



Global Minor Use Summit: GLP Field Trials and Field Data Books

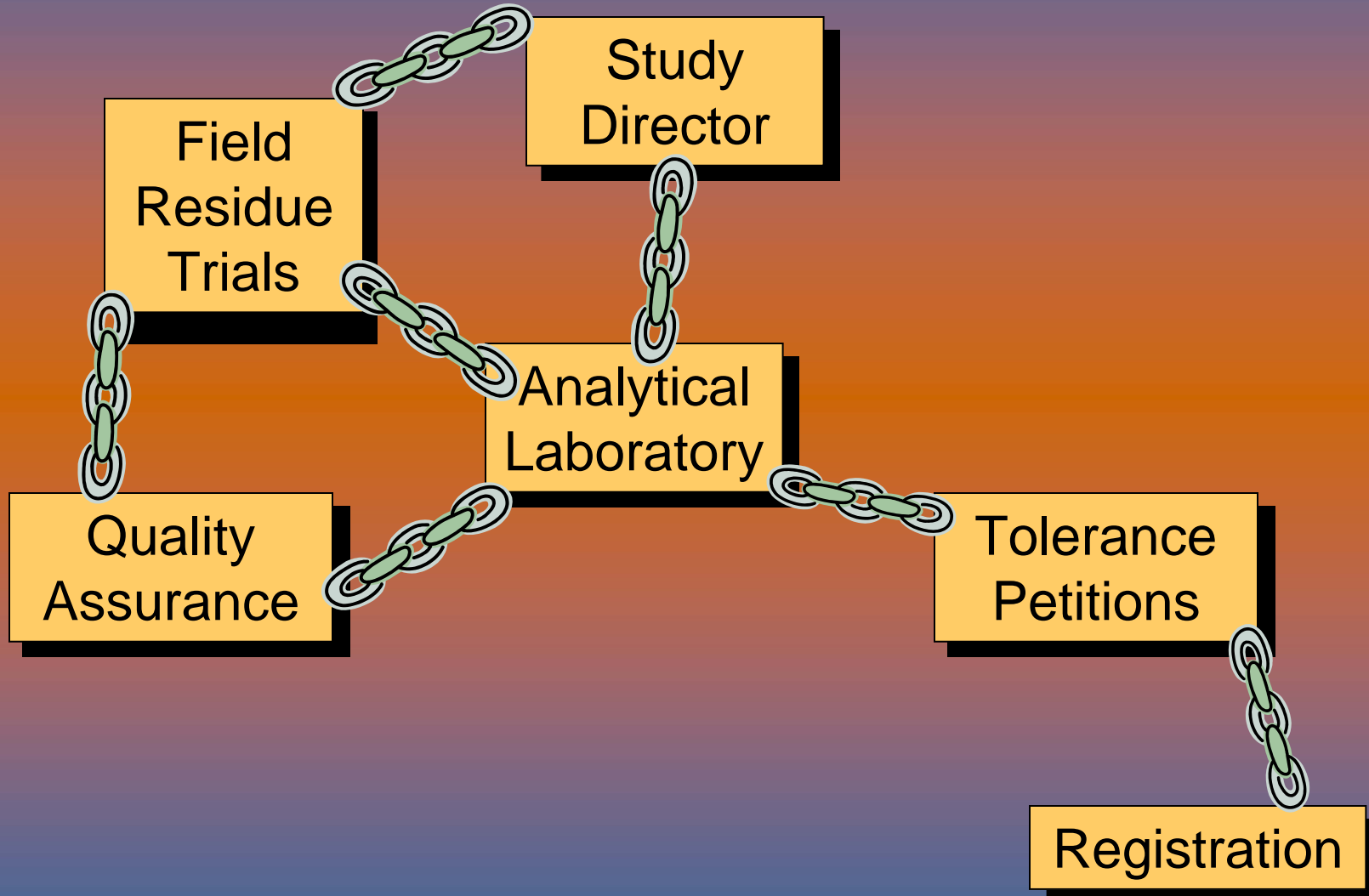
Dr. Robin Bellinder
Cornell University
Department of Horticulture
Field Research Director
USA

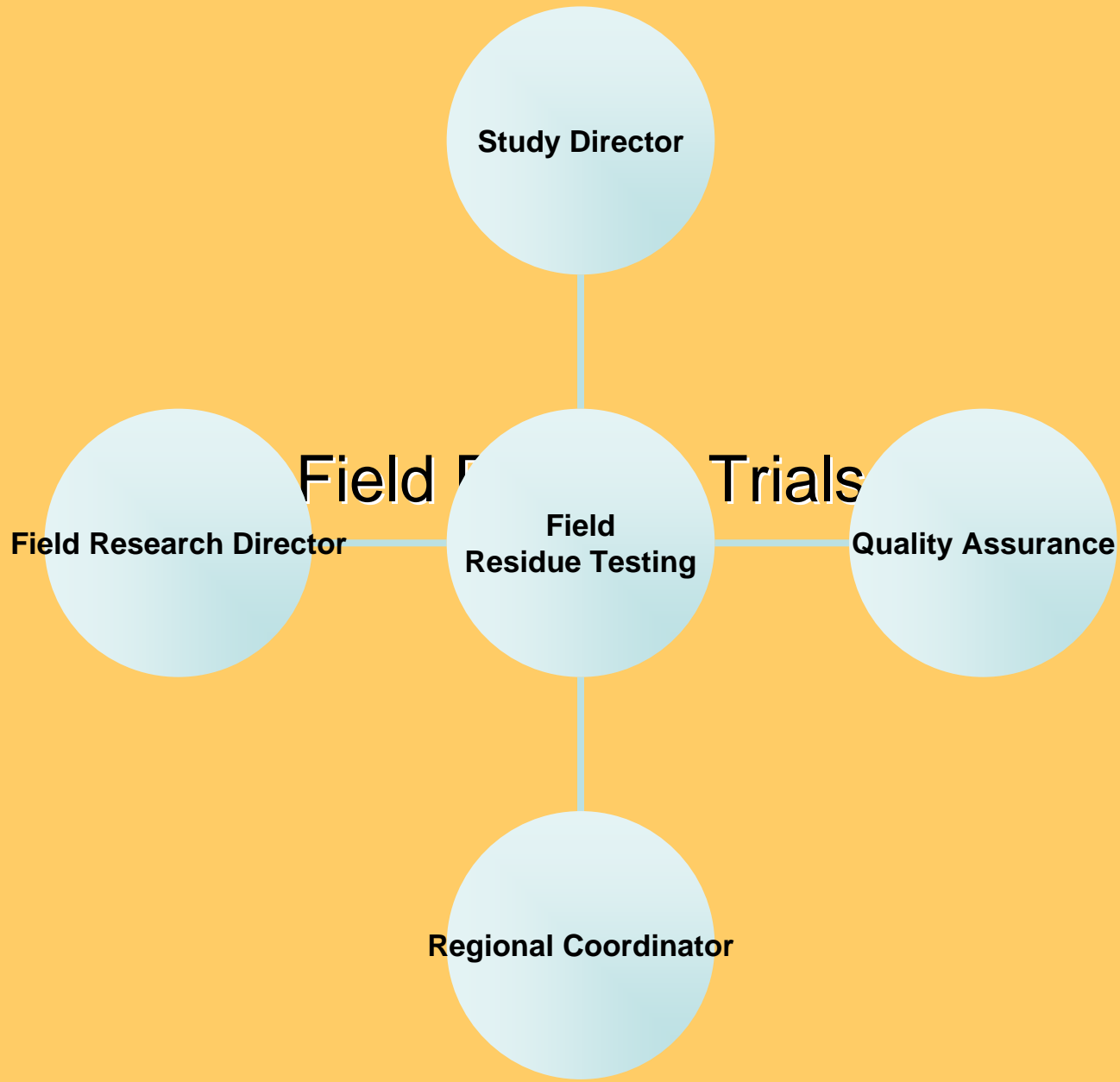


Outline

- Chain of Events
- Field Research Director
- The Basic's
 - The Protocol
 - Standard Operating Procedures
 - Field Data Book
- Residue Trial Walk Through

Chain of Processes





Field Research Director (FRD)

Role

1. Conduct GLP field residue trials
2. IR-4 Partner – outreach to local growers
3. Budget and funding of IR-4 Field Research Center



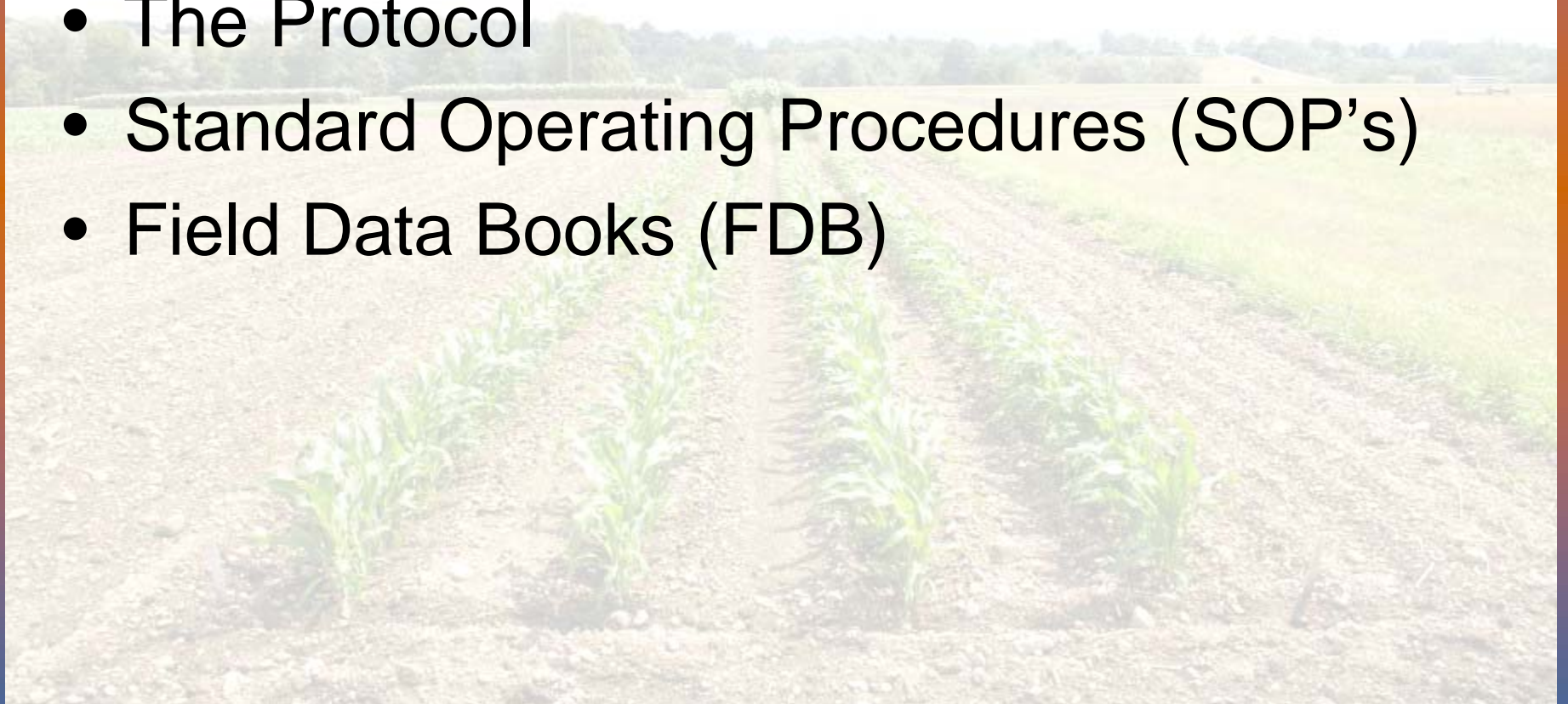
Field Research Director (FRD)

Responsibilities

1. Conduct/oversee field trials according to the protocol and GLP standards.
2. Act as work partner in GLP compliance (understand & implement)
3. Collect and submit data in a timely manner
4. Develop, update and implement SOPs
5. Provide oversight of science/agronomics of field research
6. Communicate and provide feedback to SD, QA, and Staff
7. Respond promptly to QA questions
8. Provide leadership and training to personnel
9. Maintain Research Facility
10. Working partnership within IR-4 (RFC, SD, QA, etc.)
11. Review protocols and provide comments to the SD
12. Serve as knowledgeable resource on crop production in region
13. Provide solutions to trial problems in conjunction with SD on day-to-day problems
14. Educate public and administration on role of IR-4. Communicate IR-4 mission to growers and other stakeholders
15. Develop budget for the IR-4 Field Research Center. Provide funds and “physical” resources
16. Find additional sources of funding for equipment/employees

The Basic's

- Good Laboratory Practices (GLP's)
- The Protocol
- Standard Operating Procedures (SOP's)
- Field Data Books (FDB)



The Basic's

Good Laboratory Practices (GLP)

"...(GLP's) compliance monitoring program ensures the quality and integrity of test data submitted to the Agency in support of a pesticide product registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)..." EPA

Definition: *Are a set of principles that provides a framework within which laboratory/field studies are planned, performed, monitored, recorded, reported and archived.*

- They consist of a system of management controls to ensure the consistency and reliability of results
- Assure the regulatory agency (EPA) that data submitted are a true reflection of the results obtained during the study

The Basic's The Protocol

- Definition: *Contains both the field and laboratory phases of the study and detail the proposed sites for the research.*
- Every IR-4 study has one protocol
- Approved by the SD with a signature and date
- FRD and the LRD receive entire protocol to provide information on rates of test substance application, crop sampling, and lab analysis info.
- No trial should be initiated until the FRD has a signed protocol in their possession.

The Basic's Standard Operating Procedures (SOP's)

Definition: *To provide guidance when conducting field research studies under GLP's*

- Required for all trials that are conducted in the support of the registration of pesticides.
- Part of *all* phases of research (Headquarters, Field and Laboratory)

Consists of:

- SOP # AND Revision #
- Who submitted and When
- Title
- Purpose
- Scope

The Basic's SOP's

- Specifically outline the procedures involved in all activities required to perform a residue trial
- Also outline research facility and equipment
- Are revised as-needed, but at least every five years
- Are signed by the FRD and Regional Field Coordinator prior to the beginning of each season
- IR-4 HQ archives

The Basic's SOP's

STANDARD OPERATING PROCEDURES TABLE OF CONTENTS

GENERAL	
SOP #: 1.1:7	General requirements..... 1
SOP #: 1.2:8	Numbering system..... 3
SOP #: 1.3:6	Format..... 4
SOP #: 1.4:9	Designation of Field Research Director..... 5
SOP #: 1.5:6	SOP's for sponsored research..... 6
PERSONNEL	
SOP #: 2.1:12	Personnel..... 7
FACILITIES	
SOP #: 3.1:9	Site selection for field studies..... 8
SOP #: 3.2:9	Field season data storage..... 10
SOP #: 3.3:14	Chemical storage facility..... 11
EQUIPMENT/CALIBRATION	
SOP #: 4.1:9	Calibration and use of a laboratory balance..... 12
SOP #: 4.2:7	Measuring a liquid formulation..... 13
SOP #: 4.3:13	Calibration/maintenance of CO ₂ backpack sprayer..... 14
SOP #: 4.4:12	Calibration of CO ₂ 'G' sprayer..... 16
SOP #: 4.5:12	Calibration of sprayer for directed applications..... 18
SOP #: 4.6:11	Calibration of sprayer for banded applications..... 20
SOP #: 4.9:3	Calibration of instruments and gauges..... 23
SOP #: 4.10:4	Maintenance of freezers..... 24
SOP #: 4.11:2	Remedial action for equipment malfunction..... 25
SOP #: 4.12:2	Calibration/maintenance of mist blower..... 26
AGRONOMIC PRACTICES	
SOP #: 5.1:7	Field preparation for seeding or transplanting..... 28
SOP #: 5.2:5	Method for seeding and transplanting..... 29
SOP #: 5.3:7	Commodity maintenance..... 30
PESTICIDE APPLICATION	
SOP #: 6.1:9	General procedures in the application of pesticides..... 31
SOP #: 6.3:10	Procedures for application of study pesticide(s)..... 32
SOP #: 6.4:8	Cleanup of application equipment..... 34

STANDARD OPERATING PROCEDURES TABLE OF CONTENTS

SOP #: 6.5:3	Procedure for mist blower application..... 35
DATA HANDLING	
SOP #: 7.1:11	Recording of raw data..... 36
SOP #: 7.4:9	Completion of data and sample collection forms..... 38
SOP #: 7.5:8	Collection and recording of data from monitoring devices..... 39
SOP #: 7.6:8	Data storage during the active life from monitoring..... 40
RESIDUE SAMPLE HANDLING	
SOP #: 8.1:5	When to obtain residue samples..... 42
SOP #: 8.2:9	Method of sample collection..... 43
SOP #: 8.3:8	Sample identification and records..... 44
SOP #: 8.4:11	Packing and storage procedures..... 45
SOP #: 8.5:8	Sample shipping procedures..... 47
REPORTING	
SOP #: 9.3:9	Disposition of forms and reports..... 49
DATA RETENTION	
SOP #: 10.1:10	General procedures regarding data retention..... 50
SOP #: 10.2:6	Retention times for documents..... 51
SOP #: 10.3:7	Information to be retained..... 52
EPA AUDIT PROCEDURES	
SOP #: 12.1:5	Procedures to follow prior to an EPA inspection..... 53
SOP #: 12.2:3	Procedures to follow during to an EPA inspection..... 55
SOP #: 12.3:3	Procedures to follow after an EPA inspection..... 56
APPENDIX	
Summary of SOP revisions, including dates of inactivated SOP's..... 57	

The Basic's Field Data Book (FDB)

- Contains all information for a particular trial
- Is *the* legal document
- Where everything is documented:
 - PART 1. Good Laboratory Practice Compliance Information
 - PART 2. Personnel Log
 - PART 3. Notes & Communication Log
 - PART 4. Test Substance Records
 - PART 5. Trial Site Information
 - PART 6. Application Records
 - PART 6a. Application Records-Airblast Sprayer
 - PART 7. Sample Collection and Storage
 - PART 8. Residue Sample Shipping
 - PART 9. Meteorological and Irrigation Records
- Also Contains Protocol Changes

The Basic's Field Data Book (FDB)

FIELD ID NO. _____

CHAIN OF CUSTODY FOR IR-4 FIELD DATA BOOK

FIELD RESEARCH DIRECTOR: _____
 After receipt of this IR-4 Field Data Book, the Field Research Director shall start the chain of custody log by completing the first part. Once raw data entry has begun in the Field Data Book, the data books are to be in the custody of the Field Research Director (or personnel under the Field Research Director's supervision). When the Field Data Book is transferred to another individual (e.g. sending completed Field Data Book to IR-4 Regional Field Coordinator), the sender must note to whom and when the data book is sent. The recipient must sign the next block and date the form upon receipt.

Signature of Field Research Director: _____ Date: _____

Printed name: _____ Initials: _____

Field Data Book sent/given to: _____ Date Sent: _____

Signature of recipient: _____ Date Received: _____

Printed name of recipient: _____ Initials: _____

Field Data Book sent/given to: _____ Date Sent: _____

Signature of recipient: _____ Date Received: _____

Printed name of recipient: _____ Initials: _____

Field Data Book sent/given to: _____ Date Sent: _____

Signature of recipient: _____ Date Received: _____

Printed name of recipient: _____ Initials: _____

Field Data Book sent/given to: _____ Date Sent: _____

Page 1 of 2 Trial Year 2007

FIELD ID NO: _____
 IR-4 FIELD DATA BOOK

PART 6. APPLICATION RECORDS

A. EQUIPMENT
INSTRUCTIONS: Complete a separate form for each piece of test substance application equipment used in the trial.

EQUIPMENT USED FOR APPLICATION NUMBER(S) _____

EQUIPMENT IDENTIFIER¹ _____
¹Each test substance application equipment must have a unique identifying name or code

APPLICATION EQUIPMENT TYPE (Check one) TRACTOR _____ BACKPACK _____ GRANULAR _____
 OTHER _____ (Describe) _____

PROPELLANT (Check one) CO₂ _____ COMPRESSED AIR _____ PUMP _____
 OTHER _____ (Describe) _____

NUMBER OF NOZZLES OR HOPPER OUTLETS USED:	
SPACING BETWEEN NOZZLES OR HOPPER OUTLETS:	MESH SIZE USED IN THE STRAINERS:
NOZZLE BRAND/TYPER/SIZE (e.g. T-JET 8004, even flat fan):	

TYPE OF APPLICATION (Check all that apply)
 1) FOLIAR _____ TO THE GROUND _____
 2) BROADCAST _____ BANDED _____ DIRECTED _____ IN-FURROW _____
 3) OTHER _____ (Describe) _____

TREATED AREA² _____
²Calculated width of nozzle discharge pattern (CWNDP) at proper boom height X length of plot sprayed or treated. For a broadcast application, CWNDP = (# of nozzles X nozzle spacing). For a banded application, CWNDP = # of nozzles X swath per nozzle. If application is directed enter treated row width X # of rows X length of plot sprayed or treated. Treated row width may differ from actual row width when the actual row width is wider than local commercial practices. In this circumstance, the application rate should be calculated using the maximum commercial row width, and an explanation should be included on this page. Contact the Study Director if guidance is needed.

DOES TREATED AREA = PLOT AREA (from Parts 5C and 5F)? YES _____ NO _____

IF NOT, PLEASE EXPLAIN: _____

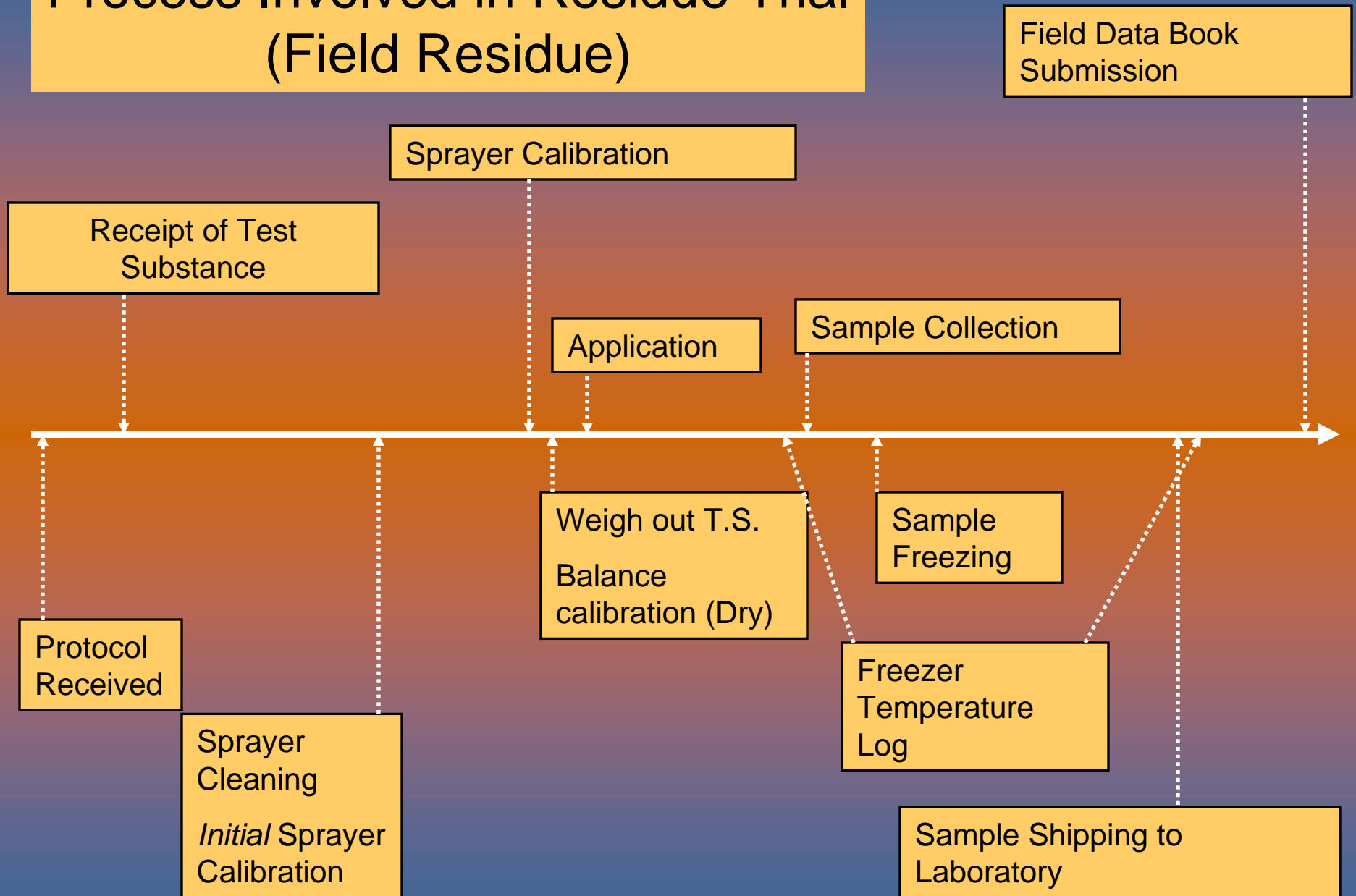
ABOVE DATA ENTERED BY: _____ DATE: _____

PART 6 PAGE _____ Trial Year 2007

Total number of pages in this section at initial pagination _____

COMPLETE IF APPROPRIATE: "THIS IS A TRUE COPY OF THE ORIGINAL"
 THE ORIGINAL IS IN IR-4 FIELD DATA BOOK NO. _____ INITIALS _____ DATE _____

Process Involved in Residue Trial (Field Residue)



Field Season Data Storage

- All data books in locked cabinets
- Cabinet in building with fire protection devices
- Limited access



Test Substance Receiving and Storage

- Beginning point of record keeping
- T.S. is evaluated for proper container information
- Each T.S. container is given a unique ID
- S.D. contacted with any irregularities
- T.S. storage temperature is monitored and logged weekly
- T.S. under lock and key
- Chemical log is initiated



Weighing a Dry Substance & Balance Calibration

- Serviced/Calibrated Annually
- Re-calibrated immediately prior to weighing using standardized weights
 - 1 weight above and 1 weight below T.S.
- Calibration records
- All excess product returned to container
- Documentation of amount removed



Measuring a Liquid Formulation

- Accuracy +/- 1% Vol.
- Pipettes or syringes
- Funnel/Glass Container
- Directly into spray tank/trt. bottles
- Record volume removed



Sprayer Cleaning & Calibration

- Initial pre-season cleaning/calibration
 1. Nozzles & Screens cleaned with 50% solution acetone
 2. Triple rinse
 3. Boom flushed 50% acetone or ammonia solution
 4. Triple rinse
- Record maintenance

Calibration*:

1. Timed discharge/nozzle
2. Capture discharge
3. Record volume collected
4. < 5% variation allowed
5. Repeat 3X = Ave. total boom output

**Performed prior to each appl.*



Speed Calibration

- Assures accurate application
- Especially useful with tractor appl.
- Repeat 3X
- Assists with variable field conditions

FIELD ID NO: _____

IR-4 FIELD DATA BOOK

PART 6. APPLICATION RECORDS

D. SPEED CALIBRATION FOR APPLICATION NUMBER(S) ____

INSTRUCTIONS: Complete a separate form for additional times when a complete calibration or calibration recheck of application equipment is required.

EQUIPMENT IDENTIFIER _____

SPEED CALIBRATION DATE _____ PERFORMED BY _____ (INITIALS)

TERRAIN OF CALIBRATION TRACK (e.g. tilled field,) _____

BRIEFLY DESCRIBE PROCEDURE USED FOR SPEED CALIBRATION _____

SPEED CALIBRATION: Calculate the speed of the application equipment. If appropriate, note the gear setting and/or RPM setting used in the speed calibration. Indicate the distance (in feet) of the track on which the application equipment was tested to determine speed (e.g. speed of application equipment tested for 100 ft.). The speed is calculated by dividing the length of test track (in feet or meters) by the time needed to cover that length (in seconds). Entry prompts have been provided for 2 additional runs. Show all calculations.

RUN	GEAR	RPM	Length of test track	TIME (sec)	CALCULATED SPEED (include units)
1					
2					
3					
Total of test run times (sec)			Avg. time (sec)		Avg. speed

CALCULATIONS:

NOTE: A speed re-check is not required when the nozzle output is re-checked.

WAS THIS A RECHECK OF SPEED CALIBRATION? (Check one) YES _____ NO _____

IF YES, WERE RESULTS WITHIN 5% OF ORIGINAL CALIBRATION? (Check one) YES _____ NO _____

The original calibration data, or a true copy, must be in this field data book.

NOTE: A target speed may be used for application calculations, rather than the mean of three runs, as long as the mean of the three runs in the speed calibration is within 5% of the target speed.

WAS THIS A CHECK OF A TARGET SPEED? (Check one) YES _____ NO _____

IF YES, WERE RESULTS WITHIN 5% OF TARGET SPEED? (Check one) YES _____ NO _____

ABOVE DATA ENTERED BY: _____ DATE: _____

PART 6 PAGE _____ Trial Year 2007

COMPLETE IF APPROPRIATE: "THIS IS A TRUE COPY OF THE ORIGINAL"
 THE ORIGINAL IS IN IR-4 FIELD DATA BOOK NO. _____ INITIALS _____ DATE _____

Application Equipment



CO₂ Delivery System

Application Equipment



Broadcast Boom



Adjustable Directed Boom



Adjustable Boom



Unique Boom ID

Application Equipment



Offset-Mounted Spray Boom



Mist-Blower Backpack

Application

- All personnel involved will be trained
- Lower rates applied first
- Field/Envir. conditions recorded
- Mixing/Appl. time recorded
- Appl. pass time
- Back calculation-determine how much was actually applied
 - % deviation
- Post-Appl. conditions (rain or irrigation)

Application Cont'

For dry formulations:

$$\text{Actual Rate (lb ai/A)} = \frac{\text{Boom Discharge Rate (ml/sec)} \times \text{Pass Time (sec)} \times \frac{43560 \text{ ft}^2/\text{A}}{\text{Treated area (ft}^2\text{)}} \times \frac{\text{Product (g)}}{\text{Volume mix (ml)}} \div 453.59 \text{ g/lb}}{100 \text{ lb product}} \times \frac{\text{No. lb ai}}{100 \text{ lb product}}$$

For liquid formulations:

$$\text{Actual Rate (lb ai/A)} = \frac{\text{Boom Discharge Rate (ml/sec)} \times \text{Pass Time (sec)} \times \frac{43560 \text{ ft}^2/\text{A}}{\text{Treated area (ft}^2\text{)}} \times \frac{\text{Product (ml)}}{\text{Volume mix (ml)}} \div 3785 \text{ ml/gal}}{100 \text{ gal product}} \times \frac{\text{No. lb ai}}{100 \text{ gal product}}$$

7. Calculate the percent deviation from the desired (protocol) rate, using the following formula:

$$\frac{\text{Actual Rate} - \text{Desired Rate}}{\text{Desired Rate}} \times 100 = \% \text{ deviation from protocol}$$

Application Cont'

FIELD ID NO: _____

IR-4 FIELD DATA BOOK

PART 6. APPLICATION RECORDS

A. EQUIPMENT

INSTRUCTIONS: Complete a separate form for each piece of test substance application equipment used in the trial.

EQUIPMENT USED FOR APPLICATION NUMBER(S) _____

EQUIPMENT IDENTIFIER¹ _____

¹Each test substance application equipment must have a unique identifying name or code

APPLICATION EQUIPMENT TYPE (Check one) TRACTOR _____ BACKPACK _____ GRANULAR _____

OTHER _____ (Describe)

PROPELLANT (Check one) CO₂ _____ COMPRESSED AIR _____ PUMP _____

OTHER _____ (Describe)

NUMBER OF NOZZLES OR HOPPER OUTLETS USED:	
SPACING BETWEEN NOZZLES OR HOPPER OUTLETS:	MESH SIZE USED IN THE STRAINERS:
NOZZLE BRAND/TYPE/SIZE (e.g. J-JET 8004, even flat fan):	

TYPE OF APPLICATION (Check all that apply)

- 1) FOLIAR _____ TO THE GROUND _____ DIRECTED _____ IN-FURROW _____
 2) BROADCAST _____ BANDED _____
 3) OTHER _____ (Describe)

TREATED AREA² _____

²Calculated width of nozzle discharge pattern (CWNDP) at proper boom height X length of plot sprayed or treated. For a broadcast application, CWNDP = (# of nozzles X nozzle spacing). For a banded application, CWNDP = # of nozzles X swath per nozzle. If application is directed enter treated row width X # of rows X length of plot sprayed or treated. Treated row width may differ from actual row width when the actual row width is wider than local commercial practices. In this circumstance, the application rate should be calculated using the maximum commercial row width, and an explanation should be included on this page. Contact the Study Director if guidance is needed.

DOES TREATED AREA = PLOT AREA (from Parts 5C and 5F)? YES _____ NO _____

IF NOT, PLEASE EXPLAIN: _____

ABOVE DATA ENTERED BY: _____ DATE: _____

PART 6 PAGE _____ Trial Year 2007

Total number of pages in this section at initial pagination _____

COMPLETE IF APPROPRIATE: "THIS IS A TRUE COPY OF THE ORIGINAL"
 THE ORIGINAL IS IN IR-4 FIELD DATA BOOK NO. _____ INITIALS _____ DATE _____

FIELD ID NO: _____

IR-4 FIELD DATA BOOK

PART 6. APPLICATION RECORDS

I. POST APPLICATION RATE CONFIRMATION FOR APPLICATION NUMBER _____

APPLICATION DATE _____ (COMPLETE A SEPARATE FORM FOR EACH APPLICATION DATE)

RECORD PASS TIME AND PASS DIRECTION - Complete the table by providing the time required to make each pass of the application equipment through the plot and direction of that pass (e.g. N > S, SW > NE, etc.).

PASS NUMBER	TREATMENT __		TREATMENT __		TREATMENT __	
	TIME	DIRECTION	TIME	DIRECTION	TIME	DIRECTION
1						
2						
3						
4						
5						
6						
TOTAL PASS TIME						

PASS TIMES RECORDED BY (INITIALS) _____ DISCHARGE RATE (ml/sec or g/sec): _____

ACTUAL AREA TREATED (swath width or treated row or bed width x # of passes x length of plot): _____

Note: Use bed width for plots with multi-row beds.

CALCULATION OF ACTUAL APPLICATION RATE - Using information such as total pass time, plot size, tank mix amounts, and discharge rate (average of 3 outputs) determine the actual amount of formulated test substance applied to treated plots. (If the protocol does not include a rate of formulated product, then the amount of active ingredient should be determined.) Convert this amount to the amount applied per acre (or hectare), and determine deviation from target application in the protocol, rounded to the nearest whole percent. Show all calculations and label all units. It is not sufficient to merely compare the actual pass times to the "practice" pass times. The example formulas listed at the bottom of 6J may be used to calculate the application rate.

WAS ACTUAL APPLICATION RATE WITHIN -5% TO +10% OF PROTOCOL RATE?

(Check one) YES _____ NO _____ IF NO, Contact the Study Director immediately.

ABOVE DATA ENTERED BY: _____ DATE: _____

PART 6 PAGE _____ Trial Year 2007

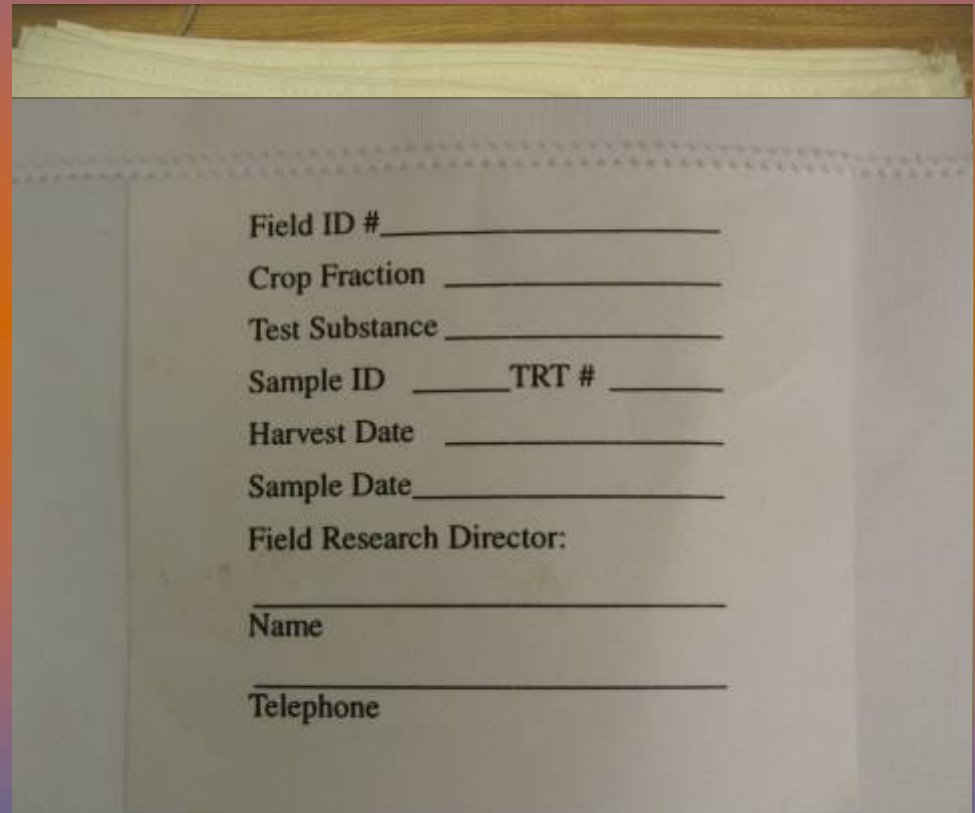
Sample Collection

- Sample methodology/size determined by protocol/crop
- Untreated -> lower rates -> higher rates
- Representative sample from each plot
- Avoid plot edges
- Duplicate samples harvested individually
- Samples weighed, bagged, labeled, and placed into a freezer
- Treated and untreated in separate coolers



Sample Collection cont'

- Avoid diseased or under/oversized crop parts
- Do not remove surface residue during handling
- Clean harvest tools
- Do not remove plant parts or trim crop unless outlined in protocol
- Additional ID Card sample with:
 - FRD
 - Project #
 - T.S./Crop
 - Dates of TRT
 - Dosage Rate
 - Plant parts collected
 - Sample date
- > Place ID card in moisture proof bag
- Samples should be placed in freezer immediately



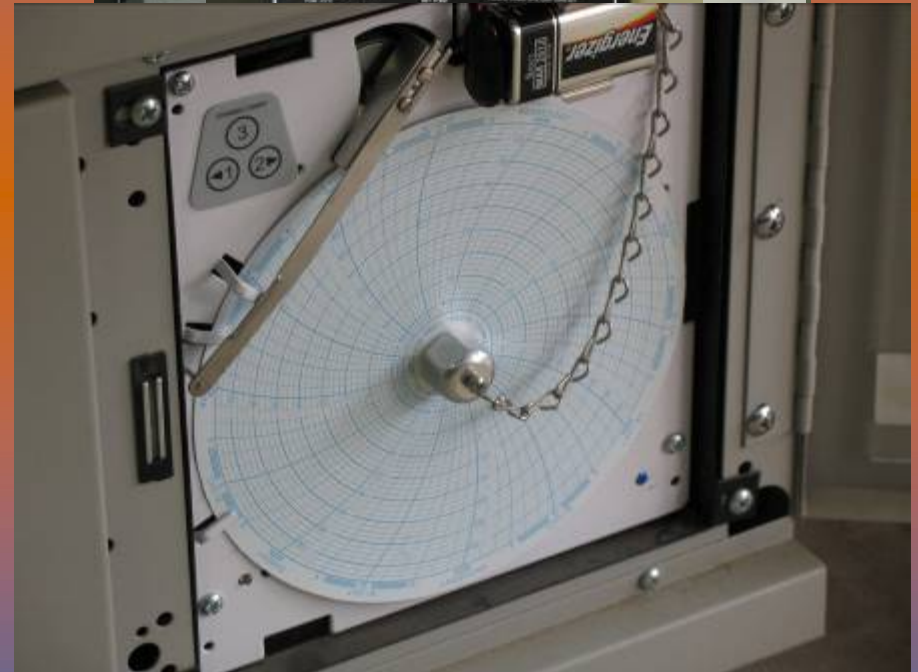
Field ID # _____
Crop Fraction _____
Test Substance _____
Sample ID _____ TRT # _____
Harvest Date _____
Sample Date _____
Field Research Director:

Name _____

Telephone _____

Storage of Samples

- Time from harvest to freezer must be recorded
- All samples will be frozen (-12.2 C) until they reach the lab
 - *Delay in return to -12.2 C for more than 24h will be a deviation*
- Samples must be physically separated in freezer
- Freezer temperature is logged
- If sample thawing occurs, notify SD and lab to see if samples are salvageable
- Log of items in freezer, their study affiliation, and number of sample bags to be kept



Sample Shipping

- *Goal is to maintain sample frozen until they reach the laboratory*
- IR-4 utilizes a freezer truck service or in some cases coolers with dry ice via shipping service
- Laboratory is notified of shipping dates
- All shipping documentation is placed in FDB
- All shipping carton containers should have name of sender and laboratory personnel and phone numbers

Conclusions

- SOP's are the backbone to residue trials
- Documentation is critical
- Good planning to avoid overlap is essential

