The Will & Why Survey: Examining America's Motivation to Participate in Clinical Studies

More and more Americans are considering clinical research studies as treatment options and they want more education about the federal and international measures designed to protect them. These revealing results come from more than 5,000 men and women of all ages who responded to "The Will & Why Survey," a Harris Interactive/BBK Healthcare Poll examining America's motivations to participate in clinical research studies. This nationwide online survey shows that while 83 percent of respondents would consider a clinical research study, only 13 percent have had the opportunity to take part in one. This is a key finding since there is a serious shortage of research study participants in the United States. Of the 50 million eligible patients, only 5 to 6 million enroll annually. At present, close to 80 percent of studies fail to recruit the required number of patients on time. Below are additional highlights of the survey results.

Survey Methodology

- *"The Will & Why Survey" was conducted via the Internet within the United States between June 5 and June 8, 2001.*
- *The total number of survey respondents was 5,348 (2,523 men; 2,825 women).*
- *Figures for age, sex, race, education and other variables were weighted where necessary in order to bring them into line with their actual proportions in the population.*

Public Perceptions and Attitudes

- *The most frequently mentioned influence on considering research participation was "If it would benefit me or someone else" (58 percent). "If I knew all about the risks" was second (48 percent); "If the risk was minimal or if the reward outweighs the risk" was third (35.3 percent); "For a cure" was fourth (35.2 percent); and "If my doctor recommended it" was fifth (34.5 percent).*
- *The vast majority of respondents (82 percent) who had participated in a clinical research study said they would participate again.*
- *When asked how they felt about clinical research studies, 89 percent of respondents said they felt it was "making a contribution to science," 87 percent said they felt it was "a chance to learn more about their condition," and 86 percent felt participants "are part of an experiment to test new medicines."*

Patient Protection Measures

- *Eighty-one percent of respondents said they were not familiar with federal and international measures to protect people who participate in clinical research studies.*
- *Sixty-six percent of respondents felt that if people were aware of measures to protect research participants, they would be more willing to participate in clinical research studies, 25 percent were not sure, and 9 percent said people would not be more willing.*
- *Eighty-five percent of respondents felt that people would benefit from more education about clinical research studies, their risks and benefits, and the protections available for research participants, 12 percent were not sure, and 3 percent saw no benefit.*

Advertising and Patient Information

- *Seventy-one percent of respondents reported having read, seen or heard an advertisement about a clinical research study.*
- *When asked where they had read, seen or heard an advertisement, 66 percent of respondents said newspaper, 43 percent said radio, 35 percent said television, 18 percent said magazine, and 13 percent said the Internet.*
- *One third of respondents reported they had read, seen, or heard information regarding clinical research studies (e.g., postcards in mail, brochures, posters, etc.).*
- *Eighteen percent of respondents said they had taken an action as a result of reading, seeing or hearing an advertisement or information on a clinical research study. Of those respondents, 58 percent called a toll-free number, 32 percent scheduled an appointment,*

- *26 percent spoke to family/friends, and 24 percent looked for information on the Internet.*
- *Nearly 30 percent of respondents reported that the advertisements or information they had been exposed to was helpful or educational.*

News Coverage

- *Fifty-two percent of respondents had read, seen or heard a news story related to a clinical research study. Of these respondents, 64 percent had seen the news story on television, 48 percent had read about it in the newspaper, 31 percent had read about it in a magazine, 24 percent had heard it on the radio, and 17 percent had read it on the Internet.*
- *When asked if the media portrays both sides of news stories regarding clinical research studies equally, predominately positive or predominately negative, 33 percent of respondents thought it was portrayed equally, 28 percent said predominately positive, 28 percent were not sure, and 11 percent thought it was predominately negative.*
- *Seventy-seven percent of respondents that had read, seen or heard a news story regarding a clinical research study said their impressions of a clinical research study had remained the same, 20 percent said their impressions improved, and 3 percent said their impressions were worse.*

Doctor's Influence

- *Only 6 percent of all respondents reported that their doctors recommended research study participation.*
- *In two previous Harris Polls, 90 percent of respondents said that they would consider participating in a clinical research study if their doctors recommended it. However, of the total number of respondents to "The Will & Why Survey" who had participated in a clinical research study (451 people), 36 percent reported that their doctors had recommended participation.*
- *Fifty-seven percent of respondents who had spoken to their doctors about a clinical research study reported that their doctors "provided useful information and guidance."*

The results of "The Will & Why Survey" reveal that most patients who have the opportunity to participate in clinical research studies will do so. This presents a clear call to action for the clinical research industry. The challenge: raising awareness and understanding of clinical research studies through education of the public. It may well be time to commit energy and resources toward achieving this goal.

The Will & Why Survey: Patient Protection Fact Sheet

Outlined below are examples of federal and international measures designed to protect the rights and welfare of individuals who participate in clinical research studies.

The Nuremberg Code

- *The Nuremberg Code was created in 1947 as a standard for judging physicians and scientists who had conducted medical experiments on concentration camp prisoners during the Second World War.*
- *The Code became the model for many later codes that were developed to ensure that research involving human subjects would be carried out in an ethical manner.*
- *The Code consists of ten principles that guide investigators in their work, including: informed consent must be obtained from study participants without coercion; experiments should be conducted as to avoid all unnecessary physical and mental suffering and injury; experiments should yield results for the good of society, unobtainable by any other means or method.*

Institutional Review Board

- *Institutional review boards (IRBs) are independent boards formed to safeguard the rights, safety and well-being of study participants.*
- *IRBs must review and approve the study protocol and amendments, informed consent forms, recruitment methods (e.g., advertisements), and all written information provided to participants.*
- *IRBs must approve, require modification or reject all research activities.*
- *IRBs continuously monitor all aspects of a clinical research study and all adverse events must be reported to them.*
- *IRBs must consider the risks to participants, the benefits, and the importance of the knowledge that may be gained.*

The Declaration of Helsinki

- *Adopted by the 18th World Medical Assembly in 1964, the Declaration serves as an ethical guide for physicians conducting biomedical research that involves human subjects.*
- *Selected principles reflect the importance of the risk/benefit assessment and informed consent, as outlined below:*
  - *A patient's interest always prevails over science in a clinical research study. Before a study begins, predictable risks in comparison with foreseeable benefits to the patient or to others must be carefully evaluated.*
  - *In any clinical research study, each potential patient must be adequately informed of the goals, methods, anticipated benefits, and potential hazards of the study and the discomfort it may involve. Patients should be informed that they can withdraw their consent and participation at any time. A research physician should obtain a patient's freely-given informed consent, preferably in writing.*
  - *The Declaration has undergone five revisions over the years to keep it aligned with modern ethical theory and research practices.*

Informed Consent

- *During the informed consent process, individuals must voluntarily confirm their willingness to participate in the research study after having been informed of the study procedures, duration of subject involvement, potential risks and benefits, alternative procedures, and confidentiality of records statement.*
- *Consent must be informed, understood and voluntary.*

Good Clinical Practice

- *A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical research studies. Good Clinical Practice (GCP) provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of study subjects are protected.*

Common Rule

- *In 1991, 17 federal departments and agencies adopted the Common Rule, a set of regulations that govern human subject research sponsored by the federal government.*
- *The Common Rule has established three main protective mechanisms: review of research by an institutional review board, informed consent of subjects, and institutional assurances of compliance.*

The Belmont Report

- *Following the signing of the National Research Act in 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavior Research was formed.*
- *The National Commission published the Belmont Report in 1979, a statement of three basic ethical principles considered relevant to research involving human subjects.*
- *According to The Belmont Report and "The Ethical Foundations of Clinical Trials" [Applied Clinical Trials, April 2001], the principles include respect for persons, beneficence and justice.*

Respect for Persons: Before participating in a clinical research study, every patient must give voluntary informed consent. Additional protections must be provided to vulnerable patients. Before enrolling in a clinical research study, patients must be informed that they may withdraw from the study at any time. The clinical research study must be approved by independent review and the reviewer(s) must have the authority and power to stop the study and/or intervene on behalf of patients.

Beneficence: A clinical research study must have value and be well designed and use a scientifically rigorous methodology appropriate to the study topic. Qualified research investigators must conduct the study. There must be a favorable risk/benefit ratio regarding the therapy being studied, and risks to which subjects will be exposed must be justified and minimized.

Justice: The patient recruitment process must be driven by suitability and equity of access, not privilege or vulnerability. Clinical research studies should make treatment as widely available as appropriate given regulatory requirements and the need for scientifically rigorous study designs, with the understanding that there are limited resources available.

Patients' Bill of Rights

- *On June 29, 2001, the United States Senate passed legislation guaranteeing patients a number of new rights under their managed care health plans. By a 59–36 vote, lawmakers agreed to a bill that included expanded powers for patients to sue their health plans in federal and state courts. The Senate bill was sponsored by John McCain (R-Ariz.), Edward Kennedy (D-Mass.), and John Edwards (D-N.C.) and won the support of all 50 Democrats and nine Republicans.*
- *The Bill passed by the Senate grants ill patients access to clinical research studies as long as they have tried all available treatments without success.*
- *The Bill is set to go on to the House of Representatives for consideration.*

European Patient Recruitment Guidelines

- *Clinical research studies in Europe are ruled by two types of legal frameworks: laws established by the European Commission and laws of individual European Union member countries.*
- *The European Agency for the Evaluation of Medicinal Products (EMEA) – established in 1995 to coordinate the scientific evaluation of the safety, efficacy and quality of medical products in Europe – published the document "Note for Guidance on Good Clinical Practice." This paper follows efforts by the International Conference on Harmonization to standardize specifications of clinical research studies in Europe, North America and Japan in order to allow for mutual recognition of study results.*
- *The EMEA document addresses the following topics among others: Institutional Review Board/ Independent Ethics Committee; Informed Consent of Study Patients; and Confidentiality of Records and Reports.*

The information referenced in this fact sheet comes from The Nuremberg Code, The Declaration of Helsinki and The Belmont Report.