

IR-4 Field Data Book (FDB) Guidance Document



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This document was reviewed/updated on behalf of the IR-4 Education & Training Committee

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IR-4 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 (<http://www.gpoaccess.gov/cfr/index.html>) 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 EPA website.

Before reading this Guidance Document and conducting trials for IR-4, it is highly recommended that all IR-4 Advisories (<http://ir4.rutgers.edu/trainingadvisories.html>) be read and understood.

I. Introduction

Field Data Books (FDBs) are used in all 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 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 fill out FDBs. It does not illustrate the only acceptable way to complete a FDB, 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).

Completed Field Data Books should be 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 FDB is essential to maintaining IR-4 timelines. On occasion, the SD may request special handling of a given FDB. Such a request must be submitted in writing to the person who has the FDB (FRD, RFC, or QA), with proper IR-4 approvals. FDBs 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 FDB(s) should stop immediately and the partially completed FDB(s) should be forwarded to IR-4 headquarters (HQ) per established routing procedures, unless other instructions are provided. Such FDBs will not be subjected to QA audit, but must be filed and eventually archived with the study data at HQ.

II. General points, common to the entire Field Data Book

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.

It is acceptable to use initials in lieu of a signature, or a signature in lieu of initials, provided that the person's initials and signature are entered in Part 2A of the FDB.

NOTE: Double-sided pages are prohibited in the IR-4 FDB, due to the increased chances of losing information during subsequent copying activities.

1. 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 should correspond to the dates test substance was measured.
2. When data is entered on a page on multiple dates, each entry must be initialed and dated. For example: 4B, Test Substance Use Log, or 8A Residue Sample Shipping Information.
3. When more than one person enters data on a page, clearly indicate who made each entry with initials and date
 - A. In some cases, the FDB prompts for the individual making the entries within the page (4B).
 - B. In other cases, a signature and date at the bottom of the page indicate the data entry person (8A). In this case, if another person enters data on the page, they must initial and date their entries. For example, if more than one person collects weather and field condition data and enters it on 6H, the person not signing the bottom of the page should initial and date each entry he/she made.
4. All entries should be clear and legible. Any change or correction to the 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 FDB that are not defined in the General Instructions at the front of the book, they must be defined somewhere in the FDB such as in Part 3.
5. Data electronically generated should be initialed and dated when printed. This includes, but is not limited to: e-mail, electronic temperature monitoring device data, and weather station data. This initialed and dated data printout then becomes the original raw data.
6. All pages must be identified with at least a complete Field ID number, as provided in the protocol. The field ID number is a trial-specific number in the format *ZZZZZ.XX-YYNNN*, where *ZZZZZ* is the study number [a number based on the Project Clearance Request number

(abbreviated as PR#)], XX are the last two digits of the year, YY is the state or province, and NNN is a one, two or three digit trial number assigned to a given state or province. Examples are 09999.01-NY19 or 08899.01-CA*109 (an "*" after the state abbreviation indicates that the trial will be conducted at a USDA-ARS site).

7. The order of the subsections of the original Field Data Book should be maintained (e. g. Part 6A, Part 6B, Part 6C, etc.), with supporting data pages placed behind the pages to which they pertain; for example copies of weather data printouts should be behind 9A, followed by 9B. Other supporting data should be included where necessary and logical. In Part 6, it is preferable that 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).

8. All pages in each Part of the FDB must be numbered including those pages not originally part of the FDB (i.e. supporting data). The pages should be numbered consecutively within each Part, starting with Page 1. The total number of pages in a particular FDB section will be recorded at the time of original pagination in the prompt provided on the bottom of the first page of that section. If a page is added after the original pagination, number the page with the previous page number and a letter, for example Part 1, page 5A. Within each part of the FDB, all the pages in the entire part should be numbered consecutively, regardless of the subsection. For example, in Part 6, no matter how many applications there have been in the trial, there should only be one Page-1, one Page-2, and so on.

9. All forms must be completed and all data prompts (lined areas and tables) must have a response. If a particular form or section of a form does not apply to the trial, some indication, such as 'NA', 'not applicable', 'none', etc., should appear.

10. Information may be submitted using customized forms or other supplementary data sheets, but extensive use of customized forms is discouraged. Where other forms are used, its equivalent FDB form must precede the new form. In this case the FDB form or section of the form must be properly annotated (e.g. see next page), lined out, initialed and dated. The customized form should be arranged in such a way that a person unfamiliar with the form can easily understand the information on that form. All of the data that is prompted for in the IR-4 form must be entered on the customized form. DO NOT REMOVE unused FDB pages – line them out.

11. Lining out should be done using a diagonal line from the top of the page or section to the bottom. If the form or section of the form is simply not needed, an initial and date are sufficient. Unused portions of tables or lined areas that are greater than 2 lines should also be lined out, initialed and dated. Blank areas after written descriptions, calculations, etc., of similar size should also be handled in this manner. Inserted printouts do not need blank areas lined out. This includes pesticide labels, weather data, maintenance chemical application lists, and other documents that are inserted into the FDB.

12. All copies included in the FDB must be certified copies, and the location of the original specified on the copy. Copies should be made from the original to assure readability. In the

case of application calibrations used for more than one application in a given day, the original will be placed in one FDB, and certified copies (see bottom of IR-4 form 6C and D) in other affected FDBs, citing the location of the original. 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 (these are allowed in some cases; contact your RFC for more information.), with true copies in all the other affected FDBs, citing the location of the original.

13. Additional pages may be added anywhere the FDB form does not provide enough space for a complete description or explanation. These additional pages should be inserted behind the pages to which the information pertains. Examples: describing a very involved application, describing a very complicated sample collection, etc.

14. When adding pages to a FDB, be careful that holes are not punched through data. If this happens, write in the lost data as though it were an I.E. (Illegible Entry). Note: After FDBs leave the FRD, they are not kept in ring binders, so holes are not necessary.

III. Review for completeness, general: During review of the introductory pages of the FDB, be certain that:

1. The Title Page is present. This is not a requirement, but the page is included with the protocol and is helpful to subsequent reviewers.
2. The **General Instructions for the Completion of the IR-4 Field Data Book** 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 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 FDB. If you do not have the original FDB anymore, then do not fill in the Pages Added table.

IV. Review for completeness, specific review, by Part:

PART 1 – GOOD LABORATORY PRACTICE COMPLIANCE INFORMATION

- 1A: Standard Operating Procedures: Should be completed or crossed out, initialed and dated with a reference to attachments. Copies of SOP Index and Title Page, where appropriate, should be inserted. If certain SOPs need to be added to the FDB, insert them here. The SOPs must cover the time from the first application through the shipment of the residue samples. That is, the approval signature must be dated before any data are collected for the trial.
- 1B: Good Laboratory Practice Statement: The GLP Compliance Form (1B) should be completed and signed by the FRD. 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 signature (and date) on this page **MUST** always be an original for each FDB, even if the non-compliance issues are the same as in other trials. If a compliance statement has been preprinted, it is important to confirm that it is correct for each individual trial; for example, a trial conducted with a granular pesticide should not have GLP exceptions noted for adjuvants or pH strips.

PART 2 – PERSONNEL INVOLVED IN TRIAL

- 2A: Identification of Individuals: This page 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). This may be a certified copy of an original, but the location of the original must be cited as either another Field Data Book, the facility files, etc. It is preferable to have an original of this Part 2A in each FDB. This page has a “true copy” prompt at the bottom, but FRD are encouraged to provide originals, thus confirming the listed people did work on this trial, not everyone associated with the test site.
- 2B: Qualifications Summary: A qualifications summary or CV and training records are to be included here for each person listed in 2A. The original CV should be 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 - NOTES AND COMMUNICATION LOG

This part should contain documentation (written logs, phone logs, emails, faxes, etc.) of any communication directly involving conduct of the trial that is not documented elsewhere or does not fit elsewhere. The types of events the communication 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. email printouts that are initialed and dated
- f. discussions with farm manager or maintenance farm crew

Although the instructions on this FDB page state “for continued entries or explanations to other sections,” a preferable location for that type of additional pages might be behind the page to which the continuation or explanation pertains.

PART 4 - TEST SUBSTANCE RECORDS

- 4A: Receipt, Storage and Disposition of Test Substance: All information requested should be entered, and the page signed and dated at the time of Test Substance Receipt. Please remember to include packing slips and any other GLP-relevant documentation and place them in the back of Part 4, after 4F. **Note:** Safety Data Sheets (SDS) are not required, but Part 4 of the FDB is a good place to include them for handy reference. If the SDS is to be included in the FDB and it arrives as a double-sided document, please make a single-sided copy prior to insertion. Double-sided pages are prohibited due to the increased chances of losing information during subsequent copying activities. A separate form is needed 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.
- 4B: Use Log: One log per container should be filled in. The dates and amounts entered here should match the dates and amounts recorded in Part 6. These entries should be made at the time of the measurement. Unused cells should be crossed out, with initials and date. If the same t.s. container is used in more than one trial, one log should be filled in for all uses and placed in one FDB, with a certified copy placed in FDBs for other trials.
- 4C: Disposition of Test Substance Containers: Prior to submitting the FDB to the RFC, the pertinent part of the page should be filled in and the other parts crossed out, with initials and dates on the lines, or the signature and date at the bottom of the page. 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 Additives: This page should be crossed out if it does not apply, or the pertinent part filled in, with the rest of the page filled in or crossed out, initialed and dated. The adjuvant label(s) should be inserted after 4F of the FDB.
- 4E: Chemical Storage Temperature Log: This table should be filled in and/or attached records referenced. If more than one t.s. was used, indicate such in lower section of 4E or cross out prompts for second t.s. The minimum and maximum storage temperatures between receipt and the last application should be entered for each test substance. Attached records must be certified, with the location of the original data cited. The temperature recording device must have a unique identifier, and that identifier must be included on all temperature log pages or temperature recording charts, and on device calibration documentation. The test substance temperature monitoring device logs and its calibration/verification data should be included in the

FDB. Test substances must be stored under conditions provided on the container label and/or associated documents. If this is not possible, contact the SD immediately.

- 4F: Balance Calibration Check: If the test substance is a dry formulation, this page should be filled in. Otherwise, it should be crossed out, initialed and dated. Attached 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 weights should be included.

NOTE: Test substance label(s), adjuvant label(s), Certificate(s) of Analysis, and other supporting documents are to be placed after the green page located behind 4F.

PART 5 - TRIAL SITE INFORMATION

If the allocated spaces for maps and plot plans are not used, they should be lined out, initialed and dated, and the attached map or diagram referenced.

- 5A: Directions to Test Site: Please record the name and location of the test site. Photocopies of the appropriate section of state or county maps, as well as computer generated maps or diagrams may be used. The rest of the page should be filled in and/or attached records referenced.
- 5B: Directions to Test Plot Area: The distance from the farm entrance to the plots, the irrigation source, and any on-site meteorological station should be shown on 5B or 5C2. If copies are used, an original should be found in the facility file. 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.
- 5C1: This checklist is to assist the researcher in meeting plot map requirements and must be completed prior to FDB submission.
- 5C2: Plot Plan: The plot plan can be drawn on a separate sheet and inserted. The plot plan must include:
- 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. 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.
 - 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.
 - 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.
 - Direction of the rows
 - North direction

Please complete this plan before making the first application. Relative positions and buffers of adjacent trials are to be indicated.

NOTE: An alternate 5C2 has been developed and may be more useful in certain situations

- 5D: Site and Soil Information Characteristics: The site and soil information should be filled in with supporting soil analysis or soil maps attached. Soil characterizations should be no more than 15 years old. Please note that USGS taxonomic information is not equivalent to a soil characterization. Preferably, cation exchange capacity, organic matter levels, and pH should be analyzed in the year in which the trial is conducted. Attached copies should be certified, with the location of the original data cited.
- 5E: Test Site History Form: Three years of pesticide/fertilizer history is requested. Attached records must be certified, with the location of the original data cited. If information was copied from another source, it must be clearly marked as transcribed. It is recommended that a second person verify the accuracy of any transcriptions. The person verifying the data does not have to be GLP trained, listed in Part 2A or sign their name in the FDB. For example, if the data is being verified by a farmer, the FRD may enter the farmer's name in the blank provided. If information was received verbally from a grower, this communication should be documented in Part 3 of the FDB.
- 5F: Test Crop Records: The trial site information must be completely filled in and agree with data in 5C. As the row/bed choices are conditional, the section that does not apply should be lined out.
- 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'.
 - Remember to include plot dimensions, the physical land area occupied by the plot. Treated area is captured on Part 6A.
- 5G/H: Cultural Practices Log and Maintenance Fertilizers and Pesticides: These pages should be filled in and/or attached records referenced. Attached records must be certified, with the location of the original data cited. Please note that transcription and verification guidance covered in Part 5E apply here also. When maintenance records are attached, the data that pertain to the plots in this trial must be clearly denoted.
- 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.

PART 6 - APPLICATION: NOTE there are different forms available on the IR-4 website for airblast sprayers and for use in greenhouse trials.

6A&B: Equipment and Diagram of Application Equipment: Both forms should be completely filled in and/or attached records referenced. Attached records must be certified, with the location of the original data cited.

- a. If the application equipment and application type does not change, these forms only need to be included once for multiple applications. 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 FDB directions for 6A).
- c. If applicable, explain why the treated area (for rate calculation purposes) does not match the physical area of the plot(s).

6C-J: These forms must be provided for every application (group these pages by application). Enter the application number in the prompt at the top of each page. This helps subsequent reviewers keep track of applications. Please remember there is a difference between treatment and application: treatments are defined in the protocol and consist of t.s rate, application type and volume while an application is a single spraying event (applying the t.s. onto the test system). In studies with more than two treatments (e.g. TRT01, TRT02, TRT03), it is useful to enter both the treatment and application number at the top of each page, as long as they are clearly distinguished (e.g. Appl. 2 for TRT03, etc.).

6C1-C2: Discharge Calibration:

- a. The entire page should be filled in, initialed and dated.
- b. The calibration or recheck should be the day of or the day before the application.
- c. If it is the first application, a full calibration must be conducted. The calculations for the calibration must be shown. Remember units.
- d. If it is a recheck, the calculations showing that it is within 5% of the original calibration must be provided.
- e. If the same calibration was used for more than one trial, the original should be placed in one FDB and certified copies, with the location of the original indicated, in all other pertinent FDBs (see the area at the bottom of the FDB page).
- f. Cells not used in the table should be lined out. If you use a single run recheck, cells for runs 2 and 3 should also be lined out.
- g. REMEMBER to fill in totals and averages.
NOTE: An alternate 6C2 has been developed for application devices with six or fewer nozzles/hoppers and may be more useful in certain situations.

6D: Speed Calibration:

- a. The entire page should be filled in, initialed and dated.
- b. The calibration or recheck should be the day of or the day before the application, and should be conducted on terrain similar to the plots.

- c. If it is the first application, a full calibration and calibration calculations are needed.
- d. If it is a recheck, the calculations showing that it is within 5% of the original calibration should be provided.
- e. If the same calibration is used for more than one trial, the original should be placed in one FDB, and certified copies, with the location of the original indicated, in all other pertinent FDBs (see the area at the bottom of the FDB page).
- f. Cells not used in the table should be lined out. If you use a single run recheck, cells for runs 2 and 3 should also be lined out.

6E&F: Delivery Rate Calibration, and Volume, Mixing and Dilution Calculations:

- a. The application number should be provided.
- b. The formula and information used in the calculations must be provided.
- c. The calculations, including units, must be clear and correct.
- d. The page should be signed and dated, and the date should correspond to the application date.
- e. Rate calculations made prior to the application are never based on the result of single-run rechecks. Generally, they are based on the result of full calibrations consisting of three runs. IR-4 permits the use of target outputs to be used in the pre-application calculations, but each target output must be supported by a three-run recheck (the mean of the three-run recheck must be within 5% of the target). If a target output has been used, the post-application rate calculation must always be determined using the three-run recheck, not the target output.
- f. In Part 6F fill in a brief description of holding, transport, and temperature monitoring of the t.s. while removed from storage.

6G, 6H, 6I and 6J must be original raw data – no copies.

6G: Application Information (original raw data - no copies):

- a. All cells should be filled in in a manner that a person unfamiliar with the application process could understand. If a data prompt does not apply, use "NA."
- b. The treatment (TRT) number should be entered at the top of the table. If more than one treatment is made at an application, a separate 6G is needed for each treatment.
- 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. The signature and date should be the same as the application date, to verify the data was entered on the day of the application. In some complex studies, although applications of more than one treatment may be made on the same day, the application numbers may not be the same for each treatment (e.g. on 6/30/05 Appl. 2 of TRT02 and Appl. 1 of TRT03). In this case, care needs to be taken to clearly indicate which application was made of which treatment.

6H: Additional Information (original raw data - no copies):

- a. The entire page should be filled in, signed and dated on the same day as the application. 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.
- 6I: Pass Times and Application Narrative: (original raw data - no copies):
- Pass times are to be recorded, with appropriate units, as soon as possible after completing the pass(es).
 - Unused cells are to be lined out, and initialed and dated.
 - The entire page should be filled in, signed and dated on the same day as the application.
 - 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.
- 6J: Post Application Rate Confirmation (original raw data - no copies):
- The discharge rate to be used in the rate confirmation calculations should be from the most recent full calibration, not from a single catch recheck. This may mean using data from the full calibration from the first application.
 - Fill in the prompt for the “actual plot area treated.” This might be different from 6A if there were problems during the application. If so, explain.
 - The back calculation must show the formula and units used. The calculation must go back to the amount of product or active ingredient (ai) **specified in the protocol** for comparison. It is required that the % deviation from the protocol target rate be calculated here, rounded to the nearest whole percent (see 6J for example formulae).
 - The volume of liquid product should be included in the total volume of spray mix. Confirm that the entry date corresponds to the application date.
 - If it is necessary to contact the SD for applications made outside the protocol rate, this communication should be documented in the appropriate locations.
- 6K: Post Treatment Records should be complete:
- 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).
 - If no irrigation was used, state this clearly to avoid questions. For example, in the space for date of first irrigation, 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.
- 6L1: If a researcher has multiple trials in the same study, he/she should read and understand the instructions set forth in 6L1 in order to sufficiently differentiate the trials from one another. Afterward, the prompts in 6L1 should be completely filled in.

6L2: This table is a template for protocol development. If a researcher has multiple trials in the same study, he/she should refer to Table 11.4 of the protocol for guidance on acceptable differentiation methods.

6M: Application Equipment Maintenance and Repair Log: This information only needs to be included once (at the end of Part 6 in the FDB), if the same equipment was used for the entire trial. An attached equipment log for the entire season is preferred. Clearly indicate routine and non-routine maintenance. Entries for all calibrations and cleanings are suggested.

PART 7. SAMPLE COLLECTION AND STORAGE

7A1-A2: General Harvesting Information (original raw data - no copies):

This section consists of two pages to provide enough space for detailed descriptions. Provide enough detail so that subsequent reviewers can reconstruct exactly how the sampling was done. If more than one crop fraction, such as roots and tops, are being sampled on the same date, separate forms may be needed for each fraction to make the sampling procedures clearly understood.

- a. The harvest date is the day the samples were cut, dug, or picked. The PHI is based on the harvest date.
- 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. If knives, rakes, scoops, shears, shovels, buckets, machinery, etc., were used, there must be a description of how the equipment was cleaned.
- f. Provide a brief, but detailed, description of how the samples were collected 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 fruit 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.
- g. If the commodity was not harvested directly into 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.
- h. Description of modifications – 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. dry crop (document where, length of time, temperatures, how contamination was avoided, what was cleaned and how)?
 3. shell 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
- i. 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.)
 - j. 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.

7B: Specific Sample Information and Inventory (original raw data - no copies):

- a. An entry must be made for each sample.
- b. The time of completion of sample collection should be as precise as possible.
- c. Elapsed time to freezer should also be as precise as possible. This entry may be expressed in a digital format (HH:MM).

7C: Freezer Temperature Log:

- a. This form must be filled in and/or attached records referenced, with temperature units (°F or °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, preferably in a FDB, or securely maintained in facility files.
- c. Unused cells must be lined out with initials and date.

7D: Freezer Contents Log:

- a. Must be filled in and/or attached records referenced.
- 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. Must be filled in and/or attached records properly referenced.
- 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 be included in the FDB.

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 documentation should be attached behind this page. Be sure to include Field ID number on the bill of lading.

8B: Residue Sample Chain of Custody Form

- a. A true copy of this completed form 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.
- b. Trial location should be listed as was done on Part 5A (name and location for test site)
- c. Complete this page and cross out any unused portions of table, with initials and date.
- d. If it is known prior to FDB submission, documentation of sample arrival at the laboratory should be attached behind this page.

8C: Sample Arrival Check Sheet: For shipment of all samples, 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. If a completed 8C is returned from the lab prior to FDB submission, place it after the original 8C and line out, initial and date the original 8C.

PART 9: WEATHER AND IRRIGATION RECORDS

9A. Daily Field Trial Weather Records

- a. The prompts weather station information (the lower portion of 9A) should be filled in.
- b. Weather data table should be completed for each month and/or weather inserted behind this form. Copies of data must be certified with the location of the original cited. Original should be in another FDB or in facility files. At some sites the weather data is kept by another entity and the FRD will not have the original in his/her possession; if this is the case, indicate so in this Part.
- c. Unused cells must be lined out with initials and date.

9B: Additional Meteorological Information:

- a. Respond to the questions on this page as appropriate.
- b. Irrigation information should be completed, if applicable.
- c. 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.

PART 10: PROTOCOL AND PROTOCOL CHANGES

- a. This is where the protocol and protocol changes should be attached. Pages in this section must also be identified with the Field ID number, like the other FDB sections. Pages in this section do not need to be numbered.
- b. Deviation Form: **Please note that the original of a deviation should be sent to the SD, even though the notification was made by phone, e-mail or FAX.** Copies of field site deviations (prior to SD signature) should be included or the unused page crossed out, initialed and dated. Copies of deviations that have been signed by the Study Director can be placed with the unsigned copies in this FDB section.