

## Most Physicians Do Not Participate in Clinical Trials Because of Lack of Opportunity, Time, Personnel Support and Resources

*13% of practicing physicians currently serve as clinical investigators; 53% have never conducted a clinical trial*

Currently about one in every eight (13%) physicians is a clinical investigator. Eighty-seven percent are not involved in conducting clinical trials: a third (34%) have participated in the past but are not currently involved, and half (53%) of the physicians have never conducted a clinical trial.

With the continuous increase in the number of clinical trials being conducted and the number of subjects required for each trial, the demand for clinical investigators is increasing. Aside from the lack of opportunity to participate as a clinical investigator, the reasons given most often for not acting as a clinical investigator are logistical: The time commitment involved (32%), a lack of personal support (30%), not having the resources to run a successful trial (26%), and the paperwork burden (24%). In addition, one in ten (11%) said they were interested in becoming an investigator but did not know where to begin. Only 17% said they had no interest in becoming a clinical investigator.

These are the results of a nationwide survey of 431 practicing physicians surveyed online by Harris Interactive between May 6 and 17, 2004.

**TABLE 1**  
**Physician Participation As Investigators In Clinical Research Studies**

"Have you ever been a Principal Investigator/Sub-Investigator for a clinical trial?"

Base: All Physicians n=431

|  | %         |
|--|-----------|
| <b>Status of physicians</b>  |           |
| No, I have <b>never been a Principal Investigator/Sub-Investigator</b> | <b>53</b> |
| Yes, I have been a Principal Investigator/Sub-Investigator in the past | 34        |
| Yes, I am currently a Principal Investigator/Sub-Investigator          | 13        |

u EDITOR u

**Humphrey Taylor**

Chairman of *The Harris Poll*®

**TABLE 2**

**Reasons For Not Participating In Trials**

“Which of the following, if any, are reasons you have not been or are no longer a Principal Investigator/Sub-Investigator?” Please select all that apply.

Base: Never a Principal Investigator/Sub-Investigator (PI/SI) or No Longer a (PS/SI) n-373

|   | %  |
|---|----|
| I have not had any (other) opportunities to act as a Principal Investigator/Sub-Investigator.       | 38 |
| The time commitment is too much.  | 32 |
| I do not have enough personnel support.   | 30 |
| I do not have the resources required to run a successful clinical trial.                            | 26 |
| The paperwork is too much of a burden.  | 24 |
| I am not interested in conducting clinical trials.  | 17 |
| I am interested in being Principal Investigator/Sub-Investigator, but I do not know where to begin. | 11 |
| My colleagues are not participating in clinical research.   | 11 |
| Rules and regulations are too stringent (i.e., not enough flexibility).                             | 9  |
| The costs of running clinical trials outweigh the benefits.   | 8  |
| The grant/contract amounts are insufficient.  | 8  |
| My patients have not expressed interest in participating in clinical trials.                        | 7  |
| My group does not meet the requirements of conducting a clinical trial.                             | 7  |
| I had a negative experience related to clinical research.   | 2  |
| I had a negative experience with a sponsor.   | 2  |
| I am not sure.  | 2  |
| I do not think research trials are ethical.   | 1  |
| Other   | 10 |

NOTE: Multiple responses allowed.

**Lack of Opportunity Biggest Factor Inhibiting Physician Involvement in Clinical Trials**

If the opportunity is not there (or known), clinical investigators will not be there. Sponsors need to inform the general population about clinical research opportunities in order to attract potential subjects, as well as inform the medical profession. Our results indicate that a variety of factors influence physicians to participate in clinical trials, altruism one of them.

**Large majorities** of our sample of current clinical investigators say they are influenced by the opportunity to help advance science and to benefit their patients. As one physician put it, “Better patient care, better outcomes, better quality of life.”

**Smaller majorities** say they are influenced by the prospect of being viewed as a thought leader, or by the fact that they have the necessary support staff, patients asking for experimental drugs, and the monetary compensation.

A small minority of physicians mentioned personal recognition, business opportunities or institutional requirements as having influenced their decision to be a clinical investigator.

Sponsors should learn from physicians’ desire to better science and create a campaign around this need. Furthermore, they should utilize the preferred method of contact, email (50%) followed by postal mail (26%).

**Retention is essential to the success of clinical research**

Physicians find time, support, resources and paperwork as barriers to their involvement. Making participation less burdensome will help retain clinical investigators.

**TABLE 3**

**Factors That Influence Physician Participation In Clinical Trials**

“Which of the following are factors that influence you or would influence you to be an investigator in a clinical trial?” Please select all that apply.

Base: current Principal Investigator/Sub-investigator (PS/SI) n=58

|  | %  |
|--|----|
| The opportunity to help advance the science  | 92 |
| The benefit of the patients  | 80 |
| The prospect of being viewed as a thought leader in my community and/or being viewed as a thought leader by my peers | 60 |
| Sufficient staff to support clinical trials  | 57 |
| Patient requests for better access to drugs that are not currently approved  | 55 |
| Monetary compensation  | 53 |
| Achievement of personal recognition in clinical trials   | 31 |
| The prospect of a strong business opportunity  | 24 |
| Institutional requirements   | 22 |
| Other  | 4  |

NOTE: Multiple responses allowed.

**Among Current Clinical Investigators, Most Devote Less Than 10% of Their Practice to Clinical Research**

**Large majorities** of these clinical investigators:

- Have worked with multiple sponsors (2-5) in the past three years (83%);
- Have a study coordinator who has received medical training (83%);
- Have staff that received training in Good Clinical Practice (76%);
- Did not have a recruitment specialist on site (77%).

**Small majorities** of these clinical investigators:

- Had devoted less than 10% of their practice time to clinical trials (62%);
- Had personally conducted one to three (i.e., fewer than four) trials in the past three years (56%);
- Believed that working on fewer than four clinical trials was the “ideal number” of clinical trials they would be willing to conduct at any given time (65%).

A significant minority (22%) of this sample would be willing to conduct between four and six trials at any given time.

Because of the low incidence of serving as a clinical investigator (i.e., 13% of practicing physicians), this survey included a small sample (58) of physicians currently involved in conducting clinical trials. As a result, data from this small sample should be treated with some caution. However, some general patterns can be observed and provide direction.

**TABLE 4**  
**Background Information On Participating Physicians**

Base: current PI/SI n=58

|  | %  |
|--|----|
| 1-10% of practice is devoted to clinical trials  | 62 |
| 11-25% of practice is devoted to clinical trials   | 30 |
| Worked with multiple sponsors (2-5) in the past 3 years  | 73 |
| Personally conducted 1-3 clinical trials in the past 3 years   | 56 |
| If given a choice, the ideal number of clinical trials PI/SI are willing to conduct at any given time (*top 2 boxes noted) |    |
| 1 to 3 clinical trials   | 65 |
| 4 to 6 clinical trials   | 22 |
| Has a study coordinator who has received medical training  | 83 |
| Staff that has been trained in Good Clinical Practices   | 76 |
| Reporting no recruitment specialist on site  | 77 |

### Patient Recruitment

A large majority of physicians (74%) indicated protocol requirements are the most common factor impairing their ability to enroll subjects. Consequently, the primary factor in deciding whether or not to accept a clinical trial is the specific study requirements (37%) followed by the feasibility of identifying the patients in the population (32%). Thirty-eight percent believe an inadequate amount of subject recruitment support was provided by the sponsor, yet even more (41%) have no preference as to which method of recruitment is used. Furthermore, 26% did not know if the sponsor provided funding for the creation and design of recruitment materials.

Not surprisingly, 74% use their own patient database as their primary resource for subject recruitment. Flyers (55%) and newspaper ads (39%) followed in popularity as recruitment methods. However, if given a choice beyond their practice database, physicians prefer newspaper ads (21%), Web-based recruitment (8%), or a patient-recruiter (8%). No one supported direct mail or banner ads.

**TABLE 5**  
**Resources/Methods For patient Recruitment**

Base: current PI/SI n=58

|  | %  |
|--|----|
| Which of the following patient recruitment resources has your site utilized? |    |
| Practice database  | 74 |
| Flyers   | 55 |
| Ads in newspapers  | 39 |
| How do you generally learn about new clinical trials?                        |    |
| Sponsors/CROs  | 75 |
| Colleagues/Peers   | 51 |
| Email distribution   | 25 |

NOTE: Multiple responses allowed. Top 3 responses for each question noted above.

## Conducting the Informed Consent Process

The informed consent process is generally conducted by the principal investigator (71%), followed by the study coordinator (63%). Forty-percent of PI/SIs indicated the subject is provided the informed consent to read on his/her own while only 20% read the informed consent to the patient and 20% provide the form to the subject while the study coordinator is present. Very few physicians (1%) use video technology to administer the informed consent; however 54% said they would be willing to use video.

On average, 42% of the physicians take 16 to 30 minutes to obtain informed consent at their site. Ninety-four percent of the sites provide the subject with a signed copy of the informed consent.

**TABLE 6**

### Informed Consent Process

Base: Current PI/SI n=58

|  | %  |
|--|----|
| Informed consent given to potential subjects to read on their own      | 40 |
| On average, the length of consent process is 16 to 30 minutes          | 42 |
| <b>Administers the informed consent for clinical trials conducted*</b> |    |
| PI's   | 71 |
| Study Coordinator  | 63 |
| Sub-Investigator   | 37 |

Note: \* Multiple responses allowed, top 3 responses for each question noted above.

## Attitudes and Perceptions of Participating Physicians

The next set of questions measured participating physicians' attitudes and perceptions on some important issues.

**Large majorities** of these investigators:

- Did **not** believe that "it is coercive" for physicians to recruit their own patients;
- Believed that physicians need to be careful about appearing to be coercive when recruiting their own patients.

On four other issues, among current principal investigators/sub-investigators, opinions were divided. There is clearly **no consensus** as to:

- Whether sponsors should be liable for inadequate conduct of the informed consent;
- Whether principal investigators are paid fairly for their services;
- Whether subjects in clinical trials receive better treatment; and
- Whether investigators' financial interests sometimes create a conflict of interest with the patients' best interest.

**TABLE 7**

**Views/Opinions Of Current Participating Physicians**

“Please indicate how strongly you agree or disagree with these statements by using the scale below.”

Base: Current PI/SI n=58

|  | 1<br>Strongly<br>Agree | 2<br>Somewhat<br>Agree | 3<br>Neither<br>Agree/Disagree | 4<br>Somewhat<br>Disagree | 5<br>Strongly<br>Disagree |
|--|------------------------|------------------------|--------------------------------|---------------------------|---------------------------|
| The sponsor should be liable for inadequate conduct of the informed consent since they ultimately benefit from the research.   | 15%                    | 25%                    | 20%                            | 23%                       | 16%                       |
| It is coercive for physicians to recruit their own patients for a clinical study because they have an established relationship with them.  | 5%                     | 14%                    | 13%                            | 41%                       | 27%                       |
| Principal Investigators are paid fair market value for their services.   | 7%                     | 33%                    | 24%                            | 27%                       | 10%                       |
| Subjects who are in clinical trials receive better treatment.  | 14%                    | 32%                    | 30%                            | 13%                       | 11%                       |
| At times, there is a conflict of interest between the patient’s best interest to participate in a clinical research study and the financial interest of the Principal Investigator/Sub-Investigator. | 14%                    | 30%                    | 10%                            | 27%                       | 20%                       |
| Physicians have to be careful about appearing to be coercive when recruiting patients from their own practice.   | 51%                    | 31%                    | 17%                            | -                         | 1%                        |

Note: Percentages may not add up to 100% due to rounding.

## Investigator – Institutional Review Board (IRB) Relations

The survey provides new information on the relationship between participating investigators and IRBs.

In our small sample:

- They are divided more or less equally between those who work with central IRBs (52%) versus local IRBs (48%).
- Just over half (55%) are involved in the IRB-approval process.
- The IRB-approval process usually takes two months or less, but in some cases it takes longer.
- About half (46%) believe the IRB-approval process takes longer than it should to approve research protocols.
- Most (64%) feel the IRB rules and regulations are appropriate.

**TABLE 8**  
**Physician Views On IRB Relations**

Base: Current PI/SI n=58

|  | %  |
|--|----|
| <b>IRB type used:</b>  |    |
| Central  | 52 |
| Local  | 48 |
| PI/SIs involved in IRB-approval process  | 55 |
| <b>Length of IRB-approval process:</b>   |    |
| Less than one month*   | 32 |
| One month  | 35 |
| Two months   | 21 |
| Three months or more   | 11 |
| Think IRB-approval process takes longer than it should to approve research protocols | 46 |
| Think IRB rules and regulations are appropriate                                      | 64 |

\*(Includes percentages for "less than one week," "1-2 weeks," "3-less than 4 weeks")

## Future Participation as an Investigator for Clinical Trials

Despite the small percentage of physicians currently participating in a clinical trial, almost all current participants (99%) plan to conduct more clinical trials in the future. It is clear that clinical investigators are intrigued by the opportunity "to advance the field of medicine and offer high quality care to patients."

## Methodology

The results published here rely on the physician 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.