

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 486-8788 Fax: (425) 483-4996 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 06/05/2012 - 06/19/2012* PEI NUMBER 3009543965
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED <b>To: David B. Audley, Executive Director</b>	

FIRM NAME International Cellular Medicine Society IRB	STREET ADDRESS 260 Court Street NE, Suite 220
CITY, STATE, ZIP CODE, COUNTRY Salem, OR 97302	TYPE ESTABLISHMENT INSPECTED Institutional Review Board

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**OBSERVATION 1**

The IRB has no and did not follow its written procedure for conducting its initial and continuing review of research. Specifically,

- A. On 02/29/12 the IRB approved a study (study # 2011-006) subject to FDA regulation. However, your current operating procedures state that the IRB will only evaluate protocols that are "considered practice of medicine and exempt from FDA regulation". The study was placed on a clinical hold by the FDA in January 2009 and the clinical investigator has not received correspondence to date stating that the study has been removed from clinical hold.
- B. Written operating procedures do not indicate the number of voting members needed to make up the IRB.
- C. Written operating procedures do not describe how the IRB will address missing records.
- D. Written operating procedures do not address the use of electronic signatures.
- E. The definition of a quorum in your written operating procedures is incorrect. Your procedure defines a quorum as "at least three (3) voting members", however, a quorum is based on the total IRB membership and is defined as a majority of the members of the IRB. A quorum is often calculated by using the half plus one technique.

**OBSERVATION 2**

Records required by 21 CFR 56 have not been maintained for three years following completion of the research. Specifically, the IRB meeting minutes dated 10/27/11 could not be located. The meeting minutes were overridden with the agenda for the meeting.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE _____, Investigator _____, Investigator	DATE ISSUED 06/19/2012
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<p><b>OBSERVATION 3</b></p> <p>Minutes of IRB meetings have not been maintained in sufficient detail to show actions taken by the IRB, the vote on actions, including the number of members voting for, against and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution.</p> <p>Specifically,</p> <p>A. Meeting minutes do not document details of changes to protocols and/or informed consents. On 02/29/12 the IRB accepted an amended protocol for study #2011-006. There is no documentation of the changes to the protocol that were reviewed. According to your current written procedures IRB meeting minutes shall include, if applicable, "the basis for requiring changes to a protocol."</p> <p>B. Meeting minutes do not identify the number of members who voted for, against or abstained from voting for each protocol reviewed. On 02/29/12 there is no record of which member(s) voted to accept the amended protocols for study # 2011-006.</p> <p>C. The 02/29/12 meeting minutes do not identify the approval period for the amended protocols for study #2011-006. According to your current written procedures, IRB meeting minutes shall include "The approval period for each initial review, continuing review and amendment."</p>			
<p><b>OBSERVATION 4</b></p> <p>For other than expedited reviews, the IRB does not always review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas.</p> <p>Specifically, a majority of the members of the IRB were not present to vote at the 02/29/12 fully convened IRB meeting. Three members were present and six members were needed to establish a quorum. Amended protocols for study # 2011-006 were accepted at this meeting. According to your current written procedures, "there must be a quorum of members present at a convened meeting. If quorum is lost, votes are not taken until it is restored. To be approved, a protocol must receive a majority of votes of members present at the meeting."</p>			
<p><b>SEE REVERSE OF THIS PAGE</b></p>	<small>EMPLOYEE(S) SIGNATURE</small> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> Investigator <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> Investigator	<small>DATE ISSUED</small> 06/19/2012	
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<b>OBSERVATION 5</b>		
<p>A list of IRB members has not been maintained, identifying members by representative capacity, indications of experience sufficient to describe each member's chief anticipated contribution to IRB deliberations, and any employment or other relationship between each member and the institution.</p> <p>Specifically, the 2011 and 2012 IRB membership rosters do not describe the members' chief anticipated contributions to IRB deliberations, indications of experience and any relationship between each member and the institution. The membership rosters only identify the IRB member by his or her name, earned degree (if applicable), country, occupation and electronic mail address. Additionally, according to your current operating procedure, "The IRB will only evaluate protocols that...are presented by ICMS members, sponsored by an ICMS member and conducted at a facility that is or will seek inclusion in the ICMS accreditation program." The relationship between the member and ICMS is also not reflected on the membership roster.</p>		
<b>OBSERVATION 6</b>		
<p>Copies have not been maintained of all correspondence between the IRB and the investigators.</p> <p>Specifically, copies of all written correspondence between the IRB and the investigator is not maintained. For example, if a proposal has been tabled the investigator will be notified via electronic mail correspondence with the reasons why the protocol was tabled. This correspondence is not maintained with the study records. According to your current operating procedures, "Within five working days after each IRB meeting a letter is prepared and sent to the PI of each protocol notifying them of the IRB determination for the protocol."</p>		
<b>OBSERVATION 7</b>		
<p>The IRB does not include at least one member whose primary concerns are in nonscientific areas.</p> <p>Specifically, one nonscientific member was not present when research was approved and reviewed by the IRB on 02/29/12.</p>		
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**OBSERVATION 8**

The IRB does not include at least one member who is not otherwise affiliated with the institution, and who is not part of the immediate family of a person who is affiliated with the institution.

Specifically, one unaffiliated member was not present at the 02/29/12 meeting. During this meeting IRB members reviewed and approved research proposals.

\* DATES OF INSPECTION:

06/05/2012(Tue), 06/08/2012(Fri), 06/14/2012(Thu), 06/19/2012(Tue)

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OF THIS PAGE

EMPLOYEE(S) SIGNATURE

[Redacted Signature] - Dotter, Investigator  
[Redacted Signature], Investigator

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06/19/2012