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## Drugs ☐

### Questions and Answers on Coast IRB April 14, 2009 Warning Letter

#### **Q: What action did FDA take today?**

A. The U.S. Food and Drug Administration today announced that Coast IRB, LLC of Colorado Springs, Colo., has agreed to voluntarily halt some aspects of its clinical trial oversight operations due to serious concerns about the company's ability to protect human subjects participating in clinical trials. Coast IRB was issued a Warning Letter outlining some of FDA's recent concerns and the restrictions agreed to by Coast IRB. Specifically, Coast IRB has agreed to: (1) Not review any new FDA-regulated studies; and (2) Not allow new subjects to be added to ongoing FDA-regulated studies.

#### **Q: Who is affected by this action?**

A. This action affects Coast IRB's ongoing FDA-regulated clinical trials of medical devices, drugs and biologics, the companies sponsoring the studies, the clinical investigators conducting the studies and potential new subjects for these studies. This action also affects review of new studies by Coast IRB. This action does not affect subjects already participating in ongoing FDA-regulated studies approved by Coast IRB. According to the company's records, the IRB currently oversees approximately 300 active human research studies conducted by some 3,000 clinical investigators.

#### **Q: Why did FDA take this action now?**

A. The FDA's action follows a recent undercover operation by the U.S. Government Accountability Office (GAO). The GAO submitted to Coast IRB for review a factitious research study involving a purportedly FDA-cleared medical device. Although no human subjects were involved, the GAO operation heightened FDA's concerns about Coast IRB's ability to protect the rights and welfare of human research subjects.

In evaluating the information provided by the GAO investigators, the FDA determined that Coast IRB violated several regulations intended to protect the rights and welfare of human research subjects in clinical trials and that the company failed to perform a robust review prior to approving the GAO study.

#### **Q: What are some of the specific problems FDA found?**

A. The FDA found that the IRB failed to:

- Determine that risks to subjects are minimized [21 CFR 56.111(a)(1)]
- Determine that risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result [21 CFR 56.111(a)(2)]
- Determine the applicability of 21 CFR Part 812 and failed to make a risk determination for the investigational device study [21 CFR 812.2(c)(2), 812.66, and 812.20(a)]
- Ensure that basic elements of informed consent are included in the IRB-approved consent form [21 CFR 50.25(a)(2) and 56.109(b)]
- Demonstrate its ability to ascertain the acceptability of the proposed research in terms of regulations, applicable law, and standards of professional conduct and practice [21 CFR 56.107(a)]

The specific problems and the significance of the problems can be found in the FDA Warning Letter posted at the following location on the [FDA web site](#)<sup>1</sup>.

#### **Q: How can I find out if the study I am in is under Coast IRB's oversight?**

A. Research subjects can contact the study staff and clinical investigator at the telephone number listed in the Informed Consent Form they signed when they agreed to participate in the study. Subjects should not stop participating in the study before speaking to their clinical investigator.

#### **Q: Will the ongoing studies that were reviewed by Coast IRB be permitted to continue?**

A. Yes. All ongoing studies that were reviewed and approved by Coast IRB will be permitted to continue

although no new subjects will be permitted to enroll into these studies.

**Q: Do all the studies reviewed by Coast IRB lack adequate protection for subjects?**

A. At this time, the FDA has no specific knowledge that any of the studies previously reviewed (either completed or presently ongoing) lack adequate protections for participating subjects. FDA's action is precautionary.

**Q: What kinds of human research studies are affected?**

A. Studies of FDA-regulated products (e.g. drugs, biologics, medical devices) reviewed and approved by Coast IRB are affected by FDA's action.

**Q: Why is FDA allowing research studies already underway to continue, while it is not allowing Coast IRB to review and approve new studies or allowing new subjects to enroll in ongoing studies?**

A. When FDA takes a regulatory action it must consider the risks and benefits to the public health. Given the information to date, FDA has to weigh the impact of additional restrictions on subjects already enrolled in the study and believes the right decision at this time is to allow studies currently underway to continue as FDA proceeds to gather more information.

**Q: What are the next steps?**

A. The restrictions placed on Coast IRB will remain in effect until the FDA is satisfied that Coast IRB has taken necessary corrective actions to bring it into compliance with FDA regulations designed to protect human research subjects. Consistent with the regulatory requirements for IRBs, Coast IRB will continue to receive and respond to reports of unexpected and serious adverse events as well as review progress reports submitted by clinical investigators in ongoing studies.

**Q: Where can research subjects go for more information?**

A. Research subjects can contact the study staff and clinical investigator at the telephone number listed in the Informed Consent Form they signed when they agreed to participate in the study.

**Q: What is the significance of today's action for sponsors and clinical investigators of these studies?**

A. IRB approval of ongoing studies is currently not affected by the FDA's action; however, no new subjects may be enrolled in these studies at this time. Sponsors whose studies have approval from Coast IRB should work together with the clinical investigators to determine next steps.

**Q: What is a clinical trial?**

A. A clinical trial is a study conducted to evaluate an investigational product. Each study is designed to answer specific scientific questions. There are benefits as well as possible risks involved in participating in a clinical trial, and there may also be some risks that are not yet known. Clinical trials help FDA find out if promising new treatments are safe and effective for patients. During a clinical trial, more and more information is gained about a new product, its risks, and how well it may or may not work.

**Q: What is an Institutional Review Board (IRB)?**

A. Under current federal law, clinical research involving human subjects and FDA-regulated products, such as drugs, biologics or medical devices, must be reviewed and approved by an "institutional review board" (IRB). An IRB is a panel of doctors, scientists and non-scientists charged with reviewing the clinical research in order to protect the rights and welfare of the subjects participating in the study.

**Q: What is informed consent?**

A. Informed consent is the process through which potential participants in a clinical trial learn specific information about a trial before deciding whether to agree to participate. To help someone decide whether to participate, the doctors and nurses involved in the trial explain the details of the study, and answer any questions that the potential subjects may have. The [informed consent document](#)<sup>2</sup> must explain that the product under study is experimental, and describe the purpose of the trial, its duration, risks and potential benefits, if any, required procedures that will be performed, other available treatments for the condition under study, and key contacts. If the subject decides to participate in the trial, the subject will sign the document. Informed consent is not a contract, and the subject may withdraw from the trial at any time.

**Q: Where can I learn more about how devices affected by this action?**

A. This link provides background on the device approval process and regulation: [More Information on Devices](#)<sup>3</sup>□

**Q: Where can I go for more information about FDA?**

A. You may refer to the FDA web page at [www.fda.gov](http://www.fda.gov)<sup>4</sup> and the following links for more information about the

FDA:

- **Center for Drug Evaluation and Research:**  
<http://www.fda.gov/Drugs/default.htm><sup>5</sup>□
- **New Drug Development and Review Process**  
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm053131.htm><sup>6</sup>□
- **Center for Biologics Evaluation and Research:**  
<http://www.fda.gov/BiologicsBloodVaccines/default.htm><sup>7</sup>□
- **Center for Devices and Radiological Health:**  
<http://www.fda.gov/MedicalDevices/default.htm><sup>8</sup>□

For more information please call 888-INFOFDA or e-mail [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)

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#### Links on this page:

1. <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm136673.htm>
2. <http://www.clinicaltrials.gov/ct2/info/glossary>
3. <http://www.fda.gov/MedicalDevices/default.htm>
4. <http://www.fda.gov/>
5. <http://www.fda.gov/Drugs/default.htm>
6. <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm053131.htm>
7. <http://www.fda.gov/BiologicsBloodVaccines/default.htm>
8. <http://www.fda.gov/MedicalDevices/default.htm>