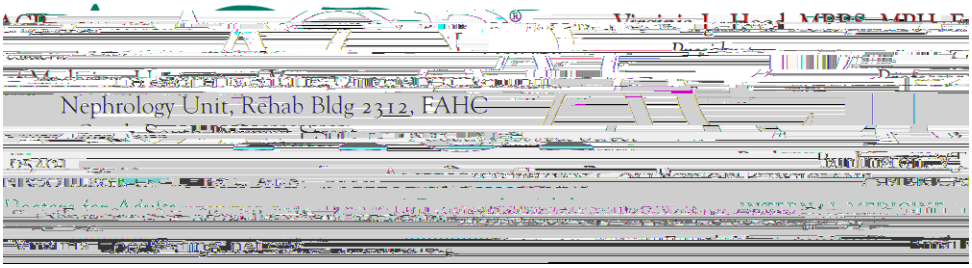

October 25, 2011

(submitted electronically at www.regulations.gov)

Jerry Menikoff, MD, JD
Office for Human Research Protections
U.S. Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Re: Docket HHS-OPHS-2011-0005
Advance Notice of Proposed Rule Making, *"Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators"*

Dear Dr. Menikoff,

The American College of Physicians (ACP) appreciates the opportunity to offer comments on the advance notice of proposed rulemaking (ANPRM) on human subjects research protections, better known as the Common Rule. ACP is the largest physician specialty society and second-largest physician membership organization in the United States. ACP represents 132,000 internal medicine physicians and medical student members. Internists specialize in primary and comprehensive care of adolescents and adults.

General comments:
ACP shares the goals of the ANPRM to modernize and make more effective the regulations for the protection of human subjects. Despite the name of the ANPRM, however, it is not always clear that the proposed changes to the regulations consistently prioritize enhancing protections for subjects over reducing burdens for investigators. Also, opportunities have been missed to try to address issues regarding education about the regulations; to clarify and provide guidance on research versus quality improvement activities; and to explore issues regarding commercial institutional review boards.

ACP policy asserts that research with human biological materials has implications for the privacy of research subjects and individuals with a genetic relationship to research subjects. Fully informed and transparent consent requires the disclosure of all potential uses of patient data. The consent process needs to include the desired preferences of research subjects regarding future contact for notification about results and/or consent for additional research participation. Research should be limited to the use specified by the protocol during the informed consent process. Communication of the risks and benefits of research involving biological material allows research subjects to make a well-informed decision. Further study is needed to resolve informed consent issues related to future research use, including biologic materials. The 2009 Institute of Medicine (IOM) report, *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*, recommends allowing future use of existing materials for research if the following conditions are

research that may be conducted with the PHI stored in the database or biobank; and (2) an IRB determines that the proposed new research is not