POLSINELLI

Research & Clinical Trials

Working across every dimension of academic medicine, Polsinelli attorneys advise academic medical centers, other health care providers and researchers on a diversity of legal and policy issues. Our counsel is anchored in a deep understanding of the health care industry and each sector of academic medicine and clinical research.

Polsinelli attorneys help clients achieve key business objectives related to the full array of products regulated by the Food and Drug Administration, as well as related health and safety regulatory agencies, in the face of state, national, and global regulatory concerns.

Polsinelli is enhanced by capabilities in the area of government investigations and regulatory advocacy. Included in its representation of academic medical centers, Polsinelli attorneys represent Comprehensive Cancer Centers and two PPS-Exempt Cancer Hospitals. We have helped academic medical centers, health systems, hospitals, physician groups and research networks across the country in negotiating clinical trial agreements, assuring clinical research compliance, defending against government investigations related to clinical research, and creating research collaborations. Combining the experience of our academic medicine and government investigations team, we regularly advise academic medical centers on investigations into academic misconduct as well as clinical trial billing concerns.

Our work covers products regulated by Food and Drug Administration (FDA), as well as the U.S. Department of Agriculture (USDA), Consumer Product Safety Commission (CPSC), Federal Trade Commission (FTC), Public Health Service (PHS), Environmental Protection Agency (EPA), U.S., Customs and Border Protection (CBP), National Institutes of Health (NIH) and the Drug Enforcement Administration (DEA).

Matters

- Advised numerous academic medical centers, health systems, hospitals, physician groups and research organizations on research policies and procedures.
- Advising clients on human subject research protection issues, including whether research is “human subject research,” whether research is exempt, and whether research may be reviewed on an expedited basis versus full Board review.
- Reviewing informed consent documents for compliance and for consistency with clinical trial agreements.
- Creating conflict of interest in research policies, and advising clients on managing identified conflicts.
- Advised on off label use of drugs and devices, obligations to obtain IND or IDE.
- Negotiating clinical trial agreements on behalf of institutions and research networks, assisting IRBs with compliance, HIPAA, GDPR and general privacy in clinical trials, clinical trial billing and billing for new treatment modalities.

- Creating a system for an efficient and cost-effective method of reviewing clinical trial agreements.
- Advising clients on HIPAA compliance in research, including whether informed consent documents meet HIPAA authorization requirements.
- Assisted numerous research organizations and institutions with obligations with respect to health data and tissue samples, including access for research purposes.
- Advised acute care hospital affiliated with academic medical center and large research institution on data ownership, access issues.
- Advised technology companies on use of data for research purposes and regulatory compliance issues that arise from such use.
- Advised companies on intellectual property issues related to research concepts and products.
- Representing clients in FDA audits and investigations related to clinical trials. Evaluating reporting obligations to government agencies, sponsors and IRBs on adverse events.
- Government investigations involving the academic medical center, affiliated sites and the faculty practice plan, including clinical research fraud, academic misconduct, modifier 25, narcotic diversion and inappropriate repackaging and distribution of drugs.
- Represented academic medical centers with a sealed qui tam alleging false billing in connection with clinical research studies.
- Successfully appealed the FDA's decision to revoke our client's mammography services certification pursuant to the terms of the Mammography Quality Standards Act (MQSA). For the first time, the FDA granted an appellant's request to overturn the agency's own decision to require patient and provider notices. We worked closely with the FDA to expedite the client's recertification, enabling it to resume its mammography services in less than one week.
- Counsel clients on appropriate regulatory pathways to market for a full range of medical devices, including Class III, Class II, general wellness products, mobile medical apps, and software as medical devices, as well as counsel regarding 21st Century Cures Act.
- Represented a medical device company on a drug shortage issue – its drug-delivery device is dependent upon two drugs currently on the FDA's drug shortage list. We advised our client on its options to encourage the FDA to exercise its regulatory authority to permit drugs into the U.S. market to alleviate the shortage, and anticipate representing the client before the agency on this matter.
- Advised a trade association to respond to recent FDA activity by CDRH which appears to run counter to a regulatory exemption from registration requirements for this particular industry.