## **Institutional Review Board**

## **Certification of Exemption Form Involving Human Subjects**

University procedures provide for expedited review of research involving human subjects exempt under federal, state, and University regulations. The exempt categories are described on pages 2 of this form. The NPU IRB Committee Chairperson may approve exempt research provided it is in accord with the general principles as stated on page 2 of this form. This form should be submitted with the full IRB application for review. Researchers are still required to certify that their research is exempt by filing this form.

Title of Study:			
Principal Investigator	School/Department		
Email address	Telephone		
PRINCIPAL INVESTIGATOR: No that, to the best of my ability to accord with the general principle Guidelines.	judge, this research q	ualifies for exemption and will	be conducted in
		(signature)	
FACULTY ADVISOR : (if studer Name:	nt application):		
Email address	Telephone		
My signature certifies that this regeneral principles stated on page		m federal regulations and that	it is in accord with the
		(signature)	
Starting Date	Anticipated Terminati	on	
Check category(ies) under winder winder     (see page 2 of this form		lifies for exemption    1    2    2    1    2	
II. Submit a copy of the full IRB	application for review		
Are data from subjects indirectly identifiable	ite for serving as a sub ojects in this research ned to be legally comp ned in a correctional or medical, academic, etc (responses, information	etent?	☐ Yes ☐ No

## RESEARCH QUALIFYING FOR EXEMPTION FROM FEDERAL REGULATIONS FOR THE PROTECTION OF HUMAN SUBJECTS

(Quoted from the Code of Federal Regulations, Title 45, Part 46.101.)

- Educational Research Conducted in Educational Settings: "Research conducted in established or commonly accepted educational settings, involving normal educational 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. <u>Survey/Interview/Observational Research:</u> "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 the 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."
- 3. <u>Survey/Interview Research not Exempted in (2). Above:</u> "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 (b)(2) of this section, 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. <u>Secondary Use of Existing Data:</u> "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." (See below for exceptions.)
- 5. Evaluation and Demonstration Projects of Federal Programs: "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: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services 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 Studies: "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."

## NORTH PARK UNIVERSITY HEALTH PROFESSIONS EXCEPTIONS TO EXEMPTION: EXPEDITED OR FULL REVIEW REQUIRED

See North Park University Health Professions Institutional Review Board Guidelines and the following for clarifying notes on and exceptions to above exemption categories. Studies of subjects involving 1a through 1e as listed below are NOT exempt and require IRB committee approval.

- 1. Research activities involving subjects except in the case of categories 1, 2, and 4, above:
  - a. Minors under the age of 18
  - b. pregnant women where pregnancy is the focus of the research;
  - c. prisoners;
  - d. fetuses in utero;
  - e. persons incompetent to provide informed consent.
- Research involving the use of medical, academic and other personal records (including psychiatric records) without consent.
- 3. Research involving the use of tissue obtained at autopsy.