

Carroll-Loye Biological Research

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8 November 2006

HSRB Submission

Carroll-Loye Protocol SCI-001– Test of a Topical Insect Repellent

IRB CORRESPONDENCE REGARDING PROTOCOL REVIEW

IRB:

Independent Investigational Review Board, Inc.

6738 West Sunrise Blvd. Suite #102

Plantation, FL 33313

TO IIRB

11/3

Hi Robert,

I am glad you received that review request fax. Sorry it didn't come through two days earlier- that appears to be the second error my machine has made recently.

In addition, Kim may have informed you to expect additional protocols today. One is the same as the tick protocol, and one is the same as the mosquito protocol. However, each has a new sponsor. Both are facing a November 8th deadline at EPA. Both were informed of that when it became evident on October 18th.

TO IIRB

11/3

Hi Robert,

The protocol and consent form of this protocol fundamentally matches that you are just now considering for EMD-003. Only the sponsor is different, and the test materials are cosmetically improved deet-based formulations. Only lotions are being tested, not sprays, so the dosimetry part of the study is much simplified based on that. The new formulations are intended to give the repellent benefits of deet while minimizing the side-effects.

I have attached the ICF for your consideration, along with the set-up form and site questionnaire. I am finalizing the protocol now.

The second sponsor I have mentioned to you and Kim seems to be missing the boat.... That is probably good news for both of us.

Thanks much; I'll be back to you shortly with the protocol if sponsor #1 keeps moving.

TO IIRB

11/3

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Hi Robert,

I hope that you will be able to process this in the current schedule. This protocol is intended for submission to US EPA. Note that the ICF that I submitted earlier today as a separate file is now embedded as an appendix of the protocol pdf.

EPA's tentative deadline is November 8th. I think that they will probably accept the required IRB documentation regarding this protocol (attendance, minutes, etc.) later in the week if absolutely necessary. However, it is important for me to receive the approval documents, if granted, for submission to EPA on Wednesday the 8th. I will fill the requirement of forwarding our correspondence to them.

Thank you and please let me know if you or the Board have any questions.

Regards,
Scott

TO IIRB
11/7

Hi Robert,

Were you able to process this protocol for review in today's meeting? If so, please let me know if you can send me a scanned version so I can submit it tomorrow with the protocol (so meeting the new "draft" 75 day advance deadline for the HSRB meeting), and also if you need me to do anything related to your transmitting the relevant IIRB docs on the protocol to John Carley at EPA OPP this week: Carley.John@epamail.epa.gov.

Best,
Scott

FROM IIRB
11/7
Hello Dr. Carroll,

Carroll-Loye Biological Research

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I have attached the approval documents for the above mentioned study. Please let me know if you need any additional documentation.

Thank you,

Julie Edmiston
Project Leader

Independent Investigational Review Board, Inc.

FROM IIRB

11/8

Hi Scott,

You should have received the PDF copy of the documents yesterday from Julie. Please let me know if they did not go through, I will resend them. As for the Minutes of the meeting and other relevant IIRB docs that are required, they will not be finalized until they are approved by the board at the next meeting, which will be next Tuesday. I will send them to John Carley at the email you provided as soon as they are available.

Robert Roogow, MS, RAC
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TO IIRB

11/8

Thanks for the heads up. After reading your email I found Julie's in my junk mail. Yikes! The ICF has scanned perfectly for the HSRB submission packet. I will copy this to John Carley as well so he is informed about the intended schedule for submission of those IIRB materials.

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Scott

TO IIRB

11/8

Dear Robert,

I just spoke with John Carley at EPA OPP who asked me to suggest to you that if your procedures have not changed since the previous submission that you just include a statement to that effect rather than resubmitting that material again.

I would contact him should you need any clarification on this.

Scott

FROM IIRB

11/8

Dear Scott,

Please use this email as notification that our procedures have not changed since the previous submission. If John or the EPA OPP require something more formal, I will be more than happy to comply in what ever form that would be acceptable. Please let me know either way.

Regards,

Robert Roogow, MS, RAC

Director of Operations

Independent Investigational Review Board, Inc.

Ph: 954-327-0778