HALL RENDER
KILLIAN HEATH & LYMAN

CLINICAL RESEARCH

Hall Render attorneys have extensive experience advising clients on bench, translational and clinical research-related matters including: legal and regulatory compliance; governmental investigations and defense; scientific misconduct allegations and investigations; reporting obligations; intellectual property and technology transfer issues and arrangements; and on the complicated relationships between health care facilities, research institutions, institutional review boards (IRBs), principal investigators, academic institutions and sponsors/grantors. We have the ability to assist entities with the initial creation and structuring of a research program (including IRB formation), as well as to conduct a comprehensive evaluation of programs and provide guidance on practical ways to improve compliance without unduly impeding operational flexibility. We offer research and IRB training and compliance programs that are tailored to the particular needs of an entity's research staff and IRB. For some clients, we provide day-to-day services to support the operation of the research function; for other clients, we serve as specialty counsel in support of in-house counsel.

We commonly provide counsel on human subject protection; compliance with federal, state and international laws and regulations regarding the collection, transfer and sharing of data; compliance with applicable laws regarding regulatory review and approvals in the research process; the identification and allocation of intellectual property rights resulting from research data and activities; and the negotiation and execution of research agreements such as Material Transfer Agreements and Clinical Trial Agreements. We advise on issues including, but not limited to, the development, registration and conduct of clinical investigations and trials; government (FDA, OIG, DHHS) audits and investigations; the impact of fraud and abuse laws on research; FDA regulations; the Common Rule; pharmaceutical pricing and clinical trial billing compliance; and medical device approval submissions (PMA, 510k).

Our ability to provide practical counsel is strengthened by the fact that our attorneys have extensive clinical, scientific, IRB and industry experience. Several Hall Render attorneys are experienced in ethical issues, are licensed and/or certified health care professionals and/or have previously served as pharmaceutical company in-house and regulatory counsel, IRB members and research administrators.

AREAS OF FOCUS

- Clinical Research Contracting
- FDA Regulations
- Good Clinical Practices (GCPs)
- Human Subject Protection (HSP)/Institutional Review Boards (IRBs)