Appendix C
The Common Rule

Until 1991, federal departments and agencies that conduct, support, or regulate research used a variety of policies and procedures to protect human research subjects. To eliminate confusion and promote uniformity, each of these departments and agencies has adopted as regulation a common Federal Policy for the protection of human research subjects. The Federal Policy applies to research involving human subjects that is conducted, supported, or otherwise subject to regulation by any of the following 17 federal departments and agencies: Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency; Agency for International Development; Department of Housing and Urban Development; Department of Justice; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; Department of Transportation; Central Intelligence Agency; and Social Security Administration. The FDA has concurred in the Federal Policy, but has not adopted the Policy in its entirety. Instead, the FDA has made selected changes to its IRB and informed consent regulations that correspond to the Federal Policy. [See Federal Register 56 (June 18, 1991): 28025-28029.]

Where a protocol is subject to review under more than one department or agency's regulations, the requirements of each set of regulations must be met. This situation may arise, for example, with Treatment INDs, or when applying the provisions on waiver of documentation of informed consent, in cases where both the FDA and DHHS have jurisdiction over the research. (See, e.g., Guidebook Chapter 2, Section B, "Food and Drug Administration Regulations and Policies," discussing Treatment INDs, and Chapter 2, Section A(ii), "45 CFR 46: Most Frequently Asked Questions," question 10.)

The adoption of the Federal Policy by these departments and agencies implements a recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (established by Act of Congress on November 9, 1978) that all federal departments and agencies "adopt as a common core the regulations governing research with human subjects issued by the Department of Health and Human Services (codified at 45 CFR 46), as periodically amended or revised, while permitting additions needed by any department or agency that are not inconsistent with these core provisions." The resulting Federal Policy was drafted by the Ad Hoc Committee for the Protection of Human Research Subjects

and the Interagency Human Subject Coordinating Committee, appointed under the auspices of the Federal Coordinating Council for Science, Engineering and Technology.

The Federal Policy is based on Subpart A of the DHHS regulations for the protection of human research subjects, adopted by DHHS in 1981. The Federal Policy now replaces Subpart A of the 1981 DHHS regulations; Subparts B and C remain unchanged; Subpart D has been modified to accommodate renumbering changes in Subpart A. [See 45 CFR 46.401(b).] Regulations for DHHS and the other departments and agencies listed above are now, in effect, identical (not including the FDA, which has regulations that differ in some significant respects, or the CIA, which follows the DHHS human subjects regulations through an Executive Order, but has not itself adopted specific human subjects regulations). Adoption of the Federal Policy incorporates DHHS's basic considerations for the protection of human subjects; the provisions of Subparts B, C, and D of the DHHS regulations are applicable to research supported or conducted by these departments and agencies at institutions that have MPAs approved by and on file with OPRR.