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**Supplement Form B**

**Research Involving Prisoners as Subjects**

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| **PI Name:**  | **Date:** Click here to enter a date. |
| Protocol Title:  | WMed Study #:  |

**Complete this form if:**

a) your research will or may include participation by prisoners, or;

b) a subject involved in ongoing research becomes a prisoner during the course of the study.

Prisoners are defined as 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 (45 CFR 46.303(c)). For additional information please see the HHS FAQs on Research Involving Prisoners <http://www.hhs.gov/ohrp/policy/faq/prisoner-research/>

1. **Prisoners as Subjects**
	1. **The subjects in this study include:**

[ ]  Individuals involuntarily confined or detained in a penal institution.

[ ]  Individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution**.**

Explain:

[ ]  Individuals detained pending arraignment, trial, or sentencing.

Explain:

[ ]  Other individuals involuntarily detained under a criminal or civil statute.

Explain:

* 1. **Where are the prisoners located?**

* 1. **Do you have permission from the facility and the appropriate authorities? Attach all documentation.**

[ ]  Yes

[ ] No

NOTE:*Research cannot be approved without documentation of approval from the facility and the appropriate authorities.*

* 1. **Are any of the subjects in this research minors in the jurisdiction where the research is taking place?**

[ ]  Yes. Complete Supplement Form A

[ ] No

1. **Allowable Categories (46.305(a)(1))**

**Check the category below that best represents the nature of the research and the degree of risk and benefit to which the prisoners in this study will be exposed.**

NOTE:The definition of minimal risk for prisoners is slightly different than the definition for other subjects. The definition of minimal risk for research involving prisoners is given in 46.303(d), is as follows:

*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.*

[ ]  **Category 1 (46.306(a)(2)(i)): The study of the possible causes, effects, and processes of incarceration, and of criminal behavior, where the study presents no more than minimal risk and no more than inconvenience to the subjects.**

Explain:

[ ]  **Category 2 (46.306(a)(2)(ii)): The study of prisons as institutional structures or of prisoners as incarcerated persons, where the study presents no more than minimal risk and no more than inconvenience to the subjects.**

Explain:

[ ]  **Category 3 (46.306(a)(2)(iii)): The study of conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).**

Explain:

[ ]  **Category 4 (46.306(a)(2)(iv)): 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.**

Explain:

**Does the study in Category 4 involve a control group which will not receive a benefit from being in the study?**

[ ]  Yes. Additional procedures required for approval. Contact the WMed IRB.

[ ] No

[ ]  **Category 5 (46.305(a): The DHHS Secretarial waiver for certain epidemiological research conducted or supported by DHHS functions as a fifth** [**category of permissible research**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.306) **[68 FR 36929]. 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.**

[ ]  Yes. If yes, the organization 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 DHHS regulations at [45 CFR 46.305(a)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.305) 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.

[ ] No

1. **Additional Criteria**
	1. **46.305(a)(2) - Are there 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?**

[ ]  Yes [ ] No

Explain:

* 1. **46.305(a)(3) - Are the risks involved in the research commensurate with risks that would be accepted by non-prisoner volunteers?**

[ ]  Yes [ ] No

Explain:

* 1. **46.305(a)(4) - Are the procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners?**

[ ]  Yes [ ] No

Explain:

* 1. **46.305(a)(5) - Is the information presented in language which is understandable to the subject population?**

[ ] Yes[ ] No

Explain:

* 1. **46.305(a)(6) - Does adequate assurance exists that parole Board 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?**

[ ]  Yes [ ] No

Explain:

* 1. **46.305(a)(7) - If there may be a need for follow-up examination or care of subjects 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 subjects of this fact?**

[ ]  Yes [ ]  No

Explain: