



Castle IRB
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IORG #: IORG0010151

CASTLE IRB COMPLIANCE STATEMENT

Castle IRB was established in 2019 as an independent Institutional Review Board (IRB) to meet the unique needs of the gene and cell therapy clinical trial industry. Soon after, Castle IRB expanded its reach to more fully serve the rare disease community, adding the capacity to review natural history and registry studies. While Castle IRB specializes in the gene/cell therapy and rare disease space, Castle IRB now provides IRB review services for most types of research, working closely with clinical trial sponsors, contract research organizations (CROs), rare disease foundations, research sites and institutions.

The mission of Castle IRB is to protect the rights and welfare of human participants in gene and cell therapy clinical trials while providing efficient, compliant IRB review of research. Using our portfolio of expertise, we strive to be the leading IRB partner in advancing safe, ethical and compliant gene and cell therapy clinical trials to accelerate the next evolution in advanced therapies.

Castle IRB is registered with the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) as IRB Organization #: IORG0010151, and IRB Registration #: IRB00012054.

Castle IRB operates in compliance with FDA 21 CFR Parts 50 and 56, the *NIH Guidelines*, and as applicable, the International Conference on Harmonisation (ICH) E6 – Good Clinical Practice, and US DHHS 45 CFR 46.

As we strive to provide the highest quality in IRB review services, Castle IRB and its parent company, Sabai Global, perform internal quality assurance reviews of its activities on a semiannual basis and routinely undergo third party audits. Castle IRB has Full Accreditation with the Association for the Accreditation of Human Research Protection Programs (AAHRPP, Inc.), the gold standard for quality in research protections. Visit the AAHRPP page for more information at <https://www.aahrpp.org>.

Questions or concerns may be directed to the Castle IRB team at 888-442-2472 extension 2 or irbteam@castleirb.com.

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Castle IRB