REPORT BRIEFING ADVISORY

Presidential Bioethics Commission Briefing on Oversight of Research Involving Human Participants

Dr. Marjorie Speers, Acting Executive Director of the National Bioethics Advisory Commission (NBAC), will discuss NBAC's recently issued report, *Ethical and Policy Issues in Research Involving Human Participants*, on September 12 at the Willard Inter-Continental at 1401 Pennsylvania Avenue NW in Washington, DC. This report was requested by the White House and is the result of a comprehensive review of the current system for the protection of human participants in research. The Commission reviewed the effectiveness of the oversight system, with particular attention to the "Common Rule," a set of regulations followed by 17 federal agencies. The Commission also examined the purpose and structure of the oversight system, ethical issues in the review of research, and the role of research sponsors, investigators, institutions, and Institutional Review Boards.

A key conclusion of the Commission is that the federal oversight system should protect the rights and welfare of human research participants, regardless of whether the research is publicly or privately sponsored. In order to accomplish that goal, NBAC recommends that there be a unified, comprehensive federal policy embodied in a single set of regulations and guidance. Since no current entity has the authority to develop federal policy for all research involving human participants, NBAC calls for legislation creating a single, independent federal office.

The National Bioethics Advisory Commission (NBAC) was established by Executive Order 12975 in October 1995 to advise the National Science and Technology Council and other appropriate government entities regarding bioethical issues arising from research on human biology and behavior. Chaired by former Princeton University President Harold T. Shapiro, Ph.D., the Commission is comprised of physicians, theologians, ethicists, scientists, lawyers, and members of the public.

WHAT: Briefing by Dr. Marjorie Speers, Acting Executive Director, NBAC

Willard Inter-Continental

1401 Pennsylvania Avenue NW

Washington, DC

WHEN: September 12, 9:30 a.m.-11:00 a.m.

RSVP: Dr. Ellen Gadbois

301-402-6060

Obtaining the Report:

The report is available at <u>www.bioethics.gov.</u> Hard copies will be available in September and may be requested by calling the NBAC Office at (301) 402-4242, or by fax at (301) 480-6900.