

NEWS RELEASE

Office of Communications
Media Contact: Ed Bodensiek
410-516-8523; ebodensiek@jhu.edu

April 16, 2007

Study: “Career” or Repeat Volunteers Raise Ethical Issues in Clinical Research

Researchers Find Healthy Volunteers Without College Degrees Almost 20 Times More Likely to Have Participated in at Least 10 Clinical Trials

Baltimore – A new study at Johns Hopkins has found that individuals with less education volunteer for more studies, and for higher risk studies, than their more educated counterparts. Now researchers are suggesting more attention be paid to ethical issues in clinical research involving healthy volunteers of all backgrounds. According to a Johns Hopkins study just published by *Clinical Pharmacology & Therapeutics*, little is known about the prevalence, nature, and severity of risks among healthy volunteers.

When healthy volunteers agree to test drug safety for conditions others have, there is little to no anticipated benefit for the participants. So why do healthy volunteers participate? Clinical research studies utilizing healthy volunteers almost always pay participants for their time and effort. Such studies often disproportionately enroll individuals of disadvantaged social class – participants with less education who may not fully understand the risks involved in clinical research.

“While generally small, the risks to healthy volunteers participating in clinical studies are real and unpredictable,” said principal investigator Nancy Kass, ScD, deputy director for public health at the Johns Hopkins Berman Institute of Bioethics and a professor at the Johns Hopkins Bloomberg School of Public Health. “Our team set out to learn more about why healthy participants volunteer in the first place. We started by

asking if volunteers from the community had a different enrollment pattern from volunteers who worked for Johns Hopkins.”

In the study, Kass and her team documented the experiences of 60 healthy clinical trial volunteers: 23 Johns Hopkins employees and 37 community volunteers. Volunteers from the community were more likely to be male, single, and less likely to have a college education. The researchers found that participants without college degrees were almost 20 times as likely as those with college degrees to have participated in more than 10 studies in the last five years. No U.S. regulation currently exists to keep track of so-called “career” or repeat volunteers, nor does a registry exist in the U.S. to help ensure that participants are not simultaneously enrolled in multiple clinical research studies.

Healthy volunteers interviewed for the Johns Hopkins study rarely mentioned the risks of participating in clinical research. When researchers asked about the bad aspects of participation, only 12 of 60 respondents discussed risk or uncertainty. One participant described “the slightly nagging feeling about risk,” while another volunteer said it was hard knowing that side effects could be “anywhere from irritating to devastating.”

Respondents were also asked about “ever being sorry” they had enrolled and to name “all the bad things” about being in studies. Twenty percent of participants said at least once they were sorry they had enrolled in a study. More than a third of respondents described pain, side effects, or frequent procedures such as blood draws or scarring as the “bad things” about participating. One respondent described “the unpleasantness of diarrhea and E. coli and all that stuff” from a bacterial challenge study. Three participants independently mentioned a facility where they experienced multiple blood draws in a short period of time, with one volunteer claiming he had been “stabbed over 36 times in my arm.”

Researchers also asked volunteers to identify the best aspects of participating as a healthy volunteer in a clinical study. Nearly half of respondents (48 percent) said helping others or contributing to science was the most positive aspect of participating, with some specifically saying they liked “playing a part” in getting helpful new drugs developed. Forty-six percent of respondents said that earning money was the best aspect of their participation. Researchers found that the college graduates in their study were three times more likely than those with less education to say money was a good aspect of

participation. Women were almost five times as likely as men to say that helping others was the best part of participating. Volunteers also mentioned the opportunity to learn more about health, science, or medicine as a positive aspect of enrolling in a clinical trial, and said they would be much more likely to return to a research site in the future if they had been treated respectfully by research staff.

With autonomous decision-making at the core of ethical research, Kass and her colleagues argue that clinical researchers can protect volunteers by remaining vigilant to minimize and manage study risks.

“Clinical trial researchers should more routinely test volunteers’ understanding of risks in individual studies, especially for risky or high-paying studies,” added Kass. “This is a practice endorsed by many researchers, but practiced by few. We need to give special scrutiny to the highest risk studies – especially when volunteers have less education, as lower education consistently is associated with poorer understanding.”

“As researchers, we must always be vigilant about minimizing and managing study risks,” added Charles Flexner, professor of clinical pharmacology at Johns Hopkins and the study’s co-author. “Ultimately, that may be the best protection volunteers can have.”

The study was funded in part by the Stavros Niarchos Foundation.

About the Johns Hopkins Berman Institute of Bioethics

One of the largest centers of its kind in the world, the Johns Hopkins Berman Institute of Bioethics is the home for collaborative scholarship and teaching on the ethics of clinical practice, public health, and biomedical science at Johns Hopkins University. Since 1995, the Institute has worked with governmental agencies, non-governmental organizations, and private sector organizations to address and resolve ethical issues. Institute faculty represent such disciplines as medicine, nursing, law, philosophy, public health, and the social sciences. Their works help anticipate and inform debates on complex moral challenges; discerns ethically acceptable alternatives in medical, scientific, and public health policy; and helps to prepare the next generation of bioethicists. More information is available at www.bioethicsinstitute.org.

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