Ethics of Informed consent

- Self-testers

- Children
- Severely ill
- Those who are impoverished (& will receive compensation)
- People with Down's, Schizophrenia, or another psychiatric disorder
- People with Alzheimer's, Huntington's, or another degenerative disorder
- Those living in developing countries
- Prisoners

What is your opinion on whether it is more important to do a controlled clinical trial for an experimental drug, or to give the experimental drug to all those in the trial? What are the most compelling arguments for both sides of this debate?

Organizers of the US-government-led trial disagree that every patient should receive experimental treatment, arguing that it will not necessarily be better than standard care. "The idea that there's no need for randomized, controlled trials presupposes that the drugs have zero side effects, that they are efficacious, and that there's no substantial variability from patient to patient," says Clifford Lane, deputy director for clinical research and special projects at the [NIH]. "I don't think any of that is true."

"These trials will be conducted in a context of fear, distrust, a lack of effective care options, the admission of multiple family members to the same centre, and sometimes violence against health-care workers," says Peter Horby, an epidemiologist at the University of Oxford, UK. "Scientific arguments cannot tell us what will work in these conditions."

Jeremy Farrar, an infectious disease researcher who heads the Wellcome Trust in London, cautions that people on the front lines of Ebola may disagree. An RCT may yield results faster, but if it's simply unacceptable for trial participants, a stepped-wedge design is preferable. "If you were there tomorrow and you were a health care worker, would you be willing to be in a control arm, when the next 3 months you will be looking after patients with Ebola?"

But at the meeting, Ripley Ballou, who heads the Ebola vaccine project for GSK, argued for an RCT—although the placebo would be replaced with an "active control," a proven vaccine (for instance, against hepa- titis B) that would at least protect participants against another virus...

Ballou didn't win over MSF. "Studies on efficacy in affected countries and more so in at-risk populations should not have a placebo or active control arm as this cannot be defended ethically," says Annick Antierens, a meeting attendee who oversees experimental Ebola products for MSF.

"Making patients' tumors go away is gratifying," Dr. Chapman (a medical oncologist at Sloan Kettering Cancer Center) told critics. "But that's not the business I'm in. I'm in the business of making people live longer. That's what I want to do."

"It's much easier to tell patients, 'We'll try this for six weeks; if it's working, great, if not, we'll shift you right away to the other trial," said Dr. Jeffrey A. Sosman of the Vanderbilt Ingram Cancer Center in Nashville. "That's how I'm going to be able to live with the randomization."

But Dr. Michael Atkins, director of the cancer clinical trials office at Beth Israel Deaconess Cancer Center in Boston, urged him to consider what he thought was the greater good: “Even though it is painful, I think completing a clean Phase III trial and determining if there truly is a survival benefit for PLX would have major value for the field and future patients.”