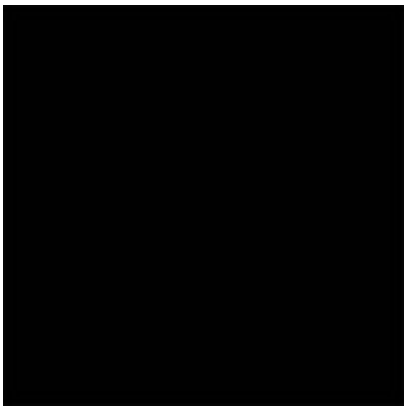
Research in a Black Box

By Brandon Keim ✉August 08, 2007 | 2:29:16 PMCategories: Biotechnology, Gene Therapy, Medical Ethics, Medicine & Medical Procedures



Part of the digging I'm doing into the death of a woman who died during a gene therapy clinical trial involves finding out what Institutional Biosafety Committees at participating hospitals saw.

Institutional Review Boards, or IRBs, are expert groups who evaluate clinical trial applications. As required by law, every hospital participating in a trial has one. The IRBs are supposed to flag problems or potential flaws. It's their job to make sure studies are well-designed and, if they're not confident of that, to keep their hospitals from joining.

It's important to note that the death hasn't officially been linked to the trial, run by Seattle-based Targeted Genetics. But reporting by the *Washington Post* suggests that there were flaws in the trial's design, particularly in informed consent statements that don't appear to have made clear its risks and benefits. So finding out what IRBs saw is very important right now.

One of the doctors responsible for recruiting people into the trial was Alan Kivitz of the Altoona Center for Clinical Research in Duncansville, Pennsylvania. (I have no reason to suspect that anything untoward happened at the Center. Before the identity of the woman who died became public, I had a hunch that she lived in Pennsylvania, so I figured I'd call them first.)

The Center's website lists Pam Keenan as a contact person for anyone interested in joining a trial. I left a message for Pam yesterday. Lisa Riley, the Center's Clinical Research Administrator, called back today. She said that they weren't discussing the Targeted Genetics trial.

I then asked if she could give me any information about the Center's IBC*. No, she couldn't do that, she said. This would constitute talking about the trial. She explained that it was Center policy not to discuss anything about the trials, including the IBC*, with anyone outside the office.

Now, if the Center was part of a state university, or receiving NIH money, I'd be legally entitled to information about the IRB and what they'd discussed regarding the trial. (I'm actually submitting a FOIA request for IRB minutes to Northwestern University, another trial location.) Since the Center's private, they don't have to do this.

But they could do it, if they wanted to. And at the very least they could tell me who's on the IRB, let me call them, and then the IRB could refuse to share that information. Instead they've decided to pull a full black-box routine.

I'm not asking for private medical information. I'm asking to see what the IRB discussed when deciding whether to risk their patients' health in medical experiments. If they're not willing to reveal the substance of those discussions, or even to say who took part in them -- well, that's their right, but it's disturbing.

Riley said that the Center does share information about their IRB with patients. I'm glad they at least do this. But the general public should have access to this information, too. It's a necessary check on the power of IRBs. The more that medical research is conducted transparently, the safer it will be.

And while the Altoona Center for Clinical happens to be the subject of this post, I don't doubt that their policy is widely observed among private hospitals running clinical trials. So that's something to else to add to our list of questions to ask for prospective gene therapy trial participants: just how open is your hospital? Is somebody watching their watchers?

Image: Susanne Christensen

** During the conversation with Lisa Riley and the writing of this post, I mistakenly used the phrase "Institutional Biosafety Committee" when I meant to say "Institutional Review Board." The former oversee the safety of research more generally, while it's the latter that review clinical trials. While I believe that she understood that I meant IRB rather than IBC, and do not back down from my conclusions, this sort of careless mistake is unacceptable in this context. My sincere apologies.*