
VIII Annual Symposium on Biomedicine, Ethics and Society: "Rethinking Informed Consent: The limits of autonomy"

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Informed consent as a tool for exploitation

In the United States, an enormous underground economy has emerged around drug testing, especially on healthy volunteers. As drug research has moved out of universities and into the private sector, industry-funded testing sites have begun to recruit healthy volunteers and pay them to test drugs for safety and toxicity. Unlike patients in treatment studies, who may enroll in order to get access to experimental therapies, healthy volunteers take part in research studies mainly for the money. As a result, these volunteers are often people who have time to spare but very little money, health insurance or other financial resources: homeless people, students, undocumented immigrants, squatters, and people who are temporarily unemployed. Some cities have such a high concentration of medical research facilities that a community of volunteers can support themselves entirely by enrolling in research studies.

The amount of money paid to healthy volunteers varies widely. Some research facilities have a policy of paying very little. Ethicists and Institutional Review Boards have generally agreed with that policy, arguing that money will compromise consent. They suggest that money will "coerce" the poor into volunteering for risky or uncomfortable studies. But many healthy volunteers themselves argue just the opposite. They suggest that the threat of compromised consent here acts as a tool for exploitation. Pharmaceutical companies can keep costs low and impoverished people will volunteer for their studies anyway, simply because they need the money.

I will argue that healthy volunteer studies have been almost completely commercialized in the United States, yet ethicists and regulators still treat them as a humanitarian enterprise. The intention may be noble, but the result has been unfair to research subjects, who are asked to undergo significant risks and discomfort without fair compensation. Investigators, on the other hand, are paid handsomely. Ethicists and regulators should shift their ethical concern from informed consent to issues of exploitation and safety.