September 2021

Real-world trials need real-world consent

Cory E. Goldstein
Western University, cgoldst2@uwo.ca

Traditional clinical trials test whether a novel medical treatment works in ideal settings. But the real world is messy and unpredictable. Patients and doctors need to know whether medical treatments work in the context of routine clinical care. The solution: pragmatic trials. These trials are embedded into clinical settings and ideally include all patients who will receive treatment in clinical practice. But recruiting patients by obtaining their written informed consent may disrupt the workflow of busy clinics to the extent that the trial no longer mirrors clinical practice, consequently undermining the aim of the trial. Since consent is a central protection of patient autonomy, the question arises: how can the ends of autonomy and pragmatism both be served? My solution is to operationalize respect for autonomy as the requirement to obtain verbal consent with documentation in patients' medical records. This solution promotes patient autonomy and facilitates pragmatic trial conduct.