From "Robert Roogow" <rroogow@iirb.com>
Sent 07/26/2007 09:13 AM
To John Carley/DC/USEPA/US@EPA
cc "'Scott P Carroll'"<spcarroll@ucdavis.edu>
Subject RE: Meeting minutes for SPC-001 & SPC-002/Procedures & membership

Dear Mr. Carley,

Please find attached a copy of our Board minutes for Scott Carroll's two protocols SPC-001 and SPC-002. Please note that there have been no changes to our Board Membership or to our Board Principles & Procedures. If you require anything further please do not hesitate to contact me.

Regards,

Robert Roogow, MS, RAC
Director of Operations
Independent Investigational Review Board, Inc.
Ph: 954-327-0778
Fax: 954-327-5778
rroogow@iirb.com

(See attached file: 7-17-2007 (SPC-001 & SPC-002).doc)


7-17-2007 (SPC-001 & SPC-002).doc

Tuesday, July 17, 2007
MINUTES

ATTENDANCE:

PRESENT	ABSENT
Kim Lerner	Rabbi Akiva Mann
David Wells, MD	George Garbarino
Anita McSharry, RN	
Shari Somerstein, RPh	GUEST
Edward Wiederhorn	Katy Kysela
Glenn Moran, MD	

ALSO PRESENT
Glenn Moran, MD

I. CALL TO ORDER

The meeting was called to order at 10:00 AM, by Chairman, Kim Lerner. The meeting was held at 6738 West Sunrise Blvd., Suite 102, Plantation, FL 33313.

II. APPROVAL OF THE 7/10/2007 MINUTES

The minutes of the meeting held 7/10/2007 were reviewed and unanimously approved as reviewed.

III. REVIEW PROTOCOLS

J (Protocol SPC-001) EFFICACY TEST OF PICARIDIN-BASED PERSONAL INSECT REPELLENTS WITH MOSQUITOES UNDER FIELD CONDITIONS

Principal Investigator: Scott P. Carroll, PhD

- Approval Clinical Research Protocol dated: 7/16/2007
- Informed Consent Form Treated (Ver. 7/17/2007)
- Informed Consent Form Untreated Subjects (Ver. 7/17/07)
- Administrative Letter version dated 7/17/2007
- Site Questionnaire
- The Experimental Subject's Bill of Rights

Motion was made, seconded and the Committee unanimously approved the Research Protocol, the Investigator, Informed Consent Form Treated Subjects, Informed Consent Form Untreated Subjects, Administrative Letter and The California Experimental Subject's Bill of Rights for the above noted research study. The Site Questionnaire was reviewed and unanimously accepted.

The Informed Consent Form Treated Subjects and Informed Consent Form Untreated Subjects is unanimously approved as revised. The Committee recommended that changes be made to the Informed Consent Forms. The approved Informed Consent Forms are identified as Version 7/17/2007 and stamped, "Approved 7/17/2007". The Informed Consent Form contains all regulatory required consent elements. The Experimental Subject's Bill of Rights is stamped "Approved 7/17/2007".

The Committee evaluated that the risks to the subjects were minimized and that a reasonable risk/benefit ratio is established. Based on the duration of the study and the risks to the subjects, the approval is granted for a 12 month period, with a progress report required prior to continued approval. See Approval letter for Investigator's responsibilities and file for supporting documents.

M (Protocol SPC-002) EFFICACY TEST OF PICARIDIN-BASED PERSONAL TICK REPELLENTS

Principal Investigator: Scott P. Carroll, PhD

- Approval Clinical Research Protocol dated: 7/10/2007
- Informed Consent Form (Ver. 7/17/2007)
- Administrative Letter dated 7/17/2007
- Site Questionnaire
- The Experimental Subject's Bill of Rights

Motion was made, seconded and the Committee unanimously approved the Research Protocol, the Investigator(s), Informed Consent Form, The California Experimental Subject's Bill of Rights, Administrative Letter for the above noted research study. The Site Questionnaire were reviewed and unanimously accepted.

The Informed Consent Form is unanimously approved as submitted. The approved Informed Consent Form is identified as Version 7/17/2007 and stamped, "Approved 7/17/2007". The Informed Consent Form contains all regulatory required consent elements. The Experimental Subject's Bill of Rights is stamped "Approved 7/17/2007".

The Committee evaluated that the risks to the subjects were minimized and that a reasonable risk/benefit ratio is established. Based on the duration of the study and the risks to the subjects, the approval is granted for a 12 month period, with a progress report required prior to continued approval. See Approval letter for Investigator's responsibilities and file for supporting documents.