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| **IRB Reviewer Checklist –Additional Considerations**  IRB#:  PI Name: | | | | | | | |
| **Additional Criteria for Research Involving Prisoners (45 CFR 46 Subpart C)**  **The research under review represents one or more of the categories: (Select at least one)** | | | | | | | |
| **Cat 1** | | The research involves the study of the possible causes, effects, and processes of incarceration, and of criminal behavior that present no more than Minimal Risk and no more than inconvenience to the subjects | | | | | |
| **Cat 2** | | The research involves the study of prisons as institutional structures or of Prisoners as incarcerated persons that present no more than Minimal Risk and no more than inconvenience to the subjects | | | | | |
| **Cat 3** | | The research proposes to study the conditions particularly affecting prisoners as a class (e.g., research on hepatitis which is more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).  If the research is conducted or supported by DHHS, the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics and the Secretary has published notice, in the Federal Register, of his/her intent to approve such research.  *Research proposals in this category that are not conducted or supported by HHS do not require a Secretarial consultation.* | | | | | |
| **Cat 4** | | The research proposes to study the practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participants. If the research is conducted or supported by DHHS and the research requires the assignment of prisoners to control groups that may not benefit from the research, the Secretary has consulted with appropriate experts including experts in penology, medicine,  and ethics and the Secretary has published notice, in the Federal Register, of his intent to approve such research. Research proposals in this category that are not conducted or supported by HHS do not require a Secretarial consultation. | | | | | |
| **Cat 5** | | Epidemiologic studies when the research proposes to study the prevalence or incidence of a disease by identifying all cases or to study the potential risk factor associations for disease. The study presents no more than minimal risk, no more than an inconvenience to the participants and prisoners cannot be the particular focus of the study. | | | | | |
| **In order to approve research involving prisoners, the IRB must determine that the following 7 requirements are satisfied:** | | | | | | | |
| **Yes** | **No** | | | **NA** | | 1. The research falls into one of the allowable categories of prisoner research listed above. | |
| **Yes** | **No** | | | **NA** | | 2. Advantages to the prisoner as a result of participation are not coercive. | |
| **Yes** | **No** | | | **NA** | | 3. The risks involved in this research are commensurate with risks that would be accepted by non-prisoner volunteers. | |
| **Yes** | **No** | | | **NA** | | 4. Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. | |
| **Yes** | **No** | | | **NA** | | 5. Information is presented in language which is understandable to the participant population. | |
| **Yes** | **No** | | | **NA** | | 6. Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole. Each prisoner is clearly informed in advance (through the proposed consent process) that participation in the research will have no effect on his/her parole. | |
| **Yes** | **No** | | | **NA** | | 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 or individual prisoners’ sentences, and for informing participants of this fact. | |
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| Additional Criteria for Department of Defense (DOD) Research (All must be “Yes” or “N/A”)  Regarding the definition of minimal risk (see footnote 1), the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests in normal persons” shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g. emergency responder, combat soldier, pilot) or having a medical condition (e.g. chronic pain, frequent medical tests). | | | | | | | |
| Yes  No | | | The investigator and research staff are aware of the specific requirements of research under a Department of Defense Addendum and have been educated about these requirements, including the requirement that surveys to be performed on DoD personnel, must be submitted, reviewed and approved by the DoD after the research protocol is reviewed and approved by the IRB | | | | |
| Yes  No | | | The research does **NOT** involve prisoners of war as subjects. This includes any person capture, detained, held, or otherwise under the control of Department of Defense personnel (military and civilian, or contractor employee). Such persons include: Enemy Prisoners, Civilian Internees, Retained Persons, and Lawful and Unlawful Enemy Combatants. Such persons do not include Department of Defense personnel being held for law enforcement purposes. | | | | |
| Yes  No | | | Military personnel are not being compensated for research conducted while on duty. | | | | |
| Yes  No  N/A | | | | | | | If the research involves an interventions or interactions with subjects, the research does not involve a waiver of consent or parental permission unless a waiver is obtained from the Secretary of Defense. **(“N/A” if no interactions or interventions with subjects)**  **The Assistant Secretary of Defense for Research and Engineering may waive the requirements for consent when all of the following are met:**  The research is necessarily to advance the development of a medical product for the Military Services.  The research might directly benefit the individual experimental subject.  The research is conducted in compliance with all other applicable laws and regulations. |
| Yes  No  N/A | | | | | | | If the research involves cognitively impaired adults, there is anticipated direct benefit to the subject |
| Yes  No  N/A | | | | | | | For research involving more than minimal risk to subjects: **(“N/A” if no more than minimal risk)**  An independent medical monitor has been appointed by name.  The medical monitor is a physician, dentist, psychologist, nurse, or other healthcare providers capable of overseeing the progress of the research protocol, especially issues of individual subject/patient management and safety.  The medical monitor is independent of the investigative team  The medical monitor possessed sufficient educational and professional experience to serve as the subject advocate.  The medical monitor has the authority to stop a research study in progress, remove individual subjects from a study, and take whatever steps are necessary to protect the safety and well-being of research subjects until the IRB can assess the medical monitor's report.  A written summary of the monitor's duties, authorities and responsibilities has been provided to the IRB and is appropriate. |
| Yes  No  N/A | | | | | | | For research involving more than minimal risk to subjects **AND** involving military personnel: **(“N/A” if no more than minimal risk OR if not involving military personnel)**  Unit officers and noncommissioned officers will not influence the decisions of their subordinates to participate or not to participate as research subjects.  Unit officers and senior non-commissioned officers in the chain of command will not be present at the time of research subject solicitation and consent during any research recruitment sessions in which members of units under their command are afforded the opportunity to participate as research subjects.  When applicable, officers and non-commissioned officers so excluded will be afforded the opportunity to participate as research subjects in a separate recruitment session.  During recruitment briefings to a unit where a percentage of the unit is being recruited to participate as a group, an ombudsman not connected in any way with the proposed research or the unit will be present to monitor that the voluntary nature of individual subjects is adequately stressed and that the information provided about the research is adequate and accurate. |
| Yes  No  N/A | | | | | | | The disclosure regarding provisions for research-related injury follows the requirements of the Department of Defense component. **(“N/A” if no requirements of the Department of Defense component,)** |
| Yes  No  N/A | | | | | | | If the research involves Human Subjects who are not U.S. citizens or Department of Defense personnel, and is conducted outside the United States, and its territories and possessions: **(“N/A” if no category applies)**  The permission of the host country has been obtained.  The laws, customs, and practices of the host country and the United States will be followed.  An ethics review by the host country, or local Naval IRB with host country representation, will take place. |
| Yes  No  N/A | | | | | | | When conducting multi-site research a formal agreement is required to specify the roles and responsibilities of each party including a Statement of Work (SOW) and specific assignment of responsibilities. **(“N/A” if not multi-site research)** |
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| Additional Criteria for Department of the Navy (DON) Research (All must be “Yes” or “N/A”) | | | | | | | |
| Yes  No  N/A | | | | | For research involving more than minimal risk to subjects, the protocol includes an arrangement for emergency treatment and necessary follow-up of any research-related injury. **(“N/A” if no more than minimal risk)** | | |
| Yes  No  N/A | | | | | If the research involves any of the following, the Secretary of the Navy has approved the research: **(“N/A” if no category applies)**  Waiver or alteration of the consent process.  Exceptions to the requirement for the consent process under 21 CFR 50.24.  Request for waiver of requirements of Department of the Navy policy regarding human research protections.  Research involving severe or unusual intrusions, either physical or psychological, on Human Subjects (such as consciousness-altering drugs or mind control techniques).  Prisoners.  Potentially or inherently controversial topics (such as those likely to attract significant media coverage or that might invite challenge by interest groups). | | |
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| Additional Criteria For Department of Justice (DOJ) Research (All must be “Yes”) | | | | | | | |
| Yes  No  N/A | | | | | If the research involves the federal Bureau of Prisons, the IRB’s approval will be submitted to the Bureau Research Review Board for final approval before the research can begin. **(“N/A” if the research does not involve the federal Bureau of Prisons)** | | |
| Yes  No | | | The research has a Privacy Certificate approved by the National Institute of Justice Human Subjects Protection Officer. | | | | |
| Yes  No | | | All research staff have signed Employee Confidentiality Statements that are maintained by the investigator. | | | | |
| Yes  No | | | The consent document discloses  Confidentiality can be broken if the subject reports immediate harm to subjects or others.  The research staff do not have to report child abuse unless the subject agrees in writing to allow such reporting. | | | | |
| Yes  No | | | A copy of all data will be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials. | | | | |

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| **Additional Criteria For Bureau of Prison (BOP) Research** (All must be “**Yes**”) | | | | |
| Yes  No | The project will not involve medical experimentation, cosmetic research, or pharmaceutical testing. | | | |
| Yes  No | The research design will be compatible with both the operation of prison facilities and protection of human participants. | | | |
| Yes  No | The investigator will observe the rules of the institution or office in which the research is conducted. | | | |
| Yes  No | The investigator has signed a statement in which the investigator agrees to adhere to the provisions of 28 CFR 512. | | | |
| Yes  No | The research proposal will be reviewed by the Bureau of Prisons Research Review Board. | | | |
| Yes  No | The project must have an adequate research design and contribute to the advancement of knowledge about corrections. | | | |
| Yes  No | The selection of participants within any one organization must be equitable. | | | |
| Yes  No | Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. | | | |
| Yes  No | Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are both:   * No longer in Bureau of Prisons custody. * Participating in authorized research being conducted by Bureau employees or contractors. | | | |
| Yes  No | If the investigator will be receiving records in a form not individually identifiable, advance adequate written assurance that the record will be used solely as a statistical research or reporting record has provided to the Bureau of Prisons. | | | |
| Yes  No | Except as noted in the consent statement to the participant, the investigator will not provide research information that identifies a participant to any person without that participant’s prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain. | | | |
| Yes  No | Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system | | | |
| Yes  No | If the investigator is conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the investigator may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project. | | | |
| Yes  No | The consent will disclose: | | | |
| Identification of the investigators  Anticipated uses of the results of the research.  A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable). | | A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.  A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility. | |
| Yes  No | The investigator has academic preparation or experience in the area of study of the proposed research | | | |
| Yes  No | The application includes the following information: | | | |
| Names and current affiliations of the investigators  Title of the study  Purpose of the study  Location of the study  Methods to be employed  Anticipated results  Duration of the study  Number of participants (staff or inmates) required and amount of time required from each participation  A comprehensive statement, which includes: • Review of related literature  Detailed description of the research method  Significance of anticipated results and their contribution to the advancement of knowledge  Specific resources required from the Bureau of Prisons of Prisons  Indication of risk or discomfort involved as a result of participation | | | Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur  Description of steps taken to minimize any risks  Description of physical or administrative procedures to be followed to ensure the security of any individually identifiable data that are being collected for the study  Description of physical or administrative procedures to be followed to destroy research records or remove individual identifiers from those records when the research has been completed  Description of any anticipated effects of the research study on organizational programs and operations  Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules  A statement regarding assurances and certification required by 28 CFR 46, if applicable. |
| Yes  No | The investigator will assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the investigator. | | | |
| Yes  No | At least once a year, the investigator will provide the Chief, Office of Research and Evaluation, with a report on the progress of the research | | | |
| Yes  No | At least 12 working days before any report of findings is to be released, the investigator will distribute one copy of the report to each of the following:  the chairperson of the Bureau of Prisons Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The investigator will include an abstract in the report of finding | | | |
| Yes  No | In any publication of results, the investigator will acknowledge the Bureau of Prisons's participation in the research project | | | |
| Yes  No | The investigator will expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau of Prisons | | | |
| Yes  No | Prior to submitting for publication the results of a research project conducted under this subpart, the investigator will provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons of Prisons. | | | |
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| **Additional Criterion for Environmental Protection Agency (EPA) Research and Research Intended to be Submitted to the Environmental Protection Agency (**Must be **“Yes” or “N/A”)** | | | | |
| Yes  No | The research does not involve the intentional exposure of pregnant women, nursing women, or children to any substance. | | | |
| Yes  No  N/A | | If the results of research involving an intentional exposure of human subjects are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA) the IRB’s determinations and approval will be submitted to the EPA Human Subjects Research Review official for final review and approval before the research can begin. **(“N/A” if the results of research involving an intentional exposure of human subjects are NOT intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA))** | | |
| Yes  No  N/A | | If the research involves children, the research meets the criteria for either category #1 or #2. **(“N/A” if the research does not involve children)** | | |
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| Additional Criterion for Department of Energy (DOE) Research (Must be “Yes”) | | | | |
| Yes  No | The “Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements” submitted by the investigator verifies compliance with the Department of Energy requirements for the protection of Personally Identifiable Information | | | |
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| Additional Criterion for Department of Education (ED) Research (Must be “Yes” or “N/A”) | | | | |
| Yes  No  N/A | | If prior consent[[1]](#footnote-1) or written documentation of consent or parental permission is waived, the research does NOT involving gathering information about any of the following: (1) political affiliations or beliefs of the student or the student’s parent; (2) mental or psychological problems of the student or the student’s family; (3) sex behavior or attitudes; (4) illegal, anti-social, self-incriminating, or demeaning behavior; (5) critical appraisals of other individuals with whom respondents have close family relationships; (6) legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; (7) religious practices, affiliations, or beliefs of the student or student’s parent; or (8) income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program), **(“N/A” if neither consent nor written documentation of consent were waived)** | | |

1. Prior consent means prior consent of the student, if the student is an adult or emancipated minor; or prior written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any Department of Education-funded survey, analysis, or evaluation. [↑](#footnote-ref-1)