Field ID No. _____

CHAIN OF CUSTODY FOR IR-4 FIELD DATA BOOK

FIELD RESEARCH DIRECTOR: _____

After receipt of this IR-4 Field Data Book, the Field Research Director shall start the chain of custody log by completing the first part. Once raw data entry has begun in the Field Data Book, the data books are to be in the custody of the Field Research Director (or personnel under the Field Research Director's supervision). When the Field Data Book is transferred to another individual (e.g. sending completed Field Data Book to IR-4 Regional Field Coordinator), the sender must note to whom and when the data book is sent. **The recipient must sign the next block and date the form upon receipt.**

.....

Signature of Field Research Director: _____Date:_____

Printed name: _____ Initials: _____

Field Data Book sent/given to: _____ Date Sent: _____

.....

Signature of recipient: _____ Date Received: _____

Printed name of recipient: _____ Initials: _____

Field Data Book sent/given to: _____ Date Sent: _____

.....

Signature of recipient: _____ Date Received: _____

Printed name of recipient: _____ Initials: _____

Field Data Book sent/given to: _____ Date Sent: _____

.....

Signature of recipient: _____ Date Received: _____

Printed name of recipient: _____ Initials: _____

Field Data Book sent/given to: _____ Date Sent: _____

.....

Signature of recipient: _____ Date Received: _____

Printed name of recipient: _____ Initials: _____

Field Data Book sent/given to: _____ Date Sent: _____

Field ID No.___________________________

Additional Chain of Custody Signature Blocks: **DO NOT LINE OUT THIS PAGE!**

……

Signature of recipient: ____ Date Received: ________________

Printed name of recipient: _____________________________________ Initials: ______________________

Field Data Book sent/given to: ____ Date Sent: _____________

……

Signature of recipient: ____ Date Received: ________________

Printed name of recipient: _____________________________________ Initials: ______________________

Field Data Book sent/given to: ____ Date Sent: _____________

……

Signature of recipient: ____ Date Received: ________________

Printed name of recipient: _____________________________________ Initials: ______________________

Field Data Book sent/given to: ____ Date Sent: _____________

……

Signature of recipient: ____ Date Received: ________________

Printed name of recipient: _____________________________________ Initials: ______________________

Field Data Book sent/given to: ____ Date Sent: _____________

……

Signature of recipient: ____ Date Received: ________________

Printed name of recipient: _____________________________________ Initials: ______________________

Field Data Book sent/given to: ____ Date Sent: _____________

……

Signature of recipient: ____ Date Received: ________________

Printed name of recipient: _____________________________________ Initials: ______________________

Field Data Book sent/given to: ____ Date Sent: _____________

FIELD ID NO: _____

FIELD DATA BOOK REVISIONS FOR TRIAL YEAR 2024

Revisions are made in response to suggestions made by Field Cooperators, Regional Field Coordinators, Quality Assurance professionals, Study Directors, and EPA Auditors. They are intended to prompt for additional information where needed, to reduce misunderstandings of the data prompts, and to facilitate the transcription of the data into final reports**. The following are changes made for the 2024 field data book:**

Part 5D: removed "(formerly 5F)" from the title

Part 5E: removed "(formerly 5D)" from the title

Part 5F: removed "(formerly 5E)" from the title

FIELD ID NO: _____

GENERAL INSTRUCTIONS FOR THE COMPLETION OF THE IR-4 FIELD DATA BOOK

This book is designed for use in collecting data in the course of completing a field trial sponsored by the IR-4 Project that **must** be conducted in compliance with the EPA or OECD Good Laboratory Practice Standards. It has been extensively updated in recent years. **DO NOT USE PAGES FROM FIELD DATA BOOKS FROM PREVIOUS YEARS. DO NOT PASTE "Trial Year 2022" ONTO AN OLD VERSION OF A FIELD DATA BOOK PAGE.** (Inserts such as bills of lading do not need to have the Trial Year; field ID# and page# are sufficient.) This Field Data Book (**FDB**) is an authentic record of your work. The IR-4 FDB is divided into Parts, each containing the following information:

PART NO.	SUBJECT
PART 1	GOOD LABORATORY PRACTICE COMPLIANCE INFORMATION
PART 2	PERSONNEL INVOLVED IN TRIAL
PART 3	NOTES AND COMMUNICATION
PART 4*	TEST SUBSTANCE RECORDS (Receipt/storage/disposition records, test substance use log)
PART 5	TRIAL SITE INFORMATION (Maps, soil characterization information, crop/pesticide history, and test crop records)
PART 6*	APPLICATION RECORDS (General equipment information, equipment calibration records, delivery rate calibration/calculations, treatment information, and environment records during treatment)
PART 7	SAMPLE COLLECTION AND STORAGE (General sampling information, sample balance calibration, sample log, freezer temperature and inventory)
PART 8	RESIDUE SAMPLE SHIPPING (Residue sample shipping forms)
PART 9	WEATHER AND IRRIGATION RECORDS
PART 10	PROTOCOL & PROTOCOL CHANGES

*Parts 4 and 6 (and some other FDB pages) are available in versions specific for trials with airblast applications and for greenhouse and seed treatment trials. If you have not received the appropriate Part 4 or 6, then you should contact your Regional Field Coordinator, or print the pages from the IR-4 website under Programs / Food Crops / Food Crop Researcher – Resources / Field Data Book.

If the instructions below are followed, the IR-4 FDB can serve as both a scientific record and a legal document. Failure to comply is not necessarily a protocol deviation, but will result in time-consuming follow-up work by the Study Director, Regional Field Coordinator, QA Officer, and/or the Field Research Director.

1. One copy of each form (template) has been provided. However, some forms require completion of that form on various dates (e.g. Treatment Information Form must be completed for each application date). Prior to entering data, make appropriate number of photocopies of the template(s). Insert the Field ID on each page. If additional templates are needed, contact the Regional Field Coordinator, or print them from the IR-4 website under Food Crop Researcher – Resources / Field Data Book.

2. Some data requested on a form can be applicable to more than one IR-4 field trial. When this occurs, a verified true copy of the completed form can be made and inserted in the proper Part(s) of other IR-4 FDB's. A verified true copy is made by marking on the copy that "THIS IS A TRUE COPY OF ORIGINAL" or similar statement, noting which IR-4 FDB or other documents contain the original and having the person responsible for verifying the copy, initial and date the verification statement. In general, Parts 6G, 6H, 6I, 7A, and 7B should not be copied; they should have original entries. Contact the Study Director if a possible exception exists.

3. Staples and paper clips should not be used on pages in the FDB. Photographs and small pieces of paper with data should be taped to a standard-sized, blank piece of paper.

4. NOTES AND COMMUNICATIONS: More than one day's entry may be made on one page in the log in Part 3. Each day's entry must be dated and initialed. If a day's entry continues on more than one page, both pages must have the day's entry dated. Several trials within the same study under one Field Research Director may be documented on one form; but SEPARATE STUDIES MUST BE DOCUMENTED ON SEPARATE FORMS. When several trials are documented, true copies of the communication records must be placed in each FDB to which the comments apply. (The original goes in one of the FDB's.)

5. Follow all directions on how to complete the FDB carefully. When completing forms, you should enter all of the requested information, if possible. If a particular form or section of the FDB form does not require a response, make a line-out (diagonal line from the top of the page or field to the bottom), then initial and date the line-out or the bottom of the page. (This does not apply to Part 3.) If the requested data are not applicable, give an explanation. Some forms allow the submission of equivalent information versus completion of forms (e.g. verified true copy of recording temperature monitor printout instead of completing the temperature log). Inserted printouts do not need blank areas lined out.

6. All entries should be clear, understandable, legible, and made with a pen in **indelible blue or black ink**. Changes to the raw data can only be made by **drawing a single line** through the original entry so as not to obscure it. The date, signature (or initials) and reasons for change (brief description or Error Code) must accompany any change. Acceptable Error Codes include:

AW=Accidental Write-over	**LE=Late Entry**	**SP=Spelling Error**
CE=Calculation Error	**ME=Measurement Error**	**TE=Transcription Error**
EE=Entry Error	**NA=Not Applicable**	**UE=Unnecessary Entry**
IE=Illegible Entry	**NI=New Information**	**NR=Not Recorded**
IW=Inappropriate Word	**PE=Pagination Error**	**WE=Wrong Entry**

Other error codes can be used; however, the codes must be outlined in an approved SOP or noted in this IR-4 FDB. Circling error codes is not required, but may be done for clarity.

7. **Do not write on the back of any page in the FDB. Do not insert 2-sided documents (pages with printing on both sides) in the FDB. If necessary, make one-sided copies of 2-sided documents for the FDB, and save the original in facility files. The MSDS/SDS for the test substance and adjuvant are not needed in the FDB, though copies should be retained by the field personnel at each trial.** The *OBSERVATIONS, EXPLANATIONS AND COMMUNICATION LOG* (Part 3) can be used to record observations, notes, phone calls, correspondence, and other events that have no specific place in the IR-4 FDB. Also, if there is not enough space in a section of a form to record the complete entry, add another page, or make a reference to Part 3 and complete the entry there.

8. If entries are made on a page over more than one day, each day's entry must be initialed and dated. When more than one person enters data on a page in one day, each of the initials (or signatures) must be dated. Data that have been recorded on non-FDB pages that are being inserted into the FDB must be initialed and dated, even if the data are also transcribed onto an FDB page. Multi-page documents, which are themselves paginated, may be inserted into a FDB with initial and date on the first page only.

9. The FDB should be complete when submitted, with the permissible exceptions of laboratory receipt forms, certificates of analysis, and protocol deviation forms that have been signed by the Study Director. Occasionally, additional exceptions may be made with the permission of the Regional Field Coordinator. Do not make a notation that the requested information will be submitted at a future date. Make a copy that includes each page of the IR-4 FDB for your records. **Send the original to the designated Regional Field Coordinator.**

10. If there are any questions on how to conduct research or capture information in the IR-4 FDB, contact the Study Director and the Regional Field Coordinator. Additionally, the Study Director should be contacted if:
    - the protocol requires changes
    - unforeseen or unavoidable circumstances force a change from protocol directions
    - actual application rate deviates more than - 5% or +10% from the protocol rate

Supported by State, U.S. Hatch Act, and other U.S. Department of Agriculture Funds.

FIELD ID NO: ____________________

OPTIONAL PAGES REMOVED FROM THE FIELD DATA BOOK			
FDB Part	**Enter X if removed**	**Initials**	**Date**
2B			
2C			
4F			
5C3			

♦♦♦

PAGINATION INSTRUCTIONS FOR THE FIELD DATA BOOK

Initial pagination of the Field Data Book:

Pages should be numbered consecutively within each Part, starting each Part with Page 1. Do not paginate sub-parts separately. (There should not be Part 6A, page 1, followed by Part 6B, page 1. Part 6 is paginated as 1, 2, 3… until the last page in Part 6.) **When an FDB Part is initially paginated, the total number of pages in that part is entered at the bottom of page 1 next to the words "Total number of pages in this section at initial pagination".** It is not necessary to enter this total on each page within the section. All pages, including those not originally part of the FDB (such as Bills of Lading), should be paginated and identified with the field ID number. Pages in Part 10 (Protocol & Protocol Changes) do not need pagination or field ID numbers; these pages are intended for reference for the field personnel while they are in possession of the Field Data Book. Pages in Part 6 should be grouped by application#. I.e. all of the pages related to application #1 should come first, followed by all of the pages related to application #2, and so on.

Additional pages inserted into the Field Data Book after it has been paginated:

If a page is added after the FDB has been paginated, number that page with the previous page number and a letter. E.g. a page inserted after Part 6, page 15, would be Part 6, page 15A. If two pages had been added here, the second page would be Part 6, page 15B. The total number of pages that had been entered on page 1 is not revised. The addition of these pages to the Field Data Book must be noted on the table on the next page, with the initials of the person who inserted the pages and the date of entry. **Each row of the table should include only pages entered within one Part on one date (see example below); however all entries made on one date should be initialed and dated as a group. After all new pages have been entered on a particular date, a horizontal line must be drawn across the "Initials" and "Date" column to indicate which entries are confirmed by the initials and date above the line.** Unused portions of this table should not be lined out.

The insertion of a page number does not require initials/date to be entered on that page.

Example: PAGES ADDED TO THE FIELD DATA BOOK AFTER INITIAL PAGINATION			
FDB Part	**Identity of inserted pages (e.g. 6A-B, 9A)**	**Initials**	**Date**
6	7A, 14A	MJ	8/8/21
7	2A, 14B		
4	3A-C	MR	10/1/21
5	1A	KH	2/28/22
6	7B-F, 14C, 20A		

Note: The broken lines under initials and dates are intended to indicate hand-drawn lines. It is not necessary to actually draw the lines broken up this way; they may be continuous.

Field ID No. _____

PAGES ADDED TO THE FIELD DATA BOOK AFTER INITIAL PAGINATION

The information below is added by the person who inserts the new pages into the original Field Data Book, not the field cooperator who is sending the new pages. Each row of the table should include only pages entered within one Part on one date; all entries made on one date should be initialed and dated once as a group. **After all new pages have been entered on a particular date, a horizontal line must be drawn across the "Initials" and "Date" column to indicate which entries are confirmed by the initials and date above the line** (see pg. 6 for example)**.**

FDB Part	Identity of inserted pages (e.g. 6A-B, 9A)	Initials	Date

Do not line out unused portions of this table.

(Additional "Pages Added" tables may be inserted if needed.)