



**BJS**

## **Protection of Human Subjects and Privacy Certificate Requirements For Applicants for Funding from the Bureau of Justice Statistics**

The Bureau of Justice Statistics (BJS) and its fund recipients are required to comply with regulations designed to protect human subjects and ensure the confidentiality of data. Applicable regulations include the confidentiality regulation, 28 CFR Part 22, which implements 42 USC 3789g; the Common Rule, 28 CFR Part 46; and the OJP Instruction 1564.1, “Protection of Human Subjects of Research and Statistical Activities,” April 26, 1999. BJS staff and recipients of grants, cooperative agreements, contracts, and interagency agreements, including subprojects, are required to comply with both the Office of Justice Programs (OJP) confidentiality regulation and the Common Rule.

Confidentiality regulation: 28 CFR Part 22 implements 42 USC 3789g and provides for the confidentiality of any information identifiable to private persons collected by either BJS staff or fund recipients. Private persons are defined by Part 22 to include any “persons,” including any organizations other than an agency of Federal, State or local government. The regulations require a Privacy Certificate from fund applicants (28 CFR 22.23). This certificate assures that information identifiable to private persons will not be either disclosed or used improperly and describes procedures which the recipient will follow to protect identifiable information. (See attached Privacy Certificate for a model.)

The regulation also requires that data may be collected and revealed only for research or statistical activities. Respondents must be told the following: the types of information to be collected; that the data will be revealed for research or statistical activities only; and that participation is voluntary and may be terminated at any point.

Identifiable individual records are immune from legal processes and cannot be revealed to other agencies within the U.S. Department of Justice (DOJ). Identifiable information which can be revealed according to the regulation include public records, the original records from which data have been obtained, and information regarding future criminal conduct.

The Common Rule: The Common Rule is a set of core regulations, adopted by 17 Departments and Agencies in 1991, which requires that human subjects of Federally supported research and statistical activities must be protected against undue and unnecessary risks. The regulations, at 28 CFR Part 46 for DOJ, set up procedures to establish and operate an Institutional Review Board (IRB) to review human subjects research. No Federal funds may be awarded<sup>1</sup> for any research involving human subjects without IRB review and approval, unless the research is exempt.

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<sup>1</sup>BJS funds may be used for project development, but documenting compliance with the Common Rule must precede any contact with human subjects.

The Institutional Review Board (IRB): An IRB is a body of at least 5 members, representing a variety of backgrounds, which reviews research and statistical activities to protect human subjects and evaluate the risks and benefits to them. Most research institutions have an IRB.

For an IRB to be authorized to review BJS research, it must have a written document, called an assurance, which states that the institution will abide by the requirements of the Common Rule and describes the institution's IRB, including its composition and procedures (see 28 CFR Part 46, especially sections 46.103, 46.107, and 46.108.). The assurance must be approved either by the Director of BJS or the head of another government agency, including but not limited to the head of the Office for Protection from Research Risks (OPRR), Department of Health and Human Services (DHHS). The approval may be for either a single project (a single project assurance or SPA) or multiple projects (a multiple project assurance or MPA).

If an IRB has received a SPA or MPA from OPRR, DHHS, for the type of research in question, it must comply with the DHHS regulations regarding human subjects found at 45 CFR Part 46. In addition to the Common Rule, the DHHS regulations include additional parts (subparts B, C, and D), which extend beyond the Common Rule to provide extra protections for children, prisoners, pregnant women, and fetuses.

Review of research: Research is defined as any investigation contributing to generalizable knowledge. Data obtained through either intervention or interaction with individuals and data with identifiers are covered by the Common Rule. According to the Common Rule, research involving human subjects may (1) be exempt from IRB review, (2) be eligible for an expedited review, or (3) require full IRB review.

(1) The regulations provide an exemption from IRB review for research covered by a confidentiality statute and research where data cannot be identified either directly or through identifiers linked to the subjects. Specifically, exemptions from IRB review are included in the Common Rule for the following:

- (A) survey and interview procedures, educational tests, and observations of public behavior either conducted under a Federal confidentiality statute or in which subjects cannot be identified and disclosure would not put subjects at risk;
- (B) research involving existing data, documents, or records, if the data are publicly available or recorded without identifiers;
- (C) some demonstration projects studying public programs; and
- (D) some research conducted in educational settings.

(2) Expedited review is allowed for certain kinds of research involving no

more than minimal risk. Examples include studies of existing data, documents, or records. The IRB will determine if expedited review is sufficient for a particular research project. Generally, one member of an IRB can provide expedited review.

(3) Other research involving human subjects must be given full IRB review.

### *Responsibilities of BJS fund applicants*

To comply with these requirements, fund applicants must include the following in their application:

(1) a Privacy Certificate (see form in application package) if the project involves data identifiable to private persons, or documentation that the research or statistical project does not require a Privacy Certificate because no identifiable private persons are involved.

(2) BJS Screening Sheet for Protection of Human Subjects (see form in application package). This form guides applicants in applying the Common Rule to their projects.

Before funds are awarded, applicants will also provide the following:

(1) If question 12 on the BJS Screening Sheet for Protection of Human Subjects is checked "A." The project is not research or does not involve human subjects. No other documentation is needed.

(2) If question 12 is checked "B." The project may be exempt from IRB review. Must provide certification and explanation by the fund applicant, OJP's Office of General Counsel, or OJP's IRB, that the project qualifies for an exemption under 28 CFR 46.101(b).

(3) If question 12 is checked "C." The project has qualified for expedited review. Must provide the certification of review and approval of an IRB member of either the applicant's or OJP's IRB under expedited review.<sup>2</sup>

(4) If question 12 is checked "D." The project has qualified for full IRB review and approval. Must provide the certification of review and approval of either the applicant's or OJP's IRB.<sup>3</sup>

(5) If question 12 is checked "E." The project has qualified for full IRB review and approval and the applicant's IRB has approval of its assurance from OPRR,

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<sup>2</sup> Prior to the awarding of BJS funds, a paper or electronic copy of the fund applicant's IRB assurance must be in the designated OJP file or BJS must have a written agreement allowing the OJP IRB to review and approve the project.

<sup>3</sup> Prior to the awarding of BJS funds, a paper or electronic copy of the fund applicant's IRB assurance must be in the designated OJP file or BJS must have a written agreement allowing the OJP IRB to review and approve the project.

DHHS. Must provide certification of review and approval of the applicant's IRB and of compliance with subparts B, C, and D of 45 CFR Part 46, which provide extra protections for children, prisoners, pregnant women, and fetuses.<sup>4</sup>

Awards will not be made prior to the submission of adequate documentation. For cases in which the applicant is applying for an award which includes funds to be used for project development purposes, BJS will consider requests for a later deadline submission of required human subjects documentation. However, in these cases, receipt and approval of documentation must precede any contact with human subjects; funds will not be made available for these activities until all documentation is received. Questions can be addressed to the BJS Human Subjects Protection Officer, Maureen Henneberg, Associate Director, BJS, at (202) 616-3282, [Maureen.Henneberg@usdoj.gov](mailto:Maureen.Henneberg@usdoj.gov), or 810 7<sup>th</sup> Street N.W., Washington, D.C. 20531.

Attachments:

Model Privacy Certificate

BJS Screening Sheet for Protection of Human Subjects

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<sup>4</sup>Prior to the awarding of BJS funds, a paper or electronic copy of the fund applicant's IRB assurance must be in the designated OJP file.