# Institutional Review Board-01c University of South Florida 3702 Spectrum Blvd, Suite 155, USF Research Park

### March 26, 2007 IRB MEETING MINUTES

The Chair, Dr. Bercu, called the Institutional Review meeting to order on March 26, 2007 at 2:30 p.m.

Members present	Affiliation	<u>Status</u>	Expertise/Experience
Barry Bercu, M.D. Chairperson, Pediatrics	USF	Scientist	Children, Cognitively Impaired
Lauren DeLand, RN VA representative	JAHVA	Scientist	Cardiology/ ER/SICU
Linda Detman, Ph.D.	USF	Scientist	Sociology/Mothers/ General population Diversity/Community Affairs
Hiram Green, B.A.	USF	Non-scientist	
Clement Gwede, Ph.D.,	USF/MCC	Scientist	Oncology/Nursing/Health Education/radiation Nutrition/Women's Health
Nagi Kumar, Ph.D.	USF, MCC	Scientists	
Richard Lush, Ph.D. Vice-Chair	USF, MCC	Scientist	Pharmacology/therapeutics
John Merritt, M.D. FACP VA representative	USF, VA,	Scientist	Internal Medicine/spinal cord injury/elderly
Pamela Munster, M.D.	USF, MCC	Scientist	Medical Oncology Hematology/physiology
Ex-Officios present			
Sandra Thomas	JAHVA	Non-voting	Compliance officer,
Gene Gunner	TGH	Non-voting	Research services Research and Sponsored
Carol Bone	MCC	Non-voting	Projects Protocol review and Monitoring

#### IRB Staff present

Laurie A. Tozier

**USF DRIC** 

Non-voting

Federal regulations, Institutional policies

Henry Zych

**USF DRIC** 

Non-voting

Federal regulations, Institutional policies

Norma Epley

(During discussion of Committee Business)

#### **Consultants**

None

#### **Members Absent**

Mortimer Brown, Ph.D.

USF

Scientist

Psychology, cancer

Survivor

William J. Harris

N/A

Non Scientist

Ethicist/business

Arzu llercil, MD Daniel Sullivan, M.D. USF, TGH USF, MCC Scientist Scientist Cardiology/Internal med.

Scientist Medical oncology

Biochemistry/hematology

The IRB chair stated before the board that no member may participate in the review, discussion or vote of a project or activity in which she/he has a conflicting interest. The IRB member must leave the room prior to discussion, review and vote of the project and cannot be counted towards the quorum. The excused member can be recalled to provide information that is requested by the IRB.

# **Approval of Minutes**

A motion was made to approve the November 27, 2006 minutes. The motion was seconded. The motion carried

The IRB voted For - 7

Against - 0

Abstain - 0

(Total present -7)

# **Discussion - Committee Business**

Ms. Epley joined the meeting.

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Kirkpatrick, Anthony

# A Pilot Study of a 5-Day Infusion of Ketamine for Intractable Complex Regional Pain Syndrome

Ms. Epley presented a request from the Principal Investigator. The Board discussed the pending research that was last reviewed at the April 24, 2006 IRB meeting, in terms of this request. It was noted at the April 24, 2006 meeting the IRB requested revisions to the study. To date, the PI has not responded to all of those requested revisions and is asking the IRB to grant him an additional 30 day extension time in which to respond.

There was dissenting discussion regarding this request. It was noted that it is IRB policy that a response is due within 90 days of IRB review and the PI has had more time to respond to the revisions than given to other investigators. After further discussion a recommendation was made to grant a 30 day extension to Dr. Kirkpatrick from today in which to respond. The PI must complete ALL the requested revisions in their entirety otherwise it will not be reviewed.

There were no further comments raised by the IRB. A motion was made to allow an additional 30 days in which the PI has to respond to the IRB requested revisions.

The motion was seconded and carried unanimously.

The IRB voted For - 6

Against - 1

Abstain - 0

(Total present -7)



## **Deferred Final Report**

