SOP Log Sheet

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STANDARD OPERATING PROCEDURES (SOPs)
FOR
IR-4 NORTHEAST REGION FIELD OFFICE

CONDUCTED UNDER GOOD LABORATORY PRACTICES

University of Maryland (UMD)
Lower Eastern Shore Research and Education Center (LESREC)
27664 Nanticoke Road
Salisbury, MD 21801

REVISION NUMBER: 0
YEAR: 2018

SOPs Table of Contents

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1.0	Standard Operating Procedures	
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3.0	Handling of Field Data Notebooks	
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Submitted by: Marylee Ross Date: 07/23/18
Marylee Ross, *Northeast Regional Field Coordinator*

Approved by: Daniel Rossi Date: 07/31/18
Daniel Rossi, *Northeast Regional Director*

I have read and understand the listed SOPs:

Megan James Date: 07/23/18
Megan James, *Assistant Regional Field Coordinator*

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SOP #1.0 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 IR-4 Northeast Region Field Office, University of Maryland (UMD).

PROCEDURES:

1. All SOPs will be uniquely identified by number.

   Format: [SOP number.Revision number] [Title]
   Example: 1.0 NER Field Office Standard Operating Procedures

2. 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 Northeast Regional Director (RD). SOPs are effective as of the date approved by the RD.

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

5. 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.

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SOP #2.0 **IR-4 Regional Field Office Management**

PURPOSE: To define the position and requirements of the Regional Field Coordinator (RFC) as it pertains to the Good Laboratory Practices (GLP) compliant responsibilities.

SCOPE: Applies to the role of RFC for the IR-4 Project. This is further outlined in the context of the entire IR-4 project in the IR-4 Handbook.

PROCEDURES:

1. RFC: Oversees and coordinates the activities of Field Research Directors (FRDs) consisting of state, industry and contract scientists who conduct Magnitude of Residue (MOR) 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 FRDs.

2. RFC assigns field-testing sites within his/her region, provides sample bags, reviews Field Data Books (FDBs) for accuracy and completeness, and facilitates the FRDs' conduct of a field trial.

3. 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.

   A. RFC will ensure conduct of MOR trials fulfill requirements of GLP.

   B. The RFC will ensure that the FRD, and their staff, have sufficient training and experience to conduct MOR trials as outlined in the protocols. Conducting MOR trials includes all activities specified in the protocol such as:

      a) maintaining a crop
      b) applying the test substance
      c) harvesting, storing, and shipping crop samples
      d) accurately completing the Field Data Book on time
      e) providing timely responses to QA audits
      f) reporting all deviations from the protocol or SOPs to the SD

   C. The RD /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/ 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 in compliance.

4. 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. RFC communicates with the IR-4 Northeast Region (NER) stakeholders as to progress and status of the IR-4 NER projects.

6. RFC organizes annual meetings for IR-4 NER State Liaisons and other representatives to discuss and identify regional needs.

7. The Northeast Region Field Office will maintain curriculum vitae (CVs), job description and training records of the RFC and designated support staff. CVs and training records will be archived at IR-4 Headquarters annually, after review and/or revision as necessary. Date and signature of RFC and the designated person on the CV and training record will serve as verification of review. Copies will be placed on the UMD Server. Current files will be maintained in the RFC office.

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SOP #3.0 Handling of Field Data Books

Purpose: To define requirements for all personnel when handling field raw data in the form of Field Data Books (FDBs) sent to the Northeast Region Field Office.

Scope: Applies to all Good Laboratory Practices (GLP) FDBs for the Magnitude of Residue (MOR) trials conducted in the Northeast Region IR-4 Program.

Procedures:

1. FDBs (the ordinal raw data documenting a MOR trial) will be sent to the Northeast Region Field Office upon completion of a trial. Documented arrival of crop samples at the appropriate analytical laboratory will be considered the completion of the field portion of a residue trial.

2. Upon receipt at the Northeast Region Field Office each FDB's Chain of Custody will be signed by the Regional Field Coordinator (RFC) or designee.

3. Upon receipt at the Northeast Region Field Office each original FDB will be scanned, saved to the UMD server and an external drive, logged in to the Quality Control (QC) Record Book and shelved in a fireproof/locking filing cabinet.

4. FDBs will undergo a QC Review in the Northeast Region Field Office by the RFC or the Assistant Regional Field Coordinator.

   A. The purpose of a QC Review is to ensure that the documentation in the FDB is in GLP Compliance. The reviewer will use a standard checklist provided by the Northeast Region Field Office as a guide for conducting the review.

   B. The reviewer will send an email to the appropriate Field Research Director (FRD), or their designee, to request any clarifications or corrections they deem necessary to complete the documentation for the trial represented by the FDB. The FRD or designee will respond via email to the QC reviewer's questions and suggested edits. The QC reviewer is authorized 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 FDB and the email correspondence will be printed and provided in Part 3 Notes and Communications Log section of the FDB.

   C. All additions and corrections made to the FDB pages are scanned and provided to the FRD or designee via email for records at the FRD office. The scans are filed on the UMD server and an external drive in the Northeast Region Field Office.

5. Upon completion, the FDB Chain of Custody is signed to the appropriate Quality Assurance Unit. The book is forwarded with a Confirmation of Receipt letter via USPS Priority Mail (or an appropriate trackable mail system). The date of shipment is documented in the QC Record Book.

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SOP #4.0 **Review and Approval of Northeast Region Field Research Centers' Standard Operating Procedures**

PURPOSE: To define procedures for the Northeast Regional Field Coordinator (RFC) or designee to approve Northeast Region Field Research Director's (FRD) Standard Operating Procedures (SOPs) prior to implementation of SOPs.

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

PROCEDURES:

1. The RFC or Designated Reviewer (DR) will ask FRDs for SOP edits and updates via email reminder once per year.

2. FRDs will send the RFC or DR a copy of their revised SOPs.

3. The RFC or DR will review the SOPs, ensuring appropriate Quality Assurance (QA) suggested changes have been incorporated as well as updates that assure the SOPs match the work being conducted by the FRD.

4. RFC signs and dates the Approval Page.

5. The RFC or DR will scan a digital copy of the final version of the SOPs and email a copy to IR4 Headquarters QA for placement on the IR-4 field program server.

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