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Statement of Compliance

Sitero IRB is duly constituted, fulfilling all requirements for diversity and has written procedures for initial and continuing review of human subjects research; prepares written minutes of convened meetings; and retains records pertaining to the review and approval process.

Sitero IRB is organized and operates in compliance with the United States Department of Health and Human Services regulations as described in 45 CFR Part 46 (i.e., The Common Rule), the United States Food and Drug Administration regulations as described in 21 CFR Parts 50 , 56, and the International Conference on Harmonization (ICH) E6 *Good Clinical Practice* (GCP) as applicable.

Specific jurisdictions may require compliance with additional guidelines and regulations.

Sitero IRB is registered with both OHRP and the FDA. Sitero has voluntarily obtained a Federalwide Assurance (FWA).

IRB Organization (IORG) Number: 0011484
FWA Number: 00032739 (expiration date: 09/28/2027)
IRB Registration Number: 00013619 (expiration date: 09/16/2025)

Sitero is in the process of accreditation from the Association of the Accreditation of Human Research Protection Programs (AAHRPP).