

THURSDAY, NOVEMBER 16, 1978  
PART IV



---

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

**Office of the Secretary**



**ADDITIONAL PROTECTIONS  
PERTAINING TO BIOMEDICAL  
AND BEHAVIORAL RESEARCH  
INVOLVING PRISONERS AS  
SUBJECTS**

Legislation  
regarding  
prisoners

[4110-08-M]

## Title 45—Public Welfare

## SUBTITLE A—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, GENERAL ADMINISTRATION

## PART 46—PROTECTION OF HUMAN SUBJECTS

## Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

AGENCY: Department of Health, Education, and Welfare.

ACTION: Final rule.

SUMMARY: These regulations stipulate additional requirements for Institutional Review Boards (Boards), provide for prisoners or representatives of prisoners on Boards when prisoners are involved, outline additional duties for Boards, and specify the conditions under which research involving prisoners is permitted.

EFFECTIVE DATE: These regulations shall become effective on November 16, 1978.

## FOR FURTHER INFORMATION CONTACT:

Normand R. Goulet, Ph. D., Office for Protection from Research Risks, National Institutes of Health, 9000 Rockville Pike, Bethesda, Md. 20014, 301-496-7005

## SUPPLEMENTARY INFORMATION:

On January 5, 1978, the Department of Health, Education, and Welfare (Department) published (43 FR 1050) proposed rules providing additional protections for prisoners involved in research conducted or supported by the Department. Interested individuals, institutions and organizations were invited to submit comments. A total of 57 comments were received.

## RESPONSE TO PUBLIC COMMENTS

The public comments and the Department's responses are discussed below in the order of their reference to the proposed regulations as they appeared in the FEDERAL REGISTER. The Department, having reviewed these comments, has decided to allow two additional types of research:

(1) Certain research on conditions particularly affecting prisoners as a class; and

(2) Certain research intended to benefit the subjects but which involves the use of control subjects to whom such benefit may not be expected.

Neither of these research categories may be approved until additional and

more stringent review procedures are conducted. These requirements are detailed in § 46.306(a)(2) of these regulations.

*Comment:* Twelve respondents commented on the proposals to require that the Board should 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 \* \* \*” and that no Board should consist entirely of members of only one sex.

Several respondents felt that it was misleading and inappropriate to propose a change in Board composition in what was presented as proposed regulations on research involving prisoners. They felt that such a publication was not conspicuous enough to insure appropriate comment. In addition, it was noted that no justification was presented in the introductory comments which preceded the proposed changes. It was felt that a substantial change of this magnitude deserved to be published separately, with a full and adequate explanation of its meaning, and clearly labelled for comments by the affected and interested public.

Other respondents felt that changes to the existing criteria for Board membership should be proposed only when supported by clear evidence that present criteria are inadequate to provide protection to human subjects. The proposal should document these inadequacies for the public and should explain why they are attributable to the absence of certain types of people on the Board, as opposed to other reasons.

Several respondents felt that the current requirements, along with existing equal employment opportunity and affirmative action policies, are sufficient to the Department's needs and obligations. Placing additional limitations on the composition of Boards would further increase the difficulties in: (a) finding Board candidates who are willing and qualified to serve; (b) assembling a committee of workable size; (c) serving staggered terms because of vacations, sabbaticals, etc.; (d) constituting an appropriate committee in a smaller institution; and (e) precluding the overuse of minorities on Boards. These respondents felt that further limitations would be counterproductive in adversely affecting the quality of decisions and would detract from the respect shown to the Board's advice and counsel.

Finally, some respondents had concern for the potential for disagreement on the adequacy of the phrase, “diversity of the members' racial and cultural backgrounds.” They felt that definitions were needed and that there

would be as many definitions as there would be anthropologists.

*Response:* The Department does not feel that the language proposed by the Commission for Boards to be qualified for the review of research in prisoners differs so significantly from the existing requirement that all Boards be “\* \* \* sufficiently qualified through the maturity, experience, and expertise of its members and diversity of its membership to insure respect for its advice and counsel” as to present any great difficulties for grantee and contractor institutions. The only significant change is in the substitution of “diversity of members' racial and cultural backgrounds” for “diversity of membership.” Coupled with the existing requirement for the inclusion of persons competent to judge community attitudes, the present regulatory language has required existing Boards to acquire the same “diversity of racial and cultural backgrounds” that would be required under the change in language. No additional difficulties (a) in finding candidates, (b) with Board size, (c) in staggering terms, or (d) precluding the overuse of minorities, other than those already encountered, need be anticipated. Similarly, the requirement for the inclusion of at least one member of the opposite sex has already been met without obvious difficulty by the great majority of Boards.

The Department also notes that the Commission's recently published recommendations with respect to Board operations provides an early opportunity to reopen these issues. Consequently, the Department has concluded that no purpose will be served by delaying implementation of the provisions incorporated in §§ 46.106(b)(1) and 46.106(b)(3).

*Comment:* Two respondents commented upon § 46.302, which states that the purpose of this subpart is to provide additional safeguards for the protection of prisoners involved in research. One respondent suggested that the introduction of additional protections would make it virtually impossible for prisoners to participate in research and that this runs counter to the philosophical cornerstones of modern penology. The commenter argued that participation in research (1) reduces the pervasive idleness of prisoners, and (2) encourages the assumption of responsibility on the part of the prisoners for their actions and welfare. The commenter felt that research participation should be encouraged, developed, and sustained.

*Response:* Testimony gathered by the Commission does not reflect general agreement among penologists that participation in research is an acceptable means to counteract undesirable aspects of incarceration or to assist in the rehabilitation of prison-

ers. In fact, most testimony before the Commission opposed the use of prisoners in any form of medical research not intended to benefit the individual prisoner. However, the Department has determined that research which is in the long range interests of prisoners as a class may be approved if the Secretary, after consulting appropriate experts, including experts in penology, medicine and ethics, and publishing a notice in the FEDERAL REGISTER, concurs with the approval recommendation of the IRB.

*Comment:* The other commenter on § 46.302 expressed the view that the Department has improperly accepted the Commission's position that prison conditions are so coercive that prisoners cannot give informed consent. In so concluding, it is argued, the Commission overlooked a significant legal aspect of informed consent, namely capacity. A person is able or unable to give informed consent according to whether or not he has the legal capacity to do so. A lack of legal capacity is based on minority or insanity considerations. Assuming that a prisoner suffers neither disability, his/her legal capacity to give informed consent, as well as to handle all of his/her other affairs, is undiminished.

*Response:* The Commission's basic question, as noted in its report (42 FR 3076 at 3078) is whether a prisoner is so situated as to be able to exercise free power of choice; i.e., whether a consent, even if informed, can be considered truly voluntary. The right to be secure in one's person is a constitutional right. The Supreme Court has held in *Brady v. United States*, 397 U.S. 742 (1970) that "waiver of constitutional rights must be voluntary." As noted in *Kaimowitz v. Department of Mental Health*, 42 U.S.L.W. 101 (1973), "the very nature of (the prisoner's) \* \* \* incarceration diminishes the capacity to consent." The Commission concluded that age and mental incompetence alone are not the only factors in establishing the validity of consent. The Department agrees. No changes are made in § 46.302 as proposed.

*Comment:* Eight respondents commented upon the definitions incorporated in § 46.303. Regarding the definition of "prisoner," several commenters indicated that clarification is needed concerning which individuals are included in the definition. They asked whether "prisoner" includes people in halfway houses, persons on parole, those serving time in alternative settings such as college campuses, persons committed to mental hospitals through legal proceedings, juveniles housed in correctional facilities, persons housed in group homes or private care facilities, etc.

*Response:* The proposed definition of "prisoner" encompasses any individ-

ual involuntarily confined or detained for any period of time in an institution, such as a penal facility, a hospital by civil commitment, a prerelease center, or in a similar institution or facility which is not considered a normal, private, day-to-day residence. The term includes individuals sentenced to an institution under a criminal or civil statute, individuals detained by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or to incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. The term also includes inmates in educational release or work release programs. The term "prisoner" does not include either those persons voluntarily confined or those persons subject to a civil commitment procedure which is not an alternative to criminal prosecution. Under the proposed definition, persons on parole or residing on college campuses are in fact not involuntarily confined to an institution and are therefore clearly not "prisoners." Similarly, persons committed to mental hospitals, group homes, halfway houses, or who are out-clients, are not "prisoners" unless their commitment is by virtue of a statute or commitment procedure which is an alternative to criminal prosecution or incarceration in a penal institution.

*Comment:* It was also suggested that definitions of "biomedical" and "behavioral" research are needed. While carefully constructed biomedical research can be tested against the "reasonable probability of improving the health and well-being of the subject," this is an unrealistic standard for a good deal of behavioral research which has nothing to do with health and touches well-being only in the most indirect way. In addition, behavioral and psychological effects of criminality, personality, and demographic and life experience antecedents of criminality should be added to the allowable research as this information can almost solely be obtained from prisoners.

*Response:* Most research on the effects of criminality, personality and demographic and life experience of criminality would be admissible under paragraph (a)(2)(A) of § 46.306 as studies "of the possible causes, effects and processes of incarceration", and of criminal behavior, or under Paragraph (a)(2)(B) as studies of "Prisoners as incarcerated subjects" or under (a)(2)(C) as "Research on conditions particularly affecting prisoners as a class." The fact that a research project could not qualify under paragraph (a)(2)(D) requiring promise of "improving the health and well-being of the subject" (with the possible exception of control subjects, the use of

which requires a more stringent review process) would not block its acceptance if it qualified under any of the other three paragraphs.

At the same time, the Department agrees to the utility of defining biomedical and behavioral research. The soon to be published recommendations of the Commission on Board operations will incorporate a definition of research in both biomedical and behavioral terms. The Department will consider its adoption after it has received comment on the recommendations.

*Comment:* It has been suggested that a research project should be considered to involve no more than minimal risk and no more than inconvenience to the subject even when a breach of confidentiality could conceivably present a potentially serious risk, provided that the investigator is in compliance with the confidentiality requirements of the human subjects regulations (45 CFR 46.119).

If this suggestion were adopted, research involving a risk resulting from a breach of confidentiality would be permitted under § 46.306(a)(2)(A) without prior consultation with experts and publication of a notice in the FEDERAL REGISTER.

*Response:* The regulation (§ 46.306(a)(2)(C)) does in fact, permit research involving potentially serious risk from a breach of confidentiality, but only on a case-by-case basis after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published a notice in the FEDERAL REGISTER. The Department believes that this more conservative approach is warranted because: (1) breaches of confidentiality may occasionally occur despite compliance with confidentiality requirements; and (2) such breaches of confidentiality could be life-threatening (for example, in the case of disclosures concerning sexual assaults). Nevertheless, the Department is interested in receiving comments on this issue.

*Comment:* Four respondents commented on the composition of Boards where prisoners are involved, § 46.304. They noted that the proposed regulations specify that a majority of board members shall have no association with the prison(s) involved. They suggested that clarification of the meaning of "no association" was needed.

*Response:* The term "no association" was used generally in order to avoid as many conflicting interests as possible. It means that an individual should not be an officer, employee, agent, or trustee of the prison or have authority over or responsibility for any aspect of prison activities. However, by using the broad term "no association" the Department intends to rule out even

more remote connections with prisons as well. It should be noted that the requirement refers only to the majority of each of the Boards, exclusive of prisoner members.

*Comment:* One commenter noted that the proposed regulations require additional screening by a Board established at each prison or jail in which the study is to take place. While some institutions may have such review panels, many do not. It appears that this is unnecessarily duplicative and likely to be a factor militating against research.

*Response:* There is no requirement for duplication of review functions. Current regulations require that a Board review and certify the safeguarding of the rights and welfare of human subjects at risk in biomedical and behavioral research activities. The Board need only have one member who is a prisoner or prisoner representative. When a second Board is established for purposes of convenience or when dictated by local considerations, only one such Board need have a prisoner or prisoner representative as a member.

Where a Board does not now exist, and is required by the regulations, the establishment of such a Board will become a prerequisite for the award of a grant or contract.

*Comment:* One respondent felt that to require institutions to include prisoners or prisoner representatives as Board members would lead inevitably to pressures from other population groups for equal representation on review committees, detracting from the Board's integrity and effectiveness.

*Response:* While acknowledging that the mandatory inclusion of specific prisoner representatives on Boards could lead to increased pressures from other population groups for similar representation, the Department believes the special circumstances involved in any research on prisoners warrant this requirement, to assure that the interests of the prisoners are directly represented on the Board.

*Comment:* There were six comments on § 46.305, concerning additional duties of the Boards where prisoners are involved. One commenter noted that § 46.305(a)(4) requires that the information necessary to prisoners' consent be presented in language which is appropriate for the subject population. The commenter asked whether this item should not be reworded to include each person tested.

*Response:* Existing regulations require at § 46.103(c)(1) that subjects be given a "fair explanation" of the procedures to be followed. An explanation that is incomprehensible to the subject, whether because of differences in native tongue, dialect, or complexity,

is clearly not "fair." The requirement in § 46.305(4) serves only to reinforce this basic provision of the regulations.

*Comment:* One commenter noted that the regulations require that adequate assurance exist that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole. The commenter argued that although parole "credit" should not be given for research participation, it would be poor social policy to disallow information concerning a successful response to medical treatment if it has a bearing on the subject's ability to function well outside of the prison setting.

*Response:* The regulations require adequate assurance that parole boards not consider a prisoner's participation in research as a criterion for or against parole. Information concerning medical treatment and its bearing on the subject's ability to function in the future is strictly a physician-patient relationship and subject to constraints appropriate to that situation. These regulations are concerned only with considerations given to the physical act of participating in research in relation to parole board decisions.

*Comment:* Fifteen comments were received on permitted research involving prisoners, § 46.306. Several respondents felt that prisoners should be allowed to participate in medical research even if it does not have the intent and reasonable probability of improving the health and well-being of the subject. They argued that the regulations do not consider research which may strictly be of benefit to society as a whole.

*Response:* The Department is well aware of the past contributions of prison research, and of individual prisoners, acting as research subjects, to the general health and welfare of the Nation and of society as a whole. However it finds that there are substantial reasons for prohibiting continuation of such research and does not find any demonstrable need for continuing such research except where, as provided in § 46.306, there is reason to believe that such research is necessarily concerned with prisons as institutions; prisoners as persons of as a class; or when the research has the intent and reasonable probability of improving the health and well-being of the subject (with the possible exception of control subjects, the use of which requires a more stringent review process).

The Department, again notes that medical and medically related 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 general, these prohibitions have been based on the demonstrable inequities of such research and on the questionable voluntariness of prisoner consent. Though in theory the benefits of such research are usually to society as a whole, prisoners included, only one segment of society, prisoners, is asked to accept the research risks. Even if prisoner consent is obtained, the circumstances of that consent in a confined, restrictive, unattractive and boring environment, raise questions as to the voluntary nature of that consent. In addition, other nations active in biomedical and behavioral research have been able to conduct investigations without involving prisoners. After considerable deliberation, the department has amended § 46.306 (a)(2) so as to permit certain research on conditions particularly affecting prisoners as a class and research on practices which have the intent and reasonable probability of improving the health and well-being of the subjects, even though some subjects who are in a control group may not benefit directly from the research. The review process required before these kinds of research may be approved is more stringent, and includes the requirement that the Secretary consult appropriate experts, including experts in penology, medicine and ethics, and published in the FEDERAL REGISTER his intent to approve such research.

*Comment:* One respondent felt that the allowable research on practices as stated in § 46.306(a)(2)(C) of the proposed regulations, § 46.306(a)(2)(D) of the final regulations, appears to allow a broader range of "therapeutic" research than the preamble would lead one to expect. The respondent noted that there is not even a "minimal risk" ceiling on this type of research.

*Response:* The Commission would permit research on practices which have the intent and reasonable probability of improving the health or well-being of the subject when a prisoner benefits from a practice, no limit on the inherent, medically related risk was intended. The Commission felt that a research subject should not be deprived of health benefits (even experimental ones) simply because the subject is a prisoner. The Department agrees.

*Comment:* Several respondents felt that "minimal risk" as used in § 46.306(a)(2)(A) and (B) should be defined more precisely.

*Response:* The Department agrees. A definition of "minimal risk" has been introduced into these regulations as § 46.303(d).

*Comment:* One respondent asked whether the phrase "no more than inconvenience to the subjects" means inconvenience in actually conducting the research or does it apply to the results.

*Response:* The Department is of the opinion that the risks must be minimal or absent and present no more than inconvenience to the subjects both during the conduct of the research and later, e.g., permissible research should not present the prospect of delayed side effects involving more than minimal risk, nor should it involve the accumulation of data potentially more than minimally injurious to the prisoner.

The regulations, proposed in the January 5, 1978, publication of the FEDERAL REGISTER (43 FR 1050-1053) are hereby adopted with the changes incorporated in § 46.306(a)(2), as noted above; the addition of a definition for "minimal risk;" and minor technical and editorial changes.

Dated: September 11, 1978.

CHARLES MILLER,  
*Acting Assistant Secretary  
for Health.*

Approved: November 7, 1978.

JOSEPH A. CALIFANO, Jr.,  
*Secretary.*

Accordingly, Part 46 of 45 CFR, Subtitle A, is amended 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.

46.303 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.

(d) "Minimal risk is 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.

**§ 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 prisoners) involved, apart from their membership, on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative 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) The research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) 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;

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

(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners, unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) 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

(7) Where the 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.

(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, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) Study of prisons as institutional structures or of prisoners as incarcer-

ated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(C) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research: or

(D) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

(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. 78-32050 Filed 11-15-78; 8:45 am]