

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