HUSCH BLACKWELL

CLINICAL RESEARCH & TRIALS

To make it to market, new drugs and medical devices must first undergo clinical research and trials. Husch Blackwell negotiates the often complicated contracts that frame these trials. We advise clients on drafting informed consents that meet all regulatory requirements, as well as on interactions with institutional review boards concerning protocols and study monitoring.

For trials supported by the National Institutes of Health or other government agencies or grants, we carefully craft the proper trial documentation to ensure regulatory compliance, protect intellectual property interests, and minimize business liability exposure.

"The Husch Blackwell attorneys were fierce and tireless advocates for Virtus. In the face of aggressive actions by our competitors and FDA regulators, they developed and executed a legal plan that protected an important market for us. They have my gratitude and highest recommendation."

— Tina Guilder, CEO, Virtus Pharmaceuticals —

Representative Experience

Created and implemented an administrative review process for human research studies for a large health system, including development of related policies and procedures.

Advised clinical trial and institutional review boards (IRBs) on compliance matters.

Served as legal counsel to a health system's IRB. Attended IRB meetings; provided legal guidance; and reviewed clinical trial agreements, fee agreements, business associate agreements, and nondisclosure agreements.

Advised pharmaceutical companies and device

Contact Information

Peter J. Enko
816.983.8312
peter.enko@
huschblackwell.com

manufacturers on Food and Drug Administration (FDA) and state regulatory requirements.

Organized and supervised clinical trials for early-stage biotechnology company.

Prepared and negotiated biotechnology-related agreements, including clinical research agreements, noncompete agreements, and confidentiality agreements.

Led top-to-bottom review and enhancement of medical device manufacturer's compliance program, including clinical trials and investigation policies, procedures, and implementation.

Drafted and negotiated clinical trial agreements with principal investigators, institutions, sponsors, SMOs, and CROs.

Created legal entities to serve as providers, SMOs, and CROs.

Drafted and negotiated royalty agreements between manufacturers and physicians.

Prepared policies and procedures for IRBs and providers administering clinical trials.

Created medical director and consulting agreements between sponsors and physicians.