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CINCINNATI, OH
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Clinical research global compliance just got EASIER.

***Experienced leaders form* PROVISION RESEARCH COMPLIANCE SERVICES,** a joint venture between SCHULMAN ASSOCIATES IRB, INC. and FALCON CONSULTING GROUP, LLC. Provision offers global consultancy services for the development and implementation of **Good Clinical Practice (GCP)** and **Human Research Protection (HRP)** procedural standards and programs for the conduct of clinical research studies.

"There has never been a collaboration of GCP and HRP industry leaders specifically focused on meeting the compliance needs of research institutions around the world," said Michael Woods, President, CEO and Institutional Official at Schulman Associates IRB. *"Provision makes it easier for institutions to achieve their compliance goals and to engage in global development programs. It also helps study sponsors follow a simpler path to consistent compliance practices across a global network of research institutions.* ***Global compliance just got easier."***

Today, clinical trials are global, involving potentially hundreds of sites in a dozen or more countries. Pharmaceutical, biopharmaceutical and medical device sponsors need consistent quality and ethical standards for human subject protection and compliance to minimize regulatory risk.

Consistency is key to making a clinical trial as meaningful as possible, and the data as useful as possible. Meeting global compliance standards has been challenging because of outsourcing and the increasing complexity of the research. The approach to global compliance has often been very fragmented, and Provision offers a more comprehensive solution to achieving global compliance standards.

Enhanced Compliance for Integrity and Quality

The pharmaceutical, biopharmaceutical and medical device industries rely heavily on third parties to assist in the advancement of clinical research programs. Global contract research organizations (CROs) provide fundamental services for protocol development, study conduct, clinical program management, pharmacovigilance and data management, all directed to regulatory submissions and product approvals. Academic research institutions in locations around the world are responsible for study conduct and subject recruitment, according to the protocol as well as International Conference on Harmonisation (ICH) GCP standards and guidelines.

While there are regulations and local customs unique to countries and regions around the world, research institutions still strive to conduct research consistent with ICH GCP standards. **An alignment of GCP and HRP practices provides the essential regulatory compliance and significantly strengthens the successful performance of clinical studies.**

Experienced Research Compliance Leaders

While Provision Research Compliance Services is new, ***the two organizations behind Provision are industry leaders, with proven expertise in clinical quality assurance and human research protection.*** Provision provides services that combine the extensive GCP quality assurance expertise of Falcon Consulting Group with the HRP expertise of Schulman Associates IRB. **This new joint venture provides comprehensive solutions to improve overall quality standards for clinical studies and data integrity, and maximizes the protection of human research subjects.** Provision's services are available in more than 30 countries.

By improving GCP quality assurance and human research protection programs, clinical study data becomes more reliable and human subject protection is strengthened. This leads to more compliant submissions and more rapid approvals for patient therapies.

About Schulman Associates IRB, Inc.

Since 1983, Schulman Associates IRB has been a leader in protecting human research participants in the US, Puerto Rico and Canada. Headquartered in Cincinnati, Schulman's comprehensive IRB review services include dedicated review capabilities for all phases of research across all therapeutic areas. Schulman is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and has an unparalleled clean audit history with the Food and Drug Administration (FDA). ***For more information, please visit* http://www.sairb.com.**

About Falcon Consulting Group, LLC

Falcon Consulting Group, LLC, created in 1999 and based in Philadelphia, is a leading provider of Clinical Quality Assurance (CQA) and Good Clinical Practice (GCP) services for the pharmaceutical, biopharmaceutical, medical device and healthcare industries. Falcon offers auditing services as well as specialized consultancy and evaluation perspectives related to regulatory compliance and clinical quality assurance for research and development, with extensive services offered globally. ***For more information, please visit* http://www.falconnest.com.**

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