SOP Log Sheet

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

CONDUCTED UNDER GOOD LABORATORY PRACTICES (GLPs)

University of Maryland (UMD)
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Revision Number: 1
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SOP Index

Submitted by: Maylee Ross Date: 02/13/25
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Approved by: Simon Zebelo Date: 02/13/25
Simon Zebelo
Northeast Region Director

I have read and understand the listed SOPs:

Megan James Hickman Date: 02/13/25
Megan James Hickman
Northeast Region Assistant Field Coordinator

UMD – LESREC
Northeast Region Field Coordinator's Office

SOP #1.1 **Guidelines for Developing Standard Operating Procedures**

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

SCOPE: All SOPs in this set

PROCEDURES:

1. All SOPs will be uniquely identified by number.
   Format: [SOP number.Revision number] [Title]

2. All current, active SOPs and retired SOPs will be listed on a Table of Contents. The SOP Index listing all SOPs will be signed and dated by the Region Field Coordinator (RFC) and the IR-4 Northeast Region 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 secured shared drive and copy(s) will be kept in areas accessible to approved office personnel.

5. Each SOP should be reviewed approximately once every three years and revised to reflect current procedures, if necessary. A record of the dates of review or revision will be maintained.

6. Glossary of acronyms that will be used throughout this SOP set:

   A. CV: Curriculum Vitae
   B. DR: Designated Reviewer
   C. eFDB: electronic Field Data Book
   D. EPA: Environmental Protection Agency
   E. FRD: Field Research Director
   F. GLP: Good Laboratory Practices
   G. HQ: Headquarters
   H. IR-4: The IR-4 Project
   I. LESREC: Lower Eastern Shore Research and Education Center
   J. MOR: Magnitude of Residue
   K. NE: Northeast
   L. NER: Northeast Region
   M. QAU: Quality Assurance Unit
   N. QC: Quality Control
   O. RD: Regional Director
   P. RFC: Regional Field Coordinator
   Q. SOP: Standard Operating Procedures
   R. UMD: University of Maryland

SOP #2.1 **NE Region Field Coordinator's Office Management**

PURPOSE: To define the position and requirements of the RFC as it pertains to the GLP compliant responsibilities

SCOPE: The role of the RFC and office personnel

PROCEDURES:

1. RFC oversees and coordinates the activities of FRDs who conduct MOR trials.

2. RFC assigns field testing sites within his/her region, provides sample bags, reviews eFDBs for accuracy and completeness.

3. The RFC assists the SDs in meeting their responsibilities while monitoring progress of field trials.

   A. Ensure conduct of MOR trials fulfill requirements of GLP.

   B. 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 samples
      d) accurately completing the eFDB on time
      e) providing timely responses to QA audits
      f) reporting all deviations from the protocol or SOPs to the SD

   C. The RFC reserves the right to use a facility (or not) based on whether the facility is in GLP compliance. If needed, and in cooperation with the Quality Assurance Unit, the RFC should make constructive suggestions on how the facility may be brought into compliance. Research should not be initiated until the RFC is confident that the facility is in GLP compliance.

4. Organizes annual meeting(s) for IR-4 NER State Liaisons and other stakeholders to discuss and identify regional pest management needs.

5. Maintain CVs, job description and training records of the RFC and designated support staff. CVs and training records will be archived at IR-4 HQ with the original set of signed SOPs, after review and/or revision as necessary. Copies will be placed on the UMD secured shared drive. Current files will be maintained in the RFC office.

UMD – LESREC
Northeast Region Field Coordinator's Office

SOP #3.1 **Review of electronic Field Data Books**

Purpose: To define requirements for all personnel when reviewing field raw data through the NE RFC Office

Scope: All eFDBs resulting from MOR trials in the NER

Procedures:

1. When the RFC Office receives notification that an eFDB is complete, it will be noted in RFC records and a QC review will be done as soon as possible. QC Reviews will be conducted by the RFC, Assistant RFC or another assigned DR.

2. All data reviewed by the QC reviewer will be done utilizing assigned username credentials in the eFDB system with "read only" privileges to the data. All eFDB paper raw data for a trial will remain with the FRD and will not be handled by the RFC Office.

3. QC Review Process:

   A. Each eFDB will be reviewed to ensure:

      a) GLP compliance
      b) Protocol Compliance
      c) Site specific SOP compliance
      d) Applicable IR-4 National SOP Compliance

   B. Once the review has been completed, any findings that may result will be sent to FRD via email.

   C. Once final responses are received and appropriate changes have been made by the FRD, the QC reviewer will conclude the review with an email providing instructions on where to send all original eFDB paper raw data and any appropriate next steps for forwarding the eFDB paper raw data to QA.

   D. The RFC office will note in their records:

      a) the date that the QC review was completed
      b) the date that the eFDB paper raw data was forwarded to HQ/QA

   E. The RFC Office will ensure that a copy of the paper raw data is provided by the FRD and stored on the UMD secured shared drive.

SOP #4.1 **Review and Approval of Northeast Region Field Research Centers' Standard Operating Procedures**

PURPOSE: To define procedures for the NE RFC or DR to approve NER FRDs SOPs

SCOPE: The approval of SOPs generated at NER Field Research Centers

PROCEDURES:

1. The RFC or 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 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. He/she returns the approval page to the FRD for final signature. Once both signatures are on the approval page, the SOP set goes into effect.
5. The RFC or DR will ensure that a digital copy of the final version of the SOPs IR-4 HQ.
6. If more than one FRD is located at a field site, they only need to submit one set of SOPs with all signatures included.