

Research

Research is the engine that drives health care forward and leads to innovations and advances that improve patient care and outcomes. Hooper, Lundy & Bookman's health care attorneys provide our clients with the compliance counsel, business guidance, and transactional representation to facilitate their essential work.

Our exclusive focus on health care law includes an understanding of the intersecting web of regulatory requirements and ethical issues implicated in the development and testing of new drugs or medical devices, with a particular focus on working with our health care provider clients regarding clinical trial agreements, relationships with principal investigators, and navigating complex privacy issues regarding use of patient data.

Our full suite of representation for those involved in clinical research includes:

- Negotiation of clinical trial agreements and other research affiliation agreements
- Compliance with human subject research protections.
- Drafting of research-related policies
- · Advising on applying federal and state fraud and abuse and physician self-referral laws in the research context
- Counseling on international, federal, and state privacy laws and regulations
- Advising Institutional Review Boards (IRBs)
- Pharmaceutical pricing and clinical trial billing compliance
- · Assistance with government audits and investigations related to research, including responses to whistleblowers
- Scope of practice issues
- Medical staffing issues
- Conflicts of interest

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