

**Summary Outline of 40 CFR § 26.1115, Containing Information
and Commentary Addressing the Requirements of Each Subsection.**

§ 26.1115 IRB Records

§ 26.1115 (a) An IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

§ 26.1115 (a)(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of any injuries to subjects.

IRB documents from this list consist of protocols C-L-001, EMD-003 and EMD-004, approval letter C-L-001 ([Appendices 1A – 1D](#)), and Informed Consent Forms (“ICFs”) EMD-003 and EMD-004 ([Appendices 2A – 2B](#)).

Protocol C-L-001 is a generic protocol that describes our efficacy testing procedures in substantial but general detail. It is written at the request of the California State EPA Department of Pesticide Regulation to serve that Department’s annual review of Carroll-Loye research.

§ 26.1115 (a)(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB, the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

A statement of compliance from Ms. Kim Lerner, Chairman of Independent Investigational Review Board, Inc. (“IIRB”), is appended as [Appendix 3](#). Due to concerns about releasing minutes of Board deliberations directly to Principal Investigators (“PI”), the Chairman suggests that any request by EPA for that information be made directly by EPA to the Board.

§ 26.1115 (a)(3) Records of continuing review activities.

Not applicable to the current proposals

§ 26.1115 (a)(4) Copies of all correspondence between the IRB and the investigators.

Cover letters from the IIRB to the PI that accompanied approved ICFs are included in [Appendices 4A – 4B](#). Email correspondence associated with the review of EMD-003 and EMD-004 is provided in [Appendix 5](#).

§ 26.1115 (a)(5) List of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member’s chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution.

The required information is in the statement provided by Ms. Kim Lerner, Chairman of the IIRB is attached as [Appendix 3](#).

§ 26.1115 (a)(6) Written procedures for the IRB in the same detail as described in §26.1108 (a) and (b).

A statement of compliance from Ms. Kim Lerner, Chairman of the IIRB, is appended as [Appendix 3](#). The Chairman requests that any request by EPA for that information be made directly by EPA to the Board.

§ 26.1115 (a)(7) Statements of significant new findings provided to subjects, as required by Sec. 26.1116(b)(5).

Not applicable.