

## INSTRUCTIONS FOR COMPLETING FORM A

### PLEASE TYPE THE INFORMATION REQUESTED ON THE FRONT OF THIS FORM

Provide the required information in the space available, if at all possible. If additional space is necessary, attach a separate sheet. Submit one copy of this form to the Chair of the Institutional Review Board (IRB) for review and approval. [PLEASE NOTE: This form may be reproduced on a personal computer and printed on a high quality printer (e.g. LaserJet, DeskJet).]

**ALL SIGNATURES MUST BE ORIGINAL** on this form. After the Form A is signed by the IRB Chair, a copy of the form will be returned to the Principal Investigator and a copy will be provided to the IRB secretary.

**I.1. OBJECTIVES:** Briefly state, in non-technical language, the purpose of the research, with special reference to human subjects involved.

**I.2. SUBJECTS:** Briefly describe the subjects by number to be used, criteria of selection or exclusion, the population from which they will be selected, duration of involvement, and any special characteristics necessary to the research.

**I.3. METHODS OR PROCEDURES:** Briefly state, in non-technical language, the research methods which directly involve use of human subjects. List any potential risks, or lack of such, to subjects and any protection measures. Explain how anonymity of names and confidentiality of materials with names and/or data will be obtained and maintained. List the names of the individuals who will have access to names and/or data.

**I.4. CATEGORY(S) FOR EXEMPT RESEARCH PER 45 CFR 46:** Referring to the list below from the Code of Federal Regulations, 45 CFR 46.101(b), cite the paragraph(s) which you think entitle(s) this research project to certification as exempt from review by the Institutional Review Board. **Research activities in which the only involvement of human subjects will be in one or more of the following categories are generally exempt from full review by the IRB:**

- (1) Research conducted in established or commonly accepted educational settings, involving normal education practices, such as
  - (i) research on regular and special education instructional strategies, or
  - (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - (ii) any disclosure of human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

**PLEASE NOTE:** *An exemption cannot be used when children are involved for research involving survey or interview procedures or observations of public behavior, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed [45 CFR 46.401(b)]*

- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) above, if:

- (i) the human subjects are elected or appointed public officials or candidates for public office; or
  - (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects that are conducted by or subject to the approval of federal department or agency heads, and that are designed to study, evaluate, or otherwise examine:
- (i) public benefit or service programs;
  - (ii) procedures for obtaining benefits or services under these programs;
  - (iii) possible changes in or alternatives to those programs or procedures; or
  - (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) 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.

**PLEASE NOTE:** *Research involving special or protected populations is subject to full review by the Institutional Review Board. Please complete Form B for such research.*