

US EPA ARCHIVE DOCUMENT

Tuesday, January 02, 2007  
MINUTES

**ATTENDANCE:**

**PRESENT**

David Wells, MD  
Anita McSharry, RN  
Shari Somerstein, RPh  
Edward Wiederhorn  
Rabbi Akiva Mann  
Kim Lerner

**ABSENT**

George Garbarino

**ALSO PRESENT**

Marcos Rejtman, DO

**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 12/26/2006 MINUTES**

The minutes of the meeting held 12/26/2006 were reviewed and unanimously approved as reviewed.

**III. REVIEW PROTOCOLS**

**IV. CHAIRMAN'S REPORT**

**V. OTHER BUSINESS**

- A Revised Protocol dated 12/29/2006, Revised Informed Consent Form (Ver. 1/2/2007); SCI-001; Scott P. Carroll;

The Independent Investigational Review Board, Inc. had an opportunity to review the Revised Protocol and the revised Informed Consent Form for the above noted research study. The protocol revisions include changes to the recruitment of untreated "control" subjects, clarification of the study products, and other administrative changes throughout the document.

**ACTION:** The Revised Protocol is unanimously approved as submitted. The revised Informed Consent Form is unanimously approved as submitted. The Informed Consent Form has been revised to accommodate the Revised Protocol. The approved revised Informed Consent Form is identified as Version 1/2/2007 and stamped, "Approved 1/2/2007". All current subjects and future volunteers must sign the revised consent forms.