Abstract

An ethnographic field study about informed consent in hepatitis C clinical trials provides insight into how changes in protocol requirements and patient health status triggered the actions and decisions of researchers and human subjects during the conduct of these trials. U.S. federal guidelines recommend that informed consent should be conceptualized as more than a onetime event. Rather, a process of continuing consent should be the standard but little is understood about how exactly this process should unfold. We used a proposed typology of continuing consent to frame our analysis and were able to document that only some of the proposed types took place at the site of our study. The most frequent practice involved the researchers re-consent of their subjects for major protocol revisions. Only one subject dissented and chose to withdraw even though he was technically eligible to continue in the study. Two other types of continuing consent were not observed. We discovered an additional type of continuing consent not described in the typology whereby subjects gave implied consent through their cooperation and adherence to the on-going requirements of the protocols. Implications for the informed consent process and the need for further research are presented.

Keywords

Informed consent process, Clinical trials, Hepatitis C disease