

WORKSHEET: Additional Criteria for Approval DOJ

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This worksheet is used to determine whether non-exempt <Human Research> subject to DOJ regulations can be approved.

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All criteria in 1 must be met for research funded by the National Institute of Justice (NIJ)
All criteria in 2 must be met for research conducted within the Bureau of Prisons

1. Research funded by the National Institute of Justice (NIJ) *28 CFR §22*

1.1	<input type="checkbox"/>	The investigator has a privacy certificate approved by the NIJ human subjects protection officer
1.2	<input type="checkbox"/>	The investigator and research staff have signed employee confidentiality statements
1.3	<input type="checkbox"/>	The investigator will maintain signed employee confidentiality statements
1.4	<input type="checkbox"/>	The consent document discloses:
	1.4.1	<input type="checkbox"/> The names of the funding agencies
	1.4.2	<input type="checkbox"/> A statement describing the extent to which confidentiality of records identifying the subject will be maintained
	1.4.3	<input type="checkbox"/> A statement that private, identifiable information will be kept confidential and will only be used for research and statistical purposes or if, due to sample size or some unique feature, the identity of the individual cannot be maintained, a statement to that effect
	1.4.4	<input type="checkbox"/> If the identity of the individual cannot be maintained, what information will be disclosed, under what circumstances, and to whom
	1.4.5	<input type="checkbox"/> If the identity of the individual cannot be maintained, any risks that might result from this disclosure
	1.4.6	<input type="checkbox"/> The research team does not have to report child abuse unless the subject signs another consent document to allow such reporting

2. Research conducted within the Bureau of Prisons *28 CFR §512* (See Footnote 1)

2.1	<input type="checkbox"/>	The investigator and research staff have been trained on DOJ regulations and requirements
2.2	<input type="checkbox"/>	The investigator has academic preparation or experience in the area of study of the proposed research
2.3	<input type="checkbox"/>	The research does not involve medical experimentation, cosmetic research, or pharmaceutical testing
2.4	<input type="checkbox"/>	The research design is compatible with both the operation of prison facilities and protection of human subjects
2.5	<input type="checkbox"/>	The investigator will observe the rules of the institution or office in which the research is conducted
2.6	<input type="checkbox"/>	Any investigator who is not an employee of the Bureau of Prisons will sign a statement in which the investigator agrees to adhere to the requirements of 28 CFR §512
2.7	<input type="checkbox"/>	The Bureau of Prisons IRB will approve the research
2.8	<input type="checkbox"/>	The research has an adequate design that will contribute to the advancement of knowledge about corrections
2.9	<input type="checkbox"/>	The selection of subjects within any one organization is equitable
2.10	<input type="checkbox"/>	Incentives will not be offered to help persuade inmate subjects to participate (See Footnote 2)
2.11	<input type="checkbox"/>	One of the following is true: <input type="radio"/> Non-employees of the Bureau of Prisons will receive records in a form not individually identifiable <input type="radio"/> Advance written assurance will be provided to the Bureau that the record will be used solely as a statistical research or reporting record
2.12	<input type="checkbox"/>	Except as noted in the consent statement to the subject, the investigator will not provide research information that identifies a subject to any person without that subject's prior written consent to release the information. (See Footnote 3)
2.13	<input type="checkbox"/>	Except for computerized data records maintained at an official Department of Justice site, records that contain nondisclosable information directly traceable to a specific person will not be stored in, or introduced into, an electronic retrieval system.
2.14	<input type="checkbox"/>	The consent document discloses:
	2.14.1	<input type="checkbox"/> Identification of the investigators
	2.14.2	<input type="checkbox"/> Anticipated uses of the results of the research
	2.14.3	<input type="checkbox"/> A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the research at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable)
	2.14.4	<input type="checkbox"/> A statement describing the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law (See Footnote 4)
	2.14.5	<input type="checkbox"/> A statement that participation in the research will have no effect on the inmate subject's release date or parole eligibility

3. Notes

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4. Footnotes

4.1	The Department of Justice does not consider implementation of Bureau of Prisons programmatic or operational initiatives made through pilot projects to be research.
4.2	Soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both no longer in Bureau of Prisons custody and participating in authorized research being conducted by Bureau of Prisons employees or contractors.
4.3	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.
4.4	For example, a investigator 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.