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FDA NEWS RELEASE

FOR IMMEDIATE RELEASE

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FDA Imposes Restrictions on Coast IRB due to Violations

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.

According to the company's records, these actions may involve approximately 300 active human research studies conducted by some 3,000 clinical investigators.

Until further notice, Coast IRB has agreed to stop reviewing new FDA-regulated studies. Also, Coast IRB will direct clinical investigators in on-going FDA-regulated studies approved by Coast IRB to halt new subject enrollment. FDA has issued a Warning Letter to Coast IRB outlining its concerns and FDA will continue to actively monitor the company and take appropriate action as necessary. These restrictions will remain in effect until the FDA is satisfied that Coast IRB has taken necessary corrective actions that bring it into compliance with FDA regulations designed to protect human research subjects.

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

Today's actions follow a recent undercover operation by the U.S. Government Accountability Office (GAO). The GAO submitted to Coast IRB for review a fictitious 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, FDA determined that Coast IRB committed several violations of the laws and regulations intended to protect the rights and welfare of human research subjects in clinical trials and that the company failed to perform the robust review needed to approve a study.

The FDA's action is precautionary. Because of the potential risk to enrolled subjects and disruption to the research if on-going studies were abruptly terminated, studies that Coast IRB has already approved will be permitted to continue. However, no new subjects will be permitted to enroll in these studies until there is assurance that the research has undergone adequate review. Coast IRB continues to be obligated to receive and respond to reports of unexpected and serious adverse events as well as to review progress reports submitted by clinical investigators.

Related Links:

- [Update: Coast IRB](#)¹
- [Warning Letter / Questions and Answers](#)²
- [What Is an IRB?](#)³
- [Letter to Coast IRB, June 4, 2009](#)⁴

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