UC Davis – Western Region IR-4 Field Office
4218 Meyer Hall UC Davis, Davis, CA 95616

STANDARD OPERATING PROCEDUES – TABLE OF CONTENTS

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SOP numbering Format: [Facility ID] - [sop category] - [sop number]. [version number]

SOPs submitted by: _____ 3/6/2023
Kari Arnold **Date**
Western Region IR-4
Regional Field Coordinator - UCD

SOPs approved by: Robert H. Rice 3/16/2023
Robert Rice **Date**
Department of Environmental Toxicology
Professor and Chair

I have read and understand the listed SOPs:

Mika P. Tolson 3/6/2023
Mika Pringle Tolson, Assistant Regional Field Coordinator **Date**

Jacqueline Hale 3/9/2023
Jacqueline Hale, Office Manager **Date**

Tey Montalvo 3/10/2023
Tey Montalvo, Office Assistant **Date**

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SOP Number: UCD Field Office 10-1.4	Pg 1 of 1
Title: Standard Operating Procedures	

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

SCOPE: Applies to all SOPs in place at the University of California, Davis, Western Region IR-4 Program, Field Office.

PROCEDURES:

1.0 All SOPs will be uniquely identified by number. Each number will begin with the prefix 'UCD Field Office' to identify the research facility, followed by SOP category, sequential SOP number and version number.

SOP Categories: 10 Administration, Personnel and Data

Format: (Facility ID)-(sop category)-(sop number). (version number)
Example: (UCD Field Office)-(10)-(1). (0).

2.0 All current, active 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) or designee and the Chair of the Department of Environmental Toxicology, UCD or designee. SOPs are effective as of the date approved by the Chair.

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 from Field Research Centers will be sent to IR-4 Headquarters for archiving, a scanned original will be kept on the Western Region IR-4 Server and copy(s) will be kept in areas accessible to all field office personnel.

5.0 Each SOP should be reviewed approximately every 2 years and revised as necessary to reflect current procedures. A record of the dates of review or revision will be maintained. The current 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. Copies of outdated SOPs will be destroyed upon replacement or revision of the UCD Field Office SOPs. One scanned copy of each unique set of SOPs will be stored as a PDF on the Field Office Server for historical reference.

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SOP Number: UCD Field Office 10-2.5	**Pg 1 of 2**
Title: 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 Program. This is further outlined in the context of the entire IR-4 program 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 and contract scientists who conduct field trials by applying the test substance, providing crop samples for laboratory analysis, and collecting GLP compliant data.

2.0 The RFC assigns field-testing sites within their region, provides sample bags, ensures reviews of 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. 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) The RFC ensures that the Field Research Director and their staff have sufficient training, resources and experience to 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; and timely, prompt reporting of protocol or SOP deviations and responses to QA audits.

c) The Western Region Field Coordinator will work with IR-4 Regional Directors (RD), Regional Laboratory Coordinators (RLC), other RFCs, the ARS National IR-4 Director, Quality Assurance Unit (QAU) and SDs to meet the responsibilities as outlined above in the western region. They will provide guidance to the FRDs regarding field aspects of 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 (or when appropriate the RLC) for approval.

d) The 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 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 compliance.

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Title: IR-4 Regional Field Office Management	

4.0 The RFC should facilitate and support all new FRD participation in the following training activities before conducting GLP research, unless the FRD already has significant comparable training:

a. Basic GLP training. Required as soon as possible, and before beginning any field trials.

b. A visit to/with relevant established FRDs and a visit with the RFC or designee for hands-on training.

c. A visit to/with regional QA personnel for the purpose of orientation to the GLP audit procedures and expectations related to IR-4 field trials.

d. Various training materials and IR-4 orientation documents for new FRD training and orientation to IR-4.

5.0 The Regional Field Office will maintain curriculum vitae (CVs), and training records of the Regional Field Coordinator and designated support staff (typically Assistant Regional Field Coordinators and/or Field Program Assistants). CVs and training records will be archived at IR-4 Headquarters approximately every 2 years, 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 Field Server. Current files will be maintained in the RFC office.

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SOP Number: UCD Field Office 10-3.6	Pg 1 of 2
Title: 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 Western Region Field Research Directors to the Western Region IR-4 Field Office.

SCOPE: Applies to all GLP study Field Data Books (FDB) for the residue trials conducted in the Western Region IR-4 Program.

PROCEDURES:

1.0 Field Data Books (the original raw data documenting a residue field trial) will be sent into the Western 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 at the Western Region Field Office each notebook will be signed in as per the chain of custody page by the Regional Field Coordinator or designee.

3.0 Upon arrival at the Western Region Field Office each original notebook will be scanned, saved to the server, appropriately labeled, logged into the WR Online Database as "received" and shelved in the Western Region Field Office.

4.0 Notebooks will be assigned for a quality control (QC) review by the Regional Field Coordinator or designee. The QC reviewer(s) may be the Regional Field Coordinator or appropriately trained IR-4 staff or qualified external consultants. The RFC will maintain scanned CVs of all QC reviewers on the field server. Updated CVs will be requested, scanned and saved approximately every 2 years. If the notebooks are leaving the Western 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. If the books are remaining in the Western Region Field Office for review or being hand delivered to the QC reviewer, the QC reviewer will be documented in the online database.

5.0 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 be checked and verified using a standard EXCEL spreadsheet provided by the Western Region Field Office. Alternatively long hand methods of calculation or customized EXCEL spreadsheets may be used when appropriate for studies not suited to the standard EXCEL spreadsheets.

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Title: Handling of Field Data Notebooks	

6.0 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 notebook. The FRD or their designee will provide corrections or changes via email in response to 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 their designee. The clarifications, approved edits or changes are made to the notebook and the documentation correspondence will be printed and provided in Part 3 Notes and Communications Log Section of the Field Data Book.

7.0 Electronic scans of changed or added notebook pages are provided to the FRD via email so the FRD has a record of changed pages in the original notebook that will be sent on to QA for the Field Raw Data Audit.

8.0 When the field data book QC review is complete, the notebook is returned to the Western Region Field Office. A final complete scan is made of the notebook, QC checklist, and application verifications. The final scan is stored on the Western Region server at least until the notebook is archived at IR-4 Headquarters. The file name is updated in the online database for posting to the IR-4 Works website: https://ir4works.org/frd/field-data-notebook/ FRDs are to use this scanned copy when responding to any additional changes requested in subsequent QA audits.

8.1 If the notebook is from a confidential study, it will not be posted on the IR-4 Works website but will instead be made available to the FRD upon request.

9.0 The notebook is then signed out of the Western Region field office via the chain of custody form on the notebook. The Field office staff then sends the reviewed notebook on to the assigned QA unit for audit. The WR online 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 Western Region for QA audit, it is hand delivered to the Western Region Quality Assurance Unit.

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SOP Number: UCD Field Office 10-4.6	Pg 1 of 2
Title: Review and Approval of Western Region IR-4 Field Research Center Standard Operating Procedures (SOPs)	

PURPOSE: To define procedures for the Western Region Field Office Regional Field Coordinator or designee to approve Western Region IR-4 Field Research Directors (FRD) SOPs prior to implementation of SOPs.

SCOPE: Applies to all Western 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(s) (DR) calls for SOP edits and updates via email reminder ~ once a year or every 2 years, according to the Field Research Center's update schedule.

2.0 The RFC or designee ensures that the Field Research Director(s) sends the designated reviewer a digital copy of their revised SOPs with changes marked.

3.0 The RFC/DR reviews SOPs (ensuring QA suggested changes have been incorporated as well as updates that reflect the SOPs match the work being conducted by the FRD) returns a copy to FRD, copying any significant changes/issues to RFC and approves changes.

4.0 The RFC or designee ensures the FRD compiles a completed new set of SOPs and returns it digitally to RFC/DR.

5.0 The RFC or designee ensures the FRD prints two copies of the approved/new index page, signs both copies and mails both copies via FedEx or trackable mail to the RFC/DR. There are two original SOP documents one kept at the IR-4 Field Research Center where the FRD(s) is housed and one kept at the Western Region IR-4 Field Office.

6.0 The RFC/DR receives a digital copy of SOPs (preferably one MS Word document) and places the final version on the IR-4 field program server.

7.0 The RFC/DR receives the printed copies of the revised SOP index, signs both and returns one copy to the FRD and one copy to the WR Field Office.

8.0 The RFC/DR converts the SOP Word Document (from server) into a PDF document.

9.0 The RFC/DR scans the signed original index page and replaces the unsigned index of the SOP with a signed scanned copy of the index.

10.0 The RFC/DR checks to make sure the PDF and word document match (both in content and in format.) The RFC/DR communicates with WR Field Office that PDF is complete and also updates the SOP tracking spreadsheet.

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Title: Review and Approval of Western Region IR-4 Field Research Center Standard Operating Procedures (SOPs)	

11.0 The RFC/DR composes an SOP approval email with an attachment of the appropriate PDF of SOPs. This is sent to the appropriate FRDs (those who signed the SOPs) and copies to the designated authority for cataloging SOPs at IR-4 Headquarters, Western Region QA unit, all Western Region QC Reviewers, all WR Field Office staff along with the link to the SOPs posted on the IR-4 Works website https://ir4works.org/resources/sops/.

12.0 If the SOPs are from a private consultant, SOPs are not approved but maintained in the WR office with a copy archived at HQ. A copy of the SOPs are provided to the same set of people as in point 11.0 but the SOPs are not posted on the WR website. An electronic copy of these SOPs is maintained on the field program server.

13.0 The WR Office prints the SOP PDF file and files the paper copy in the office notebooks for WR Office use and reference.

14.0 When SOPs for WR FRDs are revised for the year, each WR-Field Research Center SOP is posted on the IR-4 works website, preferably prior to sending the approval email (see 11.0 above).