

States prior to publication of the rule in the **Federal Register**. This rule conforms 40 CFR part 761 to a decision by the Court and is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 761

Environmental protection, Hazardous substances, Labeling, Polychlorinated biphenyls (PCBs), Reporting and recordkeeping requirements.

Dated: June 13, 2003.

Stephen L. Johnson,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 761—[AMENDED]

■ 1. The authority citation for part 761 continues to read as follows:

Authority: 15 U.S.C. 2605, 2607, 2611, 2614, and 2616.

■ 2. Amend § 761.30(p)(1) by revising the introductory text to read as follows:

§ 761.30 Authorizations.

* * * * *

(p) * * * *

(1) Any person may use porous surfaces contaminated by spills of liquid PCBs at concentrations >10 µg/100 cm² for the remainder of the useful life of the surfaces and subsurface material if the following conditions are met:

* * * * *

[FR Doc. 03-15668 Filed 6-19-03; 8:45 am]

BILLING CODE 6560-50-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

Waiver of the Applicability of Certain Provisions of Department of Health and Human Services Regulations for Protection of Human Research Subjects for Department of Health and Human Services Conducted or Supported Epidemiologic Research Involving Prisoners as Subjects

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office for Human Research Protections.

ACTION: Final action on waiver.

SUMMARY: In a document published in the **Federal Register** on October 7, 2002 (67 FR 62432), the Secretary of Health and Human Services sought public comment on a proposed waiver of the applicability of certain requirements of

the Department of Health and Human Services (DHHS or Department) regulations for the protection of human subjects, 45 CFR part 46, to allow DHHS to conduct or support certain important and necessary epidemiologic research on prisoners that presents no more than minimal risk and no more than inconvenience to the prisoner-subjects. Pursuant to his authority under 45 CFR 46.101(i), the Secretary proposed the waiver of §§ 46.305(a)(1) and 46.306(a)(2) of the DHHS regulations for the protection of human subjects, which sections set forth specific requirements for any research involving prisoners that is conducted or supported by DHHS. After consideration of the public comments received, the Secretary is granting this waiver.

DATES: The waiver is effective June 20, 2003.

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Ph.D., Office for Human Research Protections (OHRP), The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; telephone 301-496-7005; e-mail istithco@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION:

Regulatory Background

The Department of Health and Human Services (DHHS) regulates research involving human subjects conducted or supported by DHHS through regulations codified at 45 CFR part 46. Subpart C of 45 CFR part 46, entitled "Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects," provides additional regulatory protections to prisoners who are research subjects.

Subpart C sets forth specific requirements for any research involving prisoners as subjects that is conducted or supported by DHHS. Subpart C lists four categories of research involving prisoners as subjects that may be conducted or supported by DHHS. Sections 45 CER 46.305(a)(1) and 46.306(a)(2) require that the institutional review board (IRB) reviewing the research and the Secretary, respectively, determine that the research involving prisoners represent one of these four categories. The first three categories, §§ 46.306(a)(2)(i), (ii), and (iii), require that the research target either (i) the possible causes, effects, or processes of incarceration and of criminal behavior; (ii) the prison as an institution or prison life; or (iii) conditions particularly affecting prisoners as a class. The fourth category, § 46.306(a)(2)(iv), permits research on practices which have the intent and reasonable probability of

improving the health or well-being of the prisoner-subject.

DHHS Conducted or Supported Epidemiologic Research

DHHS conducts or supports certain epidemiologic studies in which the purposes are as follows: (1) To describe the prevalence or incidence of a disease by identifying all cases, and (2) To study potential risk factor associations for a disease. For most such studies, the institutional review board (IRB) reviewing the study determines that the research at issue involves no more than minimal risk and no more than inconvenience to the subjects. The human participants in this type of public health research may include prisoners in the study population. State health agencies are most commonly the conduits for this type of research. Because certain epidemiologic studies conducted or supported by DHHS focus on a particular condition or disease that might affect prisoners as it would any other members of the general population, such studies do not meet any of the four categories of permissible research under subpart C, 45 CFR part 46.

Proposed Waiver

Pursuant to 45 CFR 46.101(i), the Secretary of DHHS has the authority to waive the applicability of some or all of the provisions of the DHHS regulations for the protection of human subjects to specific research activities or classes of research activities otherwise covered by the regulations. In a document published in the **Federal Register** on October 7, 2002 (67 FR 62432), the Secretary of DHHS sought public comment on a proposed waiver of the applicability of certain requirements of subpart C, 45 CFR part 46, to allow DHHS to conduct or support certain important and necessary epidemiologic research on prisoners that presents no more than minimal risk and no more than inconvenience to the prisoner-subjects. The Secretary of DHHS specifically proposed waiving the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:

(1) In which the sole purposes are (i) To describe the prevalence or incidence of a disease by identifying all cases, or

(ii) To study potential risk factor associations for a disease, and (2) Where the institution responsible for the conduct of the research certifies to the Office for Human Research Protections, DHHS, acting on behalf of