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## **STATEMENT OF COMPLIANCE**

WCG IRB is duly constituted, has written procedures for initial and continuing review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements of FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and International Conference on Harmonization (ICH) E6, Good Clinical Practice (GCP), as applicable. WCG IRB is registered with OHRP/FDA; our IRB registration number is IRB00000533, parent organization number is IORG0000432 (WCG IRB Canada registration number is IRB00002354).

WCG IRB also reviews in compliance with other applicable federal and state laws and regulations governing IRBs and research with human beings. Where appropriate, WCG IRB complies with additional regulations and guidelines (such as the Canadian Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans) as required in specific research jurisdictions.

WCG IRB continues to be fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

If you have questions or need further information, please do not hesitate to contact us.