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IR-4 North Central Region Field Coordinator's Office
Michigan State University
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East Lansing, MI 48823

STANDARD OPERATING PROCEDURES FOR IR-4 NCR FIELD OFFICE

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

SOPs submitted by:

Nicole Soldan

Nicole Soldan, NCR Regional Field Coordinator 4/13/26 **Date**

Date SOPs approved by:

Mary Hausbeck

Dr. Mary Hausbeck, Regional Director IR-4 Project 4/13/26 **Approval Date**

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SOP Number: NC Region Field Office 1.5	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 Field Coordinator's Office, 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 In the event that a SOP is no longer pertinent or applicable to actual standard operating procedures, it shall be retired. The associated unique SOP number will not be reused.

3.0 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.

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

5.0 Original signed SOPs shall be stored at IR-4 Headquarters archive, a scanned copy will be sent to HQ QA and an electronic copy will be kept in the NC RFC files.

6.0 Each SOP should be reviewed every 1-2 years, 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 NC RFC files.

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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 https://ir4.cals.ncsu.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 researchers.

2.0 Regional Field Coordinator assigns field-testing sites within his/her region, ensures that sample bags are provided, ensures that Field Data Books are reviewed 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 researchers (state or contract) under IR-4 protocols.

b) The RFC will ensure that the Field Research Director and their staff are provided with sufficient training and experience to conduct the field trials as outlined in the protocols. Conducting field trials include 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 prompt responses to QA audits. The FRD, or his/her designee also reports all deviations from the protocol or SOPs to the SD.

c) The IR-4 Regional Directors (RD), 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 Research Directors regarding GLP research and SOP development. The Field Research Director will develop SOPs to reflect the needs of their research facility and submit them to the RFC for approval.

d) The RD and RFC may use a facility in the program if it complies with GLP. If needed, and in cooperation with the QAU, the RD and RFC should make constructive suggestions on how the facility may be brought into compliance. Research should not be initiated until the RD/RFC are confident that the facility is GLP compliant.

4.0 IR-4 Recommended Training: All new FRDs and their personnel (if applicable) should follow these training activities before conducting GLP research, unless they already have significant training:

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

b) 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 personnel for orientation of GLP audit procedures and expectations related to IR-4 field trials.

d) RFC will provide training resources and IR-4 orientation materials for new FRD and personnel.

e) All FRDs and their personnel must continue GLP education/training.

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 meeting, regional priority setting meeting, and environmental horticulture meetings biennially.

6.0 The Regional Field Office will maintain curriculum vitae (CVs), job description and training records of the Regional Field Coordinators 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.

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SOP Number: NC Region Field Office 3.5	Pg 1 of 1

Title: Administration and Data: Quality Control (QC) Reviews and Handling of FDBs

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 The QC process for the electronic Field Data Book (eFDB)

1. Once FRD has completed the eFDB and part 1.B is completed, FRD will notify RFC, SD, and HQ. FRD will retain any paper forms associated with this trial.
2. The RFC will determine a QC reviewer and conduct the review of electronic documents. QC findings are sent to FRD, RFC, and SD via email. The FRD then reviews findings and makes necessary changes to the eFDB and paper forms. QC personnel will review the FRD's changes and send the FRD the completed review. FRD will upload corrected forms and upload email communications and completed review to the eFDB.
3. FRD will email RFC, FRD, and SD that QC review is completed. FRD finalizes raw data paper notebook, scans paper pages, ships the paper notebook to HQ, via trackable carrier and notifies HQ of the shipment.
4. Refer to National SOPs located in eQA system for more detailed information.

2.0 The QC process for paper Field Data Books or Canadian Raw Data Field Notebooks (RDFN)

1. Once the FRD completes the FDB/RDFN, they notify the RFC and ship the FDB to the regional office. Prior to shipping the FRD scans the FDB and retains a copy for their files.
2. Received notebooks will be signed in as per the chain of custody page by RFC or Assistant RFC.
3. The RFC, Assistant RFC, or properly trained designee will conduct a QC review.
4. The reviewer will send an email to the FRD and copy the RFC and SD with any findings. The reviewer is able to make changes and additions to the FDB/RDFN with the FRD's permission.
5. Any changes made by the QC reviewer will be scanned and 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.
6. When the field data book review is complete, the updated paper raw data, is scanned and an electronic copy is retained by the NC Region Field Office. The NC Region Field office then 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.

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SOP Number: NC Region Field Office 4.1	Pg 1 of 1

Title: Administration and Data: 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.

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, confirming that QA suggested changes have been incorporated, and any updates reflect the work being conducted by the FRD.

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

5.0 RFC signs and dates the 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 to the FRD.