From Lois Adams, interviewed by Robert Tucker and Ronald Ottes, 1 May 2001:

RO: You did other interesting things in the agency besides GAO.

LA: Well, yes. For twenty years I was on the Research on Human Subjects Committee.

RO: That's interesting. I didn't realize that the agency had a committee.

LA: This committee was formed probably in 1969, which was before I came to the agency. Do you recall John Jennings?

RO: Yes.

LA: He was one of the—not just a member. I think he was the chair of the committee when I first came to it. Frances Kelsey?

RO: Yes.

LA: Those are the two names that stand out in my mind. Joanne Sisk, you may recall her. But it was established, in essence, to implement the Helsinki Agreement on the rights of human subjects. It was designed primarily and really exclusively to look at the research done either in-house or under FDA contract. It wasn't to look at the regulated industry or their research, from a perspective of the efforts involved, but whether or not it would be ethical to do a particular study.

Part of that determination had to do with whether it would be ethical for the federal government to spend public money to do it, and, of course, part of the decision had to do with whether the particular study, in and of itself, could be ethically done. A third element was whether the science that was being used for the particular study was adequate, was appropriate to the study, and would do what the study purported to be doing.

RO: You had reviewed this before the study was undertaken.

LA: That's correct, yes. I had a continuing role in any that was done in-house. If it was done under contract, eventually that would have been turned over to people at NIH and other places.

RO: How many in-house studies of that nature does FDA do?

LA: Well, at the time, there were quite a few, particularly in biologics and medical devices. There was quite a bit of research involving human subjects, and at the time there were quite a few contracts. Certainly FDA never had a budget that allowed for a tremendous amount, but you may recall, around the time we were doing the DESI, Drug Efficacy Study Implementation, we were also beginning to look at generic drugs--I think we called them "me too" drugs--and how they related to the innovator drug.

There were studies going on in foods, particularly fortified foods, and how they affected people, whether the fortification of foods would help the nutritional value of the food and how people would react to that, things of that sort.

So it was a pretty busy committee. We met once a month, I believe, and at certain times, particularly around the end of the fiscal year, we would meet more frequently in order to be able to get all of the reviews done in time for the contract procedures.

RO: Did some of the studies FDA did itself involve human subjects?

LA: Yes.

RO: Where did they get the subjects?

LA: Some of them were FDA employees, some of them were, I guess, recruited on the campus at NIH. Most of the ones done in-house were not under contract and were done by the then Bureau of Biologics.

RT: I guess that clientele didn't include persons incarcerated in penal institutions?

LA: Some of them did initially. Those were primarily done under contract, but even though it was a contract, if FDA was paying for it or any part of it, it was reviewed by the Research on Human Subjects Committee.

RO: Did any of those get turned down because they didn't meet requirements?

LA: Primarily no. There were a couple that did, and we'll get into those, but primarily the reason they were not turned down is because the committee would work with the sponsor to change whatever was necessary, the human protection side, and to get it ironed out enough so it could proceed ethically. We didn't primarily turn things down, but worked to improve the quality.