

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: \_\_\_\_\_

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Signature of recipient: \_\_\_\_\_ Date Received: \_\_\_\_\_

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Field ID No. \_\_\_\_\_  
Additional Chain of Custody Signature Blocks: **DO NOT LINE OUT THIS PAGE!**

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## FIELD DATA BOOK REVISIONS FOR TRIAL YEAR 2020

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.

Instructions	<p>Alternate versions of Parts 4 and 6 for use in seed treatment trials are now indicated.</p> <p>Most instructions for the log in NOTES AND COMMUNICATIONS (Part 3) are now included in this section rather than in Part 3.</p> <p>A table for OPTIONAL PAGES REMOVED FROM THE FIELD DATA BOOK has been added on page 6, to indicate if 2B, 2C, and 4F have been removed.</p>
1	<p>Parts 1A and 1B have been merged into Part 1. A statement to insert the SOP index is now above the instructions for the GLP Compliance Statement.</p> <p>A single checkoff is now in place for the GLP compliance of any adjuvants used in the trial. A table with specific GLP-compliance has been added to 4D.</p>
2A	<p>“Address” has been revised to “Office Address”.</p>
2B and 2C	<p>These pages are now designated as optional. They may be removed from the Field Data Book prior to pagination if they are not needed. If pages are removed, this must be indicated (with initials and date) on the checklist that is located in the Instruction section on Page 6.</p>
3	<p>“NOTES AND COMMUNICATION LOG” is now titled “NOTES AND COMMUNICATION”. Many of the instructions have been re-located to the General Instructions section of the Field Data Book. References to faxes have been removed because faxes are rarely used.</p>
4A	<p>Prompt for Anticipated Last Application Date has been removed. An instruction has been added to contact the Study Director if the anticipated last application date is after the expiration date.</p> <p>The separate prompts for Carrier That Transported TS and Bill of Lading/Waybill/Tracking No. have been combined into a single prompt: Carrier/Tracking No.</p> <p>The prompt that asked “Was a Bill of Lading Received?” has been removed.</p> <p>Prompts for GLP status of the test substance have been moved to the top of the second table.</p> <p>Instructions to insert the TS label in this Field Data Book have been removed.</p> <p><i>Temperature monitoring should begin within 2 days of receipt of the test substance by the Field Research Director or the designated person responsible for receiving it, regardless of where (it) is held or stored.</i></p>
4B	<p>CHEMICAL NAME prompt has been revised to NAME OF TEST SUBSTANCE ON CONTAINER LABEL.</p>
4C	<p>Instructions for Part 1 have been shortened and an obsolete URL has been removed.</p>
4D	<p>A yes/no checkoff list of 4 GLP compliance items for the adjuvant has been added to this page.</p> <p>The statement at the top of the page has been shortened.</p>
4E	<p>In the instructions, “<i>certified true copy of the output (data logger disk, computer printout, etc.)</i>” has been replaced by “<i>certified true copy of the data</i>”.</p>
4F	<p>This page is now designated as optional. It may be removed from the Field Data Book prior to pagination if it is not needed. If it is removed, this must be indicated (with initials and date) on the checklist that is located in the Instruction section on Page 6.</p>
4 Divider (Green Page)	<p>The MSDS/SDS may be kept with the label (not in the Field Data Book) or it may be placed in Part 4, after this page (not in Part 10).</p>
Seed Trt Part 4	<p>Prompts for a second seed treatment have been added where appropriate.</p>
Seed Trt 4A	<p>New instruction: Please insert an image of the seed container label...after 4F.</p>
Seed Trt 4A2	<p>Part 4A2 for Seed Treatment trials is now designated as Part 4B; previous seed treatments must be listed</p>
Seed Trt 4A3	<p>Part 4A3 for Seed Treatment trials has been removed.</p>
Seed Trt 4B/C	<p>Part 4C for Seed Treatment trials now includes prompts that had previously been in 4B and 4C.</p> <p>CHEMICAL NAME prompt has been revised to NAME OF TEST SUBSTANCE ON SEED DOCUMENTATION.</p>
Seed Trt 4E	<p>Temperature records for seed should be kept from date of receipt until <u>date of planting</u>.</p>
5H	<p>New prompt: If seed was used, had there been seed treatments*? Yes/No/Seed was not used</p> <p>*If this is a seed treatment study, include only seed treatments other than the test substance.</p> <p>New column added for bracketing tank mixes.</p>
7A2	<p>If samples have not been placed in a freezer within one hour of collection, it is no longer required to enter the high and low transport temperatures, unless a min-max thermometer has been used.</p> <p>Temperature graphs must be inserted when a data logger has recorded the temperatures.</p>

## 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 2020" 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:

<u>PART NO.</u>	<u>SUBJECT</u>
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) is available in versions specific for trials with airblast applications and for greenhouse and seed treatment trials. For these types of trials, you should use the pages entitled PART 4. TEST SUBSTANCE AND SEED RECORDS FOR SEED TREATMENT TRIALS or "PART 6. APPLICATION RECORDS-AIRBLAST SPRAYER" or "PART 6. APPLICATION RECORDS-GREENHOUSE TRIALS" or "PART 6. PLANTING RECORDS-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 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. 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:
 

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



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

<b>PAGES ADDED TO THE FIELD DATA BOOK AFTER INITIAL PAGINATION</b>			
<b>IMPORTANT:</b> The information below is added by the person who inserts the new pages into the <u>original</u> Field Data Book, <u>not</u> the field cooperators who are 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 <u>once</u> 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).			
<b>FDB Part</b>	<b>Identity of inserted pages (e.g. 6A-B, 9A)</b>	<b>Initials</b>	<b>Date</b>

Do not line out unused portions of this table.  
(Additional “Pages Added” tables may be inserted if needed.)