

IRB reviewer checklist of requirements for ORI/IRB use to facilitate review of human subject research supported by

Department of Justice (DOJ), National Institute of Justice (NIJ), and Bureau of Prisons

Instructions: Review and check to indicate criteria have been considered and/or are met for items applicable to the proposed research.

FOR STUDIES SPONSORED BY NIJ:

Not Applicable (skip answering the NIJ questions below)

NIJ funded research requires a Privacy Certificate which documents the investigator's obligations under the DOJ confidentiality. As such, researchers and research staff are not required to report current or past abuse. Since this is in conflict with Kentucky child and elder abuse reporting laws, a separate consent form (addendum) allowing the mandatory reporting should be available for use in the event that a subject discloses abuse.

[NIJ SAMPLE TEMPLATE (<http://www.nij.gov/nij/funding/humansubjects/sample-form-consent-for-reporting.doc.doc>)]

Submission includes a separate CONSENT FOR STAFF TO CONTACT PROTECTIVE SERVICES TO REPORT SUSPECTED OR SELF-DISCLOSED [CHILD or ELDER AS APPLICABLE] ABUSE

Not Applicable

Additional NIJ required elements for research informed consent [28 CFR 46.116]:

- Not Applicable
- Research consent document includes a statement that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. However disclosure of future criminal intent is not covered or protected by DOJ regulations.
- If, due to sample size or some unique feature, confidentiality of the subjects' identity cannot be maintained, the subjects need to be explicitly notified. If the investigator intends to disclose any information, the subject needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The subject must be informed of any potential risks which may result from this disclosure and must explicitly provide prior written consent.
- Includes statement informing subjects that the study is funded by NIJ.

RESEARCH CONDUCTED WITHIN THE BUREAU OF PRISONS (BoP):

- Not Applicable (skip answering the BoP questions below)

1)

Additional required elements of informed consent include [28 CFR 512 (<https://ecfr.io/Title-28/pt28.2.512>)]:

- a. Identification of the researchers.
- b. Anticipated uses of the results of the research.
- c. 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).
- d. 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, indicates intent to leave the facility without authorization.
- e. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.

List elements (e.g., a, b, c) that are not applicable, if any:

2)

For research conducted within the Bureau of Prisons, off site agreements are in place indicating research will also be reviewed and monitored by the Bureau Research Review Board (BRBB).

Not Applicable

3)

The research does not involve medical experimentation, cosmetic or pharmaceutical testing.

Not Applicable

4)

Incentives to participate are not offered to inmates (beyond the offer of soft drinks and snacks to be consumed at the test setting).

Not Applicable

5)

Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are both: (i) No longer in Bureau of Prisons custody; and (ii) Participating in authorized research being conducted by Bureau employees or contractors.

Not Applicable

6)

Submission indicates that no Identifiable information will be stored in or introduced into an electronic retrieval system.

Not Applicable

Source

28 CFR 46 (<http://www.gpo.gov/fdsys/pkg/CFR-2004-title28-vol2/pdf/CFR-2004-title28-vol2-part46.pdf>), 28 CFR 22 (<http://www.gpo.gov/fdsys/pkg/CFR-2004-title28-vol1/pdf/CFR-2004-title28-vol1-part22.pdf>), 28 CFR 512 (<http://www.gpo.gov/fdsys/pkg/CFR-2004-title28-vol2/pdf/CFR-2004-title28-vol2-part512.pdf>), www.nij.gov/funding/humansubjects/welcome.htm (<http://www.nij.gov/funding/humansubjects/welcome.htm>)