improvement
  - Based on specific findings from on-site review/audit
  - Providing study site with pertinent management tools

- Institution-wide improvement
  - Common findings of deficiencies, potential or actual non-compliance within the institution
  - Modifying institutional policies and procedures
Providing Education

- Small group focused education
  - Departmental meetings
  - Study site weekly/monthly meetings

- One-on-one
  - New study coordinators orientation
  - Junior/new investigator training

- Lecture series

- Large group seminar
SUPPORTING STUDY SITE

• Facilitate communications among IRB and investigators

• Facilitate communications among different committees/units, i.e., sponsored programs, research pharmacy, radiation safety, grants & contracts, and IT

• Need-based study monitoring/regular on-site reviews
GETTING STARTED

- Obtaining institutional support
  - Granting necessary authorities
  - Organizational structure including reporting line
  - Providing resources – people and space

- Assessing resources

- Setting Program goals
  - Compliance
  - Education
  - Compliance and education

- Finding the right person
INSTITUTIONAL SUPPORT

• Who will support and enforce Program activities?
  • Institution leadership, i.e., institutional official
  • Institutional compliance director/officer
  • Human Research Protection Program Director

• What is the relationship between QA/QI Program and the IRB? (three models)
  • IRB administrator is responsible for QA/QI activities
  • A designated person within the IRB office is responsible for QA/QI activities
  • Independent of IRB operations

• Will the Program have necessary authority to achieve its goals?
ASSESSING RESOURCES

• Can I start the Program without any additional resources?
  • Evaluating existing staff and their workload
  • Creating resource by streamlining processes
  • Keeping same number of FTEs with different qualifications/experiences
  • Reducing number of FTEs and hiring higher level, more experienced staff
SETTING PROGRAM GOALS

- **Focus**
  - QA or QI
  - QA and QI

- **Target**
  - Investigators or IRB
  - Investigator and IRB

- **Approach**
  - Mandatory
  - Voluntary
  - Mandatory for QA and voluntary for QI
Finding the Right Person

- Prior education and experience
  - College graduate, advanced degree preferred
  - Minimum 3 years work experience in human research related field
    - IRB administrator - Certified IRB Professional (CIP)
    - Investigator or research coordinator with regulatory responsibilities, i.e. IRB submission
    - Direct QA/QI experience, i.e. study monitor

- Knowledge/familiarity with relevant regulations and guidelines
Finding the right person

- Skills and personalities
  - Excellent communication skills
  - Organizational skills
  - Attention to detail
  - Logical
  - Adaptable
  - Enthusiastic
  - Creative
• One staff at a time
  • Most QA/QI programs are as “small” as one person

• One site at a time
  • First hand information is most effective
    • Start with 1 routine audit/review per week
    • Provide feedback/report in a timely fashion
  • Sharing aggregated findings/improvements with investigators, IRBs and institutional leadership

• One activity at a time
  • Onsite review/audit
  • Developing QA/QI tools, templates
  • Developing study management tools for investigators and IRBs
  • Small group focused education