PI Name:	Protocol Number:
Title of Protocol:	

ADDENDUM to PRIMARY REVIEW CHECKLIST: VULNERABLE POPULATIONS CHECKLIST (PRISONERS)

RESEARCH WITH PRISONERS (Subpart C)

"Prisoner" is defined by HHS regulations at 45 CFR part 46.303(c) 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."

1. If research involves prisoners, is it approvable? (ALL MUST APPLY)

☐ Advantages to participation are not coercive;
AND
☐ Risks are commensurate with what would be acceptable to non prisoners;
AND
☐ The selection procedures are fair;
AND
☐ The information is presented in an understandable language;
AND
☐ There is no effect on decisions related to parole;
AND
☐ Provisions for follow-up are adequate.

Will this study be conducted by VA investigators while on official duty?
Yes ☐ No ☐ or
Will this study be conducted at VA facilities?
Yes ☐ No ☐
If yes, to either question address the following:

For VA-regulated research: Prisoners are considered a vulnerable population because both their incarceration and the constraints imposed on them during their incarceration may render them unable to make a truly informed and voluntary decision regarding whether or not to participate as subjects in research. Therefore, research involving prisoners must not be conducted by VA investigators while on official duty, or at VA-approved off-site facilities unless a waiver has been granted by the CRADO (Chief Research and Development Officer). If the waiver is granted, the research must be in accordance with applicable Federal regulations pertaining to prisoners as research subjects (see 45 CFR Part 46, Subpart C 46.301 – 46.306, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects).
Research involving prisoners cannot be approved unless a waiver has been granted by the VA CRADO (Chief of Research and Development Officer).

Has a waiver been approved? Yes ☐ No ☐ Pending ☐

2. If all of the previous conditions are satisfied, mark one of the following determinations (46.306):

☐ i) Research on possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
Because:

OR
☐ ii) Research on prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
Because:

OR
☐ iii) Research on conditions particularly affecting prisoners as a class, provided that the study may proceed only after the Secretary of DHHS has consulted with appropriate experts (in penology, medicine, and ethics) and published notice in the Federal Register of the intent to approve such research
Because:

OR
☐ iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subjects
Because:

AND
☐ iv) If the research includes the assignment of prisoners to control groups that might not benefit from the research, it may proceed only after the Secretary of HHS has consulted with appropriate experts and published a note in the Federal Register of the intent to approve the research
Because:

OR

☐ Under a waiver of epidemiology research where the sole purpose is for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:

In which the sole purposes are:

☐ To describe the prevalence or incidence of a disease by identifying all cases

OR

☐ To study potential risk factor associations for a disease,

AND

☐ The specific type of epidemiological research subject to the waiver involves no more than minimal risk and

☐ No more than inconvenience to the human subject participants. The waiver would allow the conduct of minimal risk research that does not now fall within the categories set out in 45 CFR 46.306(a) (2).

The range of studies to which the waiver would apply includes epidemiological research related to chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods (such as interviews and collection of biologic specimens) that generally entail no more than minimal risk to the subjects.

☐ The IRB determines that, among other things, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

The definition of minimal risk for research involving prisoners can be found at 45 CFR 46.303(d). This definition, promulgated in 1978, differs from the definition of minimal risk in subpart A of 45 CFR 46. See 45 CFR 46. 102(i).

For research involving prisoners, the definition of minimal risk requires reference to physical or psychological harm, as opposed to harm or discomfort, to risks normally encountered in the daily lives, or routine medical, dental or psychological examination of healthy persons.

Definition of Minimal Risk in Prisoner Research 45 CFR 46.303(d)	Definition of Minimal Risk in 45 CFR part 46, subpart A, 45 CFR 46.102(i)
"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**.	"Minimal risk means that the probability and magnitude of **harm or discomfort anticipated** in the research **are not greater** in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

3. Is this a Bureau of Prisons study? Yes ☐ No ☐

If yes confirm the following:

- **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.** ☐
- **Except as noted in the consent statement to the participant, the researcher must 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. ☐

- **Except for computerized data records maintained at any 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.** ☐
- **The research design is compatible with both the operation of prison facilities and protection of human participants. The researcher must observe the rules of the institution or office in which the research is conducted.** ☐

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 participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project. ☐

Confirm that the consent form includes the following statements:

Identification of the researchers

- **Description of the 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 b 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 participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate and 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.** ☐

4. Is this a National Institute of Justice (NIJ) funded study? Yes ☐ **No** ☐
If yes confirm the following:

Does the Project have a privacy certificate approved by the NIJ Human Subjects Protection Officer? **Yes** ☐ **No** ☐

Have all researchers and research staff signed employee confidentiality statements?

Yes ☐ **No** ☐

Confirm that the consent form includes the following statements:

- **a confidentiality statement that confidentiality can only be broken if the participant reports immediate harm to participants or others.** ☐
- **Under a privacy certificate, researchers and research staff do not have to report child abuse unless the participant signs another consent form to allow child abuse reporting.** ☐

Reviewer Signature:

Date: