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**DEPARTMENT
OF HEALTH,
EDUCATION, AND
WELFARE**

Office of the Secretary



**PROTECTION OF
HUMAN SUBJECTS**

**Proposed Regulations on Research
Involving Prisoners**

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[45 CFR Part 46]

PROTECTION OF HUMAN SUBJECTS**Proposed Regulations on Research
Involving Prisoners**

AGENCY: Department of Health, Education, and Welfare.

ACTION: Proposed rule.

SUMMARY: The Department of Health, Education, and Welfare (DHEW) is proposing regulations in order to implement the recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research on research involving prisoners. The proposed regulations will provide additional protection for prisoners involved in research activities conducted or supported by DHEW.

DATE: In order to receive full consideration, comments and suggestions should be received on or before March 6, 1978.

ADDRESS: Comments, requests for information, and requests for additional copies of this part of the FEDERAL REGISTER to: Dr. Normand R. Goulet, Office for Protection from Research Risks, National Institutes of Health, 9000 Rockville Pike, Bethesda, Md. 20014, 301-496-7005.

SUPPLEMENTARY INFORMATION: Basic regulations governing the protection of human subjects involved in research, development, and related activities supported by DHEW through grants and contracts were published in the FEDERAL REGISTER on May 30, 1974 (39 FR 18914).

These were extended on August 8, 1975 (40 FR 33530) to activities conducted by DHEW employees.

In the preamble to the publication of May 30, 1974, it was indicated that notices of proposed rulemaking would be developed to provide additional protection for subjects of research who may have diminished capacity to provide informed consent, including prisoners. On August 23, 1974, a notice of proposed rulemaking was published in the FEDERAL REGISTER proposing additional safeguards for the protection of prisoners (30 FR 30654).

In the meantime, on July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the requirements for informed consent to participation in biomedical and behavioral research by prisoners. The Commission was also required to investigate and study biomedical and behavioral research conducted or supported under programs administered by the Secretary of DHEW and involving prisoners to determine the nature of the consent obtained from such persons or their legal representatives be-

fore such persons were involved in research; the adequacy of the information given them respecting the nature and purpose of the research, procedures to be used, risks and discomforts, anticipated benefits from the research, and other matters necessary for informed consent; and the competence and the freedom of the persons to make a choice for or against involvement in such research. On the basis of this investigation and study, the Commission was to make such recommendations to the Secretary as it determined appropriate to assure that biomedical and behavioral research conducted or supported under programs administered by him met the requirements respecting informed consent identified by the Commission. In addition, the Commission was authorized to make recommendations to Congress regarding the protection of subjects involved in research not subject to regulation by DHEW.

To carry out its mandate, the Commission studied the nature and extent of research involving prisoners, the conditions under which such research is conducted, and the possible grounds for continuation, restriction or termination of such research. In order to obtain firsthand information on the conduct of biomedical research and the operation of behavioral programs involving inmates, Commission members and staff made site visits to four prisons and two research facilities outside prisons that use prisoners. During the visits, interviews were conducted with many inmates who have and have not participated in research programs.

The Commission then held a public hearing at which research scientists, prisoner advocates, providers of legal services to prisoners, representatives of the pharmaceutical industry, and members of the public presented their views on research involving prisoners. This hearing was duly announced and no request to testify was denied. The National Minority Conference on Human Experimentation, which was convoked by the Commission in order to assure that viewpoints of minorities would be considered, made recommendations to the commission on research in prisons. In addition to papers, surveys and other materials prepared by the Commission staff, studies on the following topics were prepared under contract: (1) Alternatives to the involvement of prisoners; (2) foreign practices with respect to drug testing; (3) philosophical, sociological and legal perspectives on the involvement of prisoners in research; (4) behavioral research involving prisoners; and (5) a survey of research review procedures, investigators and prisoners at five prisons. Finally, at public meetings commencing in January 1976, the Commission conducted extensive deliberations and developed its recommendations on the involvement of prisoners in research.

ACTION ON RECOMMENDATIONS

Pursuant to Section 205 of the National Research Act (Pub. L. 93-348) the recommendations of the National

Commission for the Protection of Human Subjects of Biomedical and Behavior Research on research involving prisoners were published in the FEDERAL REGISTER (42 FR 3076) on January 14, 1977. Comments were received from 49 individuals. After reviewing the recommendations and the comments, the Secretary has prepared the notice of proposed rulemaking set forth below, which in essence adopts the recommendations, though the proposed rules go slightly beyond the recommendations of the Commission in two respects.

1. In accordance with Pub. L. 93-348, the Commission defined the term "prisoner" with reference to section 601 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3781). In the proposed regulations, a somewhat broader definition is used which includes individuals detained in non-penal institutions by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in penal institutions. These individuals are not technically covered by the Commission's definition.

2. The Commission recommended that HEW support research using prisoners that involves more than minimal risk only if three requirements are satisfied:

(1) The research fulfilled an important social need, and the reasons for involving prisoners were compelling;

(2) The involvement of prisoners in the research satisfied "conditions of equity;"

(3) A high degree of voluntariness on the part of research subjects and openness on the part of the institution characterized the conduct of the research.

The Commission specified that to meet its standards of voluntariness and openness a prison would need to provide uncensored communication with certain people (e.g., a prisoner's lawyer, members of the prison's accrediting committee, etc.), an effective grievance procedure, and a minimum standard of living that satisfied 17 detailed and specific standards itemized by the Commission.

The Department has concluded that these requirements are so stringent that it is doubtful that any existing prison and few research projects could satisfy them. The Commission laid down these conditions because the Commission "did not find in prisons the conditions requisite for a sufficiently high degree of voluntariness and openness." In addition, the Commission stressed the "strong evidence of poor conditions generally prevailing in prisons and the paucity of evidence of any necessity to conduct research in prisons." Finally, the Commission noted that research:

Has already been prohibited in all federal prisons;

Has been prohibited in eight States; Is conducted in only about seven of the states that either permit it or don't regulate it;

And is not conducted in countries outside the United States.

In light of these considerations, the proposed rules would prohibit the Department from conducting or supporting

research that used prisoners as subjects if the research did not represent minimal risk research on incarceration or on penal institutions, and was not intended to improve the health of individual prisoners. The proposed regulations contain no exceptions. In view of the stringent conditions the Commission found would be needed to assure that consent by prisoners was voluntary, the Department could not identify any exception procedure that was both administratively practical and likely to provide the protections sought by the Commission.

In Recommendation No. (4), the Commission indicates that provision should be made " * * * for providing compensation for research-related injury." In this regard, proposed § 46.305(a)(6) requires that where the Institutional Review Board finds there may be a need for follow-up examination or care of participants after the end of their participation, " * * * adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact." With regard to financial compensation, a DHEW task force has recently completed a report on compensation of injured research subjects. (NOTE.—Copies may be obtained from National Institutes of Health, Building 31, Room 1-B-58, 9000 Rockville Pike, Bethesda, Md. 20014. Ask for Publication No. OS-77-003.) In view of the complexity of the issues involved in providing such compensation, it would be preferable to treat the matter of compensating prisoners along with the broader question of compensating subjects generally for injuries sustained in research projects.

The proposed regulations set forth below cover only research conducted or supported by DHEW. They do not cover the non-DHEW supported research which is submitted to the Food and Drug Administration to satisfy its regulatory requirements. The Secretary's rulemaking authority with respect to FDA activities has been delegated to the Commissioner of FDA. The Secretary has directed the Commissioner to issue, as soon as possible, regulations that apply the standards set out in these regulations to research that the FDA accepts to satisfy its regulatory requirements.

RESPONSES TO COMMENTS

As has already been said, 49 individuals submitted comments in response to publication in the FEDERAL REGISTER of the Commission's recommendations on research involving prisoners. These comments dealt with 13 issues, set forth below according to the frequency with which the comment was made. Also included is the Department's response to each comment.

1. *Comment:* The standards for living conditions in prisons, as listed in Section (iii) of the Commission's comment on Recommendation No. (3), are too restrictive.

Response: The Commission's intent appears to be to severely limit research which is not of direct benefit to prisoners

and to insure a high degree of voluntariness in the consent offered by prisoners. Studies by scientists engaged in prison research, by professional correctional groups concerned with prison operations, and by prison law projects have reached similar conclusions with respect to the coercive nature of the environment created by the inadequate standards of living existing in the overwhelming majority of the prisons. Since one of the fundamental provisions of the Department's regulations on protection of human subjects (§ 46.103(c)) states that informed consent must be "without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion," the Commission's overall view appears to be well founded.

2. *Comment:* The Commission went beyond its mandate in coupling penal reform to research involving prisoners at the expense of the nation's research effort.

Response: The Commission could not consider research involving prisoners without looking at a wide variety of conditions in prisons which could have a bearing on informed consent.

Examination by the Commission of prison conditions, health care practices, and rehabilitation programs revealed many deficiencies which need to be corrected.

3. *Comment:* Local committees, rather than the head of a Federal department or agency, should determine investigator competency as well as the adequacy of the research facilities involved. The Federal department or agency head does not have the ability to determine the competency of the investigator, the adequacy of the research facilities, or the social value of research programs.

Response: Since 1937, the Department has been making, through its advisory committees and national advisory councils, similar determinations with respect to highly successful grant and contract programs that now support almost half of all health-related research. There seem to be no compelling reason why Federal department or agency heads, through the use of special or regular national advisory groups and councils or other appropriate mechanisms, should not be able to make determinations related to the competency of the investigators, the adequacy of the research facilities, and the social value of research programs.

4. *Comment:* Under Recommendation No. (2), Phase I drug studies would be prohibited because the control groups of prisoners (e.g., placebo, no treatment, historical control) could not expect an improvement in their health or well-being.

Response: In Phase I studies, the Commission recommended such extensive and strict conditions to assure voluntariness that the Department now proposes to prohibit reliance on prisoners in such research completely. The Commission found a paucity of evidence that such research testing of drugs on prisoners was necessary. The Department has concluded that the need to assure

that research on human subjects is performed only on individuals who have knowingly and voluntarily consented to participate far outweighs any need that has been shown for the use of prisoners in these studies.

5. *Comment:* Research involving prisoners does not carry excessive risks, and is not of a nature such as to reduce the likelihood of participation by free volunteers.

Response: The Commission's findings indicate that prison conditions can be viewed as being coercive. Since there are other environments in which research can be carried out, prisoners should not be involved in most research.

6. *Comment:* The requirement in Recommendation No. (3) (B), that the involvement of prisoners in more than minimal risk research satisfy conditions of equity, is too vague. A regulatory agency applying this criterion would need a considerable degree of discretion or face prolonged debate, and even litigation, as to whether the agency had properly applied the criterion.

Response: The proposed regulations would impose a simple prohibition on the use of prisoners as subjects in research conducted or supported by HEW if the research involves more than minimal risks and is not intended to improve the health of the individual prisoners.

7. *Comment:* Section (iii) (9) of the Commission's comment on Recommendation No. (3), requiring medical facilities in the prison, might imply that every prison should have an accredited hospital within its walls. The implementation of such an interpretation would lead to a wasteful use of resources needed to upgrade other prison areas.

Response: The Commission's recommendation refers to "facilities," not hospitals, and need not be interpreted to require hospital accreditation. When research involves minimal or no risk, it would seem sufficient to have good quality medical facilities in the prison such as a well staffed and equipped infirmary and suitable, accredited hospital facilities available within a short distance from the prison for referral and treatment of medical emergencies. Where research involves substantial risk, the proposed regulations would prohibit DHEW support for such research.

8. *Comment:* Adequate remuneration rates, as required by Section iii(11) of the Commission's comment on Recommendation No. (3) should be set by institutional review boards and any differences between such compensation and prevailing prison wages should be placed in escrow to be paid to each participant at the time of his/her release.

Response: The remuneration referred to is that for prison labor, not research. Such rates are necessarily set by the jurisdiction in which the correctional facility lies. Essentially, Section iii(11) would limit the opportunities to conduct research in prison systems to those prisons that provide work opportunities and pay for prison labor at wages competitive with those offered for participation in research. The proposed rules avoid

the complexity and difficulty of making this determination by prohibiting the Department from conducting or supporting research covered by Recommendation No. (3).

9. *Comment:* The stipulation in Section iii(15) of the Commission's comment on Recommendation No. (3), that the racial composition of the prison staff reasonably correspond to that of the prison population, is unrealistic since minorities often represent only a small percentage of a State's population but sometimes constitute a majority of the State's prison population.

Response: This recommendation provides prison officials with adequate latitude and flexibility for exercising practical and attainable racial goals. Again, however, the proposed rules avoid the difficulty of assessing this question as it affects voluntariness by proposing a simple prohibition on DHEW support for research covered by this recommendation.

10. *Comment:* The establishment of the proposed accrediting office would be redundant and would superimpose an additional regulatory stratum.

Response: This issue is academic since the Department proposes to prohibit project covered by Recommendation No. 3.

11. *Comment:* No action should be taken with respect to the issue of compensation for research-related injury mentioned in Recommendation No. (4) (B) until the Department's task force report on the subject has been thoroughly evaluated.

Response: This is the Department's intention.

12. *Comment:* Recommendation No. (5), providing for the discontinuation of research currently in progress within one year following issuance of the regulations, might cause valid data to be lost or new studies to be jeopardized by the sudden termination of the therapeutic regimen afforded by the ongoing study.

Response: In anticipation of the issuance of final regulations, the DHEW is phasing out all supported and conducted research involving prisoners which would have been covered by Recommendation No. 3. The Commissioner of FDA will consider this matter in issuing regulation affecting non-DHEW supported research.

13. *Comment:* In Recommendation No. (1), clause (A) should be deleted and the following clause substituted: "that (A) because there will always be possible risks involved in behavioral research, specific safeguards must be provided for each risk identified, and the beneficial effects must outweigh these risks."

Response: Recommendation No. (4) would accomplish what has been suggested above.

Notice is given that it is proposed to make any amendments that are adopted effective upon publication in the FEDERAL REGISTER.

NOTE.—The Department of Health, Education, and Welfare has determined that this document does not contain a major proposal

requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

Dated: December 29, 1977.

JOYCE C. LASHOF,
Acting Assistant
Secretary for Health.

Approved: December 29, 1977.

JOSEPH A. CALIFANO, Jr.,
Secretary.

It is therefore Proposed to amend Part 46 of 45 CFR, Subtitle A, by:

§46.106 [Amended]

1. Revising the second sentence of § 46.106(b) (1) to read: "The Board must be sufficiently qualified through the maturity, experience, and expertise of its members, and the diversity of the members' racial and cultural backgrounds, to insure respect for its advice and counsel for safeguarding the rights and welfare of human subjects."

2. Renumbering §§ 46.106(b) (3) through 46.106(b) (6) as §§ 46.106(b) (4) through 46.106(b) (7), and inserting the following new § 46.106(b) (3):

(3) No Board shall consist entirely of members of only one sex.

§46.301 [Redesignated]

3. Redesignating Subpart C and § 46.301 as Subpart D and §46.401 respectively.

4. Adding the following new Subpart C.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Sec.

- 46.301 Applicability.
- 46.302 Purpose.
- 46.303 Definitions.
- 46.304 Composition of Institutional Review Boards where prisoners are involved.
- 46.305 Additional Duties of the Institutional Review Boards where prisoners are involved.
- 46.306 Permitted activities involving prisoners.

AUTHORITY: 5 U.S.C. 301.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

§46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health, Education, and Welfare involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to

make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§46.303 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "DHEW" means the Department of Health, Education, and Welfare.

(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

§46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in §46.106 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner advocate with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(2) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(3) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners;

(4) The information is presented in language which is appropriate for the subject population;

(5) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(6) Where the Board finds there may be need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying

lengths of individual prisoners' sentences, and for informing participants of this fact;

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHEW may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(A) Study of the possible causes, effects, and processes of incarceration, provided that the study presents minimal or no risk and no more than inconvenience to the subjects;

(B) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents minimal or no risk and no more than inconvenience to the subjects; or

(C) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health and well-being of the subject.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHEW shall not involve prisoners as subjects.

[FR Doc. 78-100 Filed 1-4-78; 8:45 am]