NOTE: Investigators, please include this form with the IRB application if your research involves prisoners. This includes studies of known prisoners and studies recruiting subjects at risk of becoming involuntary prisoners, such as subjects with histories of substance abuse. Remember that persons involuntarily committed to mental health facilities (Taylor Hardin Secure Mental Health Facility, Mary Starke Harper, etc.) by the courts are also prisoners.

If subjects unexpectedly become prisoners, go directly to SECTION FOUR of this form.

If your research involves prisoners with more than one vulnerability (i.e., prisoners who are also children or pregnant, are involuntarily committed to mental health facilities), attach the supplementary form for that vulnerable population as well.

Regardless of the category of your research, be sure that your application makes clear why the research must be done on prisoners.

Section 1. [45 CFR 46.306]

Indicate the category that best represents your research by checking the applicable box below, and explain in the space provided for that category why your research meets the criteria.

For research involving prisoners, the definition of minimal risk refers to 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.

☐ Category 1 (45 CFR 46.306(a)(2)(i))
My research involves the study of possible causes, effects, processes of incarceration, and of criminal behavior. (Processes of incarceration can be interpreted broadly to include substance abuse research, half-way houses, counseling techniques, criminal behavior, etc ….)

Justify how the research presents no more than minimal risk and no more than inconvenience to the subjects:

☐ Category 2 (45 CFR 46.306(a)(2)(ii))
My research involves the study of prisons as institutional structures, or of prisoners as incarcerated persons. (This category is usually used fairly narrowly as when looking at prisoner diet and conditions of prison life.)

Justify how the research presents no more than minimal risk and no more than inconvenience to the subjects:
**Category 3** (45 CFR 46.306(a)(2)(iii))

My research involves the study of conditions particularly affecting prisoners as a class. (This category is less frequently used than the previous ones and refers to such research as vaccine trials, research on hepatitis, and social and psychological problems such as alcoholism, drug addiction, and sexual assaults. Minimal risk studies should not go under this category.) For DHHS-funded research, OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.

Note: Contact the Office of Research Compliance at (205) 348-8461 for more information.

*Explain what condition(s) will be studied and provide rationale for each:*

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**Category 4** (45 CFR 46.306(a)(2)(iv))

My research involves the study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. (Note: It is rare for research involving placebo or control groups to fall in this category because of the difficulty in justifying improvement of the health or well-being of the subject being given placebo or in a control group.) For DHHS-funded research which requires 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 OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.

Note: Contact the Office of Research Compliance at (205) 348-8461 for more information.

*Explain the research practices that will be used in this study and how they are intended to improve the health and well-being of the participants:*

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**Section 2.** [45 CFR 46.305]

When an IRB is reviewing a protocol in which a prisoner will be a subject, the IRB must find and document justification that six additional conditions are met. Describe in the space provided how each condition applies to your research.

1. Advantages acquired through participation in the research, when compared to the prisoners’ current situation, are not so great that they impair their ability to weigh risks.

*Describe the possible advantages that can be expected for prisoner participants:*

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2. Risks are the same as those that would be accepted by non-prisoners.

*Describe the possible risks that can be expected for prisoner participants and justify that they are the same as for non-prisoners:*

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3. Procedures for selection are fair to all prisoners and are immune from intervention by prison authorities in prisons; control subjects must be randomly selected.

   a) *Describe how prisoners will be selected for participation:*

   b) *Describe what measures will be taken to prevent intervention by prison authorities in the selection process:*
4. Parole boards cannot take into consideration a prisoner's participation in research. Informed consent must state participation will not affect length of sentence or parole.

5. For studies that require follow-up, provisions are made including consideration for the length of individual sentences; informed consent must reflect provisions for follow-up. **Describe what provisions have been made for follow-up and how this information will be relayed to the prisoner participants:**

6. Information about the study is presented in a language understandable to prisoners. **Describe what efforts have been made to present information about the study in a language that is understandable to the prisoner population.** This may mean a non-English language or an appropriate reading level in whatever language the prisoner uses.

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**Section 3. Only complete if applicable: Epidemiologic Research Involving Prisoners and Funded by the Department of Health and Human Services (DHHS)**

Effective June 20, 2003, DHHS adopted policy that allows waiver of the requirement for documenting applicability of a 45 CFR 306(a)(2) category (as found in Section 1 of this form) for certain epidemiologic research involving prisoners. This waiver applies to DHHS conducted or supported epidemiologic research on prisoners that presents no more than minimal risk and no more than inconvenience to the prisoner-subjects.

**Check the box below if your research meets the listed criteria, then provide justification in the space provided.**

- 1. My research is funded by HHS and I request a waiver for meeting the category conditions under Section 1 of this form.
- 2. My research involves epidemiologic research intended to describe the prevalence/incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease; and
- 3. Prisoners are not the sole focus of my research.

**Justify how the research presents no more than minimal risk and no more than inconvenience to the subjects:**

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**Section 4. Complete if applicable: Prisoners are not the targeted population**

Although prisoners may not be the target population for your research, a subject could become a prisoner during the course of the study (particularly if studying a subject population at high-risk of incarceration).

**Note:** If you did not receive IRB approval for involvement of prisoners, and a subject becomes a prisoner during the study, all research interactions and interventions with, and obtaining identifiable
private information about, the now-incarcerated participant must cease until IRB approval has been
issued for their continuation in the research. If you need IRB approval for a prisoner subject to continue
participation in your research, select and complete the applicable category from Section 1, complete
section 2 and this section, then submit for IRB review.

In special circumstances in which the Principal Investigator asserts that it is in the best interest of the subject to
remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may
continue to participate in the research prior to satisfying the requirements of Subpart C. However, subsequent
IRB review and approval of this completed form, documenting that the requirements of Subpart C are met, is
required.

Prisoners are not a target population for my research, but a subject became a prisoner during
the study and I am seeking IRB approval so the subject can continue participation in the
research.

Explain the importance of continuing to intervene, interact, or collect identifiable private
information during the participant’s incarceration:

*Prisoner: An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a
criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities
(e.g., for drug detoxification or treatment of alcoholism,) under statutes or commitment procedures providing such
alternatives to criminal prosecution or incarceration in a penal institution [45 CFR 46.303(c)]. Note: Persons on
Probation and parole are usually NOT considered to be prisoners.

If you will receive or are seeking Department of Health and Human Services (HHS) funding for this study, a
certification letter must be submitted to the Office for Human Research Protections (OHRP). The research cannot
be initiated until OHRP issues approval. The Office of Research Compliance (ORC) will prepare and submit the
certification report to OHRP. Contact the Director for the Office of Research Compliance at 205-348-8461 8641
for more information.