

September 4, 1998: This is a draft report developed for the National Bioethics Advisory Commission. It does not represent conclusions and should not be cited or referenced.

1 **Appendix C**
2 **The Common Rule**

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

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

29
30 The adoption of the Federal Policy by these departments and agencies implements a
31 recommendation of the President's Commission for the Study of Ethical Problems in Medicine and
32 Biomedical and Behavioral Research (established by Act of Congress on November 9, 1978) that
33 all federal departments and agencies "adopt as a common core the regulations governing research
34 with human subjects issued by the Department of Health and Human Services (codified at 45 CFR
35 46), as periodically amended or revised, while permitting additions needed by any department or

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1 agency that are not inconsistent with these core provisions.” The resulting Federal Policy was
2 drafted by the Ad Hoc Committee for the Protection of Human Research Subjects and the
3 Interagency Human Subject Coordinating Committee, appointed under the auspices of the Federal
4 Coordinating Council for Science, Engineering and Technology.

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6 The Federal Policy is based on Subpart A of the DHHS regulations for the protection of
7 human research subjects, adopted by DHHS in 1981. The Federal Policy now replaces Subpart A
8 of the 1981 DHHS regulations; Subparts B and C remain unchanged; Subpart D has been
9 modified to accommodate renumbering changes in Subpart A. [See 45 CFR 46.401(b).]

10 Regulations for DHHS and the other departments and agencies listed above are now, in effect,
11 identical (not including the FDA, which has regulations that differ in some significant respects, or
12 the CIA, which follows the DHHS human subjects regulations through an Executive Order, but
13 has not itself adopted specific human subjects regulations). Adoption of the Federal Policy
14 incorporates DHHS’s basic considerations for the protection of human subjects; the provisions of
15 Subparts B, C, and D of the DHHS regulations are applicable to research supported or conducted
16 by these departments and agencies at institutions that have MPAs approved by and on file with
17 OPRR.

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