

Exceptional Risk: Healthy Volunteers' Perceptions of HIV/AIDS Clinical Trials

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Abstract: As with all early-stage testing of investigational drugs, clinical trials targeting HIV/AIDS can pose unknown risks to research subjects. Unlike sick participants seeking a therapeutic benefit, the motivations and barriers for healthy volunteers are more complex and understudied. Drawing on interviews and clinical trial data from 178 healthy volunteers, we examine how they perceive HIV/AIDS studies in the early stages of testing. A subset of healthy volunteers see phase I HIV/AIDS studies as particularly risky for reasons ranging from fear of catching the disease or having long-lasting and uncomfortable side effects to inexplicable fears that they cannot even articulate. Some participants have had past negative experiences in such trials that inform these views, but others cite information from staff and other participants as influential. Healthy volunteers' general fears concerning AIDS also shape their views of participating in phase I HIV/AIDS clinical trials.

Key Words: HIV, AIDS, phase I studies, healthy volunteers, risk, fear

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INTRODUCTION

Since the 1990s, clinical trials have become a global industry. As part of efforts to speed up drug development, the pharmaceutical industry increasingly outsources the clinical testing of its products to contract research organizations and other for-profit research companies.^{1,2} These companies have also expanded recruitment for clinical trials to more countries around the world, especially those that are relatively resource poor.^{3–5} Despite these massive changes in the organization of clinical trials, recruitment of research participants continues to be a major challenge that is said to delay drug development by months and sometimes years.^{6,7}

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As part of the clinical trials industry, not only are more companies engaged in the research enterprise, but a “professional” class of healthy volunteers has also emerged to support that research.⁸ In the United States, attention to such participants stems from the 1996 launch of Philadelphia “zine” *Guinea Pig Zero (GPZ)*^{9,10} and more recently has been fueled by the informational website “Just Another Lab Rat.”¹¹ “Professional” healthy volunteers are those that continually enroll in phase I clinical trials and use the compensation they get from their participation as their primary—if not sole—source of income. Many professional volunteers adopt a clinical trial lifestyle in which they adapt their behaviors, such as diet, exercise, and alcohol consumption, to increase their chances of qualifying for studies.¹² The United States is a particularly accommodating place for healthy volunteers to treat clinical trials as work because there is a high volume of trials and no regulatory limits on how much compensation participants can earn per year. In addition, there is no centralized registry of research participants, which means that healthy volunteers can easily circumvent restrictions that could otherwise limit their trial participation.^{13–15} Compensation for these trials varies dramatically based on the overall length of the trial, number of days confined to the research facility, and number of outpatient visits. The average US phase I trial typically pays between \$2000 and \$4000.¹⁶ Compensation is based primarily on time, and US regulation prohibits setting payment based on risk.¹⁷

A cadre of professional healthy volunteers is advantageous to phase I researchers who can more easily recruit US participants for their studies than can researchers for later-phase trials.¹⁸ Moreover, US healthy volunteers tend to be drawn from more diverse sociodemographic groups than are research participants affected by illness.¹⁹ Because of the financial compensation provided, healthy volunteers are often from disadvantaged minority groups that suffer economic and employment inequalities.²⁰ Healthy volunteers' social context as well as their serial participation also shapes their perceptions of the risks of clinical trials, leading to narratives in which risk is normalized as either an inescapable part of everyday life²⁰ or a transient and unremarkable part of study participation.¹⁶ This is not to say that healthy volunteers are indiscriminate about the risks they might take in clinical trials. Indeed, they often describe studies in which they would refuse to participate because of their heightened sense of risk associated with specific drugs or procedures.²¹

Given the availability of healthy volunteers in the United States, one might expect that there would be few

barriers to recruitment for HIV/AIDS clinical trials. Yet, our research suggests that a subset of US healthy volunteers see HIV/AIDS studies in particular as having more short-term and long-term risks than the average phase I trial. They describe both credible and inexplicable fears about their participation in these trials and may assert their unwillingness to enroll in them. We find that some experienced or “professional” healthy volunteers are concerned about HIV/AIDS clinical trials because of a past personal experience with such studies or information obtained from fellow participants and staff. Other healthy volunteers highlight their trial inexperience or unsubstantiated fears as the basis for their negative views of HIV/AIDS studies. In the absence of direct or indirect experience, negative associations with the disease itself can fill the gap. Healthy volunteers, unlike participants in later-phase trials, rarely invoke personal or societal benefits of participating in HIV/AIDS clinical trials. Instead, such studies are seen as “serious” and “intense,” and associated with feelings of concern, nervousness, apprehension, and fear.

BACKGROUND LITERATURE

Clinical development is typically divided into 3 required phases for drugs to receive market approval in the United States and elsewhere around the world.²² Phase I trials are those that are designed to test the safety and tolerability of new therapies, typically using healthy volunteers as research participants. Additional trials in phase II and III determine a product’s efficacy by testing it on affected patients. HIV/AIDS clinical trials depart from many other therapeutic areas because the focus is not only on treatment but also on prevention. Specifically, healthy HIV-negative volunteers are needed to determine whether vaccines or drugs can prevent HIV infection in people who are HIV-negative.²³ In the realm of HIV preventative vaccine development, developing safe and efficacious vaccines requires recruiting tens of thousands of healthy HIV-negative volunteers over an extended period.²⁴ As a result, there has been a significant focus in the scholarly literature on managing the risks to which healthy volunteers are exposed and identifying barriers to and motivators for their participation in HIV vaccine trials.²⁵

There are always risks associated with participation in clinical trials. Generally, the risks to healthy volunteers in phase I trials are relatively modest,^{26–28} with important exceptions such as the death of a participant in France in January 2016.²⁹ Drugs being developed for HIV/AIDS are typically antiretroviral agents, which means that healthy volunteers are likely to experience transient impaired taste, rashes, gastrointestinal distress, and increased white blood cell counts.^{30–33} For clinical trials conducted on healthy volunteers, unlike those with HIV-infected patients, these risks are not counterbalanced by direct medical benefits. Yet, as with any clinical trials on healthy volunteers, the expectation is that any physiological changes experienced by participants will be relatively short-term and their bodies will return to baseline.³⁴

HIV vaccine trials, however, have different risks to healthy volunteers than do drug trials. A systematic review of

phase I trials on healthy volunteers found that investigational vaccines have a statistically significant greater chance of producing severe adverse events than all other tested products.²⁶ One substantial risk unique to HIV vaccines is vaccine-induced seropositivity (VISP) or vaccine-induced seroreactivity, meaning false-positive HIV tests for study participants.^{35,36} This may occur when participants who receive the active vaccine produce antibodies to HIV on standard HIV screening tests, making it appear as though they are infected when in fact they are not. Although this might not affect the overall health of those participants, there could be potential social harms that result.^{25,36} A false-positive test for HIV can have profound impacts on participants’ personal relationships and also be a source of societal stigma. For example, individuals might face the possibility of discrimination in employment, inability to obtain insurance or a travel visa, ineligibility to serve in the US military, and/or exclusion from donating blood in some countries.^{35,36} A long-term study of VISP concluded that healthy volunteers in HIV vaccine studies should be informed of the potential that false-positive results can last for almost 17 years.³⁷ Given the seriousness of VISP, researchers have recommended that data be collected about social harms such as stigma and discrimination experienced by HIV vaccine trial participants in the same rigorous manner that physical adverse events are recorded and monitored in clinical trials.^{38,39} This would allow for the provision of appropriate support services to affected participants and would enable systematic evaluation of the impacts of social harm on study volunteers.^{38,39}

Although there is a sizeable literature on factors influencing people’s willingness to participate in HIV vaccine trials, much of this research focuses on later-phase trials that enroll high-risk HIV-negative participants.⁴⁰ Research on the challenges of recruiting and retaining volunteers in phase I/II vaccine trials nonetheless provides insights into some of the factors influencing volunteers’ willingness to participate in these studies.^{24,38,40–44} With drug trials in particular, a systematic review of barriers to HIV patients’ participation in HIV drug trials identified several major themes: safety (fear of side effects), distrust of researchers and the research process, concerns and misunderstandings about the research study design, impact of clinical trial participation on daily life and responsibilities, and social discrimination.⁴⁵ Many of the same barriers to trial participation emerge in vaccine trials as in HIV drug trials with the addition of participants expressing concern about the vaccine causing HIV/AIDS or resulting in false-positive HIV tests.²⁵

In addition to barriers to participation, there have also been studies of participation motivators. For example, a recent systematic review of motivators for participating in HIV vaccine trials showed that the benefits of trial participation varied based on phase of the trial.⁴⁶ Specifically, it was common for studies to find participants motivated both by societal benefits, such as helping find a cure or contributing to science, and personal benefits, such as protecting oneself from HIV, having current information on the disease, and financial compensation.⁴⁶ In addition, research has found that volunteers’ willingness to participate may change over the course of the screening and enrollment process with attrition

occurring in the steps between prescreening and enrollment.^{24,41,42}

Although the literature on HIV/AIDS vaccine trials contributes to our understanding of HIV-positive and/or high-risk volunteers' willingness to participate in these trials, the barriers and facilitators to recruiting healthy HIV-negative volunteers to phase I trials is understudied. In particular, there is a dearth of information about how healthy volunteers at low risk for HIV infection perceive the risks and benefits of participation in HIV drug and vaccine trials. In part, this reflects a general bias in the published literature that tends to focus more on phase III efficacy trials than on early-phase testing.¹⁹ Yet, healthy volunteers who participate in clinical trials across diverse therapeutic areas might have important insights to share on their perceptions of the differential risks of such trials.

METHODS

As part of a longitudinal, mixed-methods study of healthy volunteers' participation in phase I clinical trials, this article draws on data collected in 570 semistructured interviews and 878 clinical trial surveys with 178 healthy volunteers. Participants were recruited to our study from May to December 2013 while they were participating in a phase I clinical trial at 1 of 7 US clinics. Our recruitment method ensured that the participants would have participated as healthy volunteers in at least one clinical trial. However, participants' experience as healthy volunteers was broad at enrollment: approximately 21% were participating in their first clinical trial, 28% were enrolled in their second through

fourth study, 25% were enrolled in their fifth through 10th study, and 26% reported participating in more than 11 studies and upward to 200 clinical trials (Table 1). Our sample shows consistency with other studies of healthy volunteers,^{16,19} with the majority of participants being men (74%) and racial and ethnic minorities (68%). Specifically, 40% self-identified as black, 32% as non-Hispanic white, 21% Hispanic, 7% as more than one race, 5% as Asian, Native Hawaiian, or Pacific Islander, and 1% as American Indian. As per US funding agency reporting requirements, ethnicity data were collected separately from race, which accounts for numbers not totaling 178. Almost 20% of our participants were born outside of the United States, coming from countries in Africa, Asia, Europe, and the Americas. More than 60% of our sample were between the ages of 30 and 49 years, and 22% were between the ages of 18 and 29 years.

After their enrollment and participation in a baseline interview, participants were randomized using a 1:5 ratio into either the control arm or the full-participation arm of the study. The purpose of having 2 study arms was to determine whether the additional interviews and clinical trial data collection might unintentionally have an effect on the volunteers' perceptions, behaviors, or decisions about clinical trials during the study. The control arm (n = 33) involved interviews only at baseline and 3 years after enrollment, with no other data on trial participation collected throughout the study. The full-participation arm (n = 145) involved participating in 3 additional semistructured interviews on top of the baseline and 3-year interviews, as well as providing real-time information about their clinical trial participation. Clinical trial data were collected through the "clinical trial diary" (CTD), filled out by participants online or by a staff member over the phone.¹⁸ Ongoing participation in phase I clinical trials was not a requirement of our study; however, the full-participation arm of the study was required to fill out a CTD for every phase I study for which they screened. Most of these trials were those conducted by private companies on behalf of a pharmaceutical company. Our findings are based on interview data from participants in both the control and full-participation arms and the CTD data from participants in the full-participation arm.

Baseline interviews were conducted in person at the clinic at the time of enrollment. Subsequent follow-up phone interviews occurred at 6 months, 1 year, and 2 years for the full-participation arm, and with both arms at 3 years. At the time of this writing, we have concluded data collection but have not yet analyzed data from the 3-year interviews, so they are not included here. The interviews concentrated on participants' experiences participating in phase I trials, perceptions of the risks and benefits, assessments of different types of studies and/or procedures, and decision-making about trial enrollment. Interview questions did not focus on any particular therapeutic area because we were interested in the range of clinical trials in which healthy volunteers participate. Therefore, participants' thoughts about and experiences in HIV/AIDS studies were all unprompted. All interviews were transcribed in full, verified for accuracy, and coded using Dedoose qualitative software by 2 members of the study team. We use pseudonyms below to protect the confidentiality of our participants.

TABLE 1. Demographics of Study Participants (N = 178)

	n	%
Sex		
Female	47	26.4
Male	131	73.6
Age		
18–21	6	3.4
22–29	34	19.1
30–39	58	32.6
40–49	54	30.3
50+	26	14.6
Race/ethnicity		
Non-Hispanic white	57	32.0
Black	72	40.4
American Indian	2	1.1
Asian	6	3.4
Native Hawaiian or other Pacific Islander	2	1.1
More than one race	13	7.3
Hispanic	38	21.3
Foreign born	35	19.7
Clinical trial experience		
1 study	38	21.3
2–4 studies	49	27.5
5–10 studies	45	25.3
11–200 studies	46	25.8

RESULTS

Direct comparison of the actual risks of HIV/AIDS studies with other types of clinical trials is complex because phase I trials are conducted on all investigational drugs and have different scientific goals. From our interviews with US healthy volunteers, however, HIV/AIDS studies emerged as an exceptional type of clinical trial—along with studies of cancer and psychotropic drugs—that 38 participants (21%) directly referenced. Participants varied in their views of HIV/AIDS studies, but in general, they saw these phase I studies as particularly risky for reasons ranging from fear of catching the disease, to concern about long-lasting and uncomfortable side effects, or fears that they could not articulate. Some participants based their views on past experiences in such trials, but others cited staff and other participants as having shaped their beliefs about these studies.

Participants who were fearful of HIV/AIDS studies vacillated in their rationale. Some were concerned about actually contracting the disease itself or falsely testing positive for the disease after participating in a study. For example, Blake, a black man in his 30, asserted:

I've heard people talking about an AIDS [long pause] AIDS study—you know, where they take a—a small percentage of HIV or something like that, or like 0.01% and inject it in your body and see how a body [reacts]—but you could receive tens of thousands of dollars. I don't know if that's true. Some things I hear are a myth, but, you know, they say, they say it's a, it's-it's less than 1% of 1% of a chance that you can catch AIDS, or HIV or whatever, doing the study, you know. But I don't, I don't want to take a risk like that.

Blake had participated in about a dozen studies as a healthy volunteer over the course of 8 years, and his experience with AIDS studies was limited to what he had heard from other participants. Although he acknowledged that a risky study like this could be an urban legend, he nonetheless asserted that he would not take the risk of enrolling in HIV/AIDS trials for fear of catching the disease. Similarly, Ray, a black man in his 20s, also explicitly identified AIDS as an example of a “crazy” study that he would not participate in:

But depending on like what you're doing the study for, to me personally, I don't see like-, I mean, for Tylenol [acetaminophen], we didn't really have no long-term effect, you know, down the line, or yeah. So I think, you know, me personally, I just wouldn't do no crazy studies; as far as like AIDS medicine and all that crap, I'm cool.

Overall, Ray perceived clinical trials as generally risky and contrasted a common pain medication to “crazy,” higher risk studies such as those for AIDS medication. It should be noted that Tylenol was not being tested in any of the clinical trials in which our participants were enrolled, but they often made references to acetaminophen as a way of describing clinical

trials for pain or arthritis medications. We interpret this phenomenon as a mechanism for them to normalize the risks of certain clinical trials. Comparing Tylenol with AIDS medicine allowed Ray to make sense of the unknown harms of phase I testing. Anita, a Mexican immigrant in her 50s, also identified AIDS studies as particularly high risk: “There are, are, are [studies] for AIDS, or I think that those are more, more intense, more risky.” [Original Spanish: “*Hay, hay, hay del SIDA, o yo creo que esos son mas, mas fuertes, mas riesgosos.*”] Notably, the sources of these participants' views were not always clear. In the case of both Ray and Anita, each was enrolled in their first study when we interviewed them, suggesting that they had little personal experience or specific information on which to assess the differential risks of AIDS trials.

By contrast, 10 participants, 26% of those who discussed HIV/AIDS trials, expressed their willingness to participate in such studies or even believed they might gain direct, positive therapeutic benefits. For example, Travis, a black man in his 40s noted that he had participated in an AIDS study and dismissed any concerns about it. Comparing his experience with other types of studies that he perceived as riskier, he said

I actually run the other way from [some drug trials], especially when it says “investigational” [or] “schizophrenia.” Anything that has anything to do with them, I'm good [that is, I don't need to do them]. I've done some AIDS stuff. They make you go to the bathroom. You know, that's about it, to be honest with you.

In other words, Travis seemed to see both AIDS trials and the gastrointestinal adverse effects he experienced as fairly banal. His phrasing of “AIDS stuff” and “you know, that's about it” conveys a sense that AIDS studies have side effects that are inconvenient, but not necessarily dangerous or alarming. Having participated in more than 50 studies, Travis was more worried about the phase of development (“investigational” drugs by which he might mean first-in-human trials) and psychotropic medications.

More than minimizing the side effects, Esteban, a Mexican immigrant in his 30s, even emphasized the potential positive effects of participating in an AIDS drug trial:

I've done one study for AIDS; it was very well paid... It paid \$7000 and some change... It was a study that really inspired a lot of confidence because it strengthened your immune system. If it strengthens the immune system of a sick person, it's even more so for a healthy person. It's logical, just a little common sense. So I really liked that study. (Original Spanish: *He hecho un estudio para el SIDA, está muy bien pagado... pagaba 7.000 y cacho dólares... Era un estudio que daba mucha confianza porque te fortalecía el sistema inmune, si a una persona enferma le fortalece el sistema inmune, a una persona sana pues con más ganas. Por lógica, un poquito el sentido común, entonces ese estudio me gusto mucho.*)

Esteban interpreted the risks and benefits of the AIDS study in a unique way. He used his knowledge of AIDS as an immune system disorder and assumed that there would be a benefit to his own immune system by consuming the investigational drug. Esteban's work installing satellite television antenna, which is very physical, might have made him more inclined to perceive positive health benefits. But Travis and Esteban seem to be outliers because most participants who mentioned HIV/AIDS studies stressed that they were nervous or fearful of these types of studies and saw them as stronger medications with higher risks and longer lasting side effects. This might, in part, be related to their overall phase I trial experience. Both men had actual experience participating in HIV drug studies, and not only did neither feel harmed, but also Esteban believed himself to have benefitted personally from the drug.

Clinical trial experience level may also play a role in how participants view HIV/AIDS studies. Out of the 474 trials in which participants recalled the therapeutic purpose of the drug, five participants reported enrolling in HIV/AIDS trials during the first 2 years of our study. Their clinical trial experience at baseline ranged from 7 to 45 trials with an average of 27 clinical trials, and only 1 of these 5 participants had single-digit trial experience. By contrast, the 29 participants who expressed negative views of HIV/AIDS studies had a wider range of experience from 1 to 200 trials. More than half of these healthy volunteers had participated in fewer than 10 clinical trials, with 4 first-time participants in this group. At the same time, however, there was a disproportionate number of participants with 11 or more trials who also held negative views of HIV/AIDS studies. Even though these participants make up only 25% of our overall sample, they constitute almost half of those with negative views. The number of participants here is small, but these figures suggest that first-time participants along with those who are highly experienced may be more likely to view HIV/AIDS studies in a negative light compared to those with midlevel experience. Overall trial experience may have a curvilinear relationship to negative views. This is modified by personal experiences in HIV/AIDS studies, such as in the case of Travis, for whom not having been harmed in an HIV trial was more important than his overall trial experience.

In terms of the relationship between experience level and views of HIV/AIDS studies, Vanessa, a Columbian immigrant in her 50s who had participated in 3 trials at the time of her first interview, explicitly linked her reluctance to enroll in HIV studies to her lack of experience:

HIV and that, I won't do that. Or I've heard that the ones for schizophrenia or mental illness, I don't know. I've never done any of those, but they say that some of them have—I don't know. Some people say they have side effect; other people say that nothing happen [sic]. But still, I don't-, like I say, I'm not a pro at this. I just kind of started.

After noting that she had heard mixed information from other participants, she highlighted her phase I trial inexperience as the reason for her avoidance of such studies.

Vanessa's quote also illustrates that other participants can serve as a source of information about HIV/AIDS trials. Bruce, a white man in his 40s with experience in 20 trials, had also received information on side effects from other participants:

I remember the HIV drugs that were coming out at some point in the 90s or early 2000s. I think those offered a lot of side effects that were overwhelming to some people. And so, you know, I realized that, and because of that, I just didn't do them. I mean, I didn't wanna have all those kinda side effects. I mean, people would tell me they'd be sick throughout the entire study, and I'm like, "Well, geez, that doesn't sound like fun; that doesn't sound like a vacation; that doesn't sound like anything I wanna do."

In addition to information coming from other participants, 2 healthy volunteers noted they had become concerned about HIV/AIDS studies as a result of information they received from phase I clinic research staff. For example, Calvin, a black man in his 30s, recalled that a motherly staff member took him aside:

[She said,] "I don't want you doing, you know, anything with cancer or HIV; promise me." So, "Wow, okay." She was like, "Save your money, keep going to school, you know, but never do a cancer or an HIV medication drug." She was like, "I would not do too many [trials] at all anyway, but definitely don't do those 2." So my apprehension toward those always was and always will be.

Calvin began participating in trials in 1999 and reported participating in more than 100 clinical trials. Despite being quite experienced with clinical trials, however, he noted that he has avoided HIV studies because of the early warning he received from this staff member. Participants' relationships with research staff vary dramatically, but participants often spoke of trusting informal information that staff gave them about studies. Unlike the informed consent process, participants attributed staff's advice or insider knowledge to the rapport that develops over the course of the participant repeatedly returning to the same clinic.

Personal experience with long-lasting and uncomfortable side effects also corroborated participants' views. Steve, a white man in his 40s who was another experienced participant having enrolled in 70 trials, described HIV studies in particular as scary:

If the informed consent [form] looked a little too scary, I'll pass on it, unless I'm really desperate. Like for example, I won't do HIV studies anymore because I did one back in '99, and it was the only one—it was the worst side effects I ever had in a study—it was the only one where I got sick and vomited.

Because of his negative personal experience with that HIV study over a decade ago, Steve claimed he would avoid such studies in the future.

Some participants, however, did not cite staff, other participants, or personal experience as the basis for their

views of HIV/AIDS studies. Even with his experience participating in 16 trials, Leo, a black man in his 30s, lacked specific reasons for why he wanted to avoid AIDS studies:

Those are very, very—I don’t even know what word to use. Those are serious medications like that, that’s used for, you know, serious illnesses. So I would assume that if [there were] any side effects, the side effects would be serious. And that’s just the way my brain thinks... So, you know, the information that we have [about the studies] is basic information. And I’m sure, you know, it gets deeper. So I try to make sense of the information that I have and what makes, you know, whatever makes sense to me. I just try to follow my gut and just, you know, go about it in that form.

In such instances, without clear information to help weigh the risks of studies, it seems reasonable to follow instincts and gut reactions to the different types of illnesses being targeted by investigational drugs. The problem with this strategy, however, is that it is likely to rely on unspoken and possibly even unconscious negative associations and stigma related to pop-

ulations afflicted by different diseases. The HIV/AIDS epidemic was assumed in the 1980s and 1990s to affect only gay men and drug users, 2 populations already stigmatized as immoral among Christian conservatives in the United States.⁴⁷ Negative media portrayals of AIDS, especially those from the 1990s, might also play a part in shaping participants’ fears about HIV/AIDS studies.⁴⁸ For Leo, as with Ray and Anita above, there was an intangible feeling, regardless of the information provided about a clinical trial, that AIDS studies are riskier because the illness itself is such a serious one.

CONCLUSIONS

Overall, HIV/AIDS studies emerged from a subset of the interviews with healthy volunteers as examples of phase I trials with exceptional risk. The reasons for this exceptional risk included fears of catching the disease, attempts to avoid long-lasting and uncomfortable side effects, as well as inexplicable fears that were difficult to articulate. Some participants had past negative experience in such trials that informed these views, but others were influenced by information from staff and other participants. There were no differences based on sex or ethnicity in participants’ views of these risks. However, our data suggest that blacks and participants in their 40s are more likely to hold negative views of HIV trials than are whites and younger healthy volunteers. We are hesitant to interpret these differences for race and age because the unprompted nature of participants’ reflections on HIV trials means that we do not have data from nearly 80% of our total sample regarding their perceptions of HIV trials. In the first 2 years of our longitudinal study, 5 participants of the 145 in our full-participation arm (those who provided details on their trial participation) reported actually enrolling in an HIV or AIDS-related study during that time-frame. Of the 509 total clinical trials in which our participants enrolled, only 8 were HIV or AIDS studies (Table 2). This accounts for less than 2% of the studies participated in over a 2-year period. All these HIV/AIDS studies were sponsored by a pharmaceutical company and conducted in a clinic operated by that company or in a private, commercial research clinic. Although our participants also enrolled in studies at universities or government clinics, none of these studies were related to HIV.

While our data set illustrates a broad range of therapeutic areas in which healthy volunteers enroll in trials, it is unclear how many phase I HIV/AIDS trials were initiated by research facilities during the timeframe of our study or how many of our participants had the opportunity to participate in an HIV/AIDS trial. Based on the small number of our participants enrolling in HIV/AIDS trials, however, our data suggest—perhaps counterintuitively—that professional healthy volunteers are not the most likely to participate in these studies. Future research could investigate more systematically healthy volunteers’ perceptions of these studies by asking them directly about their views, sources of information, and opportunities for participating in HIV/AIDS trials. Our findings nonetheless suggest that fear concerning AIDS shapes the views of a subset of healthy volunteers who participate in phase I trials. As participation from healthy volunteers is critical to the development of HIV/AIDS drugs

TABLE 2. Number of Clinical Trials by Aggregate Illness (N = 509)

	n	%
Brain-related (includes Parkinson, Alzheimer, and psych drugs)	70	13.8
Pain	54	10.6
Cancer and cancer-related	35	6.9
Does not recall	35	6.9
Liver-related (includes hepatitis C)	34	6.7
Cardiovascular disease (includes hypertension and cholesterol)	34	6.7
Autoimmune diseases (includes multiple sclerosis)	34	6.7
Blood-related	31	6.1
Diabetes	28	5.5
Arthritis	27	5.3
Infectious disease (includes antibiotics)	21	4.1
Gastrointestinal-related	19	3.7
Kidney-related	13	2.6
Lung-related	9	1.8
Bone-related	8	1.6
HIV	8	1.6
Hormone-related	7	1.4
Sexual-related	7	1.4
Sleep-related	7	1.4
Addiction	5	1.0
Skin-related	5	1.0
Allergies	3	0.6
Antifungal	3	0.6
Immunosuppressant	3	0.6
Muscle-related	3	0.6
STI	3	0.6
Anesthetic	2	0.4
Pancreas-related	1	0.2

STI, sexually transmitted infection.

and vaccines, future research should continue to explore the complex motivations of this subpopulation.

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