



Patient Advocacy Council

Institutional Review Board

Application for Exempt Review

601 Bel Air Blvd., Suite 315

Mobile, Alabama 36606

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Web Site: www.pacirb.com

INVESTIGATOR INFORMATION		
Principal Investigator's Name:		
Name of Practice/Clinic:		
Mailing Address:		
Phone number: ())	Fax number: ())	E-mail address:
Principal Investigator's Specialties:		
RESEARCH INFORMATION		
<p>Under federal regulations and the Patient Advocacy Council, Inc. Institutional Review Board policies and procedures, certain research activities may be exempt from Institutional Review Board review. The types of research, which may be exempt are described in the Exempt from Review List [see attached]. If you believe that your research constitutes one of the types of research which may be exempt from Institutional Review Board review, please provide the following information:</p>		
Protocol Title:		
Description of the purpose of the research project:		
Specific research objectives:		
Description of the subjects/research population:		
List of human material/data to be reviewed/collected:		
The manner in which all subject material will be identified to the researchers, including direct identifiers and/or indirect identifiers such as codes that may be linked to the subjects:		
The specific category/categories under which you believe the research may be exempt: _____		

<p>Does the principal investigator, the principal investigator's family, the study staff, or the study staff's family have any financial relationship with the sponsor other than payment for the conduct of the research?</p> <p>If yes, please describe this relationship (i.e., stock ownership or other equity interest, consultation fees, patents, copyrights, trademarks, etc.). Interests valuing over \$10,000 and interest greater than 5% ownership in an organization should be reported.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Principal Investigator's Signature:	Date:

FOR IRB USE ONLY	
<p>Reviewer's Comments:</p> <p><input type="checkbox"/> Project is exempt from IRB review. Identify the item number from the attached list that makes this project exempt</p> <p><input type="checkbox"/> Project must be reviewed by the IRB. Please submit the Application for Initial Review to receive full Board review.</p>	
Reviewer Signature:	Date:

Exempt from Review List

- I. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - (a) research on regular and special education instructional strategies; or
 - (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- II. 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 through identifiers linked to the subjects; and
 - (b) any disclosure of the human subjects' responses outside the research could reasonably place the subject risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- III. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not otherwise exempt 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.

- IV. Research involving the collection of 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 Principal Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- V. 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;
 - (d) possible changes in methods or levels of payment for benefits or services under those programs.

- VI. 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 and Safety and inspection Service of the U.S. Department of Agriculture.