

**Date: Fri, 14 Apr 2006 04:10:37 -0700**

**To: nglassee@iirb.com**

**From: Scott P Carroll <spcarroll@ucdavis.edu>**

**Subject: Protocol Submission EMD-003**

**Cc:**

**Bcc:**

**X-Attachments: :Scott Carroll:1125232:Carroll EMD-003.doc: :Scott**

**Carroll:1125232:EMD-003.Carroll.ICF.doc: :Scott Carroll:1122283:EMD-**

**003.study.setup.form: :Scott Carroll:1122283:Site\_Questionnaire EMD-003.doc:**

--

**Scott P. Carroll, Ph.D.**

**Carroll-Loye Biological Research**

**711 Oak Avenue**

**Davis, CA 95616**

**Tel (530) 297-6080**

**Fax (530) 297-6080**

**email spcarroll@ucdavis.edu**

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**Reply-To: <nglassee@iirb.com>**

**From: "Nadine Glasse" <nglassee@iirb.com>**

**To: "Scott P Carroll" <spcarroll@ucdavis.edu>**

**Subject: RE: Protocol Submission EMD-004**

**Date: Fri, 14 Apr 2006 08:38:48 -0400**

**Organization: Independent Investigational Review Board**

**Thread-Index: AcZftF5z0s1jm2RQMmyypIB3IXj1AAC4qAA**

**X-UCD-Spam-Score: 0.001 () BAYES\_00**

**X-Scanned-By: MIMEDefang 2.49 on 169.237.104.20**

**Status:**

Good Morning,

I received all three transmissions. The Chairman is aware that the study is in house. Have a Great Weekend.

Nadine Glasse  
Project Leader  
Independent Investigational Review Board, Inc.  
6738 West Sunrise Blvd, Suite 102  
Plantation, FL 33313  
nglasse@iirb.com  
Tel: 954-327-0778  
Fax: 954-327-5778

-----Original Message-----

From: Scott P Carroll [mailto:spcarroll@ucdavis.edu]  
Sent: Friday, April 14, 2006 7:12 AM  
To: nglasse@iirb.com  
Subject: Protocol Submission EMD-004

thanks again

--

Scott P. Carroll, Ph.D.  
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Date: Fri, 14 Apr 2006 07:22:00 -0700

To: <nglasse@iirb.com>

From: Scott P Carroll <spcarroll@ucdavis.edu>

Subject: RE: Protocol Submission EMD-004

Cc:

Bcc:

X-Attachments:

Thanks!

Good Morning,

I received all three transmissions. The Chairman is aware that the study is in house. Have a Great Weekend.

Nadine Glasse

Project Leader

Independent Investigational Review Board, Inc.

6738 West Sunrise Blvd, Suite 102

Plantation, FL 33313

nglasse@iirb.com

Tel: 954-327-0778

Fax: 954-327-5778

-----Original Message-----

From: Scott P Carroll [mailto:spcarroll@ucdavis.edu]

Sent: Friday, April 14, 2006 7:12 AM

To: nglasse@iirb.com

Subject: Protocol Submission EMD-004

thanks again

--

Scott P. Carroll, Ph.D.

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--  
Scott P. Carroll, PhD  
Department of Entomology  
Center for Population Biology  
University of California–Davis  
Davis, CA 95616

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**From: "Debbie Siano" <dsiano@iirb.com>**  
**To: "Scott Carroll" <spcarroll@ucdavis.edu>**  
Subject: new submission  
Date: Tue, 18 Apr 2006 09:08:24 -0400

X-Priority: 3  
X-UCD-Spam-Score: 0.089 () BAYES\_40,HTML\_50\_60,HTML\_MESSAGE  
X-Scanned-By: MIMEDefang 2.49 on 169.237.104.156  
Status:

Hello Scott,  
I am back from vacation..... I see that you have 2 studies going for today. That is great!! I will get on those. The MSDS's that you sent are we using all of them for both studies? Let me know, and I will let you know if I need any thing additional for the submissions.....  
thanks....

Debbie Siano  
Project Leader  
Independent Investigational Review Board, Inc.  
6738 West Sunrise Blvd. Ste 102  
Plantation, FL 33313

Office (954) 327-0778  
Fax (954) 327-5778

E-Mail <mailto:DSIANO@IIRB.COM>DSIANO@IIRB.COM

**Date: Tue, 18 Apr 2006 11:14:30 -0700**

**To: "Debbie Siano" <dsiano@iirb.com>**

**From: Scott P Carroll <spcarroll@ucdavis.edu>**

**Subject: ICF corrections**

**Cc:**

**Bcc:**

**X-Attachments: : Scott Carroll: I 125232: EMD-003. Carroll. ICF. doc: : Scott  
Carroll: I 125233: EMD-004. Carroll. ICF. doc:**

Debbie,

I have made the following corrections to the ICFs for EMD-003 and -004.

Should you need me I will be reachable on my cell at 530-902-8267, and then back at my  
desk by 4 your time.  
Thanks!

EMD-003

Page 1

Title of Study:

-Corrected number

Sponsor:

Nature and Purpose:

-Corrected sponsor

Page 2

Study Design:

-Changed to three test materials.

EMD-004

Page 1

Sponsor:

-Corrected sponsor

Nature and Purpose:  
-Changed to field test of mosquitoes  
-Corrected sponsor

Study Duration: Changed to field site

Page 2

Study Design:

-Changed to three test materials.

-Included lower legs (this is a mosquito study thing).

-Removed reference to receiving no material on one limb because it implies that the some subjects will be exposed without protection without their control. Normally, I am the untreated control. On occasion one of my highly experienced (> 10 years) technicians joins me with full knowledge in that role as a second untreated control subject. Is there a way we can write in leeway to have that second, experienced subject? If we can't come up with a way to do that now I could forego having the possibility of a second untreated control for the time being.

Procedures: I added lower legs under the application procedure  
-Also added: If any mosquitoes land you will remove them immediately. (How is that?).  
Could also say 'If any mosquitoes land you will remove them immediately with a hand-held suction device.'

Risks and Discomforts:

-Added: Measures will be implemented to remove mosquitoes before they have an opportunity to bite.

--

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From: "Debbie Siano" <dsiano@iirb.com>  
To: "Scott Carroll" <scarroll@ucdavis.edu>  
Subject: CALL

Date: Tue, 18 Apr 2006 13:22:40 -0400

X-Priority: 1

X-UCD-Spam-Score: 0.002 () BAYES\_50,HTML\_MESSAGE

X-Scanned-By: MIMEDefang 2.49 on 169.237.104.156

Status:

Hi Scott,

can you give me a call as soon as you get a free moment....thanks

Debbie Siano

Project Leader

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E-Mail <mailto:DSIANO@IIRB.COM>DSIANO@IIRB.COM

From: "Debbie Siano" <dsiano@iirb.com>  
To: "Scott Carroll" <scarroll@ucdavis.edu>  
Subject: emd-003

Date: Tue, 18 Apr 2006 14:15:37 -0400

X-Priority: 3

X-UCD-Spam-Score: 0.089 () BAYES\_40,HTML\_MESSAGE

X-Scanned-By: MIMEDefang 2.49 on 169.237.104.156

Status:

Hi Scott,

You may also want to take a look at this study....I see Avon (page 1) also please be sure the number of participants is correct and the study design ( i think there are 3 test materials not 2 i looked quickly) and procedures are correct....also is the payment correct??? still 14.00 an hour???

thanks...

Debbie Siano  
Project Leader

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E-Mail <mailto:DSIANO@IIRB.COM>DSIANO@IIRB.COM

**Date: Thu, 11 May 2006 08:51:08 -0700**

To: Iirb105@aol.com, "Debbie Siano" <dsiano@iirb.com>  
From: Scott P Carroll <spcarroll@ucdavis.edu>  
Subject: US EPA requests IIRB information for its protocol review  
Cc:  
Bcc:  
X-Attachments:

Dear Kim and Debbie,

William Jordan of the US EPA is in charge of implementing the new rule concerning human safety in pesticide exposure studies. He is in possession of our protocols EMD-003 and EMD-004, reviewed by IIRB in late April. He emailed this morning with a request for information about IIRB, which will hopefully be easy to obtain.

The information he requests is in blue, below. He would like to have it by next Tuesday. In order to be able to present your information together with other information that he has also requested from us in a coherent manner, I would like to receive your materials by the end of the day tomorrow if that is in any way possible. Jordan has presumed that the required documents will already be in your files.

I will contact you by telephone today to help coordinate this.

Thanks very very much,

Scott



- As required by §26.1115(a)(2): Minutes of IRB meetings . . . in sufficient detail to show attendance at the meetings; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

- As required by §26.1115(a)(4), copies of all correspondence between the IRB and the investigators (including application forms and all attachments).

- As required by §26.1115(a)(5):
  - o A 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;
  - o any employment or other relationship between each member and the institution, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.
- As required by §26.1115(a)(6), written procedures for the IRB in the same detail as described in §26.1108(a) and (b).

Please provide information responsive to these requirements as quickly as possible. Since all but the last item are documents that should already exist, we hope you will respond by close of business on Tuesday, May 16 2006. If you are unable to provide any of the required information, please explain why not.

--  
 Scott P. Carroll, PhD  
 Department of Entomology  
 Center for Population Biology  
 University of California–Davis  
 Davis, CA 95616  
 Tel (530) 297-6080  
<http://www.carroll-loye.com/>

From: "Debbie Siano" <dsiano@iirb.com>  
To: "Scott P Carroll" <spcarroll@ucdavis.edu>  
Subject: Re: US EPA requests IRB information for its protocol review  
Date: Thu, 11 May 2006 12:17:56 -0400  
X-Priority: 3  
X-UCD-Spam-Score: 0.037 () BAYES\_00,HTML\_40\_50,HTML\_MESSAGE  
X-Scanned-By: MIMEDefang 2.49 on 169.237.104.35  
Status:

Scott,  
I have forwarded your request to Kim and she will address the issues.

thanks

debbie

----- Original Message -----

From: <mailto:spcarroll@ucdavis.edu> Scott P Carroll  
To: <mailto:iirb105@aol.com> iirb105@aol.com ; <mailto:dsiano@iirb.com> Debbie Siano  
Sent: Thursday, May 11, 2006 11:51 AM  
Subject: US EPA requests IRB information for its protocol review

Dear Kim and Debbie,

William Jordan of the US EPA is in charge of implementing the new rule concerning human safety in pesticide exposure studies. He is in possession of our protocols EMD-003 and EMD-004, reviewed by IIRB in late April. He emailed this morning with a request for information about IIRB, which will hopefully be easy to obtain.

The information he requests is in blue, below. He would like to have it by next Tuesday. In order to be able to present your information together with other information that he has also requested from us in a coherent manner, I would like to receive your materials by the end of the day tomorrow if that is in any way possible. Jordan has presumed that the required documents will already be in your files.

I will contact you by telephone today to help coordinate this.

Thanks very much,

Scott

. As required by §26.1115(a)(2): Minutes of IRB meetings . . . in  
sufficient detail to show

- o attendance at the meetings;
- o the basis for requiring changes in or disapproving research; and
- o a written summary of the discussion of controverted issues and their resolution.

. As required by §26.1115(a)(4), copies of all correspondence between the IRB and the investigators (including application forms and all attachments).

. As required by §26.1115(a)(5):

- o A 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;
- o any employment or other relationship between each member and the institution, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

. As required by §26.1115(a)(6), written procedures for the IRB in the same detail as described in §26.1108(a) and (b).

Please provide information responsive to these requirements as quickly as possible. Since all but the last item are documents that should already exist, we hope you will respond by close of business on Tuesday, May 16 2006. If you are unable to provide any of the required information, please explain why not.

--

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 University of California-Davis  
 Davis, CA 95616

Tel (530) 297-6080  
<http://www.carroll-loye.com/>

**Date: Thu, 11 May 2006 15:14:05 -0700**  
**To: KLerner@iirb.com, DSiano@iirb.com**  
**From: Scott P Carroll <spcarroll@ucdavis.edu>**  
**Subject: More re EPA request for IRB documentation**

Cc:  
Bcc:  
X-Attachments:

Dear Kim and Debbie,

To further clarify what EPA is asking for, I provide in blue additional text which mentions a point that may or may not be important. See in particular (2). I have also copied in the relevant text from the ruling which is the basis for the content of most of my previous email on this subject. Thank you.

Section 26.1125 specifies the information that must be submitted in connection with a proposal to conduct new research with human subjects covered by the rule. This information generally includes (1) certain records that the Institutional Review Board (IRB) is required to maintain [see section 26.1115(a)]; (2) to the extent not covered in the IRB's records, a discussion of key issues which the IRB is required to consider and resolve in approving proposed research [see section 26.1125 (a) – (d)]; and (3) documentation of the IRB's approval of the proposed research [see section 26.1125(f)].

--

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Date: Fri, 12 May 2006 13:18:57 -0700

To: KLerner@iirb.com, DSiano@iirb.com  
From: Scott P Carroll <spcarroll@ucdavis.edu>  
Subject: A last note re EPA request for IRB documentation

Cc:  
Bcc:

X-Attachments:

Dear Kim and Debbie,

In the list of IRB information requested by EPA Bill Jordan from section 261115 (a) that I forwarded yesterday, he seems to have included everything except the required information on voting:

'the vote on these actions including the number of members voting for, against, and abstaining...'

Hopefully that is already a part of your compiled records.

We hope to have everything assembled by close of business Monday, meaning that it would be very helpful for me to have your records by midday Monday.

Thank you again,  
Scott

--

Scott P. Carroll, Ph.D.  
Carroll-Loye Biological Research  
711 Oak Avenue  
Davis, CA 95616