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Protocol Issues & QA Communication

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PART I: PROTOCOL ISSUES

Or What the Study Director Does Not Want You to Know

Why Would There Be Issues

Not all studies created equal

In a “rut” for common projects

Confusion with multiple trials/studies

Protocol template was used!

Confusing language

Double Check

Test Substance Label

- Expiration Date
- Batch Number
- CAS/Code Number
- Name
- Storage conditions

Personnel Information

- Address & Contact info

Study Director Signature & Date

Just To Be Sure

Plot Size

Isolation Distance

Crop variety

Growth stage

Sample Sizes

Event Calendar

DATA REQUIREMENTS!!

PART II: QA COMMUNICATION

Or What You Don’t Want the Study Director to Know

Getting Your Point Across

§ 160.35 (b)(3): "…Any problems which are **likely** to affect the integrity found during the course of an inspection shall be brought to the attention of the study director and management **immediately**."

§ 160.35 (b)(4): "**Periodically** submit to management and the study director written **status reports** on each study, noting any problems and corrective actions taken."

What Does it Mean

If you find something amiss during your inspection, you are to make sure the SD & management know about it RIGHT NOW!

Call or email.

Just note the issue and move on – SD/mgt must decide if impact is detrimental.

Documentation will be required in raw data.

Randy‘s Way (or the Right Way)

Major problems mean I am making a phone call

Email notification of each inspection/audit sent

Formal written QA report sent

Monthly status report to management

Now for the Report

A QA Inspection Report is generated for every event:

- **In-life**
- **Data audit**
- **Report Audit**
- **Facility Inspection**

We also maintain a list of all studies as a "status report" which can be provided.

QA Role

QAU exists to be the eyes & ears of study management

If something is going to affect the outcome or results, it is our obligation to report to SD/management!

Doesn't mean it WILL affect integrity, let mgt figure it out.

Be open and honest with PFIs/PAIs.

Be a problem-solver; not the problem

In Summary

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READ the protocol!

Take nothing for granted.

Double check the requirements.

Be open and honest with the PIs

Have a communication plan w/ SD & Mgt.

Ask questions and check documentation