

Subpart G—Protocol for and Conduct of a Nonclinical Laboratory Study

§ 58.120 Protocol.

(a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain, as applicable, the following information:

- (1) A descriptive title and statement of the purpose of the study.
- (2) Identification of the test and control articles by name, chemical abstract number, or code number.
- (3) The name of the sponsor and the name and address of the testing facility at which the study is being conducted.
- (4) The number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system.
- (5) The procedure for identification of the test system.
- (6) A description of the experimental design, including the methods for the control of bias.
- (7) A description and/or identification of the diet used in the study as well as solvents, emulsifiers, and/or other materials used to solubilize or suspend the test or control articles before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.
- (8) Each dosage level, expressed in milligrams per kilogram of body weight or other appropriate units, of the test or control article to be administered and the method and frequency of administration.
- (9) The type and frequency of tests, analyses, and measurements to be made.
- (10) The records to be maintained.
- (11) The date of approval of the protocol by the sponsor and the dated signature of the study director.
- (12) A statement of the proposed statistical methods to be used.

(b) All changes in or revisions of an approved protocol and the reasons therefor shall be documented, signed by the study director, dated, and maintained with the protocol.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987; 67 FR 9585, Mar. 4, 2002]

§ 58.130 Conduct of a nonclinical laboratory study.

- (a) The nonclinical laboratory study shall be conducted in accordance with the protocol.
- (b) The test systems shall be monitored in conformity with the protocol.
- (c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data.
- (d) Records of gross findings for a specimen from postmortem observations should be available to a pathologist when examining that specimen histopathologically.
- (e) All data generated during the conduct of a nonclinical laboratory 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 date 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.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987; 67 FR 9585, Mar. 4, 2002]

Subparts H–I [Reserved]