

HIV-Infected African Americans are Willing to Participate in HIV Treatment Trials

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BACKGROUND: Despite the high prevalence rates of HIV infection in the African-American community, African Americans remain underrepresented in HIV treatment trials.

OBJECTIVE: (1) To develop a questionnaire that measures attitudes and concerns about HIV treatment trials among HIV-infected African Americans at a university-based clinic. (2) To determine actual participation rates and willingness to participate in future HIV treatment trials among HIV-infected African Americans at a university-based clinic.

DESIGN: Questionnaire development and cross-sectional survey.

SETTING, PARTICIPANTS, AND MEASUREMENTS: In a sample of 200 HIV-infected African-American adults receiving medical care at the Pittsburgh AIDS Center for Treatment (a university-based ambulatory clinic), we assessed research participation rates and willingness to participate in future HIV treatment trials, trust in the medical profession, sociodemographic characteristics, attitudes, and concerns about HIV treatment trials.

MAIN OUTCOME MEASURES: Research participation rates and willingness to participate in future HIV treatment trials.

RESULTS: Only 57% of survey respondents had ever been asked to participate in an HIV treatment trial but 86% of those asked said yes. Prior research participation was significantly related to willingness to participate in future HIV treatment trials ($P=.001$). Contrary to previous studies, neither trust/distrust in the medical profession nor beliefs about the dishonesty of researchers was associated with research participation rates or willingness to participate in future HIV treatment trials.

CONCLUSIONS: Having never been asked to participate in research is a major barrier to the participation of HIV-infected African Americans in HIV treatment trials. African Americans who seek medical care for HIV infection should be asked to participate in HIV treatment trials.

KEY WORDS: African Americans; HIV treatment trials; research participation; research ethics; patient participation rates.

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INTRODUCTION

In the United States, the HIV epidemic disproportionately affects the African-American population. In 2004, African Americans accounted for 49% of the estimated 42,524 AIDS cases diagnosed; this rate was 10 times that for whites.¹ Despite these disproportionate numbers, African Americans remain underrepresented in HIV treatment trials.²⁻⁵ In a 1995 study, among 4,604 HIV-infected individuals, African Americans were significantly less likely to be in trials than all other races or ethnicities.⁶ As of October 1999, African Americans accounted for only 23% of the adults enrolled in HIV treatment trials.⁷ Recent data from the HIV Cost and Services Utilization Study confirmed that HIV-infected African Americans are less likely to have access to experimental treatment or to participate in research than whites.³

Numerous studies exploring the barriers to African Americans' participation in medical research concluded that compared to whites, African Americans are more distrustful of researchers and less willing to participate in research.⁸⁻¹⁰ However, a study comparing African Americans who participate in research with those who do not showed that research participants had more positive perceptions of clinical research.¹¹ We believe that within-culture comparisons are critical for developing effective mechanisms to increase the recruitment and retention of African Americans in research. Therefore, we developed a survey to compare the attitudes and characteristics of HIV-infected African Americans who have and have not participated in HIV trials. Given that previous studies document African Americans' distrust of research, we were particularly interested in whether research distrust influences participation rates in HIV trials.

METHODS

Questionnaire Development

Before constructing the questionnaire, we reviewed existing instruments used in past research and searched the following terms in the MEDLINE database: *African-American human*

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subjects, attitudes towards research, (HIV) clinical trials, African Americans distrust of research, research participants survey instrument, and research participants questionnaire. We found no psychometrically validated surveys that assess research participants' trust of physician-researchers or their attitudes about HIV trials. However, previous studies identified the following variables that influenced the participation of African Americans and other minority groups in research: knowledge of research,^{5,10} African American (dis)trust of researchers and the medical community,⁷⁻¹⁰ economic group membership,⁷ altruism,⁷ religiosity,⁷ knowledge of informed consent,¹⁰ low socioeconomic status,¹² speaking a primary language other than English,¹² personal inconvenience,¹² and fear of medical procedures.¹² We incorporated these variables into our questionnaire, often using the same language found in previous studies' instruments. One of the authors (GS), a psychometrician, reworded some questions and rating scales to increase consistency across the questions from the multiple sources and reduce ambiguity where it existed. We included questions about sociodemographic characteristics, insurance status, social support networks, drug and alcohol use, prior research participation, and willingness to participate in future HIV trials.

To measure trust, we included The Trust in the Medical Profession (TIMP) scale, an 11-item scale with a single factor structure, good internal consistency, and good response variability (Cronbach alpha=.89).¹³ The scale uses a 5-point Likert response of "strongly agree" to "strongly disagree" and the responses are averaged to form a composite score that ranges from 1 to 5.¹²

To measure religiousness, we included items from the Multidimensional Measurement of Religiousness/Spirituality for Use in Health Research.¹⁴ The final questionnaire was a one-time only, self-administered, anonymous questionnaire with items from content areas that were of importance in previous research. Except for the TIMP, the intent was not to use or develop composite measures in specific content area but to look at ratings of specific items extracted from other scales.

After developing a draft of the questionnaire, we asked content experts if it accurately represented the concepts and the full breadth of information we were trying to assess. We asked members of the Community Research Advisory Board, a group housed within the Center for Minority Health at the University of Pittsburgh Graduate School of Public Health, to review the questionnaire. We revised the questionnaire in response to their suggestions.

To further ensure that the questionnaire covered topics relevant to the target population, we conducted a focus group consisting of 12 HIV-infected African-American patient volunteers from the Pittsburgh AIDS Center for Treatment (PACT). The focus group was 40% female, all were aged 25-44, and a third had participated in HIV trials. Focus group participants were asked to review and critique the contents of the revised questionnaire. Based on their recommendations, we clarified and reworded ambiguous questions and response options, and revised the visual format of the questionnaire. Finally, we asked 5 PACT patient volunteers to complete the 56-item questionnaire to ascertain the time needed to complete it. The time varied from 20 to 45 minutes; this variation was attributed to varying education levels and reading ability. A copy of the final questionnaire is included in the [Appendix](#).

Methods

Overview. We invited all HIV-infected African-American adults receiving medical care at the PACT to complete the newly developed questionnaire. The University of Pittsburgh Institutional Review Board (IRB) approved this study. Because the survey instrument was an anonymous questionnaire, the IRB waived a written informed consent document.

Setting, Participants, and Survey Administration. The University of Pittsburgh Medical Center (UPMC) houses the PACT, a facility that provides comprehensive medical care to HIV-infected patients from diverse racial and socioeconomic backgrounds, regardless of their medical insurance status. UPMC also houses the NIH-funded Pittsburgh AIDS Clinical Trials Unit (ACTU), which conducts clinical trials of antiretroviral therapies and vaccines. Individuals registered at PACT are recruited into ongoing trials at the ACTU.

In December 2002, 897 patients were registered at PACT; 679 (76%) were men, 597 (66%) were white, and 286 (32%) were African-American. This is comparable to HIV prevalence rates among African Americans in Southwestern Pennsylvania (36%),¹⁵ but lower than prevalence rates in Pennsylvania (51%) and nationally (40%).¹⁶ All African-American patients at PACT, aged 18 years or older, were eligible for our study. The only exclusion criterion was clinical history of cognitive dysfunction as reported by the medical assistant.

Beginning in July 2003, every African-American patient presenting for a scheduled clinic visit was invited to participate in the study by the medical assistant. Patients who expressed interest were then approached by the Principal Investigator, screened for eligibility criteria, presented with the study introductory script, and asked to complete the study questionnaire. For five participants who had problems reading the questionnaire, the Principal Investigator read each question and the participant independently filled in the appropriate option on a separate questionnaire. Each participant was given a \$10 gift certificate after completing the questionnaire.

Data Analysis. We obtained descriptive statistics for (1) respondents who had ever been asked to participate in HIV trials, (2) those who agreed to participate, (3) those who enrolled, and (4) those who completed a trial. In addition, we obtained frequency distributions for the responses to the question about willingness to participate in future HIV trials. Using chi-square tests and multivariable logistic regression, we compared independent variables among the following groups: (1) those who were never asked to participate in HIV trials versus those who were asked; (2) those who agreed to participate versus those who refused; (3) those who agreed to participate and enrolled in a study versus those who agreed but never enrolled in a study; and (4) those who enrolled and completed a study versus those who enrolled but did not complete a study. Any independent variable with a *P* value of ≤ 0.15 was included in the multivariable analysis. Using backward, stepwise, logistic regression, we arrived at a predictor model for each comparison group with variables showing statistical significance at *P*<.05. We also compared independent variables among those who expressed willingness, uncertainty, and unwillingness to participate in future HIV trials.

Stata 7.0. (Stata Corporation, College Station, Tex) was used for all analyses. A *P* value of ≤ 0.05 was considered statistically significant.

RESULTS

All 228 (80% of all possible black clinic patients) HIV-infected black (African, African-American, and Caribbean-American) patients who presented to PACT from July to November 2003 were invited to join the study. Of those patients, 203 (89%) who were African Americans were recruited, 2 were ineligible because of dementia, and 1 declined. Of the 200 respondents, 3 failed to complete the TIMP scale; 197 respondents were included in all of the analyses. Subanalyses of the group of patients who required assistance with completing the survey was not done because of the relatively small number of patients⁵ in this group.

Figure 1 provides a breakdown of the subject flow and research participation rates among the respondents, illustrating the four comparison groups. Of 197 survey respondents, only 114 (57%) had ever been asked to participate in an HIV

trial, 98 (86%) agreed. Eighty (82%) of those who agreed enrolled, 69 (86%) of whom completed a trial.

Table 1 shows the sociodemographic characteristics of the respondents. Fifty-six percent were in the 25–44 age category, 78% had known about their HIV infection for >2 years, and 61% had been registered at PACT for >2 years. The mean TIMP score was 3.44 (halfway between undecided and agree, or slightly positive trust). The observed coefficient alpha on the TIMP for our subjects was 0.73 (95% confidence interval [CI] 0.67–0.78).

In the regression analyses, after controlling for being registered at PACT for >2 years, those asked to participate in a trial were significantly more likely to be employed and less likely to be negative about research participation; those who enrolled were significantly more likely to receive social support from their spiritual leader and less likely to use marijuana. Table 2 lists unadjusted odds ratios (OR) from the bivariate analyses and adjusted OR from the multivariable analyses; only statistically significant variables from the bivariate analyses are reported.

Trust in the medical profession did not play a significant role; there were no statistically significant differences in levels of trust in any of the four analyses.

Finally, we asked survey respondents about their willingness to participate in future HIV trials. Eighty-three percent

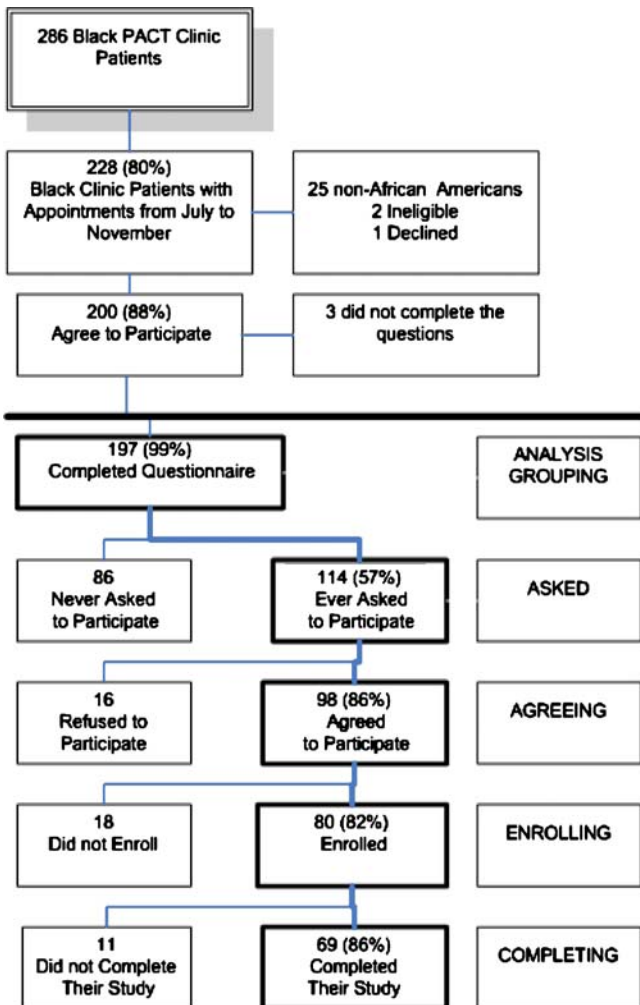


Figure 1. Breakdown of the subject flow and research participation rates.

Table 1. Sociodemographic Characteristics of 197 HIV-Infected African-American Participants

Characteristics	Percentage
Gender	
Male	56
Age (y)	
<25	5
25–44	56
45–64	36
≥65	3
Insurance status*	
Medicaid	44
Medicare	22
Private	23
None	15
Education	
Some high school	12
High school graduate	25
Trade school, college, or higher	63
Income	
<\$10,000	33
\$10,000–\$19,999	16
\$20,000–\$29,999	6
\$30,000–\$39,999	4
≥\$40,000	3
Unknown	38
Time aware of HIV infection	
<1 y	7
1–2 y	10
>2 y	78
Unknown	5
Time registered at the clinic	
<1 y	20
1–2 y	19
>2 y	61
AIDS classification based on CD4 count	
CD4<200 cells/μL	21
CD4≥200 cells/μL	45
Unknown	34

*Some patients had more than one type of insurance coverage.

Table 2. Significant Predictors of Being Asked, Agreeing, Enrolling, and Completing HIV Treatment Trials

	Unadjusted		Adjusted	
	Odds ratio	95% confidence interval	Odds ratio	95% confidence interval
ASKED: Compared with patients who were never asked to participate in an HIV treatment trial (n=84), patients who were asked to participate (n=113)*				
More likely to have known of their HIV infection for more than 2 y	2.9	1.3–6.4		
More likely to have been a patient registered at the clinic for more than 2 y	3.5	1.9–6.3	3.1	1.4–7.0
More likely to have acquired at least a trade school education or some college education	1.9	1.3–2.9		
More likely to be engaged in some form of employment	2.9	1.6–5.3	3.2	1.1–9.3
More likely to have private insurance	2.2	1.1–4.5		
Less likely to be negative about research participation	0.4	0.2–0.8	0.3	0.1–0.7
Less likely to believe that research participants must remain in a study until the protocol is completed	0.4	0.2–0.9		
AGREEING: Compared with patients who agreed to participate (n=97), patients who refused to participate in an HIV treatment trial (n=16)†				
Less likely to believe that research doctors are required to disclose risks to research participants	0.2	0.6–0.9		
Less likely to believe that research participants can leave a study at any time during the protocol	0.2	0.1–1.0	0.1	0.0–0.6
Less likely to acknowledge support from God or a higher power in dealing with their disease	0.2	0.1–1.0		

Table 2. (continued)

	Unadjusted		Adjusted	
	Odds ratio	95% confidence interval	Odds ratio	95% confidence interval
Less likely to be married or in a committed relationship	0.1	0.0–0.7		
Less likely to have tried to cut down on alcohol use at some point in their life	0.2	0.1–0.9	0.1	0.0–0.6
ENROLLING: Compared with patients who agreed to participate but did not enroll in an HIV treatment trial (n=18), patients who agreed and enrolled (n=79)‡				
More likely to have been a patient registered at the clinic for more than 2 y	5.4	1.9–15.3	6.7	2.0–22.4
More likely to receive support in dealing with their HIV disease from their minister or spiritual leader	5.0	1.5–16.5	4.0	1.1–14.8
More likely to receive support in dealing with their HIV disease from their HIV physician	4.0	1.1–15.0		
More likely to receive support in dealing with their HIV disease from their friends	3.4	1.1–10.4		
Less likely to question whether God exists	0.4	0.1–1.1		
Less likely to interpret life events without relying on God	0.2	0.1–0.6		
Less likely to use marijuana	0.3	0.1–0.8	0.3	0.1–0.9
More likely to believe research doctors are required to identify HIV treatment trials as a form of research	9.0	1.5–54.2		
More likely to believe that research doctors are required to disclose risks to research participants	3.7	0.9–15.1		

Table 2. (continued)

	Unadjusted		Adjusted	
	Odds ratio	95% confidence interval	Odds ratio	95% confidence interval
COMPLETING: Compared with patients who enrolled and completed the trial (n=68) [§] , patients who enrolled but did not complete an HIV treatment trial (n=11)				
Less likely to believe that HIV medical research tests whether new medications will benefit patients	0.2	0.0–0.8	0.2	0.0–0.8
Less likely to believe that the government has rules to ensure that medical research is done properly	0.3	0.1–1.2		

A P value of $\leq .05$ was considered statistically significant in the multivariable analysis.

The main reasons for participating were to help find a cure for AIDS (cited by 77%), to help the HIV community (53%), to get a new and effective experimental drug (47%), and to help the black HIV community (46%). Only 16% of the group reported financial compensation as a motivation for research participation.

*Independent variables with a P value of $\leq .15$ in the univariate analysis were included in the multivariable analysis.

[†]In the group of 16 patients who refused to participate, the 2 most common reasons for refusal were time constraints (cited by 36% of patients) and fear of adverse effects of medications (cited by 29%).

[‡]In the group of 18 patients who agreed to participate but did not enroll, the most common reason for failure to enroll was time constraints (cited by 56%).

[§]In the group of 68 patients who completed an HIV treatment trial, 55 (81%) said they "felt good" about contributing to research.

of prior research participants would be willing to participate in future trials. Among all respondents, 67% were willing to participate in future trials, whereas 23% were uncertain and 10% were unwilling. The reasons for willingness to participate in future trials were to help find a cure for AIDS (86%), to help the HIV community (65%) and to obtain new and effective experimental HIV medication (47%). Reasons for unwillingness and uncertainty about participation were fear of adverse effects of medications (45%), concern about the general risks of research (24%), and time constraints (21%). We assigned those uncertain about future participation to the unwilling group; in multivariable analysis the only significant factor related to willingness to participate in future research was prior research participation (adjusted OR=.6; 95% CI 1.9–11). There was no statistically significant difference in levels of trust in the medical profession between those willing, unsure, and unwilling to participate in future HIV trials. ($F_{2,194}=1.15$, $P=.3$) Only 13% of those unwilling or uncertain were concerned about the honesty of researchers.

DISCUSSION

Multiple studies document African Americans' low participation rates in HIV trials.^{3–6} However, when we surveyed HIV-infected African-American patients receiving medical care at

PACT (a university-based clinic), we found that only 57% had ever been asked to participate in an HIV trial. In fact, when asked, African Americans seemed very willing to participate in a trial. Thus, having never been asked was the major barrier to participation. Contrary to findings in previous studies, we found that neither distrust in the medical profession nor beliefs about dishonesty of researchers was significantly associated with actual participation rates or willingness to participate in future HIV trials.

These findings are consistent with recent publications that African Americans are willing to participate in research: A national study of veterans attending outpatient facilities reported no race differences in self-reported research participation.¹⁷ Wendler et al.¹⁸ performed a systematic review of 20 health research studies that reported consent rates by race or ethnicity. They also found that when invited, African Americans were not less likely and occasionally were more likely to consent to research participation compared to non-Hispanic whites.

Although the bivariate analyses show that both having been diagnosed with HIV infection for >2 years and being a patient at PACT for >2 years were significantly associated with being asked to participate in a trial, the multivariable analyses revealed that having been a patient at PACT for >2 years was the significant determinant. After adjusting for being registered at PACT for >2 years, patients asked to participate in trials were less likely to be negative about research and less likely to believe that research participants must remain in a study until the protocol is completed. This suggests that public education about research may improve participation rates.

We postulate several reasons for the finding that only 57% of respondents had ever been asked to participate in an HIV trial. First, physicians and researchers may have preconceived notions that African Americans are likely to refuse to participate in research. Assuming that African Americans are not interested in research, clinicians may not raise the issue. A similar dynamic was found in studies of organ donation where health care providers perceiving black families were less willing to donate, were requested for organ donation less frequently.¹⁹ While organ donation and research participation are different topics with different emotional impact, it is consistent with the broader communication theory that suggests that a speaker's preconceptions influence interactions. For example, white researchers may be uneasy talking to African Americans about research assuming (incorrectly) that patients will react with anger or distrust given past abuses. The relationship between the health care practitioner's ethnicity and whether patients were asked to participate in trials could not be assessed in this study because all of the practitioners at PACT are white. Further research into investigators' ethnicity, beliefs, and attitudes is needed. Second, medical researchers simply may not know how to effectively communicate with African Americans about research participation particularly in light of the history of research abuses on the African-American population. Third, researchers may believe that African Americans may not be reliable research participants and thus may be reluctant to enroll them in research. For example, Shavers-Hornaday et al.²⁰ report that researchers believe that it is more difficult to obtain African-American patients' compliance and that African Americans have higher attrition rates. Fourth,

some researchers believe that they are more likely to encounter difficulties in contacting patients from minority populations or in financing effective recruitment efforts that target these populations.^{20–22} Fifth, it is also possible that some patients were not asked to participate simply because they were ineligible for ongoing trials. Ineligibility may be because of lack of requisite clinical diagnoses and ongoing risky behaviors. However, given that the general policy at PACT is to ask all patients if they are interested in research and then to determine eligibility, this is less likely to be a reason.

Several reasons might explain our finding that 86% of African Americans asked to participate in HIV trials agreed to do so. First, it may be attributable to the unique clinical setting in which the survey was done. PACT is a university-affiliated clinic that provides comprehensive clinical and social services. Second, PACT employs an African-American peer advocate who addresses patients' concerns and complaints. Third, PACT employs a resident research coordinator who acts as a liaison between the clinic and the ACTU; familiar-face coordinators, who ask patients about research participation in an environment that caters to their medical and social needs, might positively influence research participation rates. A study of HIV-infected patients beginning HIV primary care at Boston City Hospital reported that when a research associate provided patients with information about the purpose, role, and availability of HIV clinical trials, and addressed their concerns about these trials, the overall rates of participation improved and there was no longer a significant difference between the rates of participation by whites and by people of color.²³

Our study found that trust/distrust in the medical profession was not associated with research participation rates and willingness to participate in future trials. This is contrary to reports by Sengupta et al.⁷ that African Americans' distrust about research institutions was the strongest inverse predictor of willingness to participate in AIDS clinical trials. The reasons for our distinctive findings are not clear. It may be that HIV-infected African Americans who seek medical care at a university-based clinic are less distrustful of the medical profession. Ninety percent of survey respondents indicated that their PACT physician provides considerable support in coping with their disease. El-Sadr and Capps⁴ have noted that African Americans' fear of exploitation in research and their distrust of researchers can be overcome if trust develops between the primary care provider and the patient. Similarly, Kass et al.²⁴ found in a survey of 1,900 research participants

that the patients' trust in their physicians was instrumental in the participants' decision to enroll in a research study.

The major limitation of this study is that of selection bias. Because the study population is limited to African Americans at a single university-based clinic, the findings may not be generalizable to other clinical settings. Although the distinctiveness of some of our findings may also be due in part to the desire of survey participants to provide socially desirable responses to questions, we believe this effect is minimal in our study, not only because the questionnaire was anonymous but also because participants reported considerable amounts of alcohol and substance abuse. There is evidence to suggest that when individuals self-report extensive drug use, the information provided is likely to be valid.²⁵

Future studies are needed to assess the beliefs of African Americans in other clinical settings. These studies should assess whether there is a relationship between the clinical services received, satisfaction with these services, and willingness to participate in research. Studies should also assess the relationship between how African Americans are asked about research and their willingness to participate in research.

CONCLUSION

This study demonstrates that HIV-infected African Americans seeking medical care at a university-based clinic are likely to participate in HIV trials if asked. This study suggests that HIV-infected African Americans who seek medical care for their HIV infection should be asked to participate in HIV trials.

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Potential Financial Conflicts of Interest: None disclosed.

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APPENDIX

Medical Research Survey

The University of Pittsburgh



Division of General Internal Medicine Center for Research on Health Care

Today's Date: _____

SECTION 1 INTRODUCTION**WHAT IS MEDICAL RESEARCH?**

For the purposes of this study, medical research is being defined as a scientific way for research doctors to determine if one treatment is better than another in treating HIV infection or its complications. For example, in one research project, Bactrim was compared to another medicine to see which was best in treating HIV-related pneumonia.

WHY ARE YOU DOING THIS SURVEY?

You are being asked to participate in this study because you have been identified as an African-American adult infected with HIV. We would like to know your opinion on HIV medical research. We will also ask about other topics that may affect your thoughts about research in HIV. There are no right or wrong answers and your answers will be kept completely confidential.

CONFIDENTIALITY

This is an entirely anonymous questionnaire. We are not asking for your name, date of birth, social security number or any other identification that will allow us to link this questionnaire to you personally. In addition, your responses to this survey will be kept confidential and stored in a locked file cabinet.

PLEASE DO NOT WRITE YOUR NAME ANYWHERE ON THIS SURVEY!

WE APPRECIATE YOUR HELP!

PLEASE GO TO THE NEXT PAGE.

SECTION 2 | YOUR PARTICIPATION IN HIV MEDICAL RESEARCH

1. Have you ever been asked to participate in HIV medical research?

- No
 - Not sure
 - Yes
- IF NO OR NOT SURE SKIP TO QUESTION 8

2. Have you ever agreed to participate in HIV medical research?

- No
 - Not sure
 - Yes
- IF NO OR NOT SURE SKIP TO QUESTION 5

3. Have you ever been enrolled in HIV medical research?

- No
 - Not sure
 - Yes
- IF NO OR NOT SURE SKIP TO QUESTION 5

4. Have you ever completed an HIV medical research study?

- No
 - Not sure
 - Yes
- IF NO OR NOT SURE SKIP TO QUESTION 5

SKIP AND GO TO QUESTIONS 6 AND 7 ON PAGE 4

5.

a. Which of the following statements describe your **reasons for NOT participating** in HIV medical research?

[CHECK ALL THAT APPLY]

- I do not qualify.
- I am not interested.
- I am afraid of experiments.
- I do not have enough time.
- I am afraid of shots and needles.
- I am concerned about the honesty of research doctors.
- I am concerned that African-Americans would not benefit.
- I do not have transportation.
- I have children to take care of.
- I am afraid of the side effects of the medications.
- Everyone would know about my illness.
- There is no personal benefit to me.
- They do not pay enough.
- Medical research is too risky.
- Other, specify _____

PLEASE GO TO QUESTION 8 ON PAGE 5

6. Which of the following statements describe your **reasons for participating** in HIV medical research?
[CHECK ALL THAT APPLY]

- My doctor said it would be good for me.
- To get free medical treatment.
- To get a new experimental HIV drug that works for me.
- To get the money.
- To help the HIV community
- To help the black HIV community
- To help find a cure for HIV/AIDS.
- Other, specify: _____

7. Which of the following statements **describe your experience** with HIV medical research?
[CHECK ALL THAT APPLY]

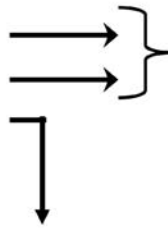
- The study took too much time.
- I felt good about contributing to research.
- I did not like the shots and/or giving blood.
- The medications worked for me.
- I received good health care.
- I had problems with transportation.
- I learned about how to stay in good health.
- I had bad side effects from the medication(s).
- Other, specify _____

8. Would you be willing to participate in **future** HIV medical research?

No

Not sure

Yes



8a. Which of the following statements describe why you **are not willing to participate** in future HIV medical research?
[CHECK ALL THAT APPLY]

- My past experience with medical research was not good.
- I will not qualify.
- I am not interested.
- I am afraid of experiments.
- I do not have enough time.
- I am afraid of shots and needles.
- I am concerned about the honesty of research doctors.
- I am concerned that African-Americans would not benefit.
- I have children to take care of.
- I am afraid of the side effects of the medications.
- Everyone will know about my illness.
- There is no personal benefit to me.
- They do not pay enough.
- Medical research is too risky.
- Other, specify: _____.

9. Which of the following statements describe why you **are willing to participate** in future HIV medical research?

[CHECK ALL THAT APPLY]

- I had a good experience in a previous study.
- To help find a cure for HIV/AIDS.
- To help the HIV community.
- To help the black HIV community.
- My doctor says it would be good for me.
- To get free medical treatment.
- To get a new experimental HIV drug that could work for me.
- To get the money.
- Other, specify: _____

SECTION 3	YOUR OPINIONS & KNOWLEDGE ABOUT HIV MEDICAL RESEARCH
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10. The following questions ask about HIV medical research. Please mark the circle that best describes your opinions.

	<i>Never</i>	<i>Sometimes</i>	<i>Usually</i>	<i>Always</i>	<i>Don't Know</i>
a. HIV medical research tests if new medications will benefit patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Research doctors are required to tell participants that the medical research study is a type of medical research.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Research doctors are required to tell participants about the risks involved in the medical research study.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Before the study starts, participants in HIV medical research are told about all the medications and tests involved in the study.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Participants are told if the HIV research study will benefit them personally.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. If a patient refuses to participate in HIV medical research, the hospital doctors can refuse to provide medical care for the patient.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. The information participants provide to the study doctors is kept private.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. Research doctors do HIV research to find out whether a new medication is better than the old one.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. Participants in HIV medical research can leave the study at any time.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j. Participants in HIV medical research must remain in the study until it is completed.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
k. If patients do not understand what will happen in an HIV research study, they will not be allowed to participate.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
l. Patients participate in HIV medical research only because they want to.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
m. Patients can be forced to participate in HIV medical research.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	<i>Never</i>	<i>Sometimes</i>	<i>Usually</i>	<i>Always</i>	<i>Don't Know</i>
n. If a participant has a bad reaction to the medication(s) given in an HIV research study, the research doctors must take care of the participant's medical treatment.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
o. Research doctors sign up more blacks than whites in their HIV studies.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
p. Research doctors sign up more poor people than rich people in their HIV studies.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
q. Research doctors try to protect the participants from the bad things that could happen in the medical research study.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
r. Whites benefit more from medical research than blacks.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
s. The reason research doctors carry out research is to build their own careers.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
t. Medical research is helping to find a cure for HIV.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
u. The government has rules to make sure medical research is done properly.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
v. The government checks up on research doctors to make sure they are following the rules.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

SECTION 4	YOUR OPINIONS ABOUT HIV INFECTION AND THE BLACK COMMUNITY
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11. Please read each of the statements listed below concerning HIV infection and the black community, and mark the circle that best indicates your opinion.

	<i>Strongly Disagree</i>	<i>Disagree</i>	<i>Undecided</i>	<i>Agree</i>	<i>Strongly Agree</i>
a. More black people are dying from HIV infection than any other race of people.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. AIDS has been spread in the black community on purpose.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Blacks participating in HIV medical research are being taken advantage of by researchers.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Many blacks are interested in participating in HIV medical research.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Blacks have the same access as whites to the best HIV medications.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. It is as important for blacks to participate in medical research as it is for whites.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

SECTION 5	YOUR OPINIONS ABOUT DOCTORS IN GENERAL
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12. Please read each of the statements listed below concerning your opinions about doctors in general, and indicate whether you Strongly Disagree, Disagree, feel Undecided, Agree, or Strongly Agree by marking the appropriate circle.

	<i>Strongly Disagree</i>	<i>Disagree</i>	<i>Undecided</i>	<i>Agree</i>	<i>Strongly Agree</i>
a. Doctors care about their patients' health just as much as their patients do.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Sometimes doctors care more about what is convenient for them than about their patients' medical needs.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Doctors are extremely thorough and careful.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. I completely trust doctors' decisions about which medical treatments are best.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Doctors are totally honest in telling their patients about all of the different treatment options available for their conditions.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Doctors think only about what is best for their patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Sometimes doctors do not pay full attention to what patients are trying to tell them.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. Doctors always use their very best skill and effort on behalf of their patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. I have no worries about putting my life in the hands of doctors.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j. A doctor would never mislead me about anything.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
k. All in all, I trust doctors completely.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

SECTION 6 YOUR HIV ILLNESS

Please remember all of your answers are completely confidential!

13. How long have you known about your HIV infection?
- Less than 1 year
 - 1-2 years
 - More than 2 years
14. How long have you been receiving HIV treatment at PACT?
- Less than 1 year
 - 1-2 years
 - More than 2 years
15. How many times have you been sick with an HIV-related problem?
- 0
 - 1
 - 2
 - 3
 - More than 3
16. Since learning that you have HIV, how many times have you had to stay overnight at the hospital for an HIV-related illness?
- 0
 - 1
 - 2
 - 3
 - More than 3

17. What is your most recent CD4 count?

- Less than 50
- 51-199
- 200-499
- More than 500
- I do not know

18. What is your viral load?

- Please specify: _____
- I do not know

19. The following is a list of sources of support that some people describe as important to them in dealing with HIV disease. Please indicate how much support you receive from any of these sources by marking the appropriate circle.

How much support from....	<i>None</i>	<i>A Little</i>	<i>A Moderate Amount</i>	<i>A Lot</i>
a. your family	○	○	○	○
b. your friends	○	○	○	○
c. your HIV doctor	○	○	○	○
d. other healthcare worker	○	○	○	○
e. God or a higher power	○	○	○	○
f. minister or other spiritual leader	○	○	○	○
g. other, please specify: _____	○	○	○	○

SECTION 7 YOUR BACKGROUND INFORMATION

Please remember all of your answers are completely confidential!

20. What is your sex?

- Male
- Female
- Trans-sexual / trans-gender

21. How old are you?

_____ years

22. Which of the following best describes the ethnic group to which you belong?

a. **FIRST**, are you:

- Hispanic/Latino
- Not Hispanic/Latino

b. **SECOND**, are you:

[CHECK ALL THAT APPLY]

- White
- Black or African American
- Asian (*Chinese, Japanese, Korean, etc.*)
- Hawaiian/Pacific Islander (*Filipino, Indonesian, Hawaiian, etc.*)
- Native American or Alaska Native
- Other, please specify: _____

23. Who do you have sex with?

- Men
- Women
- Both men and women

24. Are you married or do you have a partner?

Yes

No



25a. Are you living together?

Yes

No

25. Since you were diagnosed with HIV infection, how many children, sick persons, disabled persons, or elderly persons have you had to care for?

_____ number of people cared for

26. How many people currently live in your household, including yourself?

_____ number of people

27. What are your current living arrangements?

Private home you own

Private home you rent

Apartment you own

Apartment you rent

Dormitory

Living with family or friends (not paying rent)

Boarding house or hotel

Group home / independent living

Homeless

Other

28. Do you plan to move in the next six months?

Yes

No

29. How long have you lived in the Pittsburgh area?

- Less than 1 year
- 1-3years
- More than 3years

30. What languages are spoken in your household?

[CHECK ALL THAT APPLY]

- English
- Other, please
specify: _____

31. How much education have you completed?

- Eighth grade or less
- Some high school
- High school graduate
- Trade school or business school
- Some college
- College graduate

32. Which best describes your work status?

- Employed full time
- Employed part time
- Homemaker, not working outside the home
- Retired
- Unemployed, on disability
- Unemployed, not on disability
- Full time student
- Other

33. Please check the box next to the category that best describes your income for the past year. **Please include any salaries, wages, medical disability, or other income** you may have had.

	<i>Your Own Personal Income</i>	<i>Your Total Household Income</i>
Less than \$10,000		
\$10,000 - \$19,999		
\$20,000 - \$29,999		
\$30,000 - \$39,999		
\$40,000 - \$49,999		
\$50,000 - \$59,999		
\$60,000 - \$69,999		
\$70,000 or more		
Don't know		

34. What kind of health insurance do you currently have?

- None
 Medical assistance (Medicaid)
 Medicare
 Private
 I do not know

35. Do you currently receive public assistance?

- Yes
 No

36. Do you currently drink alcohol?

- Yes
 No

37. Have you ever tried to cut down on your drinking?

- Yes
 No
 Not applicable

38. Has anyone ever told you that you need to cut down on your drinking?

- Yes
- No
- Not applicable

39. How often do you drink more than 5 drinks in one sitting (a drink is a regular bottle or can of beer, glass of wine or shot of liquor)?

- Daily
- Every other day
- Weekends
- 1-2 times per month
- At least monthly
- Rarely
- Never

40. How often do you use marijuana?

- Daily
- Every other day
- Weekends
- 1-2 times per month
- At least monthly
- Rarely
- Never

41. How often do you use injected drugs like heroin or cocaine?

- Daily
- Every other day
- Weekends
- 1-2 times per month
- At least monthly
- Rarely
- Never

42. How often do you inhale or smoke drugs like cocaine/crack/speedball?

- Daily
- Every other day
- Weekends
- 1-2 times per month
- At least monthly
- Rarely
- Never

43. How often do you use other types of non-prescription drugs such as poppers, amphetamines...?

- Daily
- Every other day
- Weekends
- 1-2 times per month
- At least monthly
- Rarely
- Never

SECTION 8 YOUR ADDITIONAL COMMENTS

44. Now that you have completed this questionnaire, is there anything else that you would like to tell us about your thoughts on HIV medical research?

THANK YOU FOR YOUR HELP!!!

REFERENCES

1. **CDC.** HIV/AIDS Surveillance Report, 2004. Vol. 16. Atlanta: US Department of Health and Human Services, CDC: 2005:1-46. Accessed Mar 2006.
2. **NIH.** NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. NIH guide, Vol. 23, No.11, 18 Mar 1994.
3. **Gifford AL, Cunningham WE, Heslin KC, et al.** Participation in research and access to experimental treatments by HIV infected patients. *N Engl J Med.* 2003;346(18):1373-82.
4. **El-Sadr W, Capps L.** The challenge of minority recruitment in clinical trials for AIDS. *JAMA.* 1992;267:954-7.
5. **Stone VE, Mauch MY, Steger K, Janas S, Craven DE.** Race, Gender, Drug Use, and Participation in AIDS Clinical Trials. *J Gen Intern Med.* 1997;12:150-7.
6. **Diaz T, Chu SY, Sorvillo F, et al.** Differences in Participation in Experimental Drug Trials Among Persons with AIDS. *J Acquir Immune Defic Syndr Hum Retrovirol.* 1995;10:562-8.
7. **Sengupta S, Strauss RP, DeVellis R, Crouse Quinn S, DeVellis B, Ware WB.** Factors affecting African-American participation in AIDS research. *J Acquir Immune Defic Syndr Hum Retrovirol.* 2000;24:275-84.
8. **Corbie-Smith G, Thomas SB, Williams MV, Moody-Ayers S.** Attitudes and beliefs of African Americans toward participation in medical research. *J Gen Intern Med.* 1999;14:537-46.
9. **Corbie-Smith G, Thomas SB, St. George DM.** Distrust, race, and research. *Arch Intern Med.* 2002;162:2458-63.
10. **Freimuth VS, Crouse Quinn S, Thomas SB, Cole G, Zook E, Duncan T.** African Americans' views on research and the Tuskegee Syphilis Study. *Soc Sci Med.* 2001;52:797-808.
11. **Kennedy BM, Burnett MF.** Clinical research trials: a comparison of African Americans who have and have not participated. *J Cult Divers.* Winter 2002;9(4):95-101.
12. **Giuliano AR, Mokuau N, Hughes C, et al.** Participation of minorities in cancer research: the influence of structural, cultural, and linguistic factors. *Ann Epidemiol.* 2000;10:S22-S34.
13. **Hall M, Camacho F, Dugan E, Balkrishnan R.** Trust in the medical profession: conception and measurement issues. *Health Serv Res.* October 2002;37(5):1419-39.
14. **Abeles R, Ellison C, George L, et al.** The Multidimensional Measurement of Religiousness/Spirituality for Use in Health Research. A Report of the Fetzer Institute/National Institute of Aging Working Group. Kalamazoo, MI: Fetzer Institute, October 1999.
15. Department of Health. HIV/AIDS Surveillance Biannual Summary. Available at http://www.dsf.health.state.pa.us/health/lib/health/epidemiology/2004BiAnnual2PA_AIDS.pdf. Accessed Mar 2006.
16. The Henry J. Kaiser Family Foundation. State Health Facts. Available at <http://www.statehealthfacts.org/cgi-bin/healthfacts.cgi>. Accessed Mar 2006.
17. **Kressin NR, Meterko M, Wilson NJ.** Racial Disparities in participation in biomedical research. *J Natl Med Assoc.* 2000;92(2):62-9.
18. **Wendler D, Kington R, Madans J, et al.** Are racial and ethnic minorities less willing to participate in health research? *PLoS Med.* 2006;3(2):e19.
19. **Siminoff LA, Lawrence RH, Arnold RM.** Comparison of black and white families' experiences and perceptions regarding organ donation requests. *Crit Care Med.* 2003;31(1):146-51.
20. **Shavers-Hornaday VL, Lynch CF, Burmeister LF, Torner JC.** Why are African Americans under-represented in medical research studies? Impediments to participation. *Ethn Health.* 1997;(2):31-4.
21. **Dresser R.** Wanted single, white male for medical research. *Hastings Cent Rep.* 1992;22:24-9.
22. **Swanson GM, Ward AJ.** Recruiting minorities into clinical trials: toward a participant-friendly system. *J Natl Cancer Inst.* 1995;87(23):1747-59.
23. **Frederberg KA, Sullivan L, Georgakis A, Savetsky J, Stone V, Samet JH.** Improving participation in HIV clinical trials: impact of a brief intervention. *HIV Clin Trials.* 2001;2(3):205-12.
24. **Kass N, Sugarman J, Faden R, Schoch-Spana M.** Trust: the fragile foundation of contemporary biomedical research. *Hastings Cent Rep.* 1996;26:25-9.
25. **Wish E, Hoffman J, Nemes S.** The validity of self-reports, of drug use at treatment admission, and at follow-up: comparisons with urinalysis and hair assays. In: Harrison L (ed) *The Validity of Self-Reports: the Implications of Survey Research.* Rockville, MD: National Institute on Drug Abuse, 1997. Available at http://www.drugabuse.gov/pdf/monographs/monograph167/200-226_Wish.pdf. Accessed Mar 2006.
26. **Caban CE.** Hispanic research: implications of the National Institutes of Health Guidelines on inclusion of women and minorities in clinical research. *J Natl Cancer Inst Monogr.* 1995;18:165-9.
27. **Shavers VL, Lynch CF, Burmeister LF.** Racial differences in factors that influence the willingness to participate in medical research studies. *Ann Epidemiol.* 2002;12(4):248-56.
28. **Trauth JM, Musa D, Siminoff L, Jewell IK, Ricci E.** Public attitudes regarding willingness to participate in medical research studies. *J Health Soc Policy.* 2002;12(2):23-43.
29. **Svensson CK.** Representation of American blacks in clinical trials of new drugs. *JAMA.* 1989;261:263-5.
30. **Sheikh A.** Why are ethnic minorities under-represented in US research studies? *PLoS Med.* 2006;3(2):e49.