Protocol Design and Preparation

Chapter 2: PROTOCOLS

AHETF-2.C.1.

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1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes the content requirements, standard format, responsible personnel, review, and distribution of Agricultural Handlers Exposure Task Force (AHETF) study protocols, which are the written instructions to perform specific experiments investigating exposure to pesticides.

1.2 This SOP is for internal administrative use by the AHETF. It is not to be distributed to contractors, unless specific authorization is provided by the AHETF management.

1.3 This SOP was revised to correct various typographical errors throughout the document, and to designate this SOP for internal AHETF use only, as defined in section 1.2. Section 3.3 was revised to clarify the acknowledgement by AHETF monitors. Section 4.1 was revised to clarify draft protocol distribution.

2.0 DEFINITIONS

2.1 The EPA GLPs define a study as "any experiment at one or more sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance, environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media." (40 CFR Part 160, August 17, 1989, § 160.3).

2.2 A protocol is a written study plan that indicates the objectives and all methods for the conduct of a study.

3.0 PROTOCOL REQUIREMENTS

3.1 AHETF protocols must contain (but not be limited to) the following information for GLP compliance. Certain GLP requirements that are not applicable to most studies conducted by/for the AHETF have been taken into account and either modified or omitted, based upon the importance and impact of those requirements.

a. Descriptive title and objective of the study.

b. Identification of the test substance and control or reference substances by name, chemical abstract service (CAS) number or code number.

c. Name and address of sponsor (AHETF).

d. Name and address of contracted testing laboratories (including field contractors).

e. Proposed experimental start and termination dates.

f. Justification for selection of test system.

g. Procedure for test system identification.

h. Description of the experimental design including the methods for the control of bias.

I. Each level of the test, control, or reference substance to be administered, expressed in appropriate units.

j. The method and frequency of administration of the test, control or reference substance, (*e.g.,* backpack/ knapsack sprayer, granular application, *etc.)*, and the reason for its choice.

k. The type and frequency of tests, analyses, and measurements to be made.

l. The records to be maintained.

m. Dated signatures of the Study Director and AHETF Sponsor Representative (Task Force Manager, and/or Technical Committee Chair).

o. Proposed statistical methods.

p. A sample list, included in an appendix (not required for laboratory validation studies).

3.2 The Study Director or designee is responsible for preparing protocols for studies under his/her direction according to a standard format to be provided by the AHETF.

3.3 All AHETF study protocols will be signed and dated by the Study Director, and Technical Committee Chair or Task Force Manager to initiate the study and indicate Sponsor approval of the protocol. Approval signatures must be obtained from the Study Director before any data collection for that study. The protocol should be acknowledged, either electronically or in writing, by the AHETF Field Monitor and AHETF Analytical Monitor, as appropriate. Monitors do not need to sign the protocol, amendments, or deviations.

4.0 REVIEW PROCESS

4.1 Draft protocols will be forwarded to the appropriate AHETF representatives (as noted in section 6.0 and at the Study Director's discretion) and to the AHETF Quality Assurance Unit for review before finalization.

4.2 The Study Director will be notified of errors found or requested changes noted during the review process. Appropriate corrections or changes will be returned to the Study Director. The revised copy will be approved (*i.e.*, signed and dated) and distributed to the designated personnel.

5.0 PROTOCOL FORMAT

5.1 Details of the protocol must address all of the applicable items in section 3.1. of this SOP. Requests for copies of AHETF protocols may be directed to the Study Director or the AHETF Task Force Manager. Changes to the protocols will be issued according to section 8.0.

5.2 A standard design, developed by the Task Force, will be followed when preparing study protocols.

5.3 All protocol files must be written in specified word processing program, to be provided to the Task Force upon request. The software that has been selected is the Microsoft® Word® for Windows® (version XP or previous) document processing program. Macintosh® formatted data are not acceptable.

5.4 All signed pages will be optically scanned separately and stored in PDF® format. These signed pages need to be inserted into the final phase report file.

5.5 Electronic submissions to the EPA must be in Adobe® Acrobat® PDF format version 5.0. Later versions of Acrobat® may be used; however, the output must be in the 5.0 format.

6.0 DISTRIBUTION OF STUDY PROTOCOLS

6.1 The original AHETF study protocol, and any amendments, will be submitted to the AHETF QAU for review. Before study completion, the original protocol, amendments and deviations, if applicable, will be forwarded to the AHETF Archives. The following is the distribution list for protocols and amendments, as appropriate:

a. Study Director (maintain original)

b. AHETF Study Monitor, (field or analytical, as appropriate)

c. AHETF Task Force Manager

d. AHETF Technical Committee Chair

e. AHETF Quality Assurance Unit (copy during study)

f. AHETF Subcommittee Chairs (as applicable)

g. Principal Investigator(s)

h. AHETF Study Archive File (original to archives upon completion)

7.0 Protocol Amendments

7.1 A change of Study Director or any planned change or revision to an AHETF protocol is issued as a protocol amendment. The reason for the change(s) or revision(s) and the effective date(s) of each revision is documented in the amendment.

7.2 The contract principal investigator or facility management will notify the AHETF Study Director of any procedures or items in an AHETF protocol that may need to be revised, added, or deleted. The Study Director will prepare and distribute the amendment(s).

7.3 The Study Director will prepare the amendment(s), and will allow the AHETF Study Monitor(s), Task Force Manager and AHETF QAU to review it before finalization, if possible.

7.4 All protocol amendments will be approved by the AHETF Study Director and Task Force Manager, by a dated signature. The appropriate AHETF Study Monitor will acknowledge the amendment as described in section 3.3. Distributions of the original amendment and copies will be followed as outlined in section 6.1 of this SOP.

7.5 Protocol amendments are sequentially numbered according to the date of issue. The first amendment issued for a study is AHETF Protocol Amendment No. 1. The second protocol amendment issued is AHETF Protocol Amendment No. 2, and so on.

8.0 PROTOCOL DEVIATIONS

8.1 Whenever a deviation from the protocol occurs, the Study Director must be notified of the deviation. The AHETF Study Director is responsible for the documentation of any protocol deviation noted for their study.

8.2 The Study Director is required to document the nature of the deviation, date(s) of occurrence, reason for the deviation, effect on the study, and any corrective actions (if any) on an appropriate form or in the raw data. The deviation must be written in a timely manner and acknowledged with the dated signature of the Study Director.

8.3 The Study Director shall notify the appropriate AHETF Study Monitor and QAU of all deviations as soon as practicable.

8.4 All protocol deviations will be approved by the AHETF Study Director and Task Force Manager, by a dated signature. The appropriate AHETF Study Monitor will acknowledge any deviation as described in 3.3. Distributions of the original deviations and copies will be followed as outlined in section 6.1 of this SOP.