

Clinical Research Initiatives

David Hoffman & Associates assists sponsors of clinical research and academic institutions in ensuring compliance with regulatory requirements governing human participant research. There have been occasions where a lack of oversight/lack of compliance with federal regulations has led to enforcement actions against individual researchers, sponsors and/or academic institutions. We review current practices and advise entities on how to test and revise their systems to ensure regulatory and clinical compliance.

We also facilitate development of policies and standards to ensure a system that mandates training of those engaged in clinical research, that is, all investigators, data collectors and applicable clinical staff (direct care staff). Additionally, it is critical for institutions to be fully informed as to research that is occurring in their facilities whether it is investigator-initiated or sponsor-initiated clinical research. We assist institutions in developing policies and procedures to address this and other important issues associated with clinical research.

We assist researchers and their sponsors in evaluating the informed consent process. We facilitate the development of systems that ensure that research participants are fully apprised of the risks and benefits associated with the research and that the informed consent process is adequately conducted to achieve regulatory and clinical compliance.

All projects are evaluated for purposes of testing the interventions offered and the resulting feedback from the client. This evaluation may include analysis of patient outcomes, implementation issues associated with the recommendations offered by us, published papers, and/or client, patient, resident satisfaction analyses.