SOP Log Sheet

ID # 500181

Region: NC

State: MI **City:** Lansing

Location: NCR Field Regional

FRD/LRD: John Wise
Submitter

Effective Date: 1/17/18

Description of Material (s): 2018 SOPs

Reviewed By: Juliet Thompson 1/18/18
Sign/Date

Receive Date: 1/18/18 **Date to Archivist:** 1/18/18

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9/13/16 JT

IR-4 North Central Region Research Center
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STANDARD OPERATING PROCEDURES FOR IR-4 NCR FIELD OFFICE

TABLE OF CONTENTS

SOP No. NC Region Field Office	TITLE	Year Revised/ Reviewed	Date Revised/ Reviewed
	Administration and Data		
1.2	Standard operating procedures	2017	12/12/17
2.2	IR-4 Regional Field Office Management	2017	12/12/17
3.2	Handling of Field Data Notebooks	2017	12/12/17
4.0	Review and Approval of North Central Region IR-4 Field Research Center Standard Operating Procedures (SOPs)	2017	12/12/17

SOP numbering Format: [SOP number]. [version number]

SOPs submitted by: John Wise _____ 1/5/18
NCR Regional Field Coordinator **Date**

Date SOPs approved by: Jerry Baron _____ 1/17/18
Executive Director IR-4 Project **Approval Date**

I have read and understand the listed SOPs:

_____ 1-5-18
Nicole Soldan, Assistant Regional Field Coordinator **Date**

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SOP Number: NC Region Field Office 1.2	Pg 1 of 1

Title: Administration and Data ; Standard operating procedures

PURPOSE: To provide procedures for creating, revising, maintaining and archiving Standard operating procedures (SOPs).

SCOPE: Applies to all field research data which are handled through the field office of IR-4 North Central Region Research Center, Michigan State University

PROCEDURES:

1.0 All SOPs will be uniquely identified by number. Each number will begin with the prefix 'NC Region Field Office' to identify the research facility, sequential SOP number and version number.

Format: (NC Region Field Office) (SOP number.) (version number)
Example: NC Region Field Office 1.1

2.0 All current, active SOPs and retired SOPs will be listed on a Table of Contents. The SOP Table of Contents listing all SOPs will be signed and dated by the Regional Field Coordinator (RFC) and the IR-4 Executive Director. SOPs are effective as of the date approved by the Director.

3.0 Each SOP will define its scope and purpose, describe procedures routinely implemented, and the records that may be required by these procedures. Each page will be numbered.

4.0 Original signed SOPs shall be stored at IR-4 Headquarters archive, a scanned copy will be kept on the MSU CNS IR-4 Server and copy(s) will be kept in areas accessible to approved field office personnel.

5.0 Each SOP should be reviewed approximately once a year, and revised to reflect current procedures, if necessary. A record of the dates of review or revision will be maintained. The current revision SOP Table of Contents will be printed out and marked as to "reviewed by", dated and initialed by the field office personnel. This will then be permanently archived at the IR-4 Headquarters archive. Outdated SOPs will be permanently archived at the IR-4 Headquarters archive and all copies will be destroyed, with the exception of one, to be stored as a PDF on the Field Office Server.

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SOP Number: NC Region Field Office 2.2	Pg 1 of 2

Title: Administration and Data; IR-4 Regional Field Office Management

PURPOSE: To define the position and requirements of the Regional Field Coordinator as it pertains to the GLP compliant responsibilities.

SCOPE: Applies to the role of Regional Field Coordinator for the IR-4 Project. This is further outlined in the context of the entire IR-4 project in the IR-4 Handbook (available on line at http://ir4.rutgers.edu/Other/OperationalHandbook.pdf.)

PROCEDURES:

1.0 Regional Field Coordinator (RFC): Oversees and coordinates the activities of field cooperators (Field Research Directors (FRD)) consisting of state, industry and contract scientists who conduct field residue trials by applying the test substance, providing crop samples for laboratory analysis, and collecting GLP compliant data. For efficacy/crop safety (E/CS) trials RFC also oversees and coordinates the activities of FRD's.

2.0 Regional Field Coordinator assigns field-testing sites within his/her region, provides sample bags, reviews Field Data Books for accuracy and completeness, and facilitates the Field Research Director conduct of a field trial.

3.0 The RFC assists the Study Directors (SD) in meeting their responsibilities while monitoring progress of field trials, and serves as liaison between SD and FRD. The following personnel are accountable that the data generated by IR-4 personnel fulfill the requirements of GLP:

a) Regional Field Coordinator (RFC) for field trials conducted by scientists (state or contract) under IR-4 protocols.

b) The RFC will ensure that the Field Research Director and their staff with sufficient training and experience conduct the field trials as outlined in the protocols. Conducting field trials includes all activities specified in the protocol such as maintaining a crop; applying the test substance; harvesting, storing, and shipping samples; accurately completing the Field Data Book on time; and timely, prompt responses to QA audits. The FRD, or his/her designate, also reports all deviations from the protocol or SOPs to the SD.

c) The IR-4 Regional Directors (RD), Regional Laboratory Coordinators (RLC), and RFCs and the ARS National IR-4 Director will work with the Field and Laboratory Research Directors (FRD/LRD), Quality Assurance Unit (QAU) and SDs to meet the responsibilities as outlined above. They will provide guidance to the Field and LRD regarding GLP research and SOP development. The Field or Laboratory Research Director will develop SOPs to reflect the needs of their research facility and submit them to the RLC or RFC for approval.

d) The RD/RLC/RFC reserves the right to use a facility in the program based on whether or not the facility is in compliance with GLP. If needed, and in cooperation with the QAU, the RD/RLC/RFC should make constructive suggestions on how the facility may be brought into compliance. Research should not be initiated until the RD/RLC/RFC are confident that the facility is in compliance.

4.0 IR-4 Recommended Training for new FRDs and their associates (if applicable). All new FRDs and their associates (if applicable) are requested to participate in the following training activities before conducting GLP research, unless they already have significant training:

a. Basic GLP training required as soon as possible, before beginning any field trials.

b. Opportunity to visit relevant established FRD and the RFC for hands-on training and question/answer time.

c. Opportunity for regional QA personnel to meet the new FRD and his/her associates for the purpose of orienting them to the GLP audit procedures and expectations related to IR-4 field trials.

d. RFC will make available various training references and IR-4 orientation documents for new FRD training and orientation to IR-4.

e. All FRDs and their associates must continue GLP education/training as provided by IR-4 periodically.

5.0 RFC communicates with the IR-4 NCR stakeholders as to progress and status of the IR-4 NCR projects. RFC organizes annual IR-4 NCR state liaison representative committee meeting.

6.0 The Regional Field Office will maintain curriculum vitae (CVs), job description and training records of the Regional Field Coordinator and designated support staff. CVs and training records will be archived at IR-4 Headquarters annually, after review and/or revision as necessary. Initials and date on the CV and training record will serve as verification of review. Copies will be scanned and placed on the Field Server. Current files will be maintained in the RFC office.

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SOP Number: NC Region Field Office 3.2	Pg 1 of 2

Title: Administration and Data ; Handling of Field Data Notebooks

PURPOSE: To define requirements for all personnel when handling field raw data in the form of field data books sent in from the North Central Region Field Research Directors to the North Central Region IR-4 Field Office.

SCOPE: Applies to all GLP compliant Field Data Books (FDB) for the residue trials and efficacy/crop safety (E/CS) trials conducted in the North Central Region IR-4 Project.

PROCEDURES:

1.0 Field Data Books (the original raw data documenting a residue field trial) and efficacy/crop safety (E/CS) trials will be sent into the MSU North Central Region Field Office upon completion of the field trial. Documented arrival of field samples at the appropriate analytical laboratory will be considered the completion of the field portion of a residue trial.

2.0 Upon arrival to the NC Region Field Office each notebook will be signed in as per the chain of custody page by the Regional Field Coordinator or Assistant Regional Field Coordinator.

3.0 Notebooks will be assigned for review for quality control (QC) by the Regional Field Coordinator or Assistant Regional Field Coordinator. The QC reviewer(s) may be the Regional Field Coordinator or appropriately trained field staff or qualified external consultants. If the books are leaving the NC Region Field office for QC review they will be signed out via the chain of custody form in the notebook and sent via FEDEX or other trackable mail to the QC reviewer.

4.0 The role of the QC reviewer is to ensure that the documentation is complete in the notebook as to study conduct and GLP compliance. The reviewer will use a standard checklist as provided by the Regional Field Coordinator or designee as a guide to conducting the review. All application calculations will also be checked using a standard Excel spreadsheet provided on Western Region IR-4 Website or alternatively long hand methods of calculations may be done when appropriate and not suited to the Excel spreadsheet.

5.0 The reviewer will send an email to the appropriate Field Research Director (FRD) to request any clarifications or permission for corrections they deem necessary to complete the documentation for the trial represented by the notebook. The FRD or designee will provide corrections or approval of changes via email in response the QC reviewer's questions and suggested edits. The QC reviewer is permitted to make changes to the field data book with the approval of the FRD or designee. The clarifications, approved edits or changes are made to the notebook and the documentation trail (e-mail correspondence) will be printed out and provided in Part 3 Notes and Communications Log Section of the Field Data Book.

6.0 Scanned changed or added notebook pages are provided to the FRD via e-mail so the FRD retains a complete copy of the original notebook that will be sent on to QA for the Field Raw Data Audit.

7.0 It is returned to the North Central Region Field Office for a final review of the notebook, QC checklist, and application verifications.

8.0 When the field data book review is complete, the NC Region Field office sends the reviewed notebook on to the assigned QA unit for audit. The notebook is then signed out of the NC Region Field Office via the chain of custody form on the databook accompanied by an IR-4 Raw Data Transfer Form. A copy of the form is sent to IR-4 HQ. If the notebook remains in the North Central Region for QA audit, it is hand delivered to the North Central Region Quality Assurance Unit with an IR-4 Raw Data Transfer Form.

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SOP Number: NC Region Field Office 4.0	Pg 1 of 1

Title: Review and Approval of North Central Region IR-4 Field Research Center Standard of Operating Procedures (SOPs)

PURPOSE: To define procedures for the North Central Region Field Office Regional Field Coordinator or designee to approve North Central Region IR-4 Field Research Directors (FRDs) SOPs prior to implementation of SOPs.

SCOPE: Applies to all North Central Region IR-4 Field Research Directors. A Field Research Center having 2 or more FRDs should submit one set of SOPs signed by each FRD at that Center.

PROCEDURES:

1.0 The Regional Field Coordinator (RFC) or designated reviewer (DR) calls for SOP edits and updates via email reminder once per year, typically in late fall.

2.0 The RFC or DR ensures that the Field Research Directors send the designated reviewer a copy of their revised SOPs.

3.0 The RFC/DR reviews the SOPs, ensuring QA suggested changes have been incorporated as well as updates that reflect the SOPs match the work being conducted by the FRD.

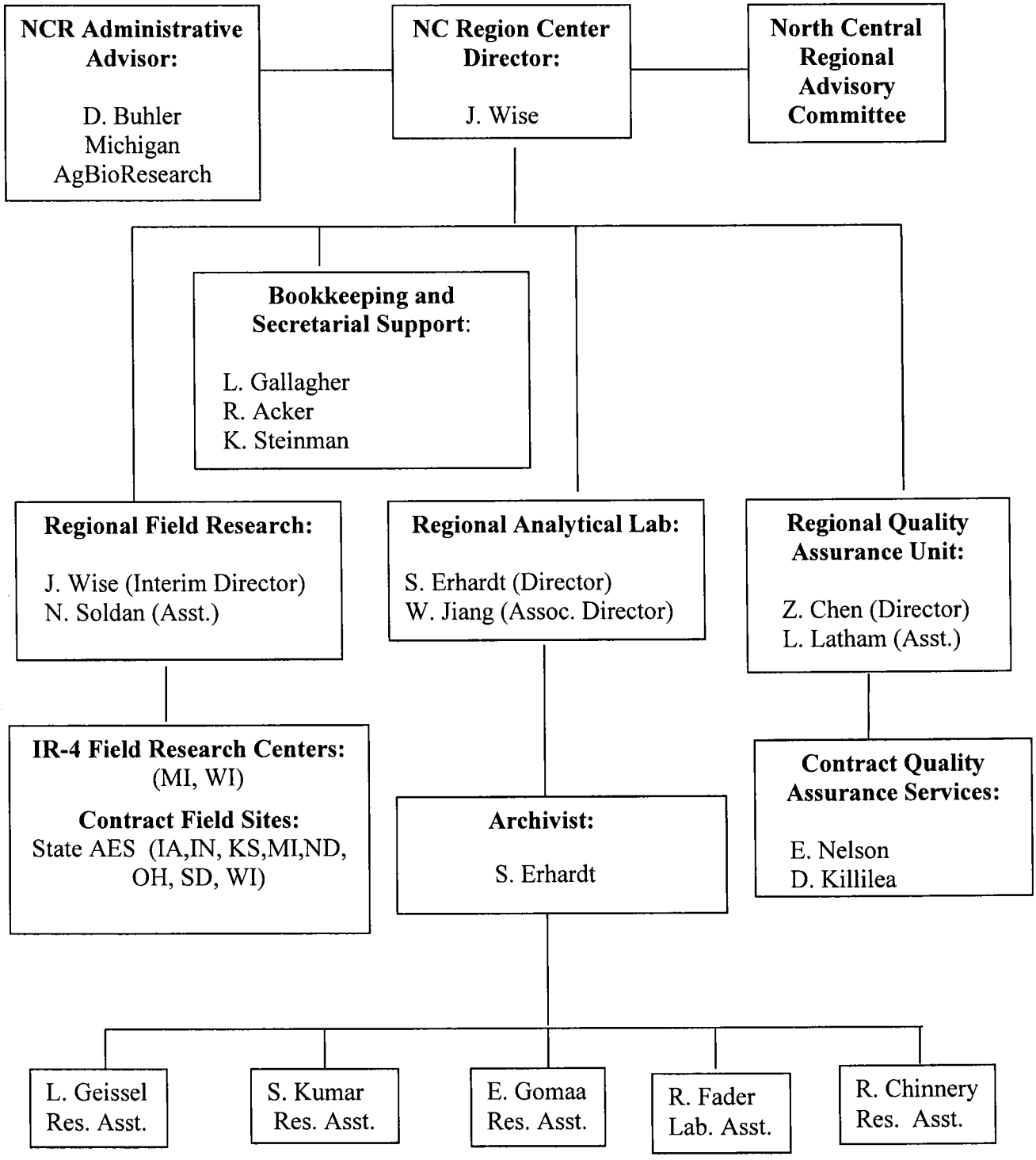
4.0 RFC updates the Approval Page and reviews Approval Page, all SOPs, and index for consistency.

5.0 RFC signs Approval Page and signs and dates all other necessary pages of the SOP.

6.0 The RFC/DR scans a digital copy of the SOP and places the final version on the IR-4 field program server.

7.0 All original signed pages are mailed back to the FRD.

Fig. 1: Organizational Structure of the NCR IR-4 Research Center at MSU



IR4-Field Data Notebook Review Checklist

Field Research Director:	Reviewer: Nicole Soldan
Study Title: Study Director: Test Site Location:	

Please fill out the following checklist and explain any deficiencies in an email or other electronic document.
Please note: Any problems which are likely to affect the study's integrity found during the course of this review must be brought to the attention of the Study Director immediately.

Field Trial Critical Events Log

[illegible]	[illegible]	[illegible]
Test substance receipt		
Test substance applications		
Sampling		
Sample Shipping and Receipt		

Parts 1,2,3. GLP		YES	NO	N/A	In Fac. File?
1.	Chain of Custody for Field Data Book completed				
2.	Codes for data changes included				
3.	SOPs referenced or present (Part 1, A)				
4.	GLP Compliance Statement signed by Field Research Director (Part 1, B)				
5.	Study personnel signatures complete (Part 2, A)				
6.	Qualifications summary (cvs, training records) (Part 2,B)				
7.	Notes and Communication Log completed (Part 3)				
8.	Notes with sufficient detail to reconstruct what was done				
9.	All in use pages signed and dated				
10.	All entries properly dated and initialed				
11.	Pages properly identified (Field ID No., Part and Page No.)				
12.	All unused pages removed or lined out, initialed and dated				

Part 4. Test Substance		YES	NO	N/A	In Fac. File?
1.	Chemical Receipt, Storage, and Disposition (Part 4, A)				
	a. Date received and/or placed in storage				
	b. Name on label				
	c. Batch/Lot number				
	d. Expiration date of test substance and source (mfg.)				
	e. Amount received				
	f. Type and condition of container				

2.	Chemical Use Log (completed/documented (Part 4, B)				
3.	Disposition of remaining compound / containers documented (Part 4, C)				
4.	Identification and Receipt of Spray Additives (Part 4, D)				
	a. Expiration Date?				
	b. Storage conditions provided?				
5	Chemical storage building temperature log (temperatures/temperature range -receipt to last application) (Part 4, E) **(RDFN: Section 4C)**				
6.	Balance calibration check (bracketing of weights for test substance) (Part 4, F) **(RDFN: Section 4D)**				

Part 5.	Trial Site	YES	NO	N/A	In Fac. File?
1.	Directions to trial site (map included) (Part 5, A)				
2.	Directions to test plot (map included) (Part 5, B)				
3.	UTC and TRT Plot layout (detailed, accurate and neatly drawn, with actual plot size and permanent reference noted, distance of UTC to TRT, approx. slope of the plots) (Part 5, C1 & C2)				
4.	Soil characterization (GLP soil analysis or SCS survey data) (Part 5, D)				
	a. % sand / silt / clay				
	b. % organic material or % organic carbon				
	c. pH				
5.	Pesticide/fertilizer history documented. (Part 5,E) Number of years? ___				
6.	Test crop records (variety, species, source, lot no., age) (Part 5, F)				
7.	Row width				
8.	Plant spacing				
9.	Cultural practices (cultivation, etc.) adequately documented (Part 5, G)				
10.	Maintenance chemicals (fertilizers/pesticides) use documented (Part 5, H)				
	Transplant and/or treated seed use documented				
11.	Crop Destruct: has a description been provided to adequately explain crop destruction or handling so that the crop is not consumed by human or animal. Date of destruction and source of info? (Part 5, I)				

Part 6.	Application	YES	NO	N/A	In Fac. File?
1.	Application equipment description (Part A); Diagram/photograph (Part B)				
2.	Application calibration accurate, verified, and according to protocol and SOP (Parts 6: C, D, E, F, each application) **(RDFN: Section 4E/F)**				
	a. Calibration records (If "NO," contact Study Director immediately)				
	b. Rate calculations (If "NO," contact Study Director immediately)				
3.	Treatment Information (Part 6, G & H)				
	a. Incorporation, method, depth and time				
	b. Measuring equipment used				
	c. Mixing order				
	d. Stage of growth of test crop				
	e. Wind speed/direction & Air temperature				

	f. Sky (cloud cover) & Humidity				
	g. Pass times and application narrative (Part 6, I) **(RDFN: Section 6J)**				
	h. Post application rate confirmation (Part 6, J)				
4.	Post treatment records (date/amount of first rain and first irrigation after each application)(Part 6, J). Also any phytotoxicity noted (Part 6, K)				
5.	Trial Differentiation Guidelines L1: Relevant (y/n) L2: Trials sufficiently differentiated?				
6.	Equipment maintenance log (sprayers, hobos, etc.)(Part 6, M)				

Parts 7, 8	Sample Collection and Shipment	YES	NO	N/A	In Fac. File?
1.	General sampling information (harvest/sample dates, PHI) (Part 7, A)				
2.	Method of sampling (Part 7, A) Description (Part 7, A2)				
3.	Processing sampling (if applicable)				
4.	Sample inventory (Part 7, B)				
5.	Interval from sampling to freezing (Notify Study Director immediately in the case of freezer failure and/or loss of sample integrity) (Part 7, B)				
6.	Freezer temperature log (temperatures/temperature range - harvest to shipment) (Part 7, C) **(RDFN: Section 7D)**				
7.	Freezer contents log (do dates match sampling log? - check-in and check-out of samples) (Part 7, D) **(RDFN: Section 7C)**				
8.	Freezer maintenance log (Part 7, E) **(RDFN: No specific prompt)**				
9.	Residue sample shipping information and date to carrier (Part 8, A)				
10.	Sample chain of custody form in raw data (Part 8, B)				
	a. Fed Ex receipt/ACDS bill of lading included/other				
11.	Confirmation of receipt by lab included				

Part 9.	Meteorological/Irrigation	YES	NO	N/A	In Fac. File?
1.	Field trial daily weather records (temp and rainfall from first application to harvest). Also, location of weather record collection and meteorological data (Part 9, A)				
2.	Field trial daily weather records (irrigation - amounts and/or schedule of irrigation events) (Part 9, A supplement)				
3.	Additional meteorological data / on-site observations / comments (Part 9B)				

Part 10.	Additional Information	YES	NO	N/A	In Fac. File?
1.	Original Protocol signed (Part 10, A)				
2.	Protocol amendments included (Part 10, A)				
3.	Deviations noted and Study Director Informed				