September 26, 1996

Dr. Robert Miller
Medical Investigations Unit
Department of Health
1300 SE Quince Street
PO Box 47866
Olympia, WA 98504-7866

Dear Dr. Miller:

I would like to thank both you and Mr. Crowell for driving up from Olympia and meeting with me. I also appreciate the time and effort which you have invested in this matter.

As I indicated, FHCRC management appeared to find the idea of anyone reviewing their clinical activities to be unacceptable, and decided that they would and could ignore their Federally mandated Institutional Review Board. The FHCRC IRB was thus a committee with responsibility for protecting patient welfare but no authority, since neither the FHCRC nor the NIH would back it. Moreover, IRB members were pressured to behave correctly and punished when they did not. This problem with the operation of the FHCRC IRB became all too obvious when the IRB encountered previously approved clinical protocols which were killing people and which it could not stop. The atmosphere at some IRB committee meetings was literally one of fear and disbelief - disbelief that this kind of behavior was occurring at a major US medical center in the late 20th century, and fear because several of us were employees of the people who were committing these offenses.

You asked why the IRB didn't stop those protocols which were causing problems: Simply put, our IRB did not have the power to do so, no matter what it may say on a piece of paper somewhere. Assuming for the moment that the IRB had not been denied information re conflict-of-interest and protocol outcomes necessary to reach such determinations, and assuming that IRB members were not pressured to behave "correctly" (i.e. verbal abuse, blocked promotions), who would have carried out IRB decisions? The IRB had no executive arm, and the two most powerful people at the FHCRC were opposed to its recommendations: Dr. Thomas' memo of 10/14/83 strongly objected to any IRB interference with clinical protocols while FHCRC Director Dr. Robert Day repeatedly refused to act on IRB requests for outside protocol reviews. At the January 17, 1984 meeting with Dr. Day and others, Dr. Kaplan and I tried to stop the most worrisome of these protocols (#126), but were overruled. When the NIH was contacted by Dr. Kaplan for advice in early 1984, they had none.

The IRB at the FHCRC was charged with protecting patients involved in medical research, yet it lacked an executive arm, lacked the support of the FHCRC, lacked access to information it needed, and lacked protection for its members. The result was the avoidable deaths of more than 20 patients. The multimillion dollar conflict-of-interest problem which I brought to your attention highlighted these deficiencies but was not the cause of them. No amount of rewriting of the conflict-of-interest rules at the FHCRC is going to address the fundamental problem. Moreover, the efficacy of any regulatory body which lives in fear of those whom it is regulating should always be questioned.

I suspect that you have difficulty believing, as did our IRB, that prominent members of the medical community are capable of the behavior which I have described. Our IRB similarly gave the FHCRC the benefit of every doubt, and we were proved to be fools. The imbalance of money, power, and legal clout between accusers and accused makes it all but impossible to successfully challenge the misconduct of institutions like the FHCRC, even when patient lives are at stake, and everyone knows it. That we struggle to find excuses for tolerating this kind of behavior reflects the sad state of the medical profession. I leave you to consider the words of Albert Einstein: "The world is a dangerous place to live in not because of those who do evil but because of those who watch and let it happen."

Thank you for your help.

Sincerely,

cc: Mr. Bill N. Crowell
Mrs. Maryellan Jansen