**IRB Member Additional Federal Agency Requirements Checklist**

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| --- | --- |
| IRB Meeting Date: Click or tap here to enter text. | eBridge #: Click or tap here to enter text. |
| Principal Investigator: Click or tap here to enter text. | Reviewer: Click or tap here to enter text. |

This checklist should be used with the *New Protocol Reviewer Checklist* for projects which are receiving funding or support from one of the noted federal agencies below. If there are any missing elements, please include these as required modifications on the *New Protocol Reviewer Checklist.*

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| --- | --- | --- | --- |
| [ ]  [DoD](#_Department_of_Defense:) | [ ]  [EPA](#_Environmental_Protection_Agency:) | [ ]  [DoJ](#_Department_of_Justice/Bureau) | [ ]  [BoP](#_Department_of_Justice/Bureau) |

# [ ] Department of Defense:

**For all research conducted or supported by the DoD or a component of the DoD:**

1. Has the project team completed the MCW Research Ethics education component? [ ]  Yes [ ]  No
2. Has the project undergone scientific review and the review is attached for consideration? [ ]  Yes [ ]  No
3. For a multi-site research project, has a formal MOU been included which describes the roles and responsibilities of each party? [ ]  Yes [ ]  No [ ]  N/A
4. Does the project involve more than minimal risk to subjects? [ ]  Yes [ ]  No
	1. If yes, has an independent medical/research monitor been named in the project? [ ]  Yes [ ]  No

*For all projects which are considered greater than minimal risk the appointment (by name) of an independent monitor is required.*

* 1. Does the project describe the medical/research monitor’s authority to stop a research project in process, remove individuals from the project and take any steps to protect the safety and well being of subject until the IRB can assess the matter? [ ]  Yes [ ]  No
1. Are there additional protections for military research subjects to minimize undue influence? [ ]  Yes [ ]  No [ ]  N/A (project is not enrolling military personnel)
2. Does the project seek to include subjects from international populations? [ ]  Yes [ ]  No
	1. If yes, are there appropriate safeguards in place for their inclusion? [ ]  Yes [ ]  No
	2. Is there a statement indicating the researcher will follow all local laws, regulations, customs and practices? [ ]  Yes [ ]  No
3. Does the project seek to include Prisoners of War as the subjects? [ ]  Yes [ ]  No
	1. If yes, research involving persons considered prisoners of war (POW) (captured, detained, held under the control of DoD personnel) is prohibited. Refer to the definition of “prisoner of war” for the Department of Defense component granting the addendum.
4. Does the project seek to use LARs to obtain consent? [ ]  Yes [ ]  No
	1. Does the project intend to provide direct benefit to the subject? [ ]  Yes [ ]  No
5. Does the project seek a waiver of consent? [ ]  Yes [ ]  No
	1. Does the project involve “experimental subjects” as defined by DoD regulations? [ ]  Yes [ ]  No
	2. If yes, has the requirement been waived by the Secretary of Defense and documentation attached? [ ]  Yes [ ]  No [ ]  N/A
6. Does the consent form include the DoD as an agency who may review records? [ ]  Yes [ ]  No [ ]  N/A (for waiver of consent requests only)

# ☐ Environmental Protection Agency:

**For research conducted or supported by the EPA:**

1. Does the project involve the intentional exposure of pregnant women, nursing women, or children to any substance? [ ]  Yes [ ]  No
	1. **If yes – per EPA regulations, this research is prohibited and can not be approved by the IRB.**
2. Does the project provide the additional protections to pregnant women and children as subjects in observational research, i.e., research that does not involve intentional exposure to any substance, as required by 40 CFR 26 Subparts C and D? [ ]  Yes [ ]  No
	1. For observational research involving minors that does not involve greater than minimal risk, are there adequate procedures for obtaining the assent of the minor and the permission of the parents/guardians as set forth in 40 CFR 26.406? [ ]  Yes [ ]  No
	2. For observational research involving minors that involves greater than minimal risk, does the research project present the prospect of direct benefit to the individual subjects or is likely to contribute to the subject’s well-being? [ ]  Yes [ ]  No
		* Is the risk justified by the anticipated benefits to the subject? [ ]  Yes [ ]  No
		* Is the relation of the anticipated benefit to the risk favorable to the subject? [ ]  Yes [ ]  No
		* Has the available alternative approaches been or is presented to the subject? [ ]  Yes [ ]  No
		* Are there adequate procedures for obtaining the assent of the minor and the consent of the parents/guardians as set forth in 40 CFR 26.406? [ ]  Yes [ ]  No
3. Does the consent form include the EPA as an agency who may review records? [ ]  Yes [ ]  No

**For research not conducted or supported by any federal agency that has regulations for**

**protecting human research subjects and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research subjects apply, including:**

1. Does the project involve the intentional exposure of non-pregnant, non-nursing adults to any substance? [ ]  Yes [ ]  No
	* If yes, EPA **prohibits** the intentional exposure of pregnant women, nursing women, or children to any substance and **the project can not be approved by the IRB.**

# [ ]  Department of Justice/Bureau of Prisons:

[ ]  **For National Institute of Justice (NIJ) funded research:**

1. Does the project include a Privacy Certificate approved by the NIJ Human Subjects Protection Officer [ ]  Yes [ ]  No
	1. If No, the project must obtain the privacy certificate before IRB approval may be granted
2. Have all researchers and research staff signed employee confidentiality statements and are they uploaded? [ ]  Yes [ ]  No
3. Does the consent form include a statement in the confidentiality section that confidentiality can only be broken if the subject reports immediate harm to subjects or others? [ ]  Yes [ ]  No
	1. If No, the statement must be included in the consent form
4. Does the consent form include a statement informing subjects that under the privacy certificate, researchers and research staff do not have to report child abuse unless the subject signs another consent form to allow child abuse reporting? [ ]  Yes [ ]  No
	1. If No, the statement must be included in the consent form

[ ]  **Bureau of Prisons:**

**For research conducted within the Bureau of Prisons:**

1. Does the project have an adequate research design and contribute to the advancement of knowledge about corrections? [ ]  Yes [ ]  No
	1. If No, the project cannot be approved
2. Does the project describe that the selection of subjects within any one organization is equitable? [ ]  Yes [ ]  No
3. Are incentives offered to inmate subjects for participation? [ ]  Yes [ ]  No
	1. If yes, describe: Click or tap here to enter text.
	2. Incentives may not be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered
4. Is compensation being offered to non-inmate subjects for participation? [ ]  Yes [ ]  No
	1. If yes, do the subjects meet the following criteria: [ ]  Yes [ ]  No
* No longer in Bureau of Prisons custody.
* Participating in authorized research being conducted by Bureau employees or contractors
1. Does the project describe how they will receive records (if applicable) from the Bureau of Prisons?
[ ]  Yes [ ]  No
	* A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency.
2. Does the project describe and indicate except as noted in the consent statement to the subject, the researcher will not provide research information that identifies a subject to any person without that subject’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
3. Does the project describe and indicate 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
4. Is the project a study of special interest to the Office of Research and Evaluation? And does the project describe any reporting requirements to the Office of Research and Evaluation? [ ]  Yes [ ]  No
	* If the researcher 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 researcher may be asked to provide ORE with the computerized research data, not identifiable to individual subjects, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.
5. Does the consent form include the following elements as for research being conducted within the Bureau of Prisons? [ ]  Yes [ ]  No
	* Identification of the researchers.
	* Anticipated uses of the results of the research.
	* A statement that participation is completely voluntary and that the subject 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, a researcher may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject 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 subject's release date or parole eligibility.