

## Public Awareness of Clinical Trials Increases: New Survey Suggests Those Conducting Trials Are Doing A Better Job of Informing Potential Participants of Opportunities

- *Informed consent process works well for most participating patients*
- *Attitudes of most participants generally positive*

This issue of the Harris Interactive *Health Care News* is the latest in a series of reports on participation in clinical trials. The first two surveys conducted in 2001 and 2003 focused only on the public and participating patients. This year's study also includes a survey of physicians and measures their attitudes, perceptions and reasons for participating or not participating in trials. The findings on physicians are available in a separate issue of *Health Care News* (Volume 4, Issue 9, June 11, 2004).

The public survey is based on online interviews with a nationwide cross section of 5,822 adults of whom 656 had participated in at least one clinical trial. The survey was conducted between May 6 and 17, 2004.

### Opportunity and Participation in Clinical Trials

Awareness of clinical trials has grown over the last three years. This year's survey has seen an increase in the number of people who say they have had the opportunity to participate in clinical research study. In 2001, 13% said this was true for them. Last year this rose to 16%. In this year's study, it has risen again to 19%.

During these three years, the number of people who say they actually participated in a clinical trial has also grown very modestly, but the change is so small that it could be a result of sampling or measurement error. Those who claim to have participated in trials have increased from 8% in 2001, to 10% last year, and 11% in this year's study.

**TABLE 1**

#### Personal Involvement In Clinical Trials

Base: All Adults \*n=5,822

	2001 <sup>1</sup>	2003 <sup>2</sup>	*2004
	%	%	%
Ever had the opportunity to participate in clinical research study	13	16	19
Ever participated in a clinical research study	8	10	11

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

<sup>1</sup> 2001 data is from the "Will & Why Survey" conducted online in June 2001 by Harris Interactive with nationwide sample of 5,348 adults, aged 18 and over.

<sup>2</sup> 2003 data is from Harris Interactive *Health Care News*, Volume 3, Issue 10, June 16, 2003.

• EDITOR •

**Humphrey Taylor**  
Chairman of *The Harris Poll*®

## Reasons for Participation

Those who have participated in clinical trials give many different reasons for doing so and generally the responses have not varied greatly from year to year. The reasons for participation mentioned most often are to advance medicine or science, to earn extra money, to help others with the same medical condition and to obtain better treatment. Other factors which influenced a large number of people include the information that they read, saw or heard about the study; wanting to obtain education for the treatment of their disease or wanting to improve their health; and their curiosity about the study or medical practice.

While several of the numbers have moved both up and down since 2001, one consistent trend is an increase in the number of people who say they participated because of what they had read, seen or heard about the study. This increased from 28% of participants in 2001 to 36% last year and to 41% in 2004. This suggests that the people conducting clinical trials are effectively informing people of the potential opportunity to participate in clinical research.

**TABLE 2**

### Reasons For Participation

“Please indicate which of the following, if any, are reasons you decided to participate in a clinical.”

Base: Have participated in clinical research study \*n=656

	2001	2003	2004*
	%	%	%
To advance medicine/science	55	54	56
To earn extra money	51	42	50
To help others with the condition	47	46	45
To obtain better treatment for your condition	56	40	44
The information I read, saw, or had heard about the study influenced me.	28	36	41
To obtain education about treatment/improving my health	33	37	39
I was curious about the specifics of the study.	29	23	32
To obtain free medication	25	24	27
My doctor recommended the study.	24	25	21
Family/Friend recommended the study	NA	NA	13
I have a life-threatening illness.	16	5	7
There were no other treatment options were available.	NA	NA	7
There are no reasons in particular.	NA	NA	1
Other	NA	NA	11

Note: Multiple responses were allowed.

## Factors Which Would Influence More People to Participate

Those who would consider participating in clinical research studies in the future also give multiple reasons which would be very likely to influence them to participate. The answers given most often include:

- Having a terminal illness;
- If they thought they might receive a new drug that would cure them;
- If they knew there were no risks involved;
- If the treatment were free of charge;
- If there were no other medical options available.

A smaller majority also say they will be very likely to participate if:

- They received money for participating;
- Their doctor recommended it;
- They thought the drug or treatment would help someone else or themselves;
- It were convenient; and
- The locations were convenient.

A substantial number but less than 50% of participants who would consider participating also say that the following would be very likely to influence them:

- Knowing that they would receive an active drug and not placebo;
- Knowing the risks associated with the treatment;
- Having a condition other than the terminal illness; and
- If there were minimal side effects associated with the treatment.

**TABLE 3**

### Factors Very Likely To Influence Decision To Participate

"On a scale from 1-5, with 1 being "Not Likely" and 5 being "Very Likely," please rate the factors below on their likeliness to influence your decision to participate in a clinical research study."

Base: Would consider participating in clinical research study n=3,684

	Those Saying "Very Likely"
	%
If I had a terminal illness	72
If I thought the drug might cure me	71
If I knew there were no risks involved	67
If there were no other medical options available to me	67
If the treatment were free of charge to me	64
If I thought the drug/treatment would help someone else or me	57
If I received money for participating	56
If my doctor recommended it	54
If the location were convenient for me	54
If it were convenient for me	53
If I knew the risks associated with the treatment	49
If there were minimal side effects associated with the treatment	48
If I knew that I would receive an active drug and not a sugar pill (placebo)	37
If I had a condition other than a terminal illness	36

## Informed Consent Process

The overwhelming majority of people who have participated in clinical trials have very positive views of the informed consent process. Very large majorities agree that they understood that participation was voluntary; that they were signing up for clinical research study and that they fully understood what was expected of them. Substantial, if somewhat smaller, majorities also said that they knew they could stop participating in the study at any time; that they were made aware of the risks involved; that they understood that they could choose other treatment options, including no treatment; that they felt comfortable asking additional questions regarding the study; and that they felt secure that their confidentiality was protected.

Other indications that the informed consent process went well were:

- Almost everyone said that they purpose of the study was clear after they had read the informed consent document;
- Their questions regarding the informed consent were answered by the study team.

Most people found the informed consent process to be informative, easy to understand and useful. Only a very small minority of participants (6%) thought the informed consent process was confusing. This suggests that researchers are writing better informed consent documents than previously believed.

**TABLE 4**

### Informed Consent Process Views

“The following statements describe how well the process was explained to you when you agreed to be part of the clinical research study. Please indicate how strongly you agree or disagree with these statements by using the scale below.”

Base: Have participated in clinical research study n=656

	“Strongly Agree”
	%
I understood that participation was voluntary.	90
I understood that I was signing up to be in a clinical research study.	89
I fully understood what was required of me (number of visits, how long the study lasted, etc.).	81
I knew I could stop participating in the study at any time.	79
I felt comfortable asking additional questions regarding the study.	79
I was made aware of the risks involved in participating in the clinical research study.	74
I was made aware of the benefits involved in participating in the clinical research study.	74
I was assured confidentiality of any and/or all other personal information that I provided, with the exception of those allowed by federal law.	73
I felt secure that my confidentiality was protected throughout the study.	71
I understood that I could choose other treatment options, including no treatment at all.	66
The informed consent document was easy to read and understand.	60

**TABLE 5**

**Overview Of Informed Consent Process**

Base: Have participated in clinical research study n=656

	Percent of Participants
Purpose of the study was clear for most respondents after reading the informed consent.	86
Majority agreed questions were answered regarding the informed consent by the study team.	81
More than half read the informed consent by themselves.	58
Study coordinator conducted the informed consent process.	56
Almost half of the respondents were neither more nor less willing to participate after the informed consent form.	48
Majority found informed consent to be:	
Informative	72
Easy to understand	55
Useful	53
Beneficial	48
Smaller percentage thought informed consent was confusing.	6

**Influences and Experiences of Former Participants**

The survey included a number of other findings which show that participation in clinical research was a positive experience for most participants:

- Most participants said that their own preferences were the main influence in deciding to participate.
- Only a relatively small percentage had any second thoughts about participating in the study; and
- Most people say that their appointments were “not at all stressful.”

**TABLE 6**

**Sources Of Influence**

Base: Have participated in clinical research study n=656

	%
Majority did not have second thoughts about participating in the study once they learned more about it.	82
The majority described their appointments at the study site as “Not at all stressful”	80
Main influence in the decision to participate in a clinical research study: No one other than myself	60

## Public Perceptions of Pros and Cons of Participating in Clinical Trials

Very large majorities of the public believe that clinical trials make a contribution to science, that participants have a chance to get free medicine, that participants learn more about their medical condition and their health in general and that participants have access to medications and treatments not readily available to the public.

Smaller majorities also believe that:

- Participants have access to the best physicians;
- Participants receive the best possible treatment; and that
- Participants do not have to pay for their medical care.

However, about half of the public also believe that those who participate in clinical trials “are like guinea pigs” and that they are “taking a gamble with their health.”

**TABLE 7**  
**Greatest Perceived Risk Of Participating In Clinical Trial**

“Which of the following do you consider to be the *greatest* risk of participating in a clinical research study?”

Base: All Adults n=5,822

	%
Health risks	59
Unproven therapy	20
Receiving a placebo (sugar pill)	10
None, I do not believe there are any risks	6
Privacy concerns	3
Other	2

**TABLE 8**  
**Perceived Pros And Cons Of Clinical Trials**

"The following statements describe how some people feel about clinical research studies. Please indicate how strongly you agree or disagree with these statements by using the scale below. "People who participate in clinical research studies..."

Base: All Adults n=5,822

People who participate in clinical research studies:		1 Strongly Agree	2 Somewhat Agree	3 Neither Agree Nor Disagree	4 Somewhat Disagree	5 Strongly Disagree
Have access to the best physicians	%	17	34	39	8	2
Get the best possible treatment	%	18	33	39	8	1
Are like guinea pigs	%	14	37	26	15	8
Are making a contribution to science	%	52	37	9	1	1
Have a chance to get free medicine	%	26	43	24	5	2
Are taking a gamble with their health	%	11	40	31	13	4
Learn more about their condition and health in general	%	32	45	19	3	1
Do not have to pay for their medical care	%	26	32	31	7	4
Spend a lot of time at the doctor's office	%	8	27	47	14	4
Are part of an experiment to test medications/ treatments already available to the public	%	10	22	32	24	11
Are part of an experiment to test medications/ treatments not already available to the public	%	44	40	12	2	1

NOTE: Numbers may not add up to 100% due to rounding.

## How Do People Learn About Clinical Trials?

The public's main sources of information about clinical trials are the media and the Internet.

**TABLE 9**  
**Method Of Learning About Clinical Trials**

Base: All Adults n=5,822

	%
Majority understand what is meant by "clinical research study"	79
Media (TV, radio, newspaper, magazine) main source of receiving information*	44

\*Multiple responses

## Public Perceptions of Why Physicians Participate in Clinical Research

Most people believe that physician interest in finding new and better medical treatment is a very important reason why physicians participate in clinical trials.

Relatively few people think that any of the following are very important reasons for physicians to participate:

- Looking for fame and recognition;
- Getting scientific papers published; or
- Receiving money from drug companies.

**TABLE 10**  
**Perceptions Of Why Physicians Conduct Clinical Research**

"Please rate how important you think each of the following is to physicians conducting clinical research."

Base: All Adults n=5,822

	All Saying "Very Important"
	%
Finding new and better treatments	80
Receiving money from drug companies	29
Getting a scientific paper published	22
Bringing fame and recognition to the physician's medical center	17

## Methodology

The results published here rely on the general population data portion of the overall survey, methodology of which is explained below.

This survey was conducted online within the United States between May 6 and 17, 2004 among a nationwide cross section of 431 physicians and 5,822 adults (aged 18 and over). Results for the general population were weighted for age, education, gender, race/ethnicity and region where necessary to bring them into line with their actual proportions in the population. This sample was also propensity weighted to adjust for respondents' propensity to be online. Physicians' results were weighted to be representative of U.S. physicians involved in direct patient care on the basis of gender and years in practice.

In theory, with probability samples of this size, one could say with 95 percent certainty that the results have a sampling error of plus or minus 5.5 percentage points (for the physicians' sample) of what they would be if the entire U.S. population of these physicians had been polled with complete accuracy. The sampling error for the results from the overall general population sample is plus or minus 1.8 percentage points of what they would be if the entire U.S. 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 (nonresponse), question wording and question order, and weighting. It is impossible to quantify the errors that may result from these factors. These online samples were not probability samples.

Note: Sampling errors will vary depending upon bases used for individual questions.

## About Harris Interactive

**Harris Interactive** ([www.harrisinteractive.com](http://www.harrisinteractive.com)) is a worldwide market research and consulting firm best known for *The Harris Poll*<sup>®</sup>, and for pioneering the Internet method to conduct scientifically accurate market research. Headquartered in Rochester, New York, Harris Interactive combines proprietary methodologies and technology with expertise in predictive, custom and strategic research. The Company conducts international research from its U.S. offices and through wholly owned subsidiaries—London-based **HI Europe** ([www.hieurope.com](http://www.hieurope.com)), Paris-based **Novatris** and Tokyo-based **Harris Interactive Japan**—as well as through the Harris Interactive Global Network of independent market- and opinion-research firms. EOE M/F/D/V

To become a member of the Harris Poll Online<sup>SM</sup> and be invited to participate in future online surveys, visit [www.harrispollonline.com](http://www.harrispollonline.com).

For more information, please contact us at:

**877.919.4765**

or visit our website at

**[www.harrisinteractive.com](http://www.harrisinteractive.com)**

### Media inquiries, contact:

Bonnie Hughes 585.214.7541

[bhughes@harrisinteractive.com](mailto:bhughes@harrisinteractive.com)

Nancy Wong 585.214.7316

[nwong@harrisinteractive.com](mailto:nwong@harrisinteractive.com)

©2004, Harris Interactive Inc. All rights reserved.  
Other product and/or company names used herein  
are trademarks of their respective owners.