IR-4 Electronic Field Data Book Guidance

This document was reviewed and authorized by:

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IR-4 ELECTRONIC FIELD DATA BOOK GUIDANCE

The collection of all data in IR-4 GLP residue studies is governed by the Good Laboratory Practice Standards (GLP's). These standards were set forth by the U.S. Environmental Protection Agency in a final rule in the Federal Register (Vol. 54, No. 158) on August 17, 1989, and can be found in their entirety in 40 CFR Part 160.1 to 160.195. Some actual text of GLP regulations is included in this guidance document for extra emphasis. If you do not have a copy of the GLP regulations, please contact your Regional Field Coordinator for a copy or find it on the IR-4 Website. http://www.ir4project.org/wp-content/uploads/2023/01/FINAL-2022-GLP-HANDBOOK-_48pgs.pdf

Before reading this Guidance Document and conducting trials for IR-4, it is highly recommended that all IR-4 Advisories, see link below, be read and understood.
Food Crop Researcher Resources – IR-4 Project https://www.ir4project.org/fc/fc-researcher-resources/

I. Introduction

Electronic Field Data Books (eFDBs) are used in trials conducted by IR-4 cooperators in support of requests to establish a pesticide tolerance, or to expand or maintain a registration. These trials must be conducted under EPA Good Laboratory Practices (GLP). Any data recording or procedure that is not conducted in adherence with GLP must be noted in the compliance statement.

This document is meant to serve as guidance for Field Research Directors (FRD) and/or Contract Researcher Organizations (CRO) on how to complete eFDBs. It does not illustrate the only acceptable way to complete an eFDB, nor does it cover all the possible permutations within IR-4 studies. It may be acceptable to handle things in a different manner, as long as all GLP issues are addressed, and the data are presented in a manner that can be efficiently reviewed by Regional Field Coordinators (RFC), Quality Control (QC), Quality Assurance (QA) personnel, and Study Directors (SD).

Electronic Field Data Books should be completed and all original paper raw data forwarded to the Regional Field Coordinator (RFC) as soon as possible after residue sample shipment, preferably within two months, unless a different interval is requested. Timely submission of the eFDB is essential to maintaining IR-4 timelines. On occasion, the SD may request special handling of a given eFDB. Such a request must be submitted in writing to the person who has the eFDB (FRD, RFC, or QA), with proper IR-4 approvals.eFDBs should not be handled differently without this authorization.If a trial is dropped or terminated, or if a study is canceled, data entry into the eFDB(s) should stop immediately and the partially completed eFDB(s) paper raw data book should be forwarded to IR-4 headquarters (HQ) per established routing procedures, unless other instructions are provided.Such eFDBs will not be subjected to QA audit, but the trial paper raw data must be filed and eventually archived with the study data at HQ. Filing and archiving the eFDB and paper raw data will be done by IR-4 HQ.

II. General points, common to the entire eFDB

GOOD LABORATORY PRACTICE STANDARDS, 40 CFR Part 160 - Environmental Protection Agency Section 160.130 Conduct of a study: (e) All data generated during the conduct of a study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.

1A. Raw data is defined by its first point of entry. It is strongly suggested that the eFDB be the first point of entry for critical data (e.g., equipment calibration, test substance mixing, test substance application, environmental data, etc.). If not the first point of data entry, transcribe data into the notebook from the raw data (this may be done at any time before notebook completion or data review) and identify the eFDB data as transcribed when saving. The original paper raw data must become part of the study file, and must be sent to HQ with any other paper raw data for the study.

1B. Data entered into an eFDB must be saved by the person entering the data, who will enter their own username and password when saving data. This does not need to be the same username who signed in to open an eFDB online or in an off-line system.

1C: Data should be entered in real time; that is, entry dates should reflect the dates when actions were taken. For example, the dates when Test Substance Use Log entries were initialed and dated on paper or the entry saved in an eFDB, should correspond to the dates the test substance was measured. However, if the data was not entered at the time the action was taken, then this data should be noted as a late entry in the data prompt or in the notes section of the eFDB form. The actual date the action occurred should be provided, but the initials/dates for the late entry must be for the date the data was entered.

1D: Data entered into the eFDB should be entered promptly (within the same day or in real time, if possible). When eFDB data is saved, the person making the entry must enter their username and password, a change rationale (if applicable) and provide whether the entry is direct or transcribed. The eFDB will save the entry and change rationale, with a time and date stamp, noting when the save occurred and whether it was transcribed in the Audit Trail.

2. Data electronically generated should be initialed and dated only if printed. This initialed and dated data printout then becomes the original raw data and is included with the paper raw data in the study.

3A. Any raw data that is not captured directly in the eFDB forms must be scanned and uploaded to the Documents tab for the trial eFDB, if the original or copy is on paper. Electronic

forms that are not printed, instead converted into a PDF or image file (i.e. PDF, JPG, JPEG, and GIF are accepted formats), and uploaded in that format to the Documents tab for the trial eFDB.

3B. Raw data that are not printed or physically copied, do not need to be printed, initialed, dated, and included in the paper raw data for a trial, as long as the file is provided electronically, the location of the original is provided, and the original is adequately retained.

4. The eFDB forms for a trial may be printed using the Print Utility, then completed by hand. The data must then be transcribed into the electronic forms and the paper raw data scanned and uploaded to the trial eFDB. These printed forms with handwritten data are paper raw data that must be kept. (E.g printed application day pages, as a backup during the event that were used for recording data are retained. If the printed back up forms are not used for data entry, they should be discarded)

5A. After an eFDB form is completed and the FRD or field user does not plan to make any further changes, the Form Data should be updated to mark the form as complete and provide the date.

5B. If parts of eFDB form are left blank and the form is marked as complete, these blanks are considered to be marked not applicable to the trial. Further changes to the form can still be made, including revising blanks to provide additional information.

5C. If an eFDB form is not needed for a particular trial, the form should be left blank and marked as complete. If a particular form or section of a form does not apply to the trial, an indication such as ‘NA’, ‘not applicable’, ‘none’, etc., may be added to those sections(s).

III. General points, common to Paper Raw Data Book

1. The eFDB Paper Raw Data Book is designed for use in collecting and maintaining paper raw data, generated in the course of completing a field trial using the eFDB system. Most raw data can be entered directly into the eFDB forms. Other required data must be uploaded as document scans or other electronic files. Optional paper forms are provided for entering required data. Upload the form(s) after data entry, to the eFDB and retain the original entries in this eFDB Paper Raw Data Book. Alternatively, provide the required data in another format via uploading to the eFDB.

2. When data is entered on a paper page on multiple dates, each entry must be initialed and dated. For example: 4B, Test Substance Use Log, or 8A Residue Sample Shipping Information. When more than one person enters data on a paper page, clearly indicate who made each entry with initials and date.

A. In some cases, the paper FDB prompts for the individual making the entries within the page.

B. In other cases, a signature and date at the bottom of the page indicate the data entry person. In this case, if another person enters data on the page, they must initial and date their entries.

3. All entries on paper should be clear and legible. Any change or correction to the paper raw data must be made by drawing a single line through the entry so as not to obliterate the original entry. The change must include the reason for the change, either as a written explanation or as an acceptable error code, as well as the initials of the person making the change and the date. If codes or abbreviations are used in the eFDB that are not defined in the General Instruction at the front of the paper raw data book, they must be defined somewhere in the eFDB.

4. Record the trial number on each paper page of trial-specific data submitted.

5. The order of the subsections of the original Electronic Field Data Book paper raw data should be maintained (e. g. Part 6A, Part 6B, Part 6C, etc.), with supporting data pages (if collected on paper) placed behind the section break pages to which they pertain. If Part 6 forms are completed on paper, it is preferable that the paper pages be arranged by application for multiple application trials. For example, application 1: 6A, 6B, 6C, 6D, 6E, etc.; application 2 (using the same sprayer, no changes): 6C, 6D, 6E, etc. (include 6A and 6B if different equipment is used).

6. All pages in each Part of the paper FDB must be numbered. See pagination instructions in the paper book.

7. Information may be submitted using customized forms or other supplementary data paper sheets. Remove any unnecessary or unused forms in the paper raw data before trial completion.

8. All copies included in the eFDB uploads must be certified copies, and the location of the original specified on the copy. Copies should be made from the original to assure readability. If raw data belongs to two or more trials, such as weather information, the original should be placed in one FDB, in facility files, or in a Common Data Book, with true copies uploaded to all the other affected eFDBs, citing the location of the original.

9. Additional paper pages may be used anywhere the eFDB form does not provide enough space for a complete description or explanation. However, comments added to the Notes section of the eFDB is the preferred method for providing additional explanations. If additional paper pages are generated, these should be scanned and uploaded, then the original wet ink paper page inserted behind the section break pages in the Paper Raw Data Book to which the information pertains. Examples: describing a very involved application, describing a very complicated sample collection, etc.

IV. Specific Paper Raw Data Book Pages

1. The *Title Page* is present for the eFDB paper raw data book. This is not a requirement, but is helpful to subsequent reviewers.

2. The *General Instructions for the Completion of the IR-4 Electronic Field Data Book Paper Raw Data* have been retained. These pages must be present as they contain the correction codes.

3. The *Chain of Custody Form* has been completed by all personnel that have had custody of the Paper Raw Data Book. The blank areas of these pages should not be crossed out.

4. The table of *Pages Added to the FDB After Initial Pagination* should only be filled in by the person **receiving** the new pages and inserting them in the original eFDB paper raw data book. If you do not have the original eFDB paper raw data anymore, then do not fill in the Pages

V. Specific eFDB Forms, by Field Data Book Part

PART 1 – GOOD LABORATORY PRACTICE COMPLIANCE INFORMATION

1A: Research Director Agreement: This form should be completed as soon as reasonably possible after receiving the eFDB and reviewing the protocol. Enter the date of protocol acknowledgment and the dates you expect to conduct the provided activities.

1B: Good Laboratory Practice Statement: The GLP Compliance Form (1B) should be completed and saved by the FRD as the last data entered in the notebook. Any procedure that is not in compliance with GLP must be marked or listed. If the GLP compliance statement provided by the FRD does not accurately reflect the trial, the FRD must approve inclusion of additional items or procedures. The username and password entered when saving represents a signature (and date) that you agree with the compliance statement provided in the instructions.

NOTE: Copies of Standard Operating Procedures (SOP) Index and Title Page, where appropriate, should be uploaded to the eFDB. The SOPs must cover the time from the first application or first GLP activity, through the shipment of the residue samples. That is, the approval signature must be dated before any data are collected for the trial.

PART 2 – PERSONNEL INVOLVED IN TRIAL

2A: Personnel involved in the Trial: This form should be completed with the names of all personnel involved in the trial, including all individuals who entered data and/or worked on the trial (general field workers, harvest assistants, QC, QA, SD, and RFC do not need to be included). If the individual has an eNotebook username, it should be provided.

2B: Qualifications Summary: A completed qualifications summary (provided in the paper raw data book) or CV and training records are to be uploaded to the eFDBfor each person listed in 2A. The original CV should be signed or initialed and dated. CVs and training records must be certified copies, citing where the originals are located.

2C: Temporary/Season Personnel Involved in Trial: This optional form may be used to list personnel who were involved in critical parts of the trial, such as timing pass times or harvesting, but who did not record data and are not listed on 2A. This sheet may be used to name the person and the portion of the trial in which they took part, along with the training they received and who did the training.

PART 3 - USE THE NOTES OR DOCUMENT UPLOADS

The Notes log section of the eFDB forms are the preferred location for the documentation of communications.The Part 3. Notes and Communication Log form provided in the paper raw data book, may instead or in addition, be used for documentation (written logs, phone logs, emails, etc.) of any communication directly involving conduct of the trial that is not documented elsewhere or does not fit elsewhere. Upload to the eFDB documents any emails that are relevant; these do not need to be initialed and dated. Uploaded e-mails do not need to also appear in a communication log. The types of events the communication log/ Notes log may include, but are not limited to:

a. notification/discussion of protocol or SOP deviations

b. discussions of GLP confirmation of the test substance

c. discussion/questions concerning the test substance application, sampling or shipping

d. any unusual events that may affect the integrity of the trial

e. discussions with farm manager or maintenance farm crew

PART 4 - TEST SUBSTANCE RECORDS

4A and 4E: Test Substance Receipt and Storage : All information requested should be entered (except for the storage temperatures), and the page saved at the time of Test Substance Receipt. Please remember to upload packing slips and any other GLP-relevant documentation and place them in the back of Part 4, in the paper raw data book. **Note**: Safety Data Sheets (SDS) are not required, but Part 4 of the eFDB paper raw data book is a good place to include them for handy reference, these do not need to be uploaded to the eFDB. A separate column in the form is added for the same test substance (t.s.) if the lot/batch numbers are different, or if there is more than one receipt date. The name of the t.s. should be entered as it appears on the container label. Be sure it agrees with the protocol and that it, along with the lot/batch number, can be traced through the packing slips and certificate of analysis. If not, contact the SD.

Test substances must be stored under conditions provided on the container label and/or associated documents. Prior to trial completion, the minimum and maximum storage temperatures between receipt and the last application should be entered for each test substance. The temperature recording device unique identifier is also required, and that identifier must be included on all temperature log pages or temperature recording charts, and on device calibration documentation. Attached to the documents section of the eFDB, records of test substance temperature monitoring device logs and its calibration/verification data. Copies must be certified, with the location of the original data cited.

B: Test Substance Use Log: One row per removal from the container should be filled in. Additional rows are added for each additional removal. The dates and amounts entered here should match the dates and amounts recorded in Part 6. These entries should be saved at the time of the measurement. If the same t.s. container is used in more than one trial, add to the Notes section to see the other eFDB for additional removals from this container and document directly in this form under Purpose.

4C: Disposition of Test Substance Containers: Prior to submitting the eFDB to the RFC, the pertinent part of the form should be filled in (how the test substance was handled after trial completion) and the other parts filled out only if the t.s. container was shipped away from the test site. Please do not return containers to the registrant without the permission of the SD and the agreement of the registrant. Please remember that retention of the t.s. container is a requirement. Container retention is not required after all study data is submitted to US EPA. To determine if retention is no longer required for a particular container, follow the procedure outlined in IR-4 Advisory #2005-01.

4D: Identification and Receipt of Spray Adjuvants: This page should be left blank and the form marked as complete if no adjuvants were used in the trial. If adjuvant(s) were used, complete the form and add additional columns for each additional adjuvant container. The adjuvant label(s) should be uploaded to the documents in the eFDB.

4E: See 4A and 4E: Test Substance Receipt and Storage form above.

4F: Balance Calibration Check: If the test substance is a dry formulation, this page should be filled in. Otherwise, it should be left blank and marked as completed. Attached copies of records must be certified, with the location of the original data cited. The standard weights used for a calibration check should bracket the amount of test substance being weighed. If using a scale/balance, a certificate of service and standardization of the scale/balance and/or weights should be uploaded to the eFDB.

NOTE: Test substance label(s), adjuvant label(s), Certificate(s) of Analysis, temperature storage records, Chain(s) of Custody, and other supporting documents are to be uploaded to the eFDB documents section

PART 5 - TRIAL SITE INFORMATION

Upload two maps and plot plan(s) to the documents section of the eFDB: 1) the location of the trial site with highways and nearest town identified, 2) a map of the test plot area within the trial site with directions to the plot from the site entrance, and 3) plot plan(s) with dimensions and locations of each plot within the plot area(s). See the instructions for the minimum requirements of each map/ plot plan. For greenhouse transplant trials, where the application is conducted during the greenhouse phase, include plot plan(s) (an maps if located at a separate address) for each plot location (i.e. Greenhouse and Field test sites).

Use electronic software to create the documents as image files or PDF(s). Or use paper forms described below.

5A and 5B: Directions to Test Site and Site Maps: Please record the name and location of the test site(s). Photocopies of the appropriate section of state or county maps, as well as computer generated or hand drawn maps or diagrams may be used and uploaded to the eFDB documents. See the instructions on the forms for details required on the maps.

The distance from the farm entrance to the plots, the irrigation source, and any on-site meteorological station should be shown on the map of the test plot area or Part 5B.1 paper hand drawn map. If copies are used the location of the original should be identified . All pages should be signed and dated. If the scale of the farm map is such that some of the finer detail, such as the irrigation source would be hard to distinguish, feel free to include two maps.

5B1: Map of The Test Plot Area within the Trial Site: This paper form is provided for optional use. Follow the instructions on the page. Scan and upload the completed form(s) to the eFDB and retain the original with the raw data. If the paper form(s) are not used, discard.

5C. Plot Plan: See instructions on this eFDB form for requirements of the uploaded plot plot(s). Complete this form to provide details that describe the plot layout, when the plot plan is actually made (or when additional details are added).

5C1: Plot Plan: This paper form is provided for optional use. Follow the instructions on the page and/or see the requirements below. Scan and upload the completed form(s) to the eFDB and retain the original with the raw data. If the paper form(s) are not used, discard.

a. Location and dimensions of the treated and untreated plots (length, width, row/bed spacing, etc.) and distances to permanent marker(s) from at least two plot corners per plot. GPS readings for permanent markers are acceptable (an SOP should be in place, including how accuracy is verified). Dimensions of buffer areas are also needed.

b. Number of rows/beds - for established plantings of trees and bushes, the number of plants in the row and the distance between rows is useful here.

c. Direction and % of slope - an arrow should be used to point down the slope. Please note that the slope may go more than one direction.

d. Direction of the rows

e. North direction

Please complete this plan before making the first application. Relative positions and buffers of adjacent trials are to be indicated. Requirements of the plot plan when there are immediately adjacent plots:

a. Distances and relative locations of immediately adjacent plots. (Adjacent plots more distant than 50 feet/15 meters for row crops, or 100 feet/30 meters for tree fruits and nuts, from the plots in this trial do not need to be included.)

b Identity of the test chemical(s) used on the adjacent plots Exception: Proprietary compounds that cannot be identified because of a secrecy agreement may be labeled as “experimental compound” in this eField Data Book (eFDB).

5D: Test Crop Records: Provide information about the test crop and add an additional column for a separate plot or planting event, if needed. The trial site information must be filled in and agree with data in Part 5C. Plot Plan. As the row/bed choices are conditional, the section that does not apply maybe marked not applicable or NA or left blank. Upload any documents to the eFDB that relate to the test crop.

a. If the seed lot is *not available*, indicate with an entry other than NA. For the purposes of the IR-4 FDB, NA = ‘Not Applicable’.

b. Remember to include plot dimensions, the physical land area occupied by the plot. Treated area is captured on Part 6A and in Form 12A.

c. If orchard crops or other perennial crops are used, include the crop age, the number of trees per plot and tree spacing (if applicable), otherwise these can be left blank or marked NA.

d. If transplants are used, include the date of transplant into the test plots, the source of the transplants, date of transplant receipt, lot no. of the transplants, and type of transplanter used, if applicable, otherwise these can be left blank or marked NA.

5E: Site and Soil Information Characteristics: The site and soil information should be filled in. If supporting soil analysis was conducted, these reports should be attached to the Documents Tab of the eFDB. Any supporting soil maps (i.e USDA Soil Conservation Service documents) may be uploaded to the Documents Tab. Preferably, cation exchange capacity, organic matter levels, and pH should be analyzed in the year in which the trial is conducted. If it is a greenhouse or greenhouse transplant trial, include the growing media and list the ingredients. If these or other prompts do not apply, these can be left blank or marked NA. Add an additional column for each separate soil characterization or plot, if multiple soil data entries apply.

NOTE: fields that require a “date” formated entry, will not accept “NA” and must be left blank if the prompt is not applicable.

5F: Test Site History: Three years of pesticide/fertilizer history is requested. Attached scanned paper or electronic records, if facility records, must be certified, with the location of the original data cited. If entered directly into the form or into Excel, add a row for each application of a fertilizer or pesticide. If not directly entered into the eFDB form, do not transcribe the history records into the eFDB form, only provide copies of the farm records. For greenhouse and greenhouse transplant trials, if the greenhouse is cleaned thoroughly and the records of the cleaning are available, the test site history of the Greenhouse pesticide records are not required, provide the cleaning records as a test site history instead.

5F.1 Source of Trial Site History: Verify whether the trial site history information was original or was copied from another source. See the instructions on the form. The FRD may enter the farmer’s name to describe it was verified by the grower . If information was received verbally from a grower, this communication should be contemporaneously documented in the notes tab of the eFDB or paper Part 3. Communication Log.

5G: Cultural Practices Log: This form should be filled in directly, Loaded from Excel and/or attach copies of the original records. Attached records must be certified, with the location of the original data cited. When cultural practice records are attached, the data that pertain to the plots in this trial must be clearly denoted. If entered directly into the eFDB form or into Excel, add a row for each cultural practice conducted on a separate date. If not directly entered, do not transcribe the cultural records into the eFDB form, only provide copies of the farm records.

5H. Maintenance Fertilizers and Pesticides Log: This form should be filled in directly, transcribed from an original document or Loaded from Excel. Attached copies of the original records referenced, if not entered originally, and indicate the entries are transcribed when saving and completing the Form Data. Attached records must be certified, with the location of the original data cited. When fertilizer and pesticide maintenance records are attached, the data that pertain to the plots in this trial must be clearly denoted. When entering into the eFDB form or into Excel, add a row for each pesticide or fertilizer application conducted (even if on the same date and for each separate date). Indicate in the Notes, if needed to describe a tank mix.

5H.1 Source of Maintenance Data and Cultural Practices: Verify whether the cultural and maintenance data was original or was copied from another source. See the instructions on the form. Add additional rows if there are multiple data sources. The FRD may enter the farmer's name to describe it as verified by the grower. If information was received verbally from a grower, this communication should be documented contemporaneously in the notes tab Part 3 of the eFDB or paper Part 3. Communication Log.

5I: Crop Destruction: You must indicate how the crop was destroyed or kept out of the food chain. This is a FIFRA requirement. Where remaining commodity is allowed to drop to the ground and rot, there should be some indication that the researcher has control over that, e.g. on an experimental research station, with limited access and/or signage denoting not to consume. Document the source of the crop destruction information as the initials of the FRD who performed it (or other personnel who are added to Part 2A) or the name of the person who performed it (if not included in the Part 2A) or the information provided as to who or what organization provided the crop destruct information. Indicate whether this data was obtained verbally.

PART 6 - APPLICATIONS:

The eFDB may use different forms than those described below, depending on the nature of the application. These descriptions below apply to standard trials, which are all those that involve a timed output and walking or driving pass times, including airblast sprayers applications, irrigation injection, and for use in some greenhouse trials. Discuss with the Study Director what, if any, different forms may be needed to document data for non-standard applications, including: container drench, seed treatments, and post harvest dips.

Provide in the Notes section or upload an electronic document with additional description, calculations or details, as needed to fully describe the application events and any unusual circumstances. If the document uploaded is an original/ trial specific, include the original in the raw data book. If the document uploaded is a copy, provide the location of the original.

6A and 6B: Application Equipment: Complete this form and attach records of the application equipment. Attached records that are copies must be certified, with the location of the original data cited. Data prompts previously provided on these forms are within the iAdvantage Forms:, The majority of the prompts are located in Form 11A Spray Equipment Description and Calibration. Form 12A contains the actual treated area.

a. If the application equipment and application type does not change, this form only needs to be completed once for multiple applications. Make note if this information applies to additional application events and/or treatments If the crop matures significantly during the conduct of the trial, more than one illustration of sprayer position relative to crop may be useful. Identifying the type of application correctly is important for determining the correct application rates – when in doubt, contact the Study Director.

b. Treated area – the area that is considered treated for rate calculation purposes, paying special attention to banded and directed applications (see the Application Type Definitions advisory document https://ir4.cals.ncsu.edu/other/Advisories/Final2004-02on10Dec04.pdf.

c. If applicable, explain why the treated area (for rate calculation purposes) does not match the physical area of the plot(s).

Form 11: Spray Equipment Description and Calibration: Complete this form and its subparts if the application involves a timed output and calibration of equipment. Select the Calc button before leaving a subpart if there are calculated entries, this does not save the data. Save Data will save for the entire Form 11, all subparts. The save is not needed between entering subparts. After saving all data, if this calibration is needed for a separate application event(s) or treatments, select Clone Calibration. Then Load Calibration to populate these values into this form in other eFDB(s). After loading a calibration, the data should be edited, if needed, before saving the original data.

Form 11A: Description of Spray Equipment: Complete this form. The prompt for List Calibration SOP(s) followed is not required. The Swath Width is particularly important to provide correctly, depending on the application type selected and protocol requirements:

a. The application is a broadcast: the swath width will be calculated automatically by multiplying the number of nozzles (entered on Form 11B) and nozzle spacing.

b. The application is a row middles or soil banded: enter the swath width as for the band width. If unsure, calculate the band/ swath width as x = treated area divided by distance traveled during the application.

c. The application is a soil directed, foliar directed, or directed to the base of the plants: enter the swath width as for the row width. If unsure, calculate the row/ swath width as x = treated area divided by distance traveled during the application.

Form 11B: Time and Distance: complete this form and select Calc to provide the average and speeds. This subpart may be completed before or after subpart Form 11C. See form Part 6D Speed Calibration for additional data prompts required.

Form 11C: Calibration Collection: complete this form by first adding the number of nozzles and select update, then enter the number of runs anticipated for calibration and select update. Add the calibration data to the table and select Calc to provide the totals and averages. Additional runs can be added if needed. See Part 6C Discharge Calibration of additional data prompts required.

Form 11D: Calibration Calculations has no user input. Select the Calc button to populate, if not already populated. This contains data previously located in Part 6E. Delivery Rate Calibration for Application. Optionally, user provided calculations may be uploaded to the eFDB.

Part 6C. Discharge Calibration: Complete this form if the application involves a calibrated output and passtime. If it is a recheck, the calculations showing that it is within 5% of the original calibration must be provided. The calibration or recheck should be the day of or the day before the application.

Part 6D. Speed Calibration: Complete this form if the application involves a calibrated output and passtime. If it is a recheck, the calculations showing that it is within 5% of the original calibration must be provided.The calibration or recheck should be the day of or the day before the application.

Form 12: Test Materials Calculations: Complete this form and its subparts if the application involves a timed output and calibration of equipment. Select the Calc button before leaving a subpart if there are calculated entries, this does not save the entries. Save Data will save for the entire Form 12, all subparts. The save is not needed between entering subparts. This contains data previously located in Part 6F. Volume, Mixing, and Dilution Calculations for Application. Optionally, user provided calculations may be uploaded to the eFDB. These values apply to the entire application (if multiple tank mixes created per treatment, use the total values for all tanks, not individual tanks)

Form 12A. Total Mixture Volume: Complete this form and select Calc.

Form 12B. Material(s)/ Formulation(s): The calculated amount suggested is provided. Enter the actual amount of test substance(s) measured and select Calc.

Form 12C. Adjuvant(s): Enter the amount of adjuvant(s) measured and select Calc.

Form 12D. Final: Enter the amount of water included in the mixture (less any water removed) and select Calc. Save the form before leaving. The provided ***calculated water volume (mL)*** entry may not be accurate depending on the calculated adjuvant amount provided.

Part 6F and 6G. Application Information: Complete the form for each application.

a. If multiple tank mixes are prepared, enter in the time mixed and start time a separate value for each tank prepared.

b. Include in the note if any additional details cannot be captured in this form.

c. The technique used to measure pH should be given, and if this data is not generated according to GLP, indicate this on the Compliance page in Part 1.

d. The application summary should include such things as number of passes, placement of boom (nozzles) in relationship to crop (angled, etc.), band widths and distance from plants, when applicable. Pay particular attention to anything that might be out of the ordinary.

Part 6H. Conditions at Application: Complete this form on the day of the application.

a. Environmental and crop conditions should be filled in so that a person unfamiliar with the trial site could understand. Simple words are preferred over BBCH codes (e.g., first leaves, 20% bloom, unripe fruit, etc.).

b. In the cleaning section include a statement such as: “the excess spray mixture was sprayed on the designated non-crop area,” “the sprayer was rinsed once with water, then washed with detergent and triple rinsed,” etc.

Form 14. Spray Application Rate Verification: Complete this form and its subparts if the application involves a timed output and calibration of equipment. Select the Calc button before leaving a subpart if there are calculated entries, this does not save the data. Save Data will save for the entire Form 14, all subparts. The save is not needed between entering subparts. This contains data previously located in Part 6I Pass Time for Applications and Part 6J Post Application Confirmation for Application. Optionally, user provided calculations may also be uploaded to the eFDB.

Form 14A. Spray Application Delivery: Complete this form, by first entering the number of expected passes and select update. Then enter the data in the table rows for each pass. Add additional rows if more passes are required. Pass times are to be recorded, with appropriate units, as soon as possible after completing the pass(es). Select Calc before moving to the next part.

Form 14B. Formulation(s): No user input. The results of the application are displayed.

Part 14C. Adjuvant(s): No user input. The results of the application are displayed. If the protocol was set up with specific requirements, the results relative to protocol are displayed, otherwise disregard those entries.

Part 14D. Rate Verification: No user input. The results of the application are displayed. The prompts for amount of excess and method of excess disposal are not required. Save Form 14 before closing. If it is necessary to contact the SD for applications made outside the protocol range, this communication should be documented in the appropriate locations.

Part 6K. Post Treatment Records should be completed at the appropriate time after application:

a. Rainfall and irrigation must be entered, even if the event occurred after the next application (but not if the next rainfall or irrigation occurred after all samples were removed from the field plots).
b. If no irrigation was used, state this clearly to avoid questions. For example, in the space for the date of first irrigation, may indicate “None used in this trial,” or “None used after this application.” If no rain or irrigation occurred between applications and harvest, state that also.
c. Provide the California Phytotoxicity Rating, if required per protocol, according to the instructions.
d. If phytotoxicity is observed, contact the SD, this communication should be documented in the appropriate locations.

Part 6L. Differentiation of Multiple Trials Conducted in Close Proximity: If a researcher has multiple trials in the same study or are conducting trials within 30 KM from another trial conducted by another researcher in the same study, he/she should read and understand the instructions in order to sufficiently differentiate one trial from the other(s) and complete the prompts. Only one Part 6L form is provided, in the first application folder, of the eFDB.

NOTE: Upload either a scan of the completed Part 6M paper form provided or another Application Equipment Maintenance and Repair Log to the eFDB. An equipment log for the entire season is preferred. Clearly indicate routine and non-routine maintenance. Entries for all calibrations and cleanings are suggested. If copies of facility records are uploaded, provide the location of the original.

PART 7 - SAMPLE COLLECTION AND STORAGE

7A.1. General Harvesting Information: If more than one crop fraction, such as roots and tops,are being sampled on the same date, separate columns may be added for each fraction to make the sampling procedures clearly understood. If the trial contains multiple sample events and/ or sampling occurs on separate dates, use a separate column for each separate date.

a. The harvest date is the day the samples were cut, dug, or picked. The PHI is based on the harvest date. Enter the last application date and the PHI is automatically calculated.

b. If drying or other procedures are required and the sample is not bagged and frozen on the day it is harvested, then the date that the sample is bagged and frozen is the sampling date.

c. For tree or bush crop trials, the number of trees/bushes from which the commodity was sampled should be indicated. If the number of trees/bushes is less than specified in the protocol, contact the SD.

d. If the protocol requires a minimum number of fruit, heads, roots, etc., clearly state the number that was collected per sample. If more than the minimum # are needed to meet a weight requirement, an approximate # is sufficient. Close approximation is preferable (e.g. if 48 jalapeños were harvested for a pepper trial, an entry of '~50' is preferable to '>24').

e. Provide a brief, but detailed, description of how the samples were harvested to address the protocol requirement for representative samples.

1. At harvest, were plants cut, dug, pulled, combined, etc.?

2. How was a representative sample obtained? A plant/fruit taken from every other plant, every x 5 feet? For multiple rows was a zig-zag pattern used? Diagonal? 5 fruits from each row? For example, a beet plant was pulled every three steps down the row, starting 5 ft. inside the beginning of the plot.

7A.2: General Sampling Information:

Add additional columns for each separate sampling event and/ or if necessary for each crop fraction, to make the sampling procedures clearly understood.

a. If the commodity was not harvested directly into residue sample bags, the explanation needs to state into what they were harvested, e.g., plastic lined baskets, buckets that had been cleaned with soap and water, etc. It is permissible to place the commodity into a plastic resealable bag within the residue sample bag anytime not explicitly forbidden in the study protocol.

b. Describe the sampled commodity, refer to the protocol for specific requirements

c. If sampling occurred after or separately from the harvest, describe the sampling procedures used to ensure a representative sample.

d. Description of modifications – Identify how did the researcher:

1. cut off roots or remove dead/senescent leaves (document what was used); how did the researcher do it; e.g. cut onion leaves 1 inch above bulb?

2. dried the crop (document where, length of time, temperatures, how contamination was avoided, what was cleaned and how)?

3. shelled beans, pit cherries, etc. (document how the process was done; if mechanical sheller, combine or other device used, include model numbers and/or unique identifiers)?

4. cut crop to reduce bulk weight or remove pits (what was done; where was it done; how was sample contamination prevented; e.g. starting with the untreated peaches first, the fruit were cut in half, the pit removed, one half of peach was placed in residue sample bag, the other discarded; the peaches were cut on the plastic covered tailgate of the project vehicle, using a separate cutting board and knife for the untreated and treated samples; the entire untreated sample was completed and bagged prior to starting on the treated samples; new gloves and plastic were used between samples and the cutting boards and knives were washed with soap and water before use)?

   Sample Modification Note: If cutting or pitting is done at the field site, the length of time between completion of sample modification and placement into transport cooler is to be recorded for each sample.

e. Describe sample cleaning (where cleaning is necessary):

1. Generally, it is sufficient to state that loose dirt and debris were brushed off by hand or with a clean brush.

2. If rinsing or other, more drastic cleaning is absolutely necessary, and allowed in the protocol, a detailed description is needed (document where it was done, how much water, running or in separate buckets, dried by patting with paper towel, etc.)

f. It is preferable to transport the unmodified crop (such as whole fruit) from the field to an area near the storage freezers, before sectioning, cutting, or otherwise modifying the crop. Thereby minimizing the time between cutting or modifying and freezing (i.e. modifying the crop could release enzymes that degrade the residue, freezing or cooling slows the enzyme action to help ensure the “worst case residue scenario”). If cutting, pitting, or similar is done at the field site, provide the length of time from modification to cooler or freezer storage (ice box or similar cool or cold storage), which should always be less than one hour.

g. Describe sample transport in enough detail that reviewers can reconstruct what was done. For example, “each sample, as bagged, was placed in a separate cooler for treated and untreated samples, with blue ice and driven to the freezers in a pickup after all samples were collected.” If untreated and treated samples were held in the same cooler, then describe how they were kept separated. If separate coolers were used, clearly state this. If a vehicle was used during transport, note this.

h. Enter the yes/ no prompts for how you prevented contamination at each harvest/ sample event.

7B: Specific Sample Information and Inventory:

a. Add a row for each sample. A separate entry must be made for each sample.

b. The approx. time of completion of sample collection should be as precise as possible. This entry should be expressed in a digital format (HH:MM AM/PM). Twenty-four hour time can be used, if the colon is used to separate the hour and minutes.

c. The approx. time that samples were placed in the freezer should also be as precise as possible. This entry should be expressed in a digital format (HH:MM AM/PM). Twenty-four hour time can be used, if the colon is used to separate the hour and minutes.

d. The elapsed time to freezer from sample collection is automatically calculated (00:00:00). The entry is interpreted as 00 (hours): 00 (minutes): 00 (seconds). The seconds entry in the time is not relevant because no times are listed with precision to seconds.

e. If samples were weighed, provide whether the scale used to determine the weight was maintained as for GLP.

f. If the weight was not recorded, provide the amount of each sample collected and the unit of measure in the Weight (unit) column.

g. If someone other than the FRD collected the samples, provide the initials for which samples were collected by whom.

Note: Upload each of these required documents.

7C: Freezer Temperature Log:

a. This form on paper is provided. Either fill it in and upload or upload facility records, with temperature units (^{o}F or ^{o}C) noted. Data must encompass the entire sample storage period. The unique identity of temperature recording device must be provided on all temperature log pages or temperature recording charts, and on device calibration documentation (inclusion of temperature recording device calibration data is suggested).

b. If records are not original, they must be certified with location of the original cited. The originals must be sent to IR-4 HQ or securely maintained in facility files.

7D: Freezer Contents Log:

a. This form on paper is provided and must be either filled in and uploaded or upload facility records.

b. Copies must be certified and the location of the original cited.

c. Arrows or brackets indicating the trial-specific entries are helpful to reviewers.

7E: Freezer Maintenance and Repair Log:

a. This form on paper is provided and must be filled in and uploaded or upload facility records.

b. Copies must be certified and the location of the original cited.

Records of calibration and/or verification of the temperature-monitoring devices involved in the trial should also be uploaded to the eFDB.

PART 8. - RESIDUE SAMPLE SHIPPING

8A: Residue Sample Shipping Information: Sample-shipping form must be completed.

a. Once sample pickup is scheduled, notify the laboratory and complete the lower section of 8A.

b. For an overnight shipment, the narrative for packing procedure should include the amount of dry ice used as well as the ratio of initial dry ice weight to sample weight.

c. Bill of lading or other shipping documentation should be uploaded.

8B: Residue Sample Chain of Custody Form: The completed form should be scanned and uploaded to the eFDB and the original is kept with the trial raw data book. A true copy should be placed in each shipping box related to the trial. It is highly recommended that these copies be sealed in plastic to prevent moisture damage. The lab will complete their entries on the Lab Use portion of the copy and handle this document per facility SOPs.

8C: Sample Arrival Check Sheet: For shipment of all samples (unless otherwise instructed by the Laboratory or Study Director), place a blank copy in each sample box from the same trial. It is highly recommended that these copies be sealed in plastic to prevent moisture damage. The lab will complete their entries on this or a similar form and handle this document per facility SOPs.

PART 9: WEATHER AND IRRIGATION RECORDS

9A. Meteorological Information

a. The prompts for weather station information should be filled in.

b. Indicate with the yes/no drop down list whether the weather was normal and if there were any severe weather events, during the trial.

c. If the trial is greenhouse only, these prompts can be left blank.

d. If yes is selected for either weather prompt, provide a description and whether there was any impact on the crop.

Information on unusual weather conditions and its potential impact on the crop is essential as the local situation may differ from official weather sites. "Normal" weather is expected to include a range of temperatures and monthly rainfall totals. It is important for the field personnel to evaluate the weather at their own location (Was weather normal?); it is very difficult for the Study Director in his/her office to do so.

9B: Additional Meteorological Information:

a. Provide whether or not the test plots were irrigated. Add additional columns if needed to describe multiple types of irrigation used.

b. The daily irrigation amounts determination description should be completed, if applicable, with as much information as possible to describe how much water was applied and how that was determined.

If the drop down lists do not provide for the most accurate descriptions of water source or irrigation type, select *other* and provide details in the notes.

9A.1: Daily Field Trial Weather Records for Trial Period:

This form on paper is provided. Either fill it in and upload it or provide electronic weather records from a public or private service or upload facility records. Temperature units (ºF or ºC) must be noted. In addition, if irrigation data was collected, upload either a scan of the trial original(s) or electronic irrigation records. Data must encompass the entire field trial period.

If a greenhouse is used, include daily humidity records. If the trial includes greenhouse transplants, with an application occuring during the greenhouse phase, include weather records for the greenhouse and field periods.

The unique identity of the weather recording device(s) must be provided (if used) and be provided on device calibration documentation (inclusion of calibration data is suggested).

If not recording on paper, upload equivalent weather information from a public or private weather data source or a copy of facility records. Include the location of the original and date accessed if from a digital weather service. Copies of facility records must be certified and the location of the original cited.

ATTACHMENTS - PROTOCOL, PROTOCOL CHANGES, AND OTHER HQ DOCS

a. This is where the protocol and protocol changes should be attached by IR-4 Headquarters. The documents can be downloaded here to view.

b. Deviation Form: This form is provided for use if needed. **Please note that the wet ink original of a deviation shall be sent to the SD, even though the notification was made by phone, text, or e-mail.** Scan(s) of field site deviations (prior to SD signature) must be uploaded prior to shipment of the original to the SD. Signed scans of SOP deviations should be uploaded to the eFDB if relevant to an active trial.

c. Paper Raw Data Book: This document should be printed as soon as trial original raw data is recorded or provided on paper. The paper original raw data must be maintained in the Paper Raw Data Book for the trial, unless maintained as for a facility record. Follow the instructions and complete the document as if it is a mini paper Field Data Book. Include in the appropriate sections any paper raw data generated during the trial.

VI. Electronic Field Data Book Recommendations:

How to Ensure you are GLP Compliant with your eFDB Device

Items to check, see 40 CFR 160, Subpart D – equipment for details (https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-160/subpart-D)

1. **eFDB Design** –The eFDB device must have adequate functionality and be suitably located for operation, maintenance, cleaning, and inspection.

    a. There must be adequate control of access to the device, particularly when forms are checked out on the device. Treat it securely, like a paper FDB or keys.

2. **eFDB SOPs** – There must be test site specific written SOPs for the methods, materials, and schedules to be used for inspection, cleaning, maintenance, testing, and/ or standardization of GLP equipment, including the eFDB device. And remedial action to be taken in the event of a malfunction. And the person responsible for the performance of the SOP(s).

    a. There must be written SOPs for how to use (enter data into) the eFDB. This is being provided as an **IR-4 National SOP.**

3. **eFDB Records** –There must be maintenance records for each eFDB device, which includes the computer make and model, and identifying code (s/n), and the eFDB software version, with dates of maintenance, testing, and/or standardized operations. And who performed the maintenance, whether it was routine or the result of a malfunction, and if so, the nature of the defect, how and when discovered, and any remedial action taken to resolve.

    a. **Maintenance log is** required for any eFDB accessing and entering data device

    b. If offline use, should have a **verification test result(s)** or other documentation of verification(s) kept with the Maintenance log(s).

4. **eFDB Records Retention** – The eFDB records above must be retained and archived as appropriate for the test site facility records SOPs.

5. **eFDB Training**- The eFDB users entering GLP data must be adequately trained, with dates and descriptions of training included in their personnel files. Training is required to be provided by an eStudy Administrator, unless approval is provided by an eStudy Administrator for another person to provide training.

6. **Using paper data that is transcribed to electronic data-** Any paper raw data must be adequately retained, with secure access, and protected from deterioration.

How to Avoid Data Loss

Data loss can occur anytime a user has a “checked out” form on their own device with original data entered, that is never “checked in” to the iAdvantage servers. This can occur if the device with the data is lost, stolen or damaged beyond restitution. Avoid these situation by:

1. Avoid leaving any eFDB device in an unattended vehicle. Power off the device or turn on Airplane Mode, anytime a device is left unattended for an extended duration in public, which helps prevent thieves from tracking the wireless signals from the device.
2. Avoid leaving any eFDB device in a vehicle or building that may overheat or freeze. Safe temperature ranges for most devices are between 50 and 95 degrees Fahrenheit (unless using a “rugged” device that is designed to be operated in extreme conditions).
3. If the device is to be operated in weather below 50 degrees, warm the device first, by turning it on inside a warm area before use. Never leave the device in freezing conditions for a long period of time. Do not use any external heat source to warm the device.
4. If the device is to be operated in hot and sunny conditions prevent it from overheating!
    a. If the device gets hot (Hot, NOT Warm, which is normal) to the touch, allow it to cool before using it.
    b. Do not place the device on a soft surface that blocks the fan vents.
    c. Do not operate the device within a case or bag that blocks fan vents.
    d. Do not place the device directly beside other sources of heat, such as printers or heat exhaust.
    e. Always turn the device off before storing it in a bag or padded case.
    f. If the device is regularly hot to the touch regardless of weather, it should be inspected and/ or serviced.
    g. If the workspace is unavoidably sunny, consider operating it under shade, such as under a pop-up canopy, in a vehicle, or by purchasing a computer shading device.
    h. If the workspace is unavoidably hot, consider purchasing a cooling device, such as supplemental cooling fans, or storing the device in a cooler with ice substitute when not directly in use.
5. Check back in eFDB forms as soon as possible, when within internet connection again. Any data prompts not completed at the time of “check in” can be completed in the online version.
6. Contact the Study Director and eStudy Administrators if any error message occurs during the entry, saving, or upload/ download of the eFDB forms.
7. Keep backup of critical paper forms available when conducting events with direct data entry in the field (i.e. print application forms in case of device failure, this data can then be recorded on paper).
8. Avoid any exposure to liquids or moisture that can enter device components. The most likely situation being a spill in the keyboard of a laptop. Detachable keyboards or keyboard covers should be used if there is potential for liquids or moisture to damage internal electronics. Tablets are less likely to have moisture exposure issues, especially if kept in a waterproof case.

Data loss could also occur if there is a critical power or internet connection failure during upload (check in) of the forms. Unless there is a sudden power outage at the test site that occurs during the upload, this situation would be a failure on the iAdvantage/ Oracle Server side. Contact an eStudy Administrator if there is any potential data loss encountered.

Feature to restore data if a sudden failure or browser closure occurs

The online eFDB forms include a feature that creates a backup of any form that is opened, every few seconds it is open. Even if no data is added or changed there is a backup created.

If the user's device or internet suddenly fails or if the browser window is closed before saving, upon opening the eFDB form(s) again, the system will prompt to either restore or discard cached data. Cached data is stored as a "cookie" on the iAdvantage server. Any user who opens the form(s) will be prompted to restore or discard the most recent backup that was not saved. This includes viewer only and writer users.

If the option to restore is selected the most recent backup will populate the form and the user can then decide to save or modify the data before saving.

If the user chooses to discard the cached data, the prompt will ask to confirm and then that backup will be discarded and only the most recently saved data will be shown.

Anytime a user opens a form and does not save it before closing the form, the prompt will appear the next time the form is open. The user should choose to save data before closing a form to avoid the prompt and only select Restore Data if they know that there was lost data that needs to be restored.

Viewer only access username roles have no reason to select to Restore Data and should only view the saved entries, which were actually recorded in the forms, by selecting to Discard.

Passwords and auto logout feature to avoid unauthorized access

The online eFDB system contains a timeout feature that will automatically log off any user who does not click into an eFDB page for 20 minutes. If the automatic logout feature triggers, the user will need to re enter their account credentials and then the system will restore the page where they left off, see above if a backup restoration pop up appears.

Passwords must be kept secured. Do not share your password. If multiple users access a eFDB device, do not use a password manager to store the username and password. The username and organization code may be saved in the browser or password manager, but passwords must not be automatically applied by a person who is not the user.

Passwords must be a minimum of six characters. There are no requirements for unique character types. If the user fails after five attempts to provide a correct password, the user will be locked out and an eStudy administrator will be notified to reset their password and to restore access.

Disaster Preparedness

Each test site must have at least one eFDB device that is capable of using the system in the offline version. If there is extreme weather anticipated and the internet will not be available, the user may check out forms in advance, to ensure continuity in operations.

The eFDB form templates (without study/ trial codes, etc) should be available as printed hard copies at each test site, as a backup for sudden outages. These blank forms are available on the IR-4 Website, Researcher Resources https://www.ir4project.org/fc/fc-researcher-resources/.

Sudden impact from a power outage or system failure should be communicated to the eStudy Administrator and Study Director as soon as possible to help resolve. Written SOPs should be available at the test site, to plan in case of extreme situations and how to avoid impact on eFDB devices and data (e.g how to avoid the device from being stored in a building that would be subject to freezing conditions during certain times of year).

Who to Contact for Help

1. If there is a single issue, question, or concern, and it is not time sensitive, e-mail at least one of the eStudy Administrators. See the IR-4 Website - HQ Staff Directory https://www.ir4project.org/hq-staff/ for contact information.
2. If there are multiple issues, questions, or concerns, and they are not time sensitive, schedule an open office half-hour Zoom meeting. See the IR-4 Website, Researcher Resources https://www.ir4project.org/fc/fc-researcher-resources/ for how to schedule office hours with an eStudy Administrator.
3. If there is any issue, question, or concern that is time sensitive, call or directly message one of the eStudy Administrators. See the IR-4 Website - HQ Staff Directory https://www.ir4project.org/hq-staff/ for contact information. There should be a follow up email after the conversation to document what was discussed and to communicate the situation to any other parties.
4. If the eStudy Administrators do not respond, contact the Study Director and/or Regional Field Coordinator.
5. If the Study Director is unavailable, contact the IR-4 Management identified in the protocol.