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February 3, 2010

Kathy Wibberly
Virginia Department of Health
109 Governor Street
Richmond, Virginia 23219

Re: Regulations for the Conduct of Human Research
12 VAC 5-20 *et seq.*

Dear Ms. Wibberly:

I have reviewed the amended regulations for the Conduct of Human Research in 12 VAC 5-20 *et seq.* The amended regulations do not conflict with other federal or state statutes or regulations and do not violate the United States or Virginia Constitutions.

The Board of Health has the authority to promulgate the regulations under Va. Code §§ 32.1-12, and 32.1-162.16 *et seq.* The regulations are consistent with the Board's mandate to implement the procedures and standards for the conduct of human research. The regulations are exempt from the public participation provisions of the Administrative Process Act under Va. Code § 2.2-4006(A)(3) and (4). The Board of Health will not exceed its statutory authority by approving the regulations. Having satisfied all legal requirements, you may proceed to take the necessary steps to promulgate these regulations.

Very truly yours,

Robin V. Kurz
Special Counsel