Study Conduct

STUDY CONDUCT

- The study shall be conducted in accordance with the protocol
  - Signed by SD/approved by Sponsor
  - Study Specific procedures amended
  - Read and Understood by all Study Participants
  - Present at all study events
  - Followed to the letter
  - Deviations documented promptly “authorized” by SD
    - Amendments issued in a timely manner
      - Signed by SD and approved by Sponsor
  - PROTOCOLS SUPERSEDE SOPs

Test/control materials (articles, substances)
- Complete documentation of receipt
- Complete documentation of each usage
- Complete documentation of storage conditions (what is ambient?)
- Complete documentation of each mixture
- Methods in place to confirm test applications were as per protocol
- Labeled with identity, batch #, expiration date (if available) and storage conditions (when appropriate)
STUDY CONDUCT

- The test system shall be monitored in conformity with the protocol
  - Periodic checks - documented
  - Pay attention to adverse weather conditions
  - Monitor for pests/disease
  - Communicate with growers
  - Appropriately identified - stakes, flags, markers
  - Any other test system requirements as specified in the protocol
  - Complete “cradle to grave” documentation

STUDY CONDUCT

SOPs

- Immediately available
- Referenced in data
- Key elements documented
- Followed to the letter
- Deviations “authorized” by SD
- Accurately reflects current procedures
- Provide sufficient detail

STUDY CONDUCT

- In-life conduct
  - If it’s not recorded, it wasn’t done
  - If it’s not documented, it’s a rumor
  - Don’t allow for assumptions
  - Are the data/study reconstructable?
  - Is there enough narrative/detail when needed?
  - Are data corrections well documented?
  - If you died or were seriously injured tomorrow – will the study be lost?
**STUDY CONDUCT**

- Routine Observations/Documentation
  - Support protocol/SOP requirements
  - Unusual responses recorded
  - Unforeseen circumstances documented and corrective actions taken
  - Routine observations taken; consistent between technicians
  - Periodic review by SD/Investigator

**REAGENT AND SOLUTION LABELING REQUIREMENTS**

- Identity
- Titer or Concentration
- Storage requirements
- Expiration date
  - Deteriorated or outdated reagents and solutions shall not be used
  - Manufacturers expiration dates may not be extended
- Additional recommendations
  - Date prepared
  - Who prepared

**Reagents and Solutions**

- Guidelines for expiration dates – when the manufacturer has not provided one
  - Dry reagents - 5 years
  - Solvents - 1 yr from date opened or 2 yrs from date received
  - Solutions/mixtures
    - No later than earliest expiring component
    - Keep volatility in mind
    - Use good science
    - May be extended upon reevaluation with SOP
- Use Common sense – have an SOP
**STUDY CONDUCT**

- Specimen Collection
  - Done according to protocol/SOP
  - Areas of plot/trees as per protocol
  - Crop stage as per protocol
  - Commodity as per protocol
  - Specimens required, collected
  - Integrity preserved (dry ice, ice packs, CO2)
  - Complete chain of custody
    - Who, what, when, how (transfers complete)

**SPECIMEN LABELING REQUIREMENTS**

- Test system (soil, water, corn,)
- Study (usually study number)
- Nature (grain, hay, DAT, PHI, etc.)
- Date of collection

- Information shall be located on the container or shall accompany specimen in a manner that precludes error in the recording and storage of data

**Sample Handling**

- Complete C of C from the time samples are taken until final values reported
- Documentation of storage at field site
- Documentation of shipping
- Documentation of receipt and logging in
- Documentation of every step of processing and analysis
Storage conditions documented at lab
Reference standards characterized
Any repeat or reanalysis documented
Electronically captured data in compliance with GLP/Part II
Personnel adequately identified
QC procedures in place – for the run and for the data and analysis
Stability data available covering samples from collection to last data

All data reported
Rejected data “mentioned” in report
Circumstances affecting data quality reported
Analytical
Raw values reported
Corrected values
Formulas present
No picking and choosing data

Rejection or reanalysis of data points
Accompanied by scientifically valid reasons
Outlier tests conducted
Reported but excluded from analysis
Values averaged or otherwise identified

QUESTIONS??????