

Type of report	Number of respondents	Hours per response	Total burden hours
Total	694	18,064

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this Notice.

Dated: September 5, 1997.

Jane Harrison,

Acting Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Consensus Development Conference on Acupuncture

Notice is hereby given of the NIH Consensus Development Conference on "Acupuncture," which will be held November 3-5, 1997, in the Natcher Conference Center of the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. The conference begins at 8:30 a.m. on November 3, at 8 a.m. on November 4, and at 9 a.m. on November 5.

Acupuncture and moxibustion are the two best known aspects of traditional Chinese medicine (TCM) in the U.S. and are used by many Americans. Acupuncture is a family of procedures involving penetration of specific superficial anatomic locations on the skin called acupuncture points with thin, solid, generally metallic, needles. Closely related to and often practices with acupuncture is moxibustion, the local and focused application of heat to acupuncture points using a compressed, powdered combustible substance (moxa), which is burned at or near the points to be stimulated.

There are a variety of approaches to functional diagnosis and treatment in American acupuncture that incorporate medical traditions from China, Japan, Korea, France, and other countries. Because an acupuncture treatment involves a procedure rather than a drug, it has been very difficult to study using the gold standard of randomized double-blind trials. Nevertheless, acupuncture is used by millions of American patients and performed by thousands of physicians, dentists, masters-degree level acupuncturists,

and other practitioners for relief or prevention of pain and a variety of health problems. The FDA, after years of deliberation, recently removed acupuncture needles from the category of "experimental medical devices" and now regulates them just as it does other devices such as surgical scalpels and hypodermic syringes, under good manufacturing practices and single-use standards of sterility.

Over the years, NIH has funded a variety of research studies on acupuncture, including studies on the mechanisms by which acupuncture may have its effects as well as clinical trials and other studies. There is also a considerable body of international literature on the risks and benefits of acupuncture, and the World Health Organization (WHO) has listed a variety of medical conditions that may benefit from the use of acupuncture and/or moxibustion. Such applications may include prevention and treatment of nausea and vomiting; treatment of pain and addictions to alcohol, tobacco, and other drugs; prevention of pulmonary problems such as asthma and bronchitis and rehabilitation from neurological damage such as stroke.

To address the most important issues regarding the American use of acupuncture, the NIH has organized this 2½ day conference to evaluate the scientific and medical data on the uses, risks, and benefits of acupuncture procedures for a variety of conditions. The conference will bring together national and international experts in the fields of acupuncture, pain, psychology, psychiatry, physical medicine and rehabilitation, drug abuse, pulmonology, health policy, epidemiology, statistics, physiology, and biophysics as well as representatives from the public.

After 1½ days of presentations and audience discussion, an independent, non-Federal consensus panel chaired by Dr. David Ramsay, president of the University of Maryland Medical Center, will weigh the scientific evidence and write a draft statement that it will present to the audience on the third day. The consensus statement will address the following key questions:

* What is the efficacy of acupuncture, compared with placebo or sham acupuncture, in the conditions for which sufficient data are available to evaluate?

* What is the place of acupuncture in the treatment of various conditions (for which sufficient data are available), in comparison with or in combination with other interventions (including no intervention)?

* What is known about the biological effects of acupuncture that helps us understand how it works?

* What issues need to be addressed so that acupuncture may be appropriately incorporated into today's health care system?

* What are the directions for future research?

The primary sponsors of this meeting are the NIH Office of Alternative Medicine and the NIH Office of Medical Applications of Research. The conference is cosponsored by the National Cancer Institute, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, the National Institute on Drug Abuse, and the NIH Office of Research on Women's Health.

Advance information on the conference program and conference registration materials may be obtained from Prospect Associates, 1801 Rockville Pike, Suite 500, Rockville, Maryland 20852, (301) 468-MEET, by e-mail at NIHconsensus@ProspectAssoc.com, or by visiting <http://consensus.nih.gov> on the World Wide Web.

The consensus statement will be submitted for publication in professional journals and other publications. In addition, the statement will be available beginning November 5, 1997, from the NIH Consensus Program Information Center, P.O. Box 2577, Kensington, Maryland 20891, phone 1-888-NIH-CONSENSUS (1-888-644-2667) and from the NIH Consensus Development Program site on the World Wide Web at <http://consensus.nih.gov>.

Dated: September 3, 1997.

Ruth L. Kirschstein,

Deputy Director, NIH.

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