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% 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**
- 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

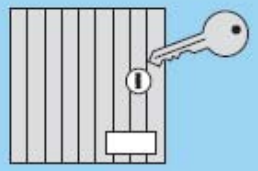
gel is probably very safe; this is a pilot study & first-time use in humans. Recommendation is for conditional approval of the ICF, as terms need defining. Sponsor was unable to provide the definitions

Unanimous approval of item with no dissenting votes

Item referred to as, "...probably very safe"

Source: Institutional review board.

Details of GAO's Bogus Medical Device Company



Mailbox used as our "suite" or office

Fictitious lead researcher with a fabricated medical license and resume

Fabricated FDA marketing approval for our device

Cell phone as the only number provided

Source: GAO.

Coupon Offered by IRB That Approved GAO's Bogus Device Protocol

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

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.

Examples Of Advertising Used By GAO's Bogus IRB

Looking for IRB review service?

Flexibility
Timely Guarantee

MARYLAND HAUSE
Institutional Review Board

HHS Approved

Clinical Trial Review Service

Fast approvals guaranteed

Areas of expertise –

Phase I-IV pharmaceuticals & medical devices
Multi-site reviews
Prior disapprovals/unfavorable opinions

www.MarylandHauseIRB.com
Speed • Quality • Customer Service

Source: GAO.

Excerpts From HHS Database Listing Additional GAO Bogus Companies

Institutional Review Boards (IRBs)	
IRB Number	**IRB Name**
IRB00006904	E-Z Reviews, Inc. IRB #1

Assurances/Components Found	
Assurance	**Institution/Component**
FWA00014102	Phaké Med Devices, Inc.

Source: GAO, HHS.

Information Submitted to HHS for Additional GAO Bogus Companies

Company name: **E-Z Reviews**

Street address: **1234 Phulovit Lane SE**
Chetesville, AZ

Senior official: **Donald McSpeed III**

Other staff: **April Phuls, Timothy Wittless, Alan Ruse**

Company name: **Phakē Medical Devices**

Street address: **2232 Wounded Limb Drive, Suite #6**
Paynesville, SC

Senior official: **Dr. Vince N. Feelgood**

Other staff: **Douglas Phakē**

Source: GAO.