

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 cm<sup>2</sup> for the remainder of the useful life of the surfaces and subsurface material if the following conditions are met:

\* \* \* \* \*

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## 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](mailto: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

the Secretary, that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and determined and documented that

(i) The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and

(ii) Prisoners are not a particular focus of the research.

The specific type of epidemiological research conducted or supported by DHHS and subject to the proposed waiver involves no more than minimal risk and no more than inconvenience to the human subject participants. The proposed waiver would allow DHHS to conduct or support a type of minimal risk research that does not now fall within the categories set out in 45 CFR 46.306(a)(2).

The range of studies to which the proposed waiver would apply includes epidemiological research related to chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods (such as interviews and collection of biologic specimens) that generally entail no more than minimal risk to the subjects.

An example of an epidemiological study that could be permitted under the proposed waiver is one in which all persons with HIV, but with none of the known risk factors for HIV, are asked to participate in a study involving an interview, review of medical records, and collection of a blood specimen. The purpose of the study is to determine other 5 potential risk factors for HIV. All states with mandatory HIV reporting laws report these cases to the Centers for Disease Control and Prevention (CDC), DHHS. Each person who meets the study definition would be asked to participate, and prisoners could well be members of the potential study group. In order for the study to be approved under this waiver, the IRB would need to ensure that, among other things, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

#### Periodic Review

The Secretary also proposed that a periodic review of the ways in which DHHS implements the proposed waiver would be conducted by OHRP to determine the adequacy of the waiver in meeting its intended need or if adjustments to the waiver might be necessary and appropriate.

#### Discussion of Comments

During the public comment period that ended on November 6, 2002, DHHS received 14 comments on the proposed

waiver from interested parties; 12 of which were supportive of the proposed waiver, one of which objected to the proposed waiver, and one of which commented on research on prisoners in general. The comments are summarized as follows:

#### *Scope of the Research Covered by the Waiver*

DHHS proposed that the waiver of applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) would apply only to certain types of research. Four commenters suggested that this waiver be expanded to other types of research. Of these, one suggested that the waiver extend to other research that poses a minimal risk and inconvenience to prisoners, such as an interview for purposes of obtaining a prisoner's oral history; one urged DHHS to consider regulatory change to 45 CFR 46.306(a)(2) to allow the type of epidemiologic research covered under the proposed waiver to be an approvable category of research under Subpart C; one suggested that the proposed waiver apply to studies in which the risk of participation is not increased by being a prisoner, or where the study involves minimal risk to the subject over the risk already taken (e.g., as part of an ongoing epidemiologic or follow-up study); and one requested that the waiver be extended to minimal risk research focused on a particular disease or condition that could affect prisoners as it would anyone else in the population.

The Department finds that it is appropriate to apply the proposed waiver of applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) solely to public health research that focuses on a particular condition or disease in order to (1) describe its prevalence or incidence by identifying all cases, including prisoner cases, or (2) study potential risk factor associations, where the human subjects may include prisoners in the study population but not exclusively as a target group. The Department therefore declines to expand the scope of the waiver as proposed.

One commenter stated that the proposed waiver should not be approved because Subpart C already permits, under certain conditions, the types of epidemiological studies under consideration. The commenter asserts that if the objective of an epidemiological study is to describe the prevalence of certain diseases or conditions among prisoners—either alone or as compared to non-prisoners—then the research should be permitted under 45 CFR 46.306(a)(2)(B).

The Department notes that, because the proposed waiver applies to studies

in which an IRB has found that prisoners are not a particular focus of the study, the research, in fact, would not be approvable under any of the current four categories of 45 CFR 46.306(a)(2):

(i) The causes, effects, or processes of incarceration and of criminal behavior; (ii) the prison as an institution or prison life; (iii) conditions particularly affecting prisoners as a class; or (iv) research on practices which have the intent and reasonable probability of improving the health or well-being of the prisoner-subject.

#### *Certification*

Two commenters questioned the certification requirement of the proposed waiver. One commenter stated that the separate certification called for in the proposed waiver is an unnecessary extra step and should be eliminated; and one commenter stated that it is unclear what additional protections will be afforded to subjects by the process of certification and how, other than in timing, will this certification be different than the current requirement.

The Department notes that the proposed waiver would not require certification separate from the certification which institutions now must make to the Secretary (through OHRP) affirming that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7). However, the proposed waiver would require that such certification include the IRB's determination and documentation that the research presents no more than minimal risk and no more than inconvenience to the prisoner-subject, and that prisoners are not a particular focus of the research.

#### *Prisoner Representative*

One commenter expressed the desire to be able to invoke the proposed waiver without the IRB needing a prisoner representative to participate in the review of the research. The Department finds that the requirements of the DHHS regulations at 45 CFR 46.304(b) must be satisfied for research that would be covered by the proposed waiver. The Department notes that if a particular research project is reviewed by more than one IRB, only one IRB needs to satisfy these requirements.

#### *Periodic Review by OHRP*

One commenter states that the proposed waiver should not be approved because it does not provide sufficient assurances about how the adequacy of the waiver or adjustments to the waiver will be periodically

reviewed. The Department believes that the proposed waiver includes adequate assurances that OHRP will conduct periodic reviews to determine the adequacy of the waiver in meeting its intended need or if adjustments to the waiver are necessary and appropriate. The Department notes that OHRP will receive and review all certifications of research covered by the proposed waiver.

#### Other

One commenter suggested that the DHHS regulations should permit prisoners to complete a study in which they were enrolled before being incarcerated. The Department finds that this comment is not relevant to the proposed waiver. The Department may consider this issue at a future time.

One commenter recommended that DHHS adopt a new rule or standard for informed consent when a prisoner is participating as a research subject and the consent occurred in the prison milieu. The Department finds that this comment is not directly relevant to the proposed waiver. The Department notes that because prisoner-subjects are afforded all of the protections of the informed consent requirements listed in § 46.116 of 45 CFR part 46, subpart A, the current standards for obtaining informed consent from prisoner-subjects are adequate.

One commenter found the example given of when the proposed waiver could be used to be incongruent with the requirement that the waiver only may apply to minimal risk research. The commenter asserted that a study of HIV is not minimal risk regarding a loss of confidentiality. The Department believes that the example given could entail no more than minimal risk for research involving prisoners as defined under 45 CFR 46.303(d): the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

One commenter stated that a prisoner should not be required to be a "guinea pig" and that a prisoner should be enrolled in research only if the prisoner agrees to participate in writing. The Department notes that the commenter's objections are not specific to the proposed waiver. The Department further notes that under §§ 46.116 and 46.117 of subpart A of the DHHS regulations for the protection of human subjects, no investigator may involve a human being as a subject in research covered by the regulations unless the investigator has obtained and

documented the informed consent of the subject in accordance with, and to the extent required by, the DHHS regulations.

One commenter states that the proposed waiver should not be approved because it represents a retreat from one of the most important values underlying Subpart C: the fair distribution of the burdens and benefits of research. The Department believes that the waiver as proposed supports the fair distribution of burdens and benefits of research permitting subjects, including some who are prisoners, to participate in certain DHHS-supported or conducted research in which the purposes are (1) to describe the prevalence or incidence of disease by identifying all cases; and (2) to study potential risk factors associations for a disease. Such studies would not be permitted without the waiver.

#### Summary

After considering the comments, DHHS is adopting the waiver as proposed. The waiver is effective June 20, 2003. All initial and ongoing projects reviewed by IRBs under DHHS-approved assurances after the effective date may be reviewed in accordance with this waiver.

Dated: April 28, 2003.

**Richard H. Carmona,**

*Surgeon General and Acting Assistant Secretary for Health.*

Approved: June 13, 2003.

**Tommy Thompson,**

*Secretary, Department of Health and Human Services*

[FR Doc. 03-15580 Filed 6-19-03; 8:45 am]

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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 0 and 54

[CC Docket No. 02-6; FCC 03-101]

#### Schools and Libraries Universal Service Support Mechanism

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** In this document, the Commission takes major steps to simplify and streamline the operation of our universal service mechanism for schools and libraries, while improving our oversight over the support mechanism. The Commission adopts a number of rules to streamline program operation, and promote the

Commission's goal of reducing the likelihood of fraud, waste, and abuse.

**DATES:** Effective July 21, 2003, except for §§ 54.500(k), 54.503, 54.507(g)(1)(i) and (g)(1)(ii), 54.514(a), and 54.517(b) which will become effective July 1, 2004. In addition, § 54.515(b) contains information collection requirements that have not been approved by the Office of Management Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date of that section.

**FOR FURTHER INFORMATION CONTACT:** Jonathan Secrest and Katherine Tofigh, Attorneys, Telecommunications Access Policy Division, Wireline Competition Bureau, (202) 418-7400.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Second Report and Order in CC Docket No. 02-6, FCC 03-101 released on April 30, 2003. This Second Report and Order was also released with a companion Further Notice of Proposed Rulemaking FNPRM. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY-A257, 445 Twelfth Street, SW., Washington, DC 20554.

#### I. Introduction

1. In this Order, we take major steps to simplify and streamline the operation of our universal service mechanism for schools and libraries, while improving our oversight over the support mechanism. In section 254 of the 1996 Act, Congress directed the Commission to establish explicit universal service support mechanisms to ensure the delivery of affordable telecommunications service to all Americans, including low-income consumers, rural health care providers, and eligible schools and libraries. Pursuant to section 254, eligible schools, libraries, and consortia that include eligible schools and libraries, may receive discounts for eligible telecommunications services, Internet access, and internal connections. The Commission has issued several orders interpreting rules governing the operation of the schools and libraries universal service support mechanism.

2. Since the inception of the schools and libraries support mechanism in 1997, schools and libraries have received over \$9.6 billion in funding commitments. This funding has provided millions of school children and library patrons access to modern telecommunications and information services. The Commission previously sought comment in a Notice of Proposed Rulemaking (*Schools and Libraries*