



November 1, 2017

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, 2012, and 2017. 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 of these 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 site inspections.

Sincerely,

Ann Johnson, PhD, MPH
IRB Director