SOP Log Sheet

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FRD/LRD: Anthony VanWoerkom
Submitter

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IR-4 North Central Region Research Center
Michigan State University
3815 Technology Boulevard, Suite 1031B
Lansing, MI 48910-8396

STANDARD OPERATING PROCEDURES FOR IR-4 NCR FIELD OFFICE

TABLE OF CONTENTS

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

SOPs submitted by: Anthony VanWoerkom _____ 3/13/20
NCR Regional Field Coordinator **Date**

Date SOPs approved by: John Wise _____ 3/13/20
Regional Director IR-4 Project **Approval Date**

I have read and understand the listed SOPs:

_____
Nicole Soldan, Assistant Regional Field Coordinator

3/13/20
Date

IR-4 North Central Region Research Center
Michigan State University
3815 Technology Boulevard, Suite 1031B
Lansing, MI 48910-8396

SOP Number: NC Region Field Office 1.3	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 NCR IR-4 external hard drive 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 MSU NCR IR-4 external hard drive.

IR-4 North Central Region Research Center
Michigan State University
3815 Technology Boulevard, Suite 1031B
Lansing, MI 48910-8396

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 MSU NCR IR-4 external hard drive. Current files will be maintained in the RFC office.

IR-4 North Central Region Research Center
Michigan State University
3815 Technology Boulevard, Suite 1031B
Lansing, MI 48910-8396

SOP Number: NC Region Field Office 3.3	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.