



IRB Statement of Compliance

IntegReview IRB, an independent IRB located in Austin, Texas, was established in 1999 and offers five weekly meetings for review of U.S., Latin American and Japan research sites, quality review by experienced individuals, competitive fees, and quality assurance/control. Designed to accelerate the IRB process without compromising accuracy or the protection of human subjects, IntegReview IRB delivers study documents to the investigator within two business days of board review.

IntegReview IRB is committed to meeting rigorous standards for quality and maintaining sound policies and procedures involved in the protection of human research participants. IntegReview IRB was initially awarded full accreditation of its human research protection program (HRPP) by the Accreditation of Human Research Protection Programs, Inc.[®] (AAHRPP) in June 2007. AAHRPP accreditation will expire in September of 2020.

Written standard operating procedures govern IntegReview IRB for initial, continuing, full board, expedited and exempt review of clinical research studies. IntegReview IRB complies with the regulations as defined in the United States Food and Drug Administration (FDA), Code of Federal Regulations, Title 21, Parts 50, 54, 56, 312 and 812, International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practices, E6, the Department of Health and Human Services (DHHS) regulations as identified in the Code of Federal Regulations, Title 45, Part 46, other regulations as applicable, as well as local and state laws.

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