

Geisinger Institutional Review Board (GIRB)

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Statement of Compliance

Geisinger IRB is organized and operates in compliance with applicable U.S. federal regulations (including, but not limited to 21 CFR Parts 50 and 56, and 45 CFR Part 46 and 164), guidance (including but not limited to OHRP, FDA and ICH GCP (Section 3) as specific to IRB review), and ethical principles underlying the involvement of human subjects in research (including The Belmont Report, Nuremberg Code and Declaration of Helsinki).

Geisinger is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Geisinger is registered with FDA and OHRP:

- Federalwide Assurance (FWA): 00000063
- IRB Registration Number: 00008345
- Organization (IORG) Number: 0000125

Geisinger IRB does not disclose the names of its members to sponsors for confidentiality purposes. Geisinger IRB membership roster is maintained, on file, and in compliance with 21 CFR 56 and 45 CFR 46. The membership roster can be provided by request of the appropriate regulatory authority.

March 15, 2021