**Innovations for Poverty Action Institutional Review Board (IRB)**

REQUEST FOR DETERMINATION OF EXEMPT STATUS

**Note: This form does not substitute for an original IRB application. Please use this form to complement your original IRB application and file it separately via** [**poverty-action.org/irb**](https://www.poverty-action.org/irb)**. Do NOT file this application via** [**humansubjects@poverty-action.org**](http://humansubjects@poverty-action.org)**.**

**Date of Application:** Click here to enter a date.

**Title of Study:** Click here to enter text.

**Former or alternate titles if known:** Click here to enter text.

**Study Manager name/email:** Click here to enter text.

**Number of research sites applied for at this time:** Click here to enter text.

**Country(ies) & Location(s):** Click here to enter text.

**Anticipated Start Date & End Date (be specific about date you plan to begin fielding study):**

**Start:** Click here to enter a date.

**End:** Click here to enter a date.

**Principal Investigator(s) filing this application (name, email):**

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# INSTRUCTIONS TO INVESTIGATOR

At the discretion of the IPA IRB, certain research activities may be exempt from review. Research involving human subjects may not start until the HSC has granted either IRB approval or has notified the investigator that the project qualifies for exemption from further review. The types of research which may be exempt are described in the attached list. It is important to note that studies involving minors cannot be exempt under category 2 [45 CFR 46.101(b)(2)] below.

If you believe that your research constitutes one of the types of research which may be exempt from review, please complement your original IRB application with the submission of this form. Please indicate which exemption category / categories may apply to your project by marking the respective checkbox / checkboxes below.

EXEMPTION FROM REVIEW

Certain research activities may be exempt from review, if approved by an authorized Committee member and confirmed in writing to the Investigator. Research may be exempt from review when the only involvement of human subjects in the research falls into one of the following categories:

Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices such that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. 45 CFR 46.101(b)(1)

Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7). 45 CFR 46.101(b)(2)

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. 45 CFR 46.101(b)(3)

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) information, which may be about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act. 45 CFR 46.101(b)(4)

Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and which are designed to study, evaluate, improve, or otherwise examine:

obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.45 CFR 46.101(b)(5)

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. 45 CFR 46.101(b)(6)

**Investigator's name, typed:**

Click here to enter text.

**Investigator's signature (or attach email with PI’s acknowledgement of this application)**

**Date:** Click here to enter a date. **Signature:**