

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: _____

Printed name of recipient: _____ Initials: _____

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

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Signature of recipient: _____ Date Received: _____

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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: _____

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: _____

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FIELD DATA BOOK REVISIONS FOR TRIAL YEAR 2021

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.

3	New instruction: DO NOT LINE OUT UNUSED SPACE ON THIS PAGE.
4F	A space to enter the units measured during the balance calibrations has been added.
5A	“Test Site” has been revised to “Trial Site”. “Location” of the Trial Site has been revised to “Physical Location” (not a P.O. Box).
5B	The instructions for this map are now displayed as an enumerated list, rather than a paragraph.
5C1	The necessary items for the plot plan (5C2) and for reporting test chemicals in adjacent plots are now in an enumerated list (no more check-off column). Slope percentage is now requested on the map.
5C2	New prompts: Date that adjacent-plot information was added to <u>this</u> map _____ Are any <u>treated</u> plots in this trial stacked with plots from another trial? YES _____ NO _____ If YES, enter the stacked trial IDs: _____
5C3	Optional page on which adjacent-plot test chemical information may be entered, instead of 5C2.
5D	Formerly 5F: Data entry cells for crop (including seeding/transplanting) are now grouped together at the top. Data entry cells for plots are now grouped together beneath. Prompts for rows/beds have been rephrased.
5E	Formerly 5D: Simplified instructions. Estimate of slope percentage has been removed from this page (now on 5C). “Date soil sample shipped to laboratory for analysis” has been removed. Copies of USDA Soil Conservation Service data (that are used to support soil characteristics entered into this table) may be kept in the facility file and verified on this page (rather than inserting many pages from USDA publications).
5F	Formerly 5E: Simplified instructions. Prompt for “Applicable Treatment(s)” is now above the table. Check-offs for Trial Site History Data are now Original and Transcribed (previously True Copy and Transcribed).
5G/H	Instructions have been simplified.
5I	New prompt for date of crop destruction, followed by prompt for description (of crop destruction).
6A	Type of Application has been reformatted for clarity. “DOES TREATED AREA (for application rate calculations) = PLOT AREA (from Parts 5C and 5F)?” has been revised to “DOES AREA USED FOR APPLICATION RATE CALCS. = PLOT AREA (from Parts 5C/5D)?”
6B	Items needed in the equipment diagram are now indicated in a bulleted list.
6C	The output calibration pages, formerly 6C1 and 6C2, have been merged into a single page with a calibration table suitable for a boom with up to 6 nozzles/outlets. For equipment with more nozzles or outlets, or for conducting a 3-run target check, an alternate form from the IR-4 website should be used.
6D	The entries for gear, RPM, and length of test track have been removed from the speed calibration table and are now single entries on this page. The table now has cells to enter only each run time, the total run time, the average, and the target or calibration time.
6E/F	Instructions have been slightly modified, including the removal of the statement about computer-generated formulas. A separate line for entering the signature of the person making the calculations has been added to 6F.

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6G	Deleted question: “Has the application equipment been used since the last calibration/recheck was performed?” (Requirements are unchanged, but this question was often misunderstood.) Redundant instructions above the table have been eliminated. The prompt for container# of the test substance has been removed. Prompt for “TIME APPLIED/ INITIALS” now reads “TIME APPLIED/BY WHOM”. Prompt for “PLACEMENT OF TEST SUBSTANCE” now reads “APPLICATION TYPE”. Data entry cells have been enlarged.
6H	Deleted prompt for entering dew level and reworded prompt for estimated %cloud cover. In the greenhouse version, a prompt has been added for SHADE CLOTH: OPEN/CLOSED/NA
6I	New prompt below narrative: WERE THERE ANY PROBLEMS DURING THE APPLICATION? YES/NO <i>If YES, then contact the Study Director as soon as possible.</i>
6J	Instructions have been streamlined to give more space for entering calculations.
6K	Revised phytotoxicity instructions for clarity.
6L	Table of differentiation options now includes just 3 items. This section now fits onto a single page. Minimum distance for trial differentiation is now 30 km (18.6 miles) rather than 20 miles. Option B has been reworded for clarity: Planting date (for annual crops) or first application date in each trial is separated by at least 30 days
6M	Instructions now state that true copies of maintenance logs may be attached.
7A1	Simplified instructions. Deleted prompt for order of sample collection, because this can be determined by the time of day of sample collection entered in 7B.
7A2	Simplified table for indicating the length of time from completion of sample modifications to placement in a cooler by eliminating the middle two columns that had required time that modifications were completed and time that sample was placed in a cooler.
7B	Replaced prompt for initials and date (of the person entering the data for each sample) to a prompt for the initials of the person who collected each sample, with a footnote that states, “These initials serve only to identify the sample collectors; it is not necessary for each collector to enter their own initials”. Deleted statement about describing crop-destruct in Part 5I of the Field Data Book. (That information is still required; just the prompt has been removed.)
7C	The indication for °C or °F has been moved above the table, with the line for initials and date.
7E	The instruction to record calibrations on the freezer has been deleted, as few freezers are calibrated.
8B	The entry line for Trial Location has been deleted. The prompt for fax# has been replaced by a prompt for email address. The column in which Treatment/Rate had been entered in the table is now a column for entering the Treatment# as given in the protocol.
10	The instruction that inserting the MSDS/SDS in this section is acceptable, has been deleting. The common practice has become to insert it in Part 4, after the green page, if it is inserted at all.
All	Throughout the Field Data Book, references to communicating by fax have been removed. Faxing is still acceptable, especially if other options are not available, but it is no longer a regular means of sending information.

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 2021" 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. (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

IR-4 HQ/October 2020

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