Hot Topics in IRB Land
Regional IRB Consortium Workshop & Meeting
Thursday, April 23, 2009
Thomas Foster, Pharm.D., FCCP, FCP, FAPHA

Center for Clinical and Translational Science Spring Meeting
Lexington Civic Center
Hot Topics

- Government “Sting” operation on OHRP and “For Profit” IRBs
  - Coast IRB censure by FDA and close
- Privacy Rule versus the Common Rule - JAMA
- Evolution of the Participant Recruitment Organizations( PRO)
Committee on Energy and Commerce

- March 26, 2009
- The Subcommittee on Oversight and Investigations held a hearing titled, “Institutional Review Boards that Oversee Experimental Human Testing for Profit”
- The hearing examined whether institutional review boards (IRBs) and the federal government are adequately protecting human subjects of biomedical research.
The Sting

### Information Submitted to HHS for Additional GAO Bogus Companies

<table>
<thead>
<tr>
<th>Company name</th>
<th>Phaké Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street address</td>
<td>2232 Wounded Limb Drive, Suite #6 Paynesville, SC</td>
</tr>
<tr>
<td>Senior official</td>
<td>Dr. Vince N. Feelgood</td>
</tr>
<tr>
<td>Other staff</td>
<td>Douglas Phaké</td>
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<tr>
<th>Company name</th>
<th>E-Z Reviews</th>
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<tbody>
<tr>
<td>Street address</td>
<td>1234 Phulovit Lane SE Chetesville, AZ</td>
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<tr>
<td>Senior official</td>
<td>Donald McSpeed III</td>
</tr>
<tr>
<td>Other staff</td>
<td>April Phuls, Timothy Wittless, Alan Ruse</td>
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Source: GAO.
Pilot Study of Safety and Efficacy of 2.5% Adhesiabloc® Gel to Reduce Adhesions Following Peritoneal Surgery
Comments From IRBs That Did Not Approve GAO's Bogus Device Protocol

Protocol was “awful” and a “piece of junk”

The “riskiest thing I’ve ever seen”

The odds of approval were “zero percent”

“Did somebody approve it...Oh Boy!”

Source: Institutional review boards.
Coupon Offered by IRB That Approved GAO’s Bogus Device Protocol

Take us for a free test drive!

Good for a ONE time research protocol review (worth $1,300)

Source: Institutional Review Board; redacted by GAO to remove identifying information.
Coast Story

- House Energy and Commerce Committee and GAO
  - The company approved the methodology for a fake clinical trial of an equally fake surgical gel, "Adhesiabloc," produced by a fake company that Congress and the Government Accountability Office had set up.
  - Fictitious testing protocol involved pouring a liter of a product into a woman's stomach following surgery. Two other companies approached by GAO rejected the proposal.
  - The FDA's original action has affected 300 human studies involving about 3,000 researchers.
Excerpts From Meeting Minutes Of IRB That Approved GAO’s Bogus Device Protocol

B) NEW SPONSOR SUBMISSIONS

1) Medical Device Studies

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

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

(i) For Review: Protocol, Version 1.4
* Decision/Vote: Approve

Voting: 7  # For: 7  # Against: 0
# [Abstain/Refruse]: 0  Name(s): [Enter member’s name]

(ii) Consent to Participate in a Research Study, Version 1.0

Unanimous approval of item with no dissenting votes

Item referred to as, “...probably very safe”

Source: Institutional review board.
Coast to Close

- **WSJ BUSINESS**
- **APRIL 22, 2009, 6:39 P.M. ET**
- **Coast IRB, Caught in Sting, to Close**
  - A Colorado company that approved a fake medical study in a congressional sting operation said it will close.
  - Coast IRB said the disclosure of the sting and an April 14 warning letter from the Food and Drug Administration describing the company's violations led several high-profile customers to pull their business. As a result, "Coast IRB's owners decided, through counsel, to cease future company operations," a company statement said.
  - The company had said earlier that it intended to temporarily halt accepting new business and to stop enrolling patients in studies that had begun while it made a thorough overhaul of its operations.
Reforming the HIPAA Privacy Rule: Safeguarding Privacy and Promoting Research

JAMA, April 1, 2009
Lawrence O. Gostin and Sharyl Nass

- Implications of the Stimulus Plan and Health Information Technology
- IOM-HIPAA fails to safeguard privacy and impedes research
- HIPAA and the Common Rule
Participant Recruiting Organizations (PROs)

*excerpt from letter received by presenter from PRO*

February 2009
37354487

[Company name], a company specializing in patient recruitment for clinical trials (also known as research studies), is currently working with a pharmaceutical company to find individuals willing to participate in a clinical trial for Chronic Obstructive Pulmonary Disease, also called COPD. We would like to provide you with information on this trial and other clinical studies that may be of interest to you or your family.

Please allow [Company name] to share with you information about this important COPD trial, including the following benefits should you qualify to be a part of the study:

- Study-related health assessments related to COPD (under the care of a local physician)
- Potential compensation for your time and travel
- Study medication at no charge to you

For more information, you only need visit this specially designed website - [Company name] -at any time, or call toll-free 1-866-XXX-XXXX between 8 a.m. and 10 p.m. Eastern time, Monday through Friday.