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| University of Washington Human Subjects DIvision | **WORKSHEET Prisoners** |
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| **PURPOSE AND APPLICABILITY** |

This Worksheet is used by HSD staff and IRB members to facilitate the review of research involving prisoners and to ensure that all regulatory requirements with respect to prisoners have been met.

It is not required to be completed or retained.

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| **REGULATIONS** |

Federal regulations concerning involvement of prisoners in research differ by agency and type of research. Before using this worksheet, you must first identify the applicable regulations as described in **GUIDANCE Prisoners**. The **GUIDANCE Prisoners** also contains information about how HSD applies its flexibility policy (**GUIDANCE Authority and Responsibilities of HSD and UW IRBs**) to prisoner research.

* **45 CFR 46, Subpart C signatories:** Central Intelligence Agency (CIA); Department of Defense (DoD); Department of Energy (DoE); Department of Health and Human Services (HHS); Department of Homeland Security (DHS); Social Security Administration (SSA).
* **Department of Defense (DoD):** In addition to Subpart C requirements, DoD-supported research cannot include prisoners of war or detainees.
* **Department of Justice (DOJ); National Institutes of Justice (NIJ); Bureau of Prisons (BOP):** See **GUIDANCE Department of Justice** and **WORKSHEET Department of Justice** for these agency-specific requirements that differ from those of Subpart C.
* **Exception From Informed Consent (EFIC) research:** The FDA regulations and 45 CFR 46 prohibit enrolling prisoners for EFIC research. The regulations do allow for continued involvement of prisoners who are inadvertently enrolled so long as the prisoners provide informed consent for their continued participation.
* **Definition of minimal risk.** HSD applies the [Subpart C definition of minimal risk](https://www.washington.edu/research/glossary/minimal-risk/) for prisoners to all prisoner research.

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| **REQUIREMENTS** |

**TABLE A: Prisoner Advocate and Special Composition of the IRB**

Apply these requirements to research involving prisoners as described below.

| **Requirement** | **Met** |
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| **Prisoner Advocate**  If the research is governed by Subpart C and is reviewed by the convened IRB, a prisoner advocate IRB member must receive all review materials and present their review to the IRB (orally or in writing) during the review and vote as an IRB member.  Per **HSD policy**, this requirement is applied to the **convened review of all prisoner research**. If a prisoner advocate cannot participate, the convened review cannot proceed.  The TOL is responsible for managing or overseeing the involvement of prisoner advocates. |  |
| **+ Guidance:**  OHRP guidance allows institutional discretion about the participation of prisoner advocates in expedited review. See the “Prisoner advocate and expedited review” section of the [**GUIDANCE Prisoners** *HSD Policy*](https://www.washington.edu/research/hsd/guidance/prisoners/#4)for full details. |  |
| **Composition of the IRB**  Subpart C requires that, not counting prisoner advocate members, a majority of the convened IRB members shall have no association with the confinement institution(s) or community supervision authority(ies) involved in the research.  Per **HSD policy**, this requirement is applied to all prisoner research reviewed by the convened IRB. |  |

**Table B: Criteria for Approval**

Apply these criteria to **all** **research involving prisoners** except where noted.

All criteria, if applicable, must be met before the inclusion of prisoners can be approved.

| **Requirement** | **Regulatory Citation**  **(45 CFR)** | **Met** |
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| Any possible advantages accruing to the prisoner through their 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 the prisoner’s ability to weigh risks of the research against the value of such advantages in the limited choice environment of the prison is impaired. | 46.305(a)(2) |  |
| The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers. | 46.305(a)(3) |  |
| 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 justification in writing for following some other procedure, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project. | 46.305(a)(4) |  |
| **Example of a potentially approvable deviation**: Randomization may not be achievable if prisoners are included incidentally. |  |  |
| The information is presented in a language understandable to the subject population. | 46.305(a)(5) |  |
| Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole. | 46.305(a)(6) |  |
| **+ Guidance:**  By legislative action, parole is not available to non-federal prisoners in Washington state who were sentenced after 1982. Though “compassionate parole” (officially called Extraordinary Medical Placement) continues to be available, this criterion generally is irrelevant for non-federal prisoners in Washington state.  This criterion is also irrelevant for expedited reviews because of the HSD policy about the type of prisoner research that is eligible for expedited review. |  |  |
| Each prisoner is clearly informed in advance that participation in the research will have no effect on their parole. | 46.305(a)(6) |  |
| **+ Guidance:**  By legislative action, parole is not available to non-federal prisoners in Washington state who were sentenced after 1982. Though “compassionate parole” (officially called Extraordinary Medical Placement) continues to be available, this criterion generally is irrelevant for non-federal prisoners in Washington state.  This criterion is irrelevant for expedited reviews because of the HSD policy about the type of prisoner research that is eligible for expedited review. |  |  |
| When the IRB finds that there may be a need for follow-up examination or care of subjects beyond the period of incarceration, adequate provision has been made for the follow-up examination or care. This includes taking into account the varying lengths of individual prisoner’s sentences and methods for locating individuals. If applicable, verify that the application describes how subjects will be located after incarceration. | 46.305(a)(7) |  |
| If there will be follow-up beyond the period of incarceration, the subjects are informed of how follow-up will occur.  If applicable, verify that the application describes how subjects will be informed about follow-up procedures. | 46.305(a)(7) |  |

**Table C: Category of Prisoner Research**

Required only for research that is subject to Subpart C requirements.

Choose the category that most closely matches the research.

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| **Category** | **Regulatory Citation**  **(45 CFR)** | **Met** |
| **The study of possible causes, effects, and processes of incarceration, and of criminal behavior.**  The study must present no more than minimal risk and no more than inconvenience to the subjects. | 46.306(a)(2)(i) |  |
| **Study of prisons as institutional structures or of prisoners as incarcerated persons.**  The study must present no more than minimal risk and no more than inconvenience to the subjects. | 46.306(a)(2)(ii) |  |
| **Research on conditions particularly affecting prisoners as a class.**  If the study involves **funding from HHS**, the study may proceed only after the Secretary of HHS has consulted with appropriate experts (including experts in penology, medicine, and ethics) and published notice in the Federal Register, of their intent to approve such research.  If the **DoD has any involvement** in the study, the study may proceed only after the Director of Defense Research and Engineering has reviewed and approved the research. | 46.306(a)(2)(iii) |  |
| **Example:** Vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere.  **Example:** Research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults. |  |  |
| **Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the *individual* subject.**  Research in this category that is **supported by HHS funding or** that has any **involvement by the DoD** **and** **that requires assignment of prisoners to control groups that may not benefit from the research** may proceed only after the Secretary of HHS has consulted with appropriate experts and published notice in the Federal Register of the intent to approve such research. | 46.306(a)(2)(i)(iv) |  |
| **Epidemiological research including prisoners that meets both of the following criteria**: | Federal Register, Vol 68, No 119, pp 36929-36931  June 20, 2003 |  |
| * **The sole purposes are to:**   + Describe the prevalence or incidence of a disease or type of injury by identifying all cases **– OR –**   + Study potential risk factor associations for a disease (e.g., environmental health factors) |  |  |
| * **The IRB has determined and documented that:**   + The research presents no more than minimal risk and no more than inconvenience to the prisoner subjects **– AND –**   + Prisoners are not a particular focus of the research |  |  |
| **+ Guidance:**  This category is sometimes called the “epidemiological waiver”. While the other four categories are described in the Subpart C regulations, this category is described elsewhere in the Federal Register. |  |  |

**Table D: Requirement for OHRP Certification and Authorization**

Required only for research that is subject to Subpart C requirements

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| **Requirement** | **Met** |
| The UW must certify to the Secretary of HHS through the Office of Human Research Protections that one of its IRBs has reviewed and approved research in compliance with the applicable regulations and OHRP must determine that the IRB review has met the special requirements for prisoner research and that the proposed research falls within the categories of permissible prisoner research. See **SOP Prisoners** for procedural details. |  |

**Table E: Requirements** **for DOJ- and BOP-supported research**

Required only for research that is supported by DOJ or BOP

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| **Requirement** | **Met** |
| Refer to **GUIDANCE Department of Justice** and **WORKSHEET Department of Justice** to ensure additional regulatory requirements for including prisoners in research are met for these agencies. |  |

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| **RELATED MATERIALS** |

[GLOSSARY Minimal Risk](https://www.washington.edu/research/glossary/minimal-risk/)

[GLOSSARY Minor Change](https://www.washington.edu/research/glossary/minor-change/)

[GUIDANCE Authority and Responsibilities of HSD and UW IRBs](https://www.washington.edu/research/policies/guidance-authority-and-responsibilities-of-hsd-and-uw-irb/)

[GUIDANCE Department of Justice](https://www.washington.edu/research/hsd/guidance/specific-agencies/doj/)

[GUIDANCE Prisoners](https://www.washington.edu/research/hsd/guidance/prisoners/)

SOP Prisoners (*access restricted to HSD)*

[WORKSHEET Department of Justice](https://www.washington.edu/research/forms-and-templates/worksheet-department-of-justice/)

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| **REGULATORY REFERENCES** |

45 CFR 46, Subpart C, “[Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html)”

OHRP Guidance, “[Prisoner Research Certification](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/prisoner-research-certification/index.html)”, July 2020

OHRP, “[Prisoner Research FAQs](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html)”

Federal Register: volume 68; number 119; Friday June 20, 2003; pages 36929-36931; “[Waiver of the applicability of certain provisions of Department of Health and Human Services Regulations for Protection of Human Research Subjects for Department of Health and Human Service Conducted or Supported Epidemiological Research](https://www.govinfo.gov/content/pkg/FR-2003-06-20/pdf/03-15580.pdf)”

[28 CFR 512](https://www.ecfr.gov/current/title-28/chapter-V/subchapter-A/part-512) (Bureau of Prisons)

[28 CFR 22](https://www.ecfr.gov/current/title-28/chapter-V/subchapter-B/part-522?toc=1) and [28 CFR 46](https://www.ecfr.gov/current/title-28/chapter-I/part-46) (National Institute of Justice)

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| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 4.2 | 10.27.2022 | 10.27.2022 | Transfer content to current template; remove extensive guidance re: advocates to instead refer to the GUIDANCE Prisoners |
| 4.1 | 08.26.2021 | 08.26.2021 | Clarify when prisoner advocate consultation is required for minor modifications and prisoner research that is eligible for expedited review |
| 4.0 | 03.25.2021 | 03.25.2021 | Significant revision of entire Prisoner document suite; change format of this worksheet from PDF to Word |
| 3.1 | 05.15.2017 | 05.15.2017 | Updated links, drop down menus for submissions and committee |
| Previous versions |  |  | Previous versions are beyond records retention requirements. |

**Keywords:** Prisoners; Vulnerable populations