

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: _____

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Signature of recipient: _____ Date Received: _____

Printed name of recipient: _____ Initials: _____

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

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Signature of recipient: _____ Date Received: _____

Printed name of recipient: _____ Initials: _____

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

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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: _____
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Signature of recipient: _____ Date Received: _____

Printed name of recipient: _____ Initials: _____

Field Data Book sent/given to: _____ Date Sent: _____
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FIELD DATA BOOK REVISIONS FOR TRIAL YEAR 2009

Revisions have been made in response to suggestions made by Field Cooperators, Study Directors, Regional Field Coordinators, Quality Assurance professionals, and EPA Auditors. They are intended to prompt for additional information where needed, to reduce misunderstandings of the data prompts by the people who use this book, and to facilitate the transcription of the data into final reports.

Instructions	Pagination instructions have been clarified to indicate that multiple, consecutive pages added after the initial pagination may be noted in the "Pages Added" table as, for example, 6 A - C, rather than 6A, 6B, 6C. Each date's entries for added pages need to be initialed and dated just once, regardless of how many FDB Parts have had new pages inserted on that date. The "Pages Added" page should remain just in front of the divider for Part 1. (<u>Do not</u> place other documents between this page and the divider.)
1B	Clarification has been added that additional pages may be used to describe GLP exceptions.
5A	A computer printout of a map is acceptable.
5D	The instructions clarify that the soil data in the table shall be transcribed.
5E & 5H	The "Formulation" heading in the table has been changed to "Trade Name" for clarification.
6A	The table of nozzle information has been slightly re-arranged. No additional data are required.
6G	The "Application Type" entry has been deleted. "-Volume of Water Removed (if applicable)" has been added for applications in which a large volume of water is first measured (e.g. 2 gallons) and then a small volume is removed (e.g. 9 mL) prior to adding the test substance. "NA" may be entered if no water is removed after the initial measurement. "Equipment used to measure pH" has been added to the table, at the bottom.
6J	The rainfall/irrigation data entered in the table should be transcribed from the data included in Part 9 <u>unless otherwise indicated on this page</u> . (Explanation is prompted when the data differ.) Rainfall and irrigation amounts may be entered in inches or millimeters. (Check-off for units has been added.)
7A	Check-off to indicate if the spray has dried on samples collected at 0-day PHI.
8A	"Were the Chain of Custody Form (8B) and the Sample Arrival Check Sheet (8C) sent with the samples?" This yes/no question has been moved up on the page, just beneath the "Name of Carrier" prompt. "Shipment Destination" is no longer requested, because it is redundant. The Shipping Address should include the name of the person to whom the samples are being sent.
9B	The instructions clarify that descriptions of unusual weather events should be entered "if 'no' is checked" (in response to the question "Was the weather normal?"). "Normal" is also clarified. "If irrigation data are placed in this field data book in a section <u>other than</u> part 9, indicate here the part and page numbers where the data are found: Part____ Pages_____" (Irrigation data are sometimes included among cultural practices in Part 5 or entered in the Notes and Communications in Part 3.)
P&C	Protocol changes pertinent to this trial that have been signed by the Study Director or received by the Field Research Director (FRD) after the Field Data Book has left the custody of the FRD do <u>not</u> need to be inserted into the Field Data Book. A true copy (of completed deviation forms) should be retained in the Field Data Book in the Protocol and Protocol Changes section (rather than Part 1).

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 PRINTED IN PREVIOUS YEARS. All of the data pages in this book should have "Trial Year 2009" in the lower right corner.** (Inserts such as bills of lading do not need to have this phrase; 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:

<u>PART NO.</u>	<u>SUBJECT</u>
PART 1	GOOD LABORATORY PRACTICE COMPLIANCE INFORMATION
PART 2	PERSONNEL LOG
PART 3	NOTES AND COMMUNICATION LOG
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
PROTOCOL & PROTOCOL CHANGES (formerly Part 10)–This part may be kept in the back of the FDB, or moved to the front of the FDB (ahead of Part 1), or inserted between other FDB Parts.	

*Part 6 is available in a version specific for airblast applications. If you intend to apply the test substance in this study via airblast and have not received the pages entitled "PART 6. APPLICATION RECORDS-AIRBLAST SPRAYER", then you should contact the Regional Field Coordinator, or print the pages from the IR-4 website: <http://ir4.rutgers.edu/Fooduse/Fieldbook/index.htm>

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: <http://ir4.rutgers.edu/FieldBook/index.htm>
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 page which is copied 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 that are included in the FDB should be taped to a standard-sized, blank piece of paper.
4. 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 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. 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).
5. All entries should be clear, understandable, legible, and made with a ballpoint 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	IW=Inappropriate Word	PE=Pagination Error
CE=Calculation Error	LE=Late Entry	SP=Spelling Error
EE=Entry Error	ME=Measurement Error	TE=Transcription Error
IC=Incorrect Comment	NA=Not Applicable	UE=Unnecessary Entry
IE=Illegible Entry	NR=Not Recorded	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.
6. 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, *OBSERVATIONS, EXPLANATIONS AND COMMUNICATION LOG* and complete the entry there. Do not write on the back of any page in the FDB.
7. If entries are made on a page over more than one day, each day's entry must be initialed and dated.
8. 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 certified, true copy that includes each page of the IR-4 FDB for your records. **Send the original to the designated Regional Field Coordinator.**
9. 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

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 the Protocol/Protocol Changes section do not need pagination, but should be identified with the field ID number. 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 vertical line must be drawn across the “Initials” and “Date” column to indicate which entries are confirmed by the initials and date above the line.** This page should be kept just in front of the divider for Part 1. Unused portions of this table should not be lined out.

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	<i>JJB</i>	<i>9/13/08</i>
7	2A, 14B		
4	3A-B	<i>URS</i>	<i>10/24/08</i>
5	1A	<i>KSS</i>	<i>8/1/09</i>
6	7B-C, 14C, 20A		

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