GREAT LAKES AGRICULTURAL RESEARCH SERVICE, INC
N6084 JOHNSON ROAD
DELAVAN, WISCONSIN 53115

STANDARD OPERATING PROCEDURE

SOP l.0 General Procedures and Considerations

Revision No. 19 - Effective May 1, 2020

Prepared by: Susan K. Bellman; Principal Investigator

Sig._____ Date: _____

Approved by: Susan K. Bellman; President

Sig. _____ Date: _____

Reviewed by:
Sig. _____ Date: _____
Reviewed by:
Sig. _____ Date: _____

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to summarize the procedures for conducting GLP trials at Great Lakes Agricultural Research Service, Inc. (GLARS). These trials will be conducted in a routine, documented manner to comply with the EPA's Good Laboratory Practice Regulation 40 CFR part 160 (GLPs). GLP trials are contracted to GLARS by various clients (sponsor companies and management companies).

2. Standard Operating Procedures (SOPs):

Specific Standard Operating Procedures have been developed to assure that all phases of GLP trials are carried out in a standardized manner. See SOP 1.1 for details on writing and reviewing SOPs. The SOPs that are currently being used at GLARS can be found in the SOP Index - Table of Contents and in the QA SOP Table of Contents.

3. Personnel:

GLARS management will maintain records of education, training, and experience for all personnel. These personnel records are maintained in the GLARS Personnel Notebook. The GLARS President will designate one employee to be responsible for the GLARS Personnel Notebook. See SOP 2.0 for details.

Employees will be trained in safety procedures (see SOP 2.5) and in GLP procedures (see SOP 2.6).

4. Facilities and Equipment:

All facilities and equipment are to be maintained and cleaned properly. See SOP 2.1 for a list of GLARS equipment. Personnel involved with a GLP trial will be familiar with facilities, equipment, and proper equipment maintenance techniques. Equipment maintenance and cleaning procedures are detailed in SOP 2.2.

5. Trial Scheduling:

Trial scheduling is necessary to ensure that applications and samplings are conducted in an accurate and timely manner. Each trial conducted at GLARS will be assigned a GLARS trial number, which will be used for tracking the trial's progress at GLARS.

Two types of project tracking schedules will be kept. The GLARS GLP Master Schedule will contain the information required in the GLPs. The GLARS Project Schedule will be used by GLARS personnel and will identify trials by test substance, crop, location, etc.

An Application/Sampling Schedule (wall charts) will also be kept so that GLARS employees can plan their work schedules on a daily basis.

See SOP 1.2 for details.

6. Protocol:

Every trial conducted under the GLPs must have a protocol signed by the Study Director. The protocol should contain information concerning test substance, test system, application requirements, sampling requirements, and shipping.

7. Principal Investigator:

All GLP trials conducted at GLARS will have a Principal Investigator (PI) who will have overall responsibility to see that the protocol is followed and that the trial is conducted using proper field research technique. The PI will also coordinate all field phases of the trial. The GLARS president will designate a PI for each trial.

8. Protocol Deviations and SOP Deviations:

There will be occasions when the protocol and/ or a SOP are not followed. An amendment is a planned addition, deletion, or change to the protocol. The Study Director should write a protocol amendment.

A deviation is an unplanned change or mistake that is usually noted after the fact. If no procedure for handling deviations is given by the client, the following procedure should be used:

A. The PI should fill out a deviation form. Use the GLARS deviation form found in SOP 5.1 if none is provided.

B. If the deviation may affect the study outcome, the PI should contact the Study Director or his/ her designee by phone or email and make him/ her aware of the problem. Then the PI should follow-up with the written deviation.

C. The GLARS QA Auditor should be made aware of the deviation and acknowledge this by signing the deviation. A copy of the signed deviation will be maintained by the GLARS QA Auditor.

D. After the deviation has been signed by the Principal Investigator and the GLARS QA Auditor, the original should be placed in the FTN.

E. The signed deviation should be transferred to the study director. The signed deviation can be emailed to the Study Director or his/ her designee or sent to the Study Director with the finalized FTN.

9. Documentation of Raw Data:

Raw data are recorded values, observations, notes, calculations, correspondence, documentation of phone calls, original shipping receipts, etc. that enable the Principal Investigator to reconstruct the GLP trial. Raw data will be documented in a paper Field Trial Notebook (FTN) or in an electronic notebook (eFTN). An eFTN will generally have supplemental paper raw data (a paper FTN). Raw data entered into a paper FTN should be written in black ink, dated, and signed or initialed. It is acceptable for the person entering raw data to sign using his or her initials after signing the personnel page of the FTN.

Raw data are the first point of entry. Transcribed data are any original raw data that have been copied from one location to another. Transcribed data should be identified as such, dated, initialed, and the original source documented.

GLARS personnel will use the date format month-day-year unless specifically required to use a different format.

There will be times when raw data entered into a paper FTN will need to be changed (misspelling, etc.). The following procedure will be used:

A. Draw a single line through the data entry to be changed. The original data must not be obscured.

B. Enter the new raw data.

C. Initial adjacent to the change, record the date, and enter the reason for the change. Codes for changing raw data can be found in Appendix A of this SOP.

See Appendix A of this SOP for common abbreviations used by GLARS personnel.

See Appendix B of this SOP for a list of common metric conversions. Use this Appendix or a website such as www.metric-conversions.org when making metric conversions. If a website is used, the source should be documented in the raw data.

Non GLP data (i.e. field history, tillage information, etc.) will at times be entered into the FTN or the eFTN. The source of the non-GLP data should be documented.

10. General Filing Procedures:

GLP records need to be maintained in an orderly, precise manner. The following filing procedures will be used:

A. Only one trial shall be filed per paper Field Trial Notebook (FTN).

B. Additional papers added to the FTN should bear the GLARS trial number, the study number, and the company trial number.

C. FTNs will be stored in the GLARS office in a fire proof, locked file cabinet. Files are accessible only to the Principal Investigators, Office Manager, Regulatory Technicians, Efficacy Technicians, Farm Technicians, Farm Operator, and the Quality Assurance Auditors.

D. FTNs must be transported to the field at various times. During transport, care will be taken to minimize damage.

E. The finalized FTN and/ or the eFTN will be transferred to the client or his/ her designee. See SOP 8.0 for details.

11. Copying:

Copies of raw data are routinely made during the conduct of a GLP trial. The following procedures are to be used when making copies:

A. Review each copy to make sure it is dark enough and legible.

B. Make sure that all of the information along the edge of the page has been copied. If necessary, reduce the page to make a good copy.

C. Stamp each copy "Exact Copy" using the red ink stamp. Initial and date the "Exact Copy" stamp. Some FTNs have an "Exact Copy" statement at the bottom of the page. This can be filled out instead of using the GLARS stamp.

12. Organizing the Field Trial Notebook (FTN):

GLP trial raw data will be organized in a paper Field Trial Notebook (FTN) or an electronic FTN (eFTN). See SOP 12.0 for procedures for eFTNs. An eFTN will generally have supplemental paper raw data (paper FTN).

Occasionally, more than one page of the same form is needed. The first page should be 16A, the second page 16B, etc. The last page number should be circled.

If a paper FTN is not supplied, then the following organization scheme is suggested. See SOP 5.1 for forms that can be used if the client's forms are not adequate.

A. Protocol and Amendments

B. GLP Compliance/ Personnel:

   a. Signature page (i.e. name, title, signature, and initials) for all personnel who assisted with the conduct of the trial. The QA Auditor does not sign this form, unless requested to do so (See SOP 8.0).

   b. Statement of Compliance with the GLPs signed by the Principal Investigator.

   c. GLARS SOP Index – Table of Contents. SOPs referenced in the raw data should be highlighted.

   d. GLARS SOP 1.0 – Appendix 1. Abbreviations and Error Codes Used by GLARS Personnel.

   e. The GLARS QA Inspection Statement (see SOP 7.0).

   f. Deviation forms (if applicable).

C. Site Information:

   a. Trial Location Road Map (see SOP 1.65).

   b. Bellman Farm Field/ PM Map for trials located on-site (see SOP 1.65).

   c. GLP trial Plot Map (see SOP 1.65).

   d. Soil/ Water Characterization, if required.

   e. Field History (see SOP 1.65).

   f. Test System Information and Cultural Practices

   g. Statement of Crop Destruction (if applicable)

D. Test Substance (See SOP 1.3):

   a. Test Substance Receipt Form

   b. Test Substance receipt paperwork

   c. Test Substance Usage Form (if applicable)

   d. Test Substance return paperwork, including Chain of Custody Form (if applicable)

   e. Monthly Chemical Storage Room Temperature Reports (if applicable)

E. Calibration/ Application (See SOPs 3.0 to 3.95):

a. Calibration Worksheet and/ or relevant pages of Equipment Calibration Log Book.

b. Application Spray Chart

g. Application/ Environmental Information

h. GLARS Rate Verification Form or client's form

F. Sampling:

a. Sampling Information Form (See SOP 4.0)

G. Shipping

a. Sample Shipping Information Form (SOP 4.5)

b. Sample Chain of Custody (COC)

c. Company requested shipping paperwork

c. Monthly Freezer Temperature Reports (See SOP 8.0)

H. Chronological Log

I. Agronomic Information (if requested in the protocol)

J. Weather Data (if requested) (See SOP 8.0)

a. Monthly Weather Data Summary Report (if requested)

b. Monthly Weather Data Reports (if requested)

c. Historical Weather Data (if requested)

d. Irrigation Scheduling (if applicable)

K. Supplemental Data

a. GLARS SOPs (SOPs referenced in the FTN, if requested) and/ or client SOPs.

b. Personnel CVs, if requested

c. Other raw data as requested in the protocol

L. Emails, memos, and other correspondence

M. Do Not Send Information

Some clients do not want such information as weather data, freezer temperature data, chemical storage room data, or print outs of electronic FTNs. Keep these data at the back of the active paper FTN. When the paper FTN is copied and transferred to the client, place the "do not send to the client" paperwork at the back of the folder with the FTN copy.

13. Test Substance Receiving, Storage, Usage, and Disposal:

The GLPs require a detailed paper trail to document that test substances (including the test substance container) have been maintained in satisfactory condition without deterioration or contamination. It is important that each test substance be received, stored, applied, and disposed of (returned, transferred to the GLARS Long Term Pesticide Treatment Storage area, transferred to farm inventory, or disposed of) in a manner such that a complete record is maintained. See SOP 1.3 for details.

14. GLP Trial Design/ Test System Area Preparation:

A. All GLP trials will be conducted at sites where GLARS can dictate or have control over those operations that can affect the outcome of the trial.

B. Wherever possible, the site location will be representative of the major production areas for the target crop.

C. GLP trials will not be combined with efficacy trials.

D. Refer to the protocol for minimum plot size, minimum buffer size, number of replications/ subplots, and sample size (i.e. a large sample size will require a larger plot, etc).

E. Plot Layout:

a. The plot layout should leave enough buffer area between the treated plot and the untreated (UTC) plot such that no drift/ volatilization/ runoff will occur to contaminate the UTC plot. Generally the UTC plot should be located upslope and upwind of the treated plot.

b. The buffer area can be planted to a commercial crop, cover crop, or left vacant. A common cover crop is red clover at 5-7 lb/acre plus annual ryegrass at 8-10 lb/acre.

c. Generally, the four corners of the plot are marked with wooden garden stakes and/ or flags. The UTC plot is usually marked in white and the treated plot is usually marked with a different color such as orange or blue. Use tall colored flags, painted wooden or fiberglass stakes, and/ or colored whiskers (metal stakes that are pushed into the ground with above ground colored plastic whiskers) in tall crops like alfalfa. The colored whiskers can stay in the ground when the alfalfa is cut. Use approximately 4-foot tall painted wooden stakes or step-in fiberglass fence posts with a colored flag attached to the top in aerial plots or in carryover studies.

d. Place a plot label in the lower left-hand corner of the plot as you are facing the plot from the front. Generally, the plot label will be a white index card (laminated) attached to a garden stake. The label should contain the GLARS Trial number, the treatment identification, and any other information requested in the protocol.

e. For biotech trials, efficacy trials, or other trials with many small plots, each plot should be labeled in the lower left corner with a wooden garden stake containing the plot number (101, 102, 103 etc.). The trial label should be on an index card as described above and placed in the lower left corner of the trial.

f. The plot layout should be documented using a Location Map, a Bellman Farm Field/ PM Map (on-site trials only), and a Trial Plot Map. See SOP 1.65.

g. Every trial should have at least one GPS coordinate documented. For RAC trials, with 2 plots, the GPS coordinate should be taken from the lower left-hand corner of the treated plot. If the RAC trial has more than 2 plots, then the GPS coordinate should be taken from one of the treated plots in the center of the trial. For biotech trials, take a GPS coordinate from each of the 4 corners of the trial or as requested in the protocol. GPS coordinates should be documented on the trial Plot Map for GLP and biotech trials and in ARM for efficacy trials.

15. Soil or Water Characterization:

Soil or water characterization samples are taken according to protocol specifications (See SOP 4.1). If soil and/or water characterization is not mentioned in the protocol it will be assumed that there is no requirement for such information.

16. Crop Maintenance (Test System Care):

Normal grower practice will be used to ensure a commercial quality crop. Refer to SOP 1.6 for crop maintenance procedures and crop development stages.

17. Crop Destruction:

The protocol should specify whether or not the treated crop should be destroyed. If crop destruction is required, it should be documented in the GLARS Farm Diary and in the FTN. Refer to SOP 1.6 for crop destruct procedures. If crop destruction is not mentioned in the protocol, it will be assumed that crop destruction is not required.

Special care should be taken when crop destruction is done for APHIS regulated trials. Refer to SOP 11.0 for procedures.

18. Statement of Compliance with GLPs:

All completed GLP trials should have a statement signed by the Principal Investigator stating that the trial was conducted according to the GLP Regulation 40 CFR Part 160. See SOP 5.1 for an example of a GLP Compliance Form.

19. APHIS Regulated Trials:

Periodically GLARS conducts trials under the APHIS Regulation. See SOP 11.0 for details about conducting APHIS regulated trials.

20. Archiving:

GLARS will archive historical records in such a way as to minimize deterioration of the documents and in accordance with the GLPs.

The GLARS Archivist is responsible for archiving non-QA data (See SOP 8.5).

A GLARS QA Auditor is responsible for archiving QA data (See SOP 7.0).

21. Quality Assurance:

The GLARS president will identify a Quality Assurance (QA) Auditor who will be separate and independent from the personnel conducting the GLP residue trial. The QA Auditor will inspect GLP trials periodically, maintain records for each inspection, and report these audit results to the Principal Investigator, the study director, the study director's management, and the GLARS President. See the GLARS QA SOP Table of Contents and QA SOPs 7.0, 7.1, 7.2, 7.3, 7.4 and 7.6 for details.

22. Plan for Closing Great Lakes Ag-Research Service, Inc.:

If GLARS should go out of business at some time in the future, the following procedure will be followed:

A. All non-trial specific active logs and files will be archived.

B. All trial specific files will be returned to the appropriate client.

C. The client for which GLARS has conducted the largest number of trials will be contacted and asked to take over responsibility for GLARS non-trial specific archived data. See SOP 8.5 for a list of archived data.

D. All other clients and the EPA will be notified in writing of the location of the archived data.

SOP 1.0 APPENDIX A
ABBREVIATIONS

GLARS TRIAL No._____
STUDY No._____
COMPANY TRIAL No._____

Abbreviation	Description	Abbreviation	Description
A	Acre; acres	ml	milliliter
Ag	Agriculture, Agricultural	mm	millimeter
AI, ai	active ingredient	MPH	miles per hour
app or appl	application	N/A	not applicable
brdcst	broadcast	NF	not found
Cal	calibration	NRCS	Natural Resource Conservation Service
cm	centimeter		
cont'd	continued	No., #	number
CRP	Conservation Reserve Program	oz	ounce
		pt	pint
cu ft, ft^3	cubic foot	PM	permanent marker
CV	curriculum vitae	PSI	pounds per square inch
(C.V.)	calculation verification		
DAT	days after treatment	lb	pound
enc	enclosed	qt	quart
F	Fahrenheit	Rd, rd	road
fl	fluid	rep, reps	replicate(s)
ft	foot; feet	rev	revision
gal	gallon	RPM's	revolutions/minute
GLARS	Great Lakes Ag-Research Service Inc.	R.S.	row spacing
		sec	seconds
GPA	gallons per acre	SOP	Standard Operating Procedure
GPM	gallons per minute		
gr	gram; grams	sq ft, ft^2	square foot
hp	horsepower	temp	temperature
ht	height	TRT	treated, treatment
hwt	hundredweight	UTC	untreated control
in	inch	vol	volume
incorp	incorporation	v/v	volume/volume
kg	kilogram	w/	with
l	liter	w/o	without
lin ft	linear feet	w/w	weight/weight
mg	milligram	wt	weight
min	minute/ minutes	yd	yard

The following codes can be used as reasons for changing raw data

Abbreviation	Description	Abbreviation	Description
SE	Spelling Error	WD	Wrong Date
AW	Accidental Write over	LE	Late Entry
CE	Calculation Error/ Rounding Error	EE	Entry Error
IC	Incorrect Comment		

SOP 1.0-APPENDIX B
CONVERSION TABLES

Area

144 square inches……..... 1 square foot
9 square feet..... 1 square yard
43,560 square feet .....4,840 square yards..... 1 acre
160 square rods..... ..... 1 acre
640 acres..... ..... 1 square mile
2.471 acres..... .....1 hectare

Length

1 inch ..... 2.5 centimeters .....25 millimeters
1 foot ..... 12 inches
1 yard ..... 3 feet
1 rod ..... 5.5 yards..... 16.5 feet
1 mile ..... 320 rods ..... 1760 yards ..... 5280 feet
1 meter.....3.3 feet.....39.4 inches..... ..... 1.09 yards
1 kilometer ..... 1000 meters..... 0.62 miles
1 Acre on 7" row spacing ..... 74,671 Linear row feet/Acre
1 Acre on 20" row spacing.....26,136 Linear row feet/Acre
1 Acre on 30" row spacing.....17,424 Linear row feet/Acre
1 Acre on 36" row spacing.....14,520 Linear row feet/Acre
1 Acre on 38" row spacing .....13,794 Linear row feet/Acre
1 Acre on 40" row spacing .....13,068 Linear row feet/Acre
1 Acre on 60" row spacing ..... 8,712 Linear row feet/Acre

Volume

1 bushel .....4 pecks
1 peck ..... 8 quarts
1 tablespoon (tbs or T) ..... 3 teaspoons (tsp or t)
1 fluid ounce .....29.6 mls..... 2 tablespoons
8 fluid ounces ..... 16 tablespoons .....1 cup
16 fluid ounces.....2 cups.....473mls.....1 pint
32 fluid ounces ..... 4 cups.....946 mls.....1 quart
128 fluid ounces .....4 quarts ..... 8.345 lbs water . .....1 gallon
1 liter ..... 33.9 ounces ..... 1.06 quarts
3,785 ml .....1 gallon
1,000 ml .....1 Liter
1 Acre - inch ..... 27,154 gallons
1 Acre - inch ..... 3,630 cubic feet

Weight

1 cubic foot ..... 7.48 gallons ..... 62.4 lbs water
1 ounce ..... 28.3 grams
1 pound ..... 16 ounces ..... 453.6 grams
2.2 pounds ..... 1 kilogram..... 1000 grams
1 ton ....2000 pounds ..... 907 kilograms
1 metric ton ..... 1,000 kilograms ..... 2205 pounds

Temperature Conversions

To convert Fahrenheit degrees into Celsius: Subtract 32, multiply by 5, and divide by 9.
To convert Celsius into Fahrenheit: Multiply by 9, divide by 5, and add 32.