CLINICAL RESEARCH SERVICES

Through the conduct of clinical research, new and innovative solutions to health care concerns can be developed. The conduct of effective clinical research requires a full understanding of the laws and ethical constructs applicable to human subject research, as well as an understanding of the operations of the research enterprise. The Hall Render Clinical Research Team consists of a number of highly skilled attorneys who have prior experience with clinical research and/or health care operations. By drawing on their backgrounds, the Clinical Research Team can provide practical advice that assures compliance while supporting reasonable operational implementation.

CONNECT WITH US

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THE CLINICAL RESEARCH ENVIRONMENT

Clinical research law is a patchwork, and the regulatory and compliance requirements can vary based on the location and funding of the research. Thorough knowledge and understanding of the interplay of federal, state and local law is necessary; as more clinical trials are conducted on a global scale, an understanding of the impact of international laws is also required. Our Clinical Research attorneys support fundamental bench research, translational research and clinical research and help assure compliance with complex regulatory requirements by:

- Assisting with review and development of compliant research protocols;
- Assisting with filings to the U.S. Food and Drug Administration ("FDA") for exemptions from the Food, Drug, and Cosmetic Act necessary to conduct research ("IND/IDE");
- Providing insight into compliance with the Federal Common Rule for federally supported research;
- Advising regarding compliance with grant requirements under National Institutes of Health ("NIH"), Agency for Healthcare Research and Quality ("AHRQ") and other federal and private funding sources;
- Assisting with development of privacy and security solutions to protect the intellectual property ("IP") and assets, tangible and intangible, created to support or conduct research;
- Negotiating confidentiality and nondisclosure agreements, clinical trial agreements, consortia agreements, collaboration agreements, material transfer agreements, data use agreements and other agreements used to facilitate and integrate research efforts across organizations;
- Assisting with allegations of research misconduct, including support of an inquiry and/or investigation and guidance regarding reporting obligations;
- Developing and implementing research-related policies and procedures;
- Advising and supporting operations of Institutional Review Boards ("IRB");
- Providing training on research-related topics, including human subjects protection, contracting issues, IRB operations, research billing, research misconduct, management of deviations from compliance and grant compliance;
- Conducting and assisting with investigations related to protocol deviations or other regulatory non-compliance; and
- Evaluating technology, privacy and security issues related to research in collaboration with the Hall Render Privacy Team and Hall Render Advisors.

REPRESENTATIVE EXPERIENCE EXAMPLE:

Hall Render's Clinical Research team has:

- Assumed primary responsibility for review and negotiation of research-related agreements (Confidentiality and Non-Disclosure Agreements, Clinical Trial Agreements, Material Transfer Agreements and Data Use Agreements), resolving client's internal staffing constraints.
- Assisted with the investigation and resolution of regulatory non-compliance for research department, coordinating notification to sponsors, Institutional Review Boards and regulatory bodies, with development of a Corrective and Preventive Action plan acceptable to all parties to resolve a FDA Notice of Observations (483).
- Supported multi-national company in developing additional clinical research capabilities, resulting in a new line of business.
- Conducted an in-depth evaluation of the Research Department of a multi-facility system to identify compliance priorities, including areas for improvement in the research compliance infrastructure, and facilitate more efficient and effective operations of the research function.

- Assisted major teaching hospital system with investigating and resolving research misconduct allegations that affected multiple commercial and federal sponsors, including working with FDA, Office for Human Research Protections (OHRP), the Office of Research Integrity (ORI) and Office of Criminal Investigations (OCI).

RESULTS

The Hall Render Clinical Research Team provides cradle-to-grave counsel regarding the conduct of research and administration and compliance of the research enterprise. As a firm dedicated to the representation of health care organizations and entities that facilitate health care delivery, our focus permits realistic, efficient and practical advice that can be tailored and readily operationalized to aid the accomplishment of each client organization's mission.

LET'S GET STARTED

Contact Hall Render to discuss how your organization can benefit from collaborative support by our health care attorneys and advisors.