



REQUESTING LEGAL COUNSEL OPINION

4/9/2021

The Duke University Health System Institutional Review Board (DUHS IRB) may, as needed, request an opinion or clarification from the Office of University Counsel for issues pertaining to research involving human subjects.

All requests for an opinion sent by an IRB Chair/Vice-Chair or staff to the Office of University Counsel should be copied to the IRB Executive Director and Lead Chair.

Issues such as acceptable language for informed consent documents, determinations regarding whether a consent document contains exculpatory language, interpretation of local and State laws, laws of other jurisdictions, federal regulations and guidance, including the Privacy Rule (HIPAA), and interpretation of Duke University Hospital policy are among the topics for which an opinion may be requested from legal counsel.

A representative of the Office of University Counsel may, from time to time, attend an IRB meeting to contribute to the deliberations related to a research protocol. A representative of the Office of University Counsel may join the IRB membership and serve as an IRB member.

Previous Version Date(s): 11/28/2007, 3/1/2016