

## Why Minorities Should Participate in Clinical Research

Minorities seldom have the opportunity to participate in clinical research studies, with potentially serious health results for their communities. Because of genetic differences, minorities often respond differently than Caucasians to medicines, with potentially dangerous dosing errors and side-effects. Unless minorities participate in clinical research studies, these health risks may never be known: only 23% of drug labels provide guidance for use by minorities.

Many factors prevent minorities from participating in clinical studies. These factors include socioeconomics, culture, language and access to physicians who conduct clinical studies.

The Food & Drug Administration (FDA) supervises clinical studies of new drugs and approves them for use by the general public. If minorities do not participate in clinical studies, it may take a long time before safe and effective dosages are determined through trial and error by the general public. If they don't participate, they do not benefit from the free medicines and medical care received by clinical study participants. Most clinical studies even compensate volunteers for their time and transportation costs. In addition, many potentially-life-saving drugs in clinical studies are not available to the general public because they are not FDA-approved.

The National Institutes of Health (NIH) first published guidelines in 1987 for including more minorities in government-funded clinical studies, but these guidelines do not apply to industry-funded research. Participants in clinical studies in 1999 included only 6% African-Americans, 1% Asians and 1% Hispanics, for a total of 8%, down from 12% in 1995. These three minorities comprise over one-third of our population.

There is good evidence that minorities can benefit by participating in clinical studies:

- In 2003, Vaxgen of Brisbane, California, announced that its study of AIDSVAX HIV/AIDS vaccine was unsuccessful. The only bright spot in the study was a favorable indication among African-Americans. However, the number of African-American participants in the study was so small that the data could not be used to obtain FDA approval for use of the vaccine in African-Americans.
- In 2005, the FDA approved a new heart medicine just for treating African-Americans with severe heart failure who had already been treated with the best available therapy. Even though clinical studies did not prove the drug was effective in the general population, a study just for African-Americans showed a 43% reduction in death vs. placebo (no treatment).
- According to the FDA, African-Americans overall have lower cancer survival rates than whites, but comparable survival rates in clinical studies.
- Twenty percent of Americans with Hepatitis C viral infections are African-Americans. However, the standard therapy for Hepatitis C (interferon plus ribavirin) appears to be less effective for African-Americans than for Caucasians. Scientific testing has not been performed to determine if a larger dosage would address the problem. The effectiveness and safety of a new and potentially more effective therapy using pegylated interferon has not been tested on African-Americans.

Information about numerous clinical studies is available at websites such as:

- [www.centerwatch.com](http://www.centerwatch.com)
- [www.cancer.org](http://www.cancer.org)
- [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

**“Our community’s health is in our hands”**