

Holly Fernandez Lynch, Consent as Contract in Clinical Research

*Abstract*

*Recently, research subjects have advanced a novel claim against the sponsors of the clinical trials in which they were enrolled. They claim harm not from the participation itself, but instead from the termination of their participation in the trial against their wishes. These plaintiff-subjects use the language of the informed consent forms they signed upon enrollment to argue that they have been denied benefits promised by sponsors and researchers, and they seek to enforce those promises through breach of contract claims. This article asks whether it is appropriate to treat informed consent as a contract in the context of medical research. It examines the potential advantages and disadvantages of this approach, recognizing that the contractual model may be protective of individual subjects ex post, but that it may have broad negative effects for research subjects as a class if adopted wholesale.*