Research Compliance Network (RCN) – Best Practices in Audit Reports

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Background

Clinical research quality assurance (QA) activities inform and motivate researchers to stay compliant with regulations and protocols. QA reports to researchers can be verbose, obscuring the relevant information. We formed a working group to develop best practices for QA reports to share with the Research Compliance Network (RCN). The RCN is a communication forum of 277+ human research protection professionals involved in quality assurance and improvement activities across 120 institutions.

Objectives

Describe best practices in audit reporting by:

- Determining main characteristics of strong audit reports
- Identifying audit findings that require review by the IRB for regulatory determinations that may result in reporting to regulatory authorities (FDA, OHRP)
- Assessing responsiveness to audit report recommendations, leadership review of reports, and success of corrective action plans
- Collecting feedback on report format that enables process improvement (report modifications) over time

Among the Working Group*:

*9 member institutions surveyed

Characteristics of Strong Reports: ASURE

- **A**ccurate
- **S**uccinct
- **U**nderstandable
- **R**equired
- **E**ducational

A State the facts; include documentation that was missing; avoid generalizations; avoid dramatic and punitive language; leave out names of people or positions

S Consider providing audit summary; highlight significant findings; note deficiencies by category; use tables, less text, be concise; include dates of review, preliminary report; response to report, close-out

U Provide scope of audit; provide study summary; list study team members & summarize audit meetings; clear presentation, formatting; provide definitions, thresholds for required actions, rationale; note regulatory non-compliance (include citation)

R Direct teams regarding timelines and due dates; conduct or request root cause analysis; provide corrective and preventative action plan ideas; prompt reporting to sponsor and/or Institutional Review Board (IRB); differentiate between requirements vs. recommendations; inform team of follow-up reviews and further actions required

E Reference which regulation/standard/protocol/policy item was not met; provide tools; include strengths; include recommendations; discuss how to apply to all studies; ask for PI/study team acknowledgement/response; maintain positive, balanced, constructive tone with logical corrective measures

Discussion

- The ASURE characteristics may be a guide for post-approval monitoring/QA program, re-evaluating the effectiveness of written communication from the QA team to research teams, or assessing effective QA report strategies for supporting compliant behavior.
- RCN members shared their enthusiasm and appreciation for these tools, whether new or experienced in the field.
- We aim to expand networking in this field by inviting discussion of the various techniques. Increased RCN membership and contributions are anticipated as a result, and we hope this will lead to further study and analysis of the QA reporting tool and mechanisms.

Other Best Practices

- Use a consistent template or format
- Make important findings easy to find
- Inform study team (either written prelim report or face-to-face) of findings
- Allow PI response to verify findings are correct and/or acknowledge findings
- Get to know study teams through education; being accessible and non-judgmental
- Ability to trend report data to inform educational initiatives
- Timely, error-free reports

Limitations

The group discussed developing a standard QA report template for adaptation by the members of the RCN, however, it became apparent that each institution had different approaches to communicating with researchers and reporting structures. Participants' programs existed in compliance programs that reported to IRBs, some were independent, and others covered regulated research misconduct investigations. Additionally, compliance programs are housed in different sizes and types of organizations (e.g., academic medical centers vs hospitals).