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January 26, 2004

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Director Office of Compliance Center
For Device and Radiological Health
Division of Biological Monitoring
Program Enforcement Branch II (HFZ-312)
2098 Gaither Road
Rockville, Maryland 20850

Dear Dr. Toth-Allen

Included in this letter is the revised Oak Lawn IRB SOP's as stated from my September 25, 2003 letter. Effort was made to make a cohesive document correcting the errors and inconsistencies from the previous Oak Lawn IRB SOP documentation. Any additional suggestions in order for the Oak Lawn IRB to be compliant as stipulated in the regulations would be welcomed.

Under the website www.accessdata.fda.gov/scripts/wlcfm/recentfiles.cfm the Oak Lawn IRB has a warning letter posted without a response posted. The Oak Lawn IRB would like to see its letter dated September 25, 2003 posted as the response.

If you have any questions feel free to contact Lin Rose or myself at 708-636-0603.

Respectfully submitted by:

Irwin Septow, O.D.