

The Many Reasons Why People Do (and Would) Participate in Clinical Trials

This issue of *Harris Interactive Health Care News* focuses on public participation in clinical trials. It explores both the reasons why some people (10%) have participated in trials and the reasons which would encourage, or inhibit, many more people from participating. We hope this information will be useful to researchers designing new clinical trials in the future.

Most People Might Be Willing to Participate in Trials (Under the Right Circumstances)

While only 10% of the U.S. adult population has ever participated in a clinical trial, fully three-quarters (77%) say that if asked they would consider participating. As tables 2, 3 and 4 will show, that consideration might or might not translate into actual participation depending on many different factors.

It is noteworthy that those who have participated in clinical trials have increased slightly from 8% in 2001 to 10% this year, possibly reflecting acceleration in the number of clinical trials (but this small difference may just be a result of sampling errors.)

These are the results of a nationwide Harris Interactive study of more than 2,000 adults surveyed online with the same methods used to predict the 2000 U.S. elections with great accuracy. The fieldwork was conducted between May 28 and 30, 2003.

TABLE 1
Personal Involvement In Clinical Trial

Base: All Adults

	2001* %	2003 %
If asked would consider participating in clinical research study	83	77
Ever had the opportunity to participate in clinical research study	13	16
Had the opportunity and was willing to participate in a clinical research study	11	13
Actually participated in a clinical research study	8	10

Note: We used the words "clinical research study" rather than "clinical trial" because the word "trial" has sometimes inhibited participation.

*2001 data taken from the "Will & Why Survey" conducted online in June 2001 by Harris Interactive with nationwide sample of 5,348 adults, ages 18 and over.

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The Main Reasons Why People Have Participated

Perhaps, beyond all other reasons for participation, the most important may be “having the opportunity to do so.” Only 16% (Table 1 above) of adults believe they have ever had such an opportunity and most of those (10% of all adults, or 63% of those who had the opportunity) have participated. As the old political saying goes “you need to be asked.”

Beyond having the opportunity to participate, reasons which were mentioned by 40% or more of those who have participated were to **advance medicine** or medical knowledge (54%), **to help others** with the condition (46%), to **earn extra money** (42%), and **obtain better treatment** (40%).

Other reasons for participating mentioned by more than a quarter of participants were **education about treatment** (37%), **what they read or heard** about the study (36%), and the fact that **their doctors had recommended participation** (25%).

Only a few participants (5%) mentioned having a life threatening disease as a reason for their participation, but that does not mean (as Table 3 will show) that this is not a powerful motivating factor. It means that it was not a factor for most former participants (who responded).

These responses are not substantially different from those obtained in an earlier Harris Interactive study in 2001.

TABLE 2
Reasons For Participation

“Please indicate which of the following are reasons why you decided to participate in a clinical research study.”

Base: Have participated in clinical research study (10% of all adults; 214 people in this study)

	2001* %	2003 %
To advance medicine/science	55	54
To help others with the condition	47	46
To earn extra money	51	42
To obtain better treatment for your condition	56	40
Education about treatment/improving your health	33	37
Based on information read, seen or heard about the study	28	36
Doctor recommended the study	24	25
Curiosity about study/medical practice	29	23
To obtain free medication	25	24
Had a life-threatening illness	16	5

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The Many (Hypothetical) Reasons for Participation in Future Trials

Table 3 shows that many different factors are likely to encourage, or inhibit, participation in trials. The conditions which the largest number of people mention as being necessary for participation in future trials are **knowing all about the risks** (72%), believing that the trial **would benefit them or other people** (71%), if the treatment was free (66%) or if they were **paid** (63%).

Most people (60%) also said that “it would depend” and that they would need more information before deciding.

Other factors, which would influence the decision of large numbers of people, include: **convenience** (60%), having **minimal side effects** (59%), the belief that the **benefits outweigh the risks** (57%), and the **hope of a cure** (52%).

It is interesting to note that those who have actually participated in a clinical trial seem to place less emphasis on knowing all about the risk and minimal side effects than those who have not.

One very important conclusion, based on these data, is that there are **many factors which encourage or discourage participation and it would be a mistake to ignore any of them.**

While the number of people mentioning these factors is somewhat lower in this 2003 study than in our 2001 survey, the rank order of importance is very similar.

TABLE 3

Circumstances Under Which Would Be Willing To Participate

“Under what conditions would you consider participating in a clinical research study?”

Base: All Adults

	Total Population		Among Former Participants
	2001*	2003	
	%	%	%
If I knew all about the risks	77	72	58
If it would benefit me or someone else	82	71	73
If the treatment was free	70	66	55
If I got paid	56	63	62
I need more information/it would depend on what the study was for	56	60	54
If it was convenient for me to participate	53	60	65
If the side effects were minimal	55	59	47
If the risk was minimal or if the reward outweighs the risk	63	57	57
For a cure	57	52	55
If my doctor recommended it	57	49	42
If I had a terminal illness	53	48	39
If I knew there was no risk	48	46	50
If there were no other medical options available to me	45	39	29
For other conditions besides terminal illnesses	35	29	27
If I knew that I would get an active drug and not a sugar pill (placebo)	29	20	14

* 2001 data taken from the “Will & Why Survey” conducted online in June 2001 by Harris Interactive with nationwide sample of 5,348 adults, ages 18 and over.

“Participants’ Rights:” Other Factors Which Are Also Very Important

Large majorities of potential participants, and former participants, mention six important entitlements or rights for people who participate in trials. More than 70% of potential participants and 67% more of former participants think they are important.

These “rights” are:

- having access to their own test results at the end of the study (90% of potential participants);
- having their expenses paid (89%);
- receiving a copy of the clinical protocol (87%);
- being paid for their time (77%);
- being seen by a doctor on every visit (76%); and
- having access to their test results throughout the study (73%).

A 56% majority of potential participants, and somewhat fewer (44%, still a large number) of former participants also believe that participants should be able to talk with other participants.

Having access to test results throughout a study is not usually done because differential rates of attrition could bias the final results. The fact that even actual participants agree with the statement that they should have access to their results throughout the study suggests that this issue needs to be covered in the Informed Consent.

The biggest difference between potential and former participants is that many more (41%) of the former than of the latter (20%) think that recognition for participation is important.

TABLE 4

What Research Participants Should Have, Or Receive

“How strongly do you agree or disagree that a research subject who participates in a clinical trial should...?”

Base: All Adults

	Total Who Agree %	Former Participants Who Agree %
Have access to their individual test results at the end of the study	90	92
Get paid for their expenses	89	85
Get a copy of the clinical protocol	87	89
Get paid for their time	77	74
Be seen by the doctor at every visit	76	67
Have access to their individual test results throughout the study	73	72
Have the chance to talk to other research subjects	56	44
Receive recognition for their study participation (such as a certificate)	41	20

Methodology

This survey was conducted online within the United States between May 28 and 30, 2003 among a nationwide cross section of 2,023 adults, ages 18 and over. Figures for age, sex, race, education, income and number of adults in the household were weighted where necessary to bring them into line with their actual proportions in the population. "Propensity score" weighting was also used to adjust for respondents' propensity to be online.

In theory, with probability samples of this size, one could say with 95 percent certainty that the results have a statistical precision of plus or minus 3 percentage points (for the overall sample) and plus or minus 10 percentage points (for the sample of "former participants" of clinical studies) of what they would be if the entire adult population had been polled with complete accuracy. Unfortunately, there are several other possible sources of error in all polls or surveys that are probably more serious than theoretical calculations of sampling error. They include refusals to be interviewed (non-response), question wording and question order, and weighting. It is impossible to quantify the errors that may result from these factors. This online survey is not a probability sample.

These statements conform to the principles of disclosure of the National Council on Public Polls

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