Alliance for human research protection

Jatinder Singh

Section Editor, JPP

http://www.ahrp.org

Access this article online	
Quick Response Code:	Website: www.jpharmacol.com
	DOI: 10.4103/0976-500X.83299

Primum non nocere – first, do no harm. The axiom has been central to the ethical practice of medicine and clinical research, and also serves as a compelling reminder that every therapeutic decision possesses the inherent potential for inflicting harm.

The last 50 years have witnessed rapid advances in drug discovery. These advances have opened up new vistas for

Address for correspondence:
Jatinder Singh, Department of Pharmacology, Government Medical College, Amritsar 143001, Punjab, India. E-mail: singh.jatinder@gmail.com

research scientists, clinicians and academic institutions for collaboration with profit-making industries, leading to commercialization of science on an unprecedented scale. This new-found alliance has also led to conflicts of interest that may cloud the judgment of professionals, the credibility of research institutions and scientific journals and affect the safety and transparency of clinical trials.

A hundred years ago, there were no regulations regarding ethical issues in clinical research. A landmark chapter in the history of research with human subjects was the framing of the Nuremberg code in 1948, which stated that, "the voluntary consent of the human subject is absolutely essential" thus clarifying that the need for obtaining consent from voluntary participants in research. In 1964, the Declaration of Helsinki was framed. These were the first formal guidelines that governed international research ethics and the need for "research combined with clinical care." The present Good Clinical Practice (GCP) guidelines have evolved from the revisions to the Declaration over a period of five decades. Adverse publicity and public opinion stemming out of the infamous Tuskegee Syphilis Study (1932–1972) highlighted the need to develop guidelines that inculcated basic ethical principles in order to carry out biomedical and behavioural research involving human subjects. The Belmont Report (1979) based on the three principles of respect for persons, beneficence and justice was an offshoot of this need.

The Alliance for Human Research Protection (AHRP) is the brainchild of Vera Sharav. She became a crusader for protection of human subjects involved in research after a personal tragedy involving the death of her teenaged son because of clozapine-induced neuroleptic syndrome. Her work is based on the rather extreme belief that biomedical research is a profit-driven corporate venture based on the sordid principle of tricking people into participating in clinical trials under the guise of medical treatment. The organisation serves as "an information resource, a public interest watchdog, and a catalyst for public debate whose goal is to unlock the walls of secrecy in biomedical research and to bring accountability to that endeavour."

The website of AHRP – http://www.ahrp.org, serves to highlight the activities and achievements of this non-profit organization.

The board of directors includes physicians and laypersons committed to fulfilling the basic objectives of "advancing responsible and ethical medical research practices, minimizing the risks associated with such endeavours and to ensuring that the human rights, dignity and welfare of human subjects are protected."

The website has a simple interface with easily navigable links. The News Section includes various sub-sections dealing with issues involved in human research. Clinical Trials includes Informed Consent, Risks, Institutional Review Board (IRB), Placebo Effect and Vulnerable Groups. The section on Informed Consent has a comprehensive document that deals with the volunteer's perspective and goes on to educate on the questions to be asked from the investigator when enrolling in clinical trials. Vulnerable groups covered in the section include children and participants from developing countries. The recent controversy about the ill-planned HPV Vaccine Trial in certain states in India and the resultant deaths of young girls has been reported in this section. The Research Integrity section deals with issues like bias, fraud, academic freedom and publications. The section highlights the way in which the pharmaceutical industry manipulates scientists and publishers to distort findings so as to favour their marketability.

Tricky subjects like conflict of interest and corrupt practices are dealt with by inclusion of case studies that have been highlighted in the press. Safety issues with various marketed drugs, vaccines and devices are regularly updated, as are the concerns as regards the inclusion of children as subjects in clinical trials and the associated harm that they incur. An archive of all the content is available by an efficient search link.

AHRP has also deposed in various cases related to human research and related issues. These interesting and thought-provoking testimonies and presentations are available on a separate link on the main page.

The overall accent of the website is on creating awareness about research involving human subjects; it succeeds in doing so by the easy-to-read and factual links. The usefulness of the website would be magnified if it were to include short presentations on the diverse topics that are pivotal in human clinical research.

The website is a must visit for clinical researchers as well as human volunteers in order to gain an insight into all ethical and related issues pertaining to clinical research involving human subjects.

How to cite this article: Singh J. Alliance for human research protection. J Pharmacol Pharmacother 2011;2:212-3.
Source of Support: Nil, **Conflict of Interest:** None declared.