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News & Events

Coast IRB -- Update

FDA is providing the following updated information regarding Coast IRB, LLC and the on-going clinical trials under its oversight.

- On April 20, Coast announced that it will cease all operations and go out of business as soon as oversight for research protocols approved by Coast IRB is transferred to other institutional review boards (IRBs). On April 23, Coast notified FDA that it will be coordinating with Chesapeake Research Review, Inc. (Chesapeake IRB) to arrange for the transfer of oversight responsibility for many of its clinical trials.
- Coast IRB noted that only those studies elected by sponsors and investigators will be transferred to Chesapeake IRB; all other studies will be transferred in accordance with the sponsor's and clinical investigator's preference.
- Coast IRB estimates that the transition may take 4-6 weeks. During this transition period, Coast IRB will remain responsible for the oversight of these studies, including the review of safety reports and conducting continuing review.
- As studies are transferred, Chesapeake IRB will be contacting study sponsors and/or clinical investigators for protocol-related information to permit it to perform its initial review. This information may include updated safety and adverse event information and recruitment materials.
- FDA is actively monitoring the above activities to help ensure the protection of the rights and welfare of human subjects involved in these clinical trials.
- For questions related to this transition process, please contact
 - o John Clark, Compliance Officer, Coast IRB, LLC at 719-325-8400 ext. 8384.
 - Theresa Straut, Executive Director, IRB Services, Chesapeake Research Review, Inc. at 410-884-2900.
 - o Joanne R. Less, Ph.D., Director, Good Clinical Practice Program, FDA at 301-827-1256.

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