Subject: Request for Additional Documentation 04/20/2010 11:03 AM

From: John Carley/DC/USEPA/US
To: rroogow@iirb.com
cc: spcarroll@ucdavis.edu, "Shawn King" sbkingster@gmail.com, klerner@iirb.com

I am reviewing the report of the completed tick repellent study, LNX-003, recently submitted to EPA by Scott Carroll of Carroll-Loye Biological Research in behalf of Lanxess, Inc. IIRB, Inc. was the IRB of record for this research.

In an email to Shawn King of CLBR dated 5 Feb 2010 at 9:21 AM, responding to his request for minutes of the IRB meeting at which the amendments to this protocol were approved, you said:

> "As for the Amendment that was approved 11/2/2009, it was approved through expedited procedures and not at a convened meeting; therefore, there are not meeting minutes for that transaction."

I was surprised to see this—it is more typical in my experience for IRBs in convened session to endorse actions taken through expedited procedures, and to reflect that endorsement in the minutes of the IRB. I have observed that to have been the practice of IIRB, Inc. in past studies.

I reviewed the IIRB, Inc. HRPP effective October 1, 2009, to see what it had to say about this, and noted the following:

- **In section 5.1, concerning expedited review:**

"The determination that changes to previously approved research are "minor" is generally understood as: no more than minimum [sic] (as defined in FDA and DHHS regulations), the risk/benefit relationship is not altered in a way that makes it less favorable, does not compromise the rights of subjects or is immediately necessary.

"In addition a minor change is one which, in the judgment of the Expedited Reviewer, makes no substantial alteration in:

1. the level of risks to subjects
2. the research design or methodology (adding procedures that are not eligible for expedited review would not be considered a minor change)
3. the number of subjects enrolled in the research (no greater than 15% of the total requested)
4. the qualifications of the research team
5. the facilities available to support safe conduct of the research
6. any other factor which would warrant review of the proposed changes by the convened IRB
7. significant payment to subjects (no more than 15% increase) however, in a minimal risk study this percentage can be reconsidered based on the total stipend." (p.31)

"The reviewer will receive the same materials that the convened IRB would have received and will be conducted following the same procedures as if the research study or modification was reviewed by the convened IRB." (p. 32)

"The Expedited Reviewer will document review of the item on a transaction checklist for each submitted item and the documentation will be filed in the study file." (p. 32)

"The Expedited Reviewer will document his/her review in the appropriate Approvable Material Checklist, approval letter, and Expedited Action Listing. The Expedited Action Listing outlining these findings will be reported to the IRB at the next regularly scheduled IRB meeting." (p. 32)

- **In section 5.2, concerning IRB meetings:**

5.2.1 IRB Meeting Procedures

"The IRB will review a summary of the actions taken by expedited review." (p. 33)

5.2.2 Meeting Records/Minutes

"The IRB will maintain minutes of each meeting. . . . Minutes of IRB meetings must contain sufficient detail to show: a. Actions taken by the IRB." (p. 34)

"The minutes will also address all discussions listed on the Agenda and any other business brought before the IRB." (p. 34)

- **In section 6, concerning IRB Records and Files:**

"IRB records may include as applicable, but are not limited to: . . .

- For initial and continuing review of research by the expedited review procedure:
  a. The specific permissible category.
  b. Description of action taken by the review.
  c. Any findings required under the regulations." (p. 55)

Taken together, these passages suggest that there are likely to be records at IIRB, Inc., documenting the decision of the expedited reviewer that the amendments were eligible for expedited review, documenting the results of the expedited review of "the same materials that the convened IRB would have reviewed," and documenting the full IRB's endorsement of the expedited reviewer's action.

If I've misunderstood the IIRB, Inc. procedures, please explain how you keep track of expedited reviews. If there are, indeed, records of the review granted to the amendments to study LNX-003 approved on November 2, 2009, please provide copies of them for our records.

Thank you very much.

John M. Carley
Program Analyst
U.S. Environmental Protection Agency
Office of Pesticide Programs
tel: 703 305-7019
fax: 703 308-4776

Subject: RE: Request for Additional Documentation 04/20/2010 02:11 PM

From: Julie Blasingim <JBlasingim@iirb.com>
To: John Carley <carley.john@epa.gov>
Cc: Kim Lerner <KLerner@iirb.com>, Robert Roogow <RRoogow@iirb.com>

Hello John,

We appreciate your response. To expand on Robert's previous email, since the submission was reviewed by expedited review, there are no meeting minutes for this item. However, in accordance with our HRPP Plan and compliance with regulatory requirements, all items reviewed under expedited review are reported to the IRB by the Expedited Report. We have attached the Expedited Report which identifies the expedited review of the Amendment. The IRB reviews the listing as noted in the IRB Meeting Minutes (see attached minutes).

We hope that this clarifies your concerns, and we appreciate the opportunity to clarify our process.

Please feel free to contact us if you need any additional information.

Warm Regards,

Julie Blasingim, MBA, CIP
Vice Chair/Director of IRB Services

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Tuesday, November 03, 2009
MINUTES

ATTENDANCE:

PRESENT
Shari Somerstein, RPh
Edward Wiederhorn
George Garbarino
Marcos Rejtman, DO
Rabbi Akiva Mann arrived 10:07AM; left 1:05 PM
Frances Conway, RN
Julie Blasingim

GUEST
Katy Kysela, Director of Research, IRB Liaison

ALSO PRESENT
David Wells, MD arrived 10:05AM

I. CALL TO ORDER

The meeting was called to order at 10:00 AM, by Chairman, Frances Conway. The meeting was held at 6738 West Sunrise Blvd., Suite 102, Plantation, FL 33313. Quorum was determined to be present and all attendees affirmed that no significant financial or non-financial conflicts of interest existed with review of any of the items listed on the agenda.

II. APPROVAL OF THE 10/27/2009 MINUTES (The order of the Minutes does not reflect the order in which they were reviewed.)

The minutes of the meeting held 10/27/2009 were reviewed and unanimously approved as reviewed.

III. REVIEW PROTOCOLS

III a. STUDY INITIAL APPROVALS

IV. OTHER BUSINESS

V. FOCUSED ITEMS

VI. EXPEDITED REPORT

The IRB reviewed an overview of the actions that were taken by expedited review and accepted the actions taken. No further evaluation or alternative action is required.

VII. ADJOURN

Motion was made to adjourn the meeting at 3:08 PM. Motion carried unanimously.

Respectfully Submitted,

Frances Conway, Chairman
Independent Investigational Review Board, Inc.

Reviewed By:

Anita McSharry, Institutional Official
Independent Investigational Review Board, Inc.

Tuesday, November 03, 2009
EXPEDITED ACTION LISTING

VIII. EXPEDITED REPORT

These requests were determined to be a minor change in previously approved research during the period (of 1 year or less) for which approval is authorized and was reviewed under expedited review procedures.

A Protocol Amendment; LNX-003; Scott P. Carroll, PhD;
- Informed Consent Form
- Amendment 1 dated 10/30/2009