

May 31, 2012


To Whom it May Concern:

The Food and Drug Administration (FDA) conducted site inspections at the University of Utah Institutional Review Board (IRB) in 2004, 2007, and 2012. The purpose of these inspections was to determine whether IRB procedures for the protection of human subjects complied with Title 21 of the Code of Federal Regulations (CFR), Parts 50 and 56. These regulations apply to clinical studies of products regulated by the FDA.

Subsequent to all three inspections, the FDA determined that the IRB adhered to the applicable statutory requirements and regulations governing the protection of human subjects. There were no findings identified during any of the three site inspections.

Please let us know if additional information is required.

Sincerely,



John Stillman, IRB Director  
University of Utah IRB