IRB Reviewer Checklist –Additional Considerations

IRB# _____ PI _____ Reviewer Signature _____ Date _____

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,)**

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).
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.
Additional Criteria For Bureau of Prison (DOJ) 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.	
Additional Criterion for Environmental Protection Agency (EPA) Research and Research Intended to be Submitted to the Environmental Protection Agency (Must be **"Yes")**		
☐ **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)**	
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	
Additional Criterion for Department of Education (ED) Research (Must be **"Yes"**)		
☐ **Yes** ☐ **No** ☐ **N/A**	If prior consent[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.