

activities being observed. Exemption 2 does not apply if children are surveyed or interviewed or if the research involves observation of public behavior and the investigator(s) participate in the activities being observed. [Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law or jurisdiction in which the research will be conducted.]

(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 section (2) above, if the human subjects are elected or appointed public officials or candidates for public office; or 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 a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) 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, (a) if wholesome foods without additives are consumed or (b) 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.

II. Instructions for Exempt and Nonexempt Human Subjects Research Narratives

If the applicant marked "Yes" for Item 12 on the ED 424, the applicant must provide a human subjects "exempt research" or "nonexempt research" narrative and insert it immediately following the ED 424 face page.

A. Exempt Research Narrative.

If you marked "Yes" for item 12a. and designated exemption numbers(s), provide the "exempt research" narrative. The narrative must contain sufficient information about the involvement of human subjects in the proposed research to allow a determination by ED that the designated exemption(s) are appropriate. The narrative must be succinct.

B. Nonexempt Research Narrative.

If you marked "No" for item 12a. you must provide the "nonexempt research" narrative. The narrative must address the following seven points. Although no specific page limitation applies to this section of the application, be succinct.

(1) Human Subjects Involvement and Characteristics: Provide a detailed description of the proposed involvement of human subjects. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, prisoners, institutionalized individuals, or others who are likely to be vulnerable

(2) Sources of Materials: Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

(3) Recruitment and Informed Consent: Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

(4) Potential Risks: Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

(5) Protection Against Risk: Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

(6) Importance of the Knowledge to be Gained: Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

(7) Collaborating Site(s): If research involving human subjects will take place at collaborating site(s) or other performance site(s), name the sites and briefly describe their involvement or role in the research.

Copies of the Department of Education's Regulations for the Protection of Human Subjects, 34 CFR Part 97 and other pertinent materials on the protection of human subjects in research are available from the Grants Policy and Oversight Staff, Office of the Chief Financial Officer, U.S. Department of Education, Washington, D.C. 20202-4248, telephone: (202) 708-8263, and on the U.S. Department of Education's Protection of Human Subjects in Research Web Site at <http://www.ed.gov/offices/OCFO/humansub.html>