

**Pensacola State College
Institutional Review Board**

EXEMPT PROTOCOL SUMMARY FORM

ACTIVITIES EXEMPT FROM COMMITTEE REVIEW

Research activities involving human subjects in the following categories may be exempt from review by Pensacola State College's Institutional Review Board. The principal investigator/project director is authorized to make the first determination of eligibility for exemption; however, the College bears the responsibility for concurring in that determination based on notice provided by the principal investigator to the Institutional Review Board.

*The following exemptions do **NOT** apply when (a) **deception** of subjects may be an element of the research; (b) subjects are **under the age of eighteen**; (c) the activity may **expose the subject to discomfort or harassment** beyond levels encountered in daily life; or (d) **fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions** are subjects of the activity.*

EXCEPT FOR THE ABOVE EXCLUSIONS, the federally-approved Categories of Exemption are:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as (a) research on regular and special education instructional strategies; (b) 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: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research reasonably place the subjects 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, or achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 if: (a) the human subjects are elected or appointed public officials, or candidates for public office, or (b) 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 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 or 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 U.S. Food and Drug Administration or approved by the U.S. Department of Agriculture.

Exempting an activity from review does not absolve the investigator(s) of the activity from ensuring that the welfare of subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity.

Questions about whether a research activity may be exempt from human subjects review can be directed to Debbie Douma, IRB Administrative Liaison, at 850-484-1705.

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Date			File Number
Title of Research Project			
Principal Investigator/Project Director	Department	Extension	Email
Co-investigator/Student Investigator	Department	Extension	Email
Co-investigator/Student Investigator	Department	Extension	Email
Anticipated Funding Source			
Projected Duration of Research	Months	Projected Starting Date	
Other organizations and/or agencies, if any, involved in the study:			

Exempt under code (see definitions on page one – check one):

1	2	3	4	5	6	
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SUMMARY ABSTRACT – Please supply the following information below: BRIEF description of the participants, the location(s) of the project, the procedures to be used for data collection, whether data will be confidential or anonymous, disposition of the data, who will have access to the data. Attach a copy of the Informed Consent Form and/or the measures (questionnaires) to be used in the project.

Investigator/Project Director Signature	Date	Co-Investigator/Student Signature (if applicable)	Date
Signature of IRB Committee Chair		Date ____/____/____	
IRB Chair Check 1 box: <input type="checkbox"/> Approved <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Refer to Full Committee Review			

Revised: 1/09/2012