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FOR IMMEDIATE RELEASE – May 3, 2004

CEDARS-SINAI MEDICAL CENTER RECEIVES FULL AAHRPP ACCREDITATION FOR ALL RESEARCH INVOLVING HUMAN SUBJECTS

LOS ANGELES, May 3, 2004 – Cedars-Sinai Medical Center announces that it has been fully accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), for all research involving the protection of patients. Cedars-Sinai is the only Medical Center in the state of California to be accredited by AAHRPP, a Washington, D.C., based non-profit organization that uses a voluntary, peer-driven, educational model to accredit institutions engaged in research involving human subjects.

Good for three years, accreditation was received after a 10-month process requiring Cedars-Sinai to conduct a rigorous self-assessment and to participate in an AAHRPP on-site evaluation. During this process, all of the Medical Center's policies, practices, staffing expertise, and resources related to the protection of the rights and welfare of research participants were examined.

“Being accredited reflects our commitment to protecting patients involved in clinical research at Cedars-Sinai,” said Shlomo Melmed, M.D., Senior Vice President of Academic Affairs and the Director of the Burns and Allen Research Institute at Cedars-Sinai. “This is a responsibility that the Medical Center and its Institutional Review Board takes very seriously and we undertook it because it was the right thing for us to do to ensure that the quality and continued improvement of on-going clinical research at Cedars-Sinai goes above and beyond regulatory requirements. We view voluntary accreditation as an outstanding peer-driven reflection of Cedars-Sinai's commitment to excellence in both the scientific rigor of our research, as well as the uncompromising protection of the rights of our research subjects.”

As one of the largest state-of-the-art clinical research facilities of any private hospital in the nation, the Institutional Review Board (IRB) at Cedars-Sinai serves to protect the rights and welfare of patients participating in research at the Medical Center. The IRB has the authority to review, approve, and monitor the progress of all clinical trials. To this end, the IRB operates under a Federal-Wide Assurance (FWA) approved by the Department of Health and Human Services, Office of Human Research Protections, to ensure that all research conducted on-site is ethical and complies with federal, state, and institutional regulations.

To help ensure compliance, AAHRPP was established in 2001 by the Association of American Medical Colleges (AAMC), and several professional societies, including the Association of American Universities (AAU) and the Federation of American Societies for Experimental Biology (FASEB), to improve the quality of research via a voluntary accreditation process that applies rigorous standards for protecting human subjects. The goal was to help institutions reach standards that surpassed even those that are set by state and

federal agencies and to help ensure consistency and uniformity among all institutions conducting research involving human subjects.

To become accredited, Cedars-Sinai had to conduct an extensive internal review requiring that every aspect of the hospital's human subjects research protection program met accreditation standards. Once this information was submitted to AAHRPP, a comprehensive site visit was conducted to evaluate the hospital's performance. During the three-day site visit, AAHRPP representatives conducted detailed audits of research records and extensively interviewed Cedars-Sinai's leaders, administrators and staff, investigators and their research teams, as well as members of the IRB.

"Although this was an intensive process for us to undertake, both the self-assessment and the site visit helped to enhance our human research protection program, raising the benchmark for the ethics and scientific merit of research at Cedars-Sinai," commented Thomas M. Priselac, President and CEO of Cedars-Sinai Medical Center.

To maintain AAHRP accreditation, Cedars-Sinai must consistently meet the same high standards it had to meet during the initial evaluation process. To do this, Cedars-Sinai will continue to evaluate its policies and procedures each year to ensure that all requirements are fully met, submitting an annual report to AAHRPP. Re-accreditation must be applied for every three years.

"By participating in the voluntary accreditation process, we alert federal agencies, medical institutions, investigators, and sponsors that our number one priority is to protect patients involved in clinical trials and that we go above and beyond compliance requirements at every level," said Dr. Melmed. "All stakeholders can be assured that Cedars-Sinai is deeply committed to the safety, integrity, and quality of our human research program."

Cedars-Sinai Medical Center is one of the largest non-profit academic medical centers in the Western United States. For the fifth straight two-year period, Cedars-Sinai has been named Southern California's gold standard in health care in an independent survey. Cedars-Sinai is internationally renowned for its diagnostic and treatment capabilities and its broad spectrum of programs and services, as well as breakthroughs in biomedical research and superlative medical education. The Medical Center ranks among the top 10 non-university hospitals in the nation for its research.

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