

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.**

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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: \_\_\_\_\_

.....

Field ID No. \_\_\_\_\_

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

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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 sent/given to: \_\_\_\_\_ Date Sent: \_\_\_\_\_  
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## FIELD DATA BOOK REVISIONS FOR TRIAL YEAR 2008

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.

All	Page number entries are now in the bottom center of each page (rather than the bottom left).
1B	GLP Compliance page now has yes/no/NA check-offs (rather than no-only check-offs). Information has been added to clarify what is expected for GLP compliance in certain data categories.
3	True copy prompt added to page bottom for use when multiple trials are conducted within one study by a single Field Research Director. (Separate studies should not be documented on the same communications page.) The following statement has been added to the instructions: <i>Printed communications such as faxes and e-mail messages that are inserted into this section should be initialed and dated.</i> A second page has been added with the table, but not the instructions, to provide more space for entries when more than one page is needed.
4A	During temporary storage of the test substance, the following note applies: <i>*Temperature monitoring should begin within two days of receipt of the test substance, regardless of where it is held or stored.</i> (A min/max thermometer is sufficient to meet this requirement when the test substance is in temporary storage.)
4E	A prompt has been added for the unique identifier for the temperature recorder.
5C	Plot map must include the distance between the untreated plot and all treated plots in this study.
5E/5H	The “Product” column has been divided into two columns labeled “Active Ingredient” and “Trade Name”.
5G/5H	The check-off instructions for indicating original data, true copies, or transcriptions now permit more than one item to be checked off. (E.g. some maintenance applications are entered directly into the Field Data Book and others are transcribed from the research facility records.)
6A	Moved “Type of Application” above nozzle table. Added “Number of Passes Made to Treat the Plot”. Clarified that “a local commercial row width” may be used for calculations when the row width in the test plot is unusually wide.
6K	<i>Application Equipment Maintenance and Repair Log</i> now has a column for entering SOP#.
7A	The prompt for the number of trees/bushes from which samples were collected now includes plants and areas of the plot. (Each sample is required by the protocol to be collected from a certain number of plants or bushes or trees or areas of the plot, depending upon the commodity involved.) “Plants” has been added to “Minimum number of fruits/heads/roots (etc.) actually collected per sample”. The prompt “Were samples collected directly into residue sample bags” has been changed to “Were harvested commodities collected directly into residue sample bags”.
7C	A prompt has been added for the unique identifier for the freezer temperature recorder.
8A	An instruction has been added to fax, mail, or e-mail the completed 8A to the study director as well as to the Regional Field Coordinator. Explanation is requested if samples were <i>not</i> kept in required frozen storage conditions prior to shipment. Check-off to confirm that 8B and 8C have been sent with the samples.

## 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 2008" 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

Additional Info: 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). Remember to 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 residue 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:

<b>AW=Accidental Write-over</b>	<b>IW=Inappropriate Word</b>	<b>PE=Pagination Error</b>
<b>CE=Calculation Error</b>	<b>LE=Late Entry</b>	<b>SP=Spelling Error</b>
<b>EE=Entry Error</b>	<b>ME=Measurement Error</b>	<b>TE=Transcription Error</b>
<b>IC=Incorrect Comment</b>	<b>NA=Not Applicable</b>	<b>UE=Unnecessary Entry</b>
<b>IE=Illegible Entry</b>	<b>NR=Not Recorded</b>	<b>WE=Wrong Entry</b>

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 in 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 no longer 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). 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, 6B, 9A)	Initials	Date
6	7A, 7B, 14A	<i>JJB</i>	<i>9/13/07</i>
7	2A	<i>JJB</i>	<i>9/13/07</i>
4	3A, 3B, 3C	<i>URS</i>	<i>10/24/07</i>
5	1A	<i>KSS</i>	<i>8/1/08</i>
6	7C, 14B, 20A	<i>KSS</i>	<i>8/1/08</i>

IR-4 HQ/October 2007

New Jersey Agricultural Experiment Station Publication No. A-27200-03-93.  
Supported by State, U.S. Hatch Act, and other U.S. Department of Agriculture Funds.

