



EXEMPT PROTOCOL SUMMARY FORM

Title of Research Project

Principal Investigator (PI) / Project Director

Phone / E-Mail Address

Projected Duration of Research (x# of months)

Projected Starting Date

Other organizations and/or agencies, if any, involved in the study

Exempt under code: 1 2 3 4 5 6

Circle One. Turn for definitions.

Please attach the following:

- o Brief description of the participants
- o Location(s) of the project and identification of any EFC resources needed to conduct the survey (e.g. web applications, data entry, coding, etc.)
- o Procedures to be used for data collection (including population and sampling methodology)
- o Dissemination and use of information collected
- o Whether data will be confidential or anonymous and who will have access to data
- o Informed Consent Form
- o Questionnaires to be used

Responsibilities of the Principal Investigator:

- ✓ Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented.
- ✓ Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair
- ✓ The Principal Investigator is responsible for retaining informed consent documents for a period of three years after the project.

Principal Investigator Signature / Date

Signature of IRB Chair:		Date:	
IRB Chair: Check One Box	Approved <input type="checkbox"/>	Approved W/ Conditions <input type="checkbox"/>	Refer to Full Committee for Review <input type="checkbox"/>

Categories of Exempt Research

Research projects that involve human participants and are exempt from review involve no risks to the participants. Examples of studies that are exempt from review are ones involving anonymous questionnaires or surveys that do not involve a sensitive topic or utilize minors, research being conducted in educational settings involving normally curriculum, and research on archival data.

The following exempt conditions have been developed and described within the Federal Common Rule (45 CFR 46).

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational 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: (1) information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside of the research could reasonable place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior that is not exempt under category (2) of this section, if: the human participants 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 indirectly through identifiers linked to subjects. (NOTE: According to the Office of Human Rights Protection, "To qualify for this exemption, the data, documents, records, or specimens must be in existence before the project begins. The principle behind this policy is that the rights of the individuals should be respected; subjects must consent to participation in research.")
5. Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits under those 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 found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection of the U.S. Department of Agriculture.