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
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
§ 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.
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

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