COAST IRB, LLC

BOARD MEETING Minutes

Board Meeting Date: October 30, 2008

Board Meeting Start Time: 6:00 P.M. MDT

Board Meeting Location: Coast IRB, LLC
5475 Mark Dabling Blvd.
Suite 351
Colorado Springs, CO 80918
- or -
Conference Call: [redacted]
Pass Code: [redacted]

I) CALL TO ORDER By Melissa Cortes, M.Ed., Chairperson **Meeting Start Time 6:07 PM MDT**

II) ATTENDANCE

Board Members:

Melissa Cortes, M. Ed. Chairperson
Koren Barrett, N.D. Vice Chair
Joel Cherlow, M.D., Ph.D.
Adam Dodd, M.D.
Pamela Geddis, M.D.
Rochelle Salmore, M.S.N., R.N
Lawrence Selman, B.B.A.

Non-Board Members:

Christy Gorey, Senior IRB Administrator
Kim Lenda, Compliance Associate, Secretary
Kathy Self, Regulatory Affairs Specialist
Susan Wampler, IRB Administrator

[redacted] was not in attendance from 6:34 PM MST to 6:35 PM MST. [redacted] was not in attendance for Section(s): VI.C.1. Items for Board Review: Changes to Research: Sponsor Submitted Changes – Protocol Amendments/Updated Investigators' (Device) Brochures.

a) [redacted]

III) CONFLICT OF INTEREST

A. **Conflict of Interest:** Chairperson asked if any board members had to abstain from any agenda items.

[redacted]

B) NEW SPONSOR SUBMISSIONS

1) Adult Population Medical Procedure/Pharmaceutical Studies - *None*

2) Medical Device Studies

(a) **Device Med-Systems- P-D015** -Pilot Study of Safety and Efficacy of 2.5% Adhesiabloc® Gel to Reduce Adhesions Following Peritoneal Cavity Surgery

Note: This Device falls under a 510k and risk assessment is not required.

(i) **For Review: Protocol, Version 1.4** **Adam Dodd, M.D.**
- Decision/Vote: Approve # Voting: 7 # For: 7 # Against: 0
  # [Abstain/Recuse]: 0 Names(s): [Enter member's name]

(ii) Consent to Participate in a Research Study, Version 1.0 **Adam Dodd, M.D.** **Melissa Cortes, M.Ed.**
- Decision/Vote: Conditionally approve # Voting: 7 # For: 7 # Against: 0
  # [Abstain/Recuse]: 0 Names(s): [Enter member's name]

(iii) **Investigator:** Jonathan Q. Kruger, M.D. **Melissa Cortes, M.Ed.**
- Community Attitudes: Community Attitudes were sufficiently described
- Decision/Vote: Approve # Voting: 7 # For: 7 # Against: 0
  # [Abstain/Recuse]: 0 Names(s): [Enter member's name]

- **Discussion:** New study, device, using a gel post-surgery. This is a single site study, 70 female adults who are already undergoing laparotomy due to infertility, pain and or/irregular vaginal bleeding with preservation of fertility. Already have planned 2nd look laparoscopy, within 6 months after the surgery. This is a double blind study in the sense that after the surgery is completed either the gel or saline is introduced by a third party. Doctor performing the surgery does not know and the subject does not know whether the patient has received the gel or the saline. This is the first study using this gel in humans, though similar devices/substances have been used in the same way, with the goal to see if it prevents adhesion formation after surgical procedures in which adhesion is a risk. This study is targeting a population where the majority of the subjects will be having surgery for reasons of preserving their fertility; therefore adhesions could negatively impact the outcome. The subjects will not be receiving reimbursement. They may participate or not, and their decision does not affect treatment. The continuing review interval recommendation is 6 months (semi-annual) even though the gel is probably very safe; this is a pilot study & first-time use in humans. Recommendation is for conditional approval of the ICF, as terms need defining. Sponsor was unable to provide the definitions pre-meeting. The protocol looks fine. The Board Chair questions whether, given this population, this specific set of patients undergoing certain procedures regarding fertility, whether they would be familiar with the vocabulary used in the consent anyway? Primary says most likely yes, and many of the words in the consent form will be associated with other procedures already covered by different consent forms from their doctor. The Safety Reviewer notes that neither the protocol nor the consent form defines or offers guidelines when discussing "significant accumulation of abdominal fluid or ascites" - Should this be spelled out and "significant" in particular defined? The Primary has no problem asking sponsor to be more specific but this parameter is not what is being looked for the purposes of the study, so it is not that imperative. The observation has to do with fluid in the abdomen, and is not critical to study procedures. Also, the Safety Reviewer has a concern or question about leaving extra fluid in the abdomen – is this standard procedure? The Primary says this is not a bad thing, it provides a buffer post-surgery to prevent adhesion. Gel substance is more sticky, stays in place during healing process and scar formation and ovary or tube heals. The gel might prevent adhesion more effectively since it does not move around as freely as a fluid. Recommendation is for approval of the protocol and the site, which the Board Chair had no issues with, and conditional approval of the ICF. The ICF can come back expedited to Chair and Primary once definitions are provided by the Sponsor.
- Vulnerable Population: No
- Significant Risk Assessment: Not applicable - 510(k) device
- Set Continuing Review: 6 months (semi-annual)
- Continuing Review Rationale: Pilot study, new device in humans
- Action Item (s): None
- Submitted by: **Denise Strasser**

IV) ADJOURNMENT

This agenda has been respectfully submitted by Coast IRB, LLC Compliance.

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Susan Wampler, IRB Administrator
On behalf of Coast IRB, LLC Compliance

Adjourned by: Melissa Cortes, M.Ed. Chairperson **Time: 7:01 PM MDT**

Submitted by: Kim Lenda, Compliance Associate, Secretary

Approved by: _____ _____
Melissa Cortes, M.Ed, Chairperson **Date**

Next Meeting Date: Tuesday November 04, 2008