TO DETERMINE IF PROPOSED STUDY WOULD MEET THE CRITERIA AS A "PRISONER STUDY"

QUESTIONS FOR PRISONER STUDY DETERMINATION

YES ☐ NO ☐ DO THE SUBJECTS THAT YOU WILL BE PRIMARILY RECRUITING MEET THE FEDERAL DEFINITION OF 'PRISONERS'?

[**Definition of Prisoner specific to Subpart C** (46.303): **Prisoner** - Any individual involuntarily confined or detained in a penal institution encompassing:

- 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
- individuals detained pending arraignment, trial, or sentencing]

**** If the study is not specifically recruiting individuals who meet any of the criteria above, but instead involves a broader subject population that only incidentally may include prisoners, the study is NOT a prisoner study****

If 'NO' above, stop here. The study is NOT a prisoner study. If 'YES' above, continue on

YES ☐ NO ☐ DOES THE PROPOSED RESEARCH FALL WITHIN ONE OF THE CATEGORIES OF PERMISSIBLE RESEARCH FOR PRISONERS? (46.306)

- **The first two categories are (i)** the study of the possible causes, effects, and processes of incarceration, and of criminal behavior, and **(ii)** the study of prisons as institutional structures or of prisoners as incarcerated persons. Research in these two categories is permissible only if the study presents no more than minimal risk, and no more than inconvenience to the subjects (45 CFR 46.306(a)(2)).

- **The third category (iii)** is research on conditions particularly affecting prisoners as a class; the regulations list as examples 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. Research in this category may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research (45 CFR 46.306(a)(2)).

- **The fourth category (iv)** is research on practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In this category, if the IRB-approved proposal is a study in which some prisoners will be assigned to a control group and these prisoners may not benefit from their participation in research, such research may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research (45 CFR 46.306(a)(2)). OHRP interprets control groups which may not benefit from research to include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo.

- The HHS Secretarial waiver for certain epidemiological research conducted or supported by HHS functions as **a fifth (v)** **category of permissible research**. The criteria for this category are that the research must have as its sole purpose **(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. The institution still must review the research under subpart C and certify to OHRP that an appropriately constituted IRB has reviewed the proposal and made all other required findings under HHS regulations at 45 CFR 46.305(a) and receive OHRP authorization prior to initiating any research involving prisoners. All of the other requirements of subpart C apply to research in this category.

If it was determined that the subject population are 'prisoners' and the study meets one of the permissible prisoner research categories above, the study must be reviewed at a convened meeting of the IRB *AND*:

- At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research proposal is reviewed by more than one IRB, only one IRB need satisfy this requirement.
    - OHRP recommends that a prisoner representative have a close working knowledge and understanding and appreciation of prison conditions from the prisoner's perspective.
    - A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.

- The IRB must meet these composition requirements for all types of review by the convened IRB, including initial review, continuing review, and review of amendments.

***If the study is determined to be a prisoner protocol: Along with the requirements of Subpart A (Common Rule), an IRB must make the following 7 additional findings required by the regulations in order to review and approve research involving prisoners:**

1. The research under review represents one of the categories of research permissible under 45 CFR 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 receiving such advantages in the limited-choice prison environment is impaired;

3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner 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 the IRB with written justification for following some other procedures, control subjects must be selected randomly from the group of available prisoners that meet the characteristics needed for that particular research proposal;

5. The information is presented in language that 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 IRB 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 (45 CFR 46.305(a)).

* OHRP notes that in order to make some of these 7 findings and meet the requirements of subpart A of 45 CFR part 46, the IRB must be familiar with the specific conditions in the local prison(s) or jail site(s) that are pertinent to subject protections, before approving the proposal for the local site (45 CFR 46.107(a)).

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