

# Pregnant pause: Is research being subtly discouraged?

*IRBs should look to their policies to see*

There's little data about exactly what is impeding research with pregnant women, says **Ruth Faden**, PhD, MPH, director of the Johns Hopkins Berman Institute of Bioethics in Baltimore, MD.

Is it funders who don't provide the money, IRBs who won't approve the studies or investigators who assume they can't get approval and don't even attempt it?

Faden says she doesn't believe that IRBs by themselves constitute a major obstacle to research with pregnant women. But she does think they lack good guidance on how to review such studies.

"You can't ask IRBs to solve this on their own," Faden says. "If you look at the situation with respect to pregnant women, the guidance is inadequate, I believe. And so when we start to look for creative solutions, starting with the IRB doesn't make the most sense."

But she says there are steps that IRBs can take to ensure they're not subtly discouraging research with pregnant women. She suggests that IRBs look

at their own policy documents with an eye toward language that may be "off-putting" to investigators.

Obviously, IRB policies must conform to federal regulations. But if they go beyond the regulations with commentary, Faden says it matters how it's presented.

"If you've got a section with the heading, 'Pregnant women,' how you set that section up can affect how people think about it," Faden says.

For example, she says such a section could start by saying, "Pregnant women are a vulnerable class because we worry about, etc...." indicating to investigators that they're going to have a hard time getting a study with pregnant women approved.

On the other hand, the section could start by saying, "The IRB recognizes the importance of medical research to advance the health of pregnant women, and is happy to review proposals..." and then go on to say what the current regulations require, Faden says.

Will semantic changes such as these help encourage more research with pregnant women? On their own, probably not, Faden concedes.

"It may be a minor point, we don't really have a reason to think that fear of IRB rejection is why this work isn't getting done," she says. "But if we're talking about the little pieces that make up a cultural frame, and we want to shift that frame, then all these little steps help." ■