# Unique TB-HIV research institute planned in South Africa

At a time when the dangers of HIV and tuberculosis (TB) co-infection are increasingly apparent, the Howard Hughes Medical Institute (HHMI) has teamed up with the University of KwaZulu-Natal in South Africa, to create a new international research facility dedicated entirely to studying these two diseases, as well as how they interact. The KwaZulu-Natal Research Institute for Tuberculosis and HIV will be housed within the grounds of the Nelson Mandela School of Medicine in Durban.

"There is no place in the world where there is a dedicated integrated TB-HIV research center, so this is really the first one of those. And what I think is so exciting about this is that it is right in the middle of the worst parts of those epidemics," says Bruce Walker, an HHMI investigator who will lead immunology research within the HIV program at the new KwaZulu-Natal Research Institute. The region is ravaged by one of the world's most devastating TB-HIV co-epidemics, with about half of the local population suffering from HIV/AIDS. It is in the province's rural area of Tugela Ferry, where a severe outbreak of extremely drug-resistant TB was reported in 2006.

Construction of the new institute, a six-story building that will contain high-security labs for TB research, is scheduled to begin in September. In addition to providing a platform for testing new vaccines and drugs, it is designed to serve as a global resource to attract top talent and train the next generation of African scientists. "There are vanishingly few opportunities for foreign-trained African researchers to come back and do research in their country," says Walker.

HHMI has promised funding worth $60 million over the next ten years to secure the long-term vision of the key HHMI scientists involved.


Associated Press

**A need for information:** TB diagnostics is one of the areas the center will study

"This is a huge investment by the Howard Hughes Medical Institute to go out and do, and it is entirely unprecedented for them to move into this direction," says William Jacobs, Jr. of the Albert Einstein College of Medicine in New York. Jacobs, an HHMI investigator, will offer expertise for the

KwaZulu-Natal Research Institute in the development of rapid diagnostic tests for TB.

*Karen Dente, Paris*

# Coast IRB hits treacherous waters

In early March, Coast IRB, a company based in Colorado Springs, Colorado that offers independent review board services for clinical trials, issued an unusual pair of press releases. The first claimed that the company had uncovered an inappropriate clinical trial and immediately alerted the authorities. A few days later, Coast reported that the inappropriate trial was actually part of a sting operation run by the US Government Accountability Office (GAO). Some journalists, including this writer, commented in news stories and blogs on what appeared to be an amusing but ultimately harmless chain of events: the GAO probed IRBs, and Coast apparently passed the test.

But, according to government investigators, Coast had in fact granted an expedited approval to the fake clinical trial, revoking it five months later only after being contacted by congressional investigators.

"Coast IRB, a for-profit company, approved a fictitious study led by a fictitious doctor and submitted by a fictitious company," stated US House Oversight and Investigations Subcommittee chairman Bart Stupak at a 26 March hearing on the matter. Worse, the GAO's sham study had been rejected up front by two other IRBs, who had slammed the protocol as being too risky.

It was not Coast's first run-in with the authorities. Precisely a year earlier, the US Food and Drug Administration (FDA) had temporarily suspended the company's ability to perform expedited trial reviews, after ruling that Coast had improperly approved a trial's recruitment poster.

Company representatives remained on the offensive, at least initially. In his opening statement, Coast chief executive officer Daniel Dueber asserted that "the Government Accountability Office, at the behest of this Committee, perpetrated an extensive fraud against my company, Coast IRB. It did so without probable cause that Coast had committed any crime. Indeed, no one at Coast has committed any crime." Dueber went on to claim that the GAO's sting operation had violated state and federal law to "prove a political point."

After a thorough grilling by the committee, however, Dueber abruptly changed tacks. In a contrite statement issued shortly after the hearing, he announced a barrage of policy changes at Coast IRB and conceded that "we were duped. Had we started from a premise of skepticism rather than trust, we would not have been."

And in a major development two weeks later, the FDA announced on 14 April that Coast IRB had agreed to voluntarily freeze ongoing reviews of clinical trials at the request of the agency—a move the FDA said could affect more than 300 trials.

*Alan Dove, Springfield, Massachusetts*