

Statement of Compliance

Advarra is organized and operates in compliance with the US and Canadian regulations and policies governing research with human subjects, as applicable. These include but are not limited to the following as applicable: US federal regulations at 21 CFR Parts 50, 56, 312, and 812; US federal regulations at 45 CFR Part 46; the pre-2018 Common Rule; the 2018 Common Rule; specific regulatory provisions of US federal departments and agencies; Part C, Division 5 of the Canadian Food and Drug Regulations; the Canadian Tri-Council Policy Statement 2; and the International Conference on Harmonisation (ICH) E6, Good Clinical Practice (GCP). Advarra may rely upon federal, state, or international policies and guidance to inform its policy development and approaches.

Advarra's IRB is registered with <u>FDA and OHRP</u>. Advarra has voluntarily obtained a Federalwide Assurance (FWA) and it has been approved by <u>OHRP</u>.

IRB Organization (IORG) Number: 0000635

• FWA Number: 00023875

IRB Registration Number: 00000971

Please note that the IRB registration number applies for both FDA and OHRP registrations and covers all general, therapeutically focused, and country-specific panels.

Advarra is fully accredited by the <u>Association for the Accreditation of Human Research Protection</u> Programs (AAHRPP).

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