HUMAN SUBJECTS PROTECTION

CERTIFICATION OF COMPLIANCE

Name of Organization

Vendor Number

Title of Project (if multiple projects are proposed, one form must be completed for each project)

Application Number (to be completed by BJS)

I. IS THE PROJECT "RESEARCH?"

Is the research project a systematic investigation designed to develop or contribute to generalizable knowledge?

Check "No" if the project is not designed to contribute to generalizable knowledge. Examples of projects that do not contribute to generalizable knowledge may include; operational activities such as program monitoring, projects designed for internal agency use, projects that do not produce public documents, and the development of agency websites.

- _____ No The project does not contribute to generalizable knowledge; therefore, is not considered "research" for the purposes of federal human subjects protection. Skip to Section III and check (B).
- Yes The project contributes to generalizable knowledge; therefore, it is considered "research" for the purposes of federal human subjects protection. Continue to Section II.

II. DOES THE PROJECT INVOLVE HUMAN SUBJECTS?

Will the researcher obtain any information about a living person by communicating with that person?

Yes - Human subjects are involved. Continue to Section III and check (A).

_____ No - Continue to the next question.

Will the researcher obtain identifiable private information (i.e., information not publicly available) about a living person?

"Identifiable information" is information where the identity of the subject may be readily ascertained. Information is "private" if the individual has a reasonable expectation that it will not be made public.

If the researcher is seeking information about a living individual that is publicly available, either from public or commercial sources, check "No." If the researcher is seeking private information about a living individual and no personal identifiers are obtained by the researcher at any point in the project, check "No."

The source of the information is irrelevant for the purposes of this question. Check "Yes" if the researcher will obtain personally identifiable private information about a living person:

- from records about the person (e.g., criminal history records, arrest records, court records),
- from third parties,
- ► from files, or
- ► from any other source.
- _____ Yes Human subjects are involved. Continue to Section III and check (A).
- _____ No Human subjects are not involved. Continue to Section III and check (C).

III. DO FEDERAL HUMAN SUBJECTS PROTECTIONS APPLY?

- A. Federal human subjects protections apply. IRB review of this project is required. An IRB must determine whether full or expedited review is warranted, or determine which exemptions apply, if any (28 CFR Part 46). Documentation from an IRB is required before human subject-related research can begin.
- B. This project is not considered "research" for the purposes of federal human subjects protection. No IRB review is required.
- C. There are no "human subjects" involved in the research project as that term is defined by federal regulations. No IRB review is required.

CERTIFICATION TO BE COMPLETED BY THE APPLICANT:

I certify that, to the best of my knowledge and belief, all of the information provided above is true, complete, and made in good faith.

Signature of Person Authorized to Certify

Title of Person Authorized to Certify

TO BE COMPLETED BY BJS

CLEARANCE BY THE BJS HUMAN SUBJECTS PROTECTION OFFICER:

I have reviewed the Human Subjects Protection Certification of Compliance. Based on the representations made in this document by the applicant and the materials submitted as part of the grant application, the research project meets the federal requirements for human subjects protections found at 28 CFR Part 46.

Signature of the BJS Human Subjects Protection Officer Date IRB documentation is: _____ included in application _____ forthcoming _____ not needed Notes:

Date

Phone number