

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**24 CFR Part 60**

[Docket No. FR-4069-F-01]

RIN 2501-AC26

Office of the Secretary; Streamlining of HUD Regulations Governing the Protection of Human Subjects

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: HUD's regulations at 24 CFR part 60 govern the protection of human subjects involved in research conducted or sponsored by HUD. These regulations are identical to those set forth by the Department of Health and Human Services (HHS). This final rule, which is part of HUD's continuing efforts to implement the President's regulatory reform initiative, amends part 60 to simply cross-reference to the HHS regulations, rather than repeating these identical provisions.

EFFECTIVE DATE: August 9, 1996.**FOR FURTHER INFORMATION CONTACT:**

Camille E. Acevedo, Assistant General Counsel for Regulations, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708-3055. (This is not a toll-free number.) Hearing- or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:**I. Background**

On June 18, 1991 (56 FR 28003), HUD and fifteen other Federal Departments and Agencies published a common rule establishing guidelines for the protection of human subjects involved in research conducted or funded by these Departments and Agencies. Adoption of these common requirements implemented a recommendation made by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (the President's Commission), which was established by 42 U.S.C. 300v. HUD has codified these requirements at 24 CFR part 60.

The President's Commission is directed by 42 U.S.C. 300v-1(c) to report biennially to the President, the Congress, and appropriate Federal Departments and Agencies on the protection of human research subjects

involved in biomedical or behavioral research. In carrying out that charge, the President's Commission must conduct a review of "the rules, policies, guidelines, and regulations of all Federal agencies regarding the protection of human subjects of biomedical or behavioral research which such agencies conduct or sponsor." Further, the review "may include such recommendations for legislation and administrative action as the [President's] Commission deems appropriate." (See 42 U.S.C. 300v-1(c).)

In December 1981, the President's Commission issued its first biennial report. Each Department or Agency receiving recommendations from the President's Commission with respect to its rules, policies, guidelines or regulations, is required by 42 U.S.C. 300v-1(b)(1) to publish the recommendations for public comment. On March 29, 1982 (47 FR 13272), the Department of Health and Human Services (HHS) published the recommendations on behalf of all affected Departments and Agencies. Among other suggestions, the President's Commission recommended that:

The President should, through appropriate action, require 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 part 46), as periodically amended or revised, while permitting additions needed by any department or agency that are not inconsistent with these core provisions. (47 FR 13272, 13294)

In May 1982, the affected Federal Departments and Agencies formed a committee, chaired by an HHS representative, to consider the recommendations made by the President's Commission and the public comments submitted on these recommendations. On June 3, 1986 (51 FR 20204), the committee published for public comment a proposed model policy for the protection of human subjects. In accordance with the recommendation made by the President's Commission, the proposed model policy was based on subpart A of the HHS regulations at 45 CFR part 46. The June 18, 1991 rule finalized the requirements set forth in the June 3, 1986 proposed model policy and considered the public comments submitted on the proposed policy.

HUD's regulations at 24 CFR part 60, which implement the model policy, are identical to the HHS regulations at 45 CFR part 46, subpart A. One of the goals of President's Clinton's regulatory reform initiative is the elimination of

repetitious regulatory provisions. Accordingly, this final rule amends 24 CFR part 60 to simply cross-reference to the HHS requirements, rather than repeating these identical provisions. Elimination of these redundant provisions will assist in HUD's goal of streamlining the content of title 24.

II. Justification for Final Rulemaking

HUD generally publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking in 24 CFR part 10. However, part 10 provides for exceptions to the general rule if the agency finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when prior public procedure is "impracticable, unnecessary, or contrary to the public interest" (24 CFR 10.1). HUD finds that good cause exists to publish this rule for effect without first soliciting public comment. This rule merely eliminates unnecessary repetition by reducing HUD's regulations at 24 CFR part 60 to a single section which cross-references the identical HHS requirements at 45 CFR part 46, subpart A. It does not establish or affect substantive policy. Therefore, prior public comment is unnecessary.

III. Other Matters*Environmental Impact*

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implements section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding of No Significant Impact is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of General Counsel, Department of Housing and Urban Development, Room 10276, 451 Seventh Street, SW, Washington, DC 20410.

Executive Order 12612, Federalism

The General Counsel has determined, as the Designated Official for HUD under section 6(a) of Executive Order 12612, Federalism, that the policies contained in this final rule will not have federalism implications and, thus, are not subject to review under that Order. This final rule eliminates unnecessary repetition by amending 24 CFR part 60 to merely cross-reference to the identical HHS regulatory provisions. The final rule will not impinge upon the relationship between the Federal Government and State and local governments.

Executive Order 12606, The Family

The General Counsel, as the Designated Official under Executive Order 12606, The Family, has determined that this final rule does not have a potential for significant impact on family formation, maintenance, and general well-being. This rule, as part of HUD's continuing efforts to implement the President's regulatory reform initiative, eliminates redundant regulatory provisions from title 24 of the CFR. No substantial change in existing HUD policies or programs will result from promulgation of this rule.

Regulatory Flexibility Act.

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) has reviewed and approved this final rule, and in so doing certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This final rule eliminates unnecessary repetition from

title 24 of the CFR. The rule reduces HUD's regulations at 24 CFR part 60 to a single section which simply cross-references to the identical HHS requirements at 45 CFR part 46, subpart A. Elimination of these redundant provisions will assist in HUD's continuing efforts to implement the President's regulatory reform initiative. This rule does not establish or affect substantive policy, and will not have any meaningful economic impact on any entity.

List of Subjects in 24 CFR Part 60

Human research subjects, Reporting and recordkeeping requirements.

Accordingly, 24 CFR part 60 is amended as follows:

PART 60—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for 24 CFR part 60 is revised to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b) and 3535(d).

2. Section 60.101 is revised to read as follows:

§ 60.101 Cross-reference.

The provisions set forth at 45 CFR part 46, subpart A, concerning the protection of human research subjects, apply to all research conducted, supported, or otherwise subject to regulation by HUD.

§§ 60.102 through 60.124 [Removed]

3. Sections 60.102 through 60.124 are removed.

Dated: June 28, 1996.

Henry G. Cisneros,

Secretary.

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