SOP Log Sheet

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FRD/LRD: Satoru Miyazaki
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STANDARD OPERATING GUIDELINES FOR IR-4 NCR FIELD OFFICE

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	Administration and Data		
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1.1, 2.1, 3.1	Reviewed S.M.	2016	04/19/16

SOG numbering Format: [SOG category] - [SOG number]. [version number]

SOGs submitted by: Satoru Miyazaki Satoru Miyazaki 2/10/15
NCR Regional Field Coordinator **Date**

Date SOGs approved by: John Wise 3/16/15
NCR IR-4 Project Director **Approval Date**

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SOG Number: MSU Field Office -1.1	Pg 1 of 1

Title: Administration and Data ; Standard operating guidelines

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

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:

1.1 All SOGs will be uniquely identified by number. Each number will begin with the prefix 'MSU Field Office' to identify the research facility, followed by SOG category, sequential SOG number and version number.

SOG Categories: Administration and Data

Format: (SOG category)-(SOG number). (version number)
Example: (MSU Field Office)-(1). (1).

2.1 All current, active SOGs will be listed on a Table of Contents. The SOG Table of Contents listing all SOGs will be signed and dated by the author, the Regional Field Coordinator (RFC) or designee and the North Central Region IR-4 Project Director. SOGs are effective as of the date approved by the Director.

3.1 Each SOG 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.

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

5.1 Each SOG 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 SOG 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 SOGs 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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SOG Number: MSU Field Office 2.1	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:

1.1.1 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 coordinates the activities of FRD's.

2.1 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.

3.1 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 will be held 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) 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.

4.1 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.

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

4.3 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.

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SOG Number: MSU Field Office 3.1	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:

1.1.1 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.

2.1 Upon arrival to the MSU Field Office each notebook will be signed in as per the chain of custody page by the Regional Field Coordinator or designee.

3.1 Notebooks will be assigned for review for quality control (QC) by the Regional Field Coordinator or designee. 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 MSU 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.

4.1 The role of the QC reviewer is to insure 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 or alternatively long hand methods of calculations may be done when appropriate and not suited to the Excel spreadsheet.

5.1.1 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 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. 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.

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6.1 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.

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

8.1 When the field data book review is complete, the MSU Field office sends the reviewed notebook on to the assigned QA unit for audit. The notebook is then signed out of the MSU 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-4HQ. The Food Use database is updated indicating the date the FDB is sent on to QA via FEDEX or an appropriate trackable mail system. If the notebook remains in the North Central Region for QA audit, it is hand delivered to the North Central Region Quality Assurance Unit.