

Notre Dame de Namur University Institutional Review Board

Forms: Exempt Checklist

No Handwritten Forms will be accepted

Fall Spring Summer _____ (Year)

Name of Principal Investigator _____

Name of Student Investigator _____

Check the category(s) that apply to this research. To qualify as exempt from the federal policy for the protection of participants, research must be limited to one or more of the following categories from 45 CFR §46.101(b):	
<input type="checkbox"/>	(1) 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.
<input type="checkbox"/>	(2) Research involving at least one of the following methods: the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures,; and/or interview procedures or observation of public behavior. In addition, the following are true: (i) The information obtained is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the participants' responses outside the research will not reasonably place the participants at risk of criminal or civil liability or be damaging to any participant's financial standing, employability, or reputation. NOTE: If children are involved in research, this research exemption does not apply, except in limited circumstances. Contact the NDNU IRB Committee Chair at 650-508-3728.
<input type="checkbox"/>	(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 item (2) of this section, if: (i) The 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.
<input type="checkbox"/>	(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 participants cannot be identified, directly or through identifiers linked to the participants.
<input type="checkbox"/>	(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: (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.
<input type="checkbox"/>	(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 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.

Note: Should the response to any item in the list change after approval, the principal investigator is required to get the approval from the IRB committee before the change can be implemented.

 For IRB Committee Use:

Approved by _____ NOT Approved by _____ Date _____

Resubmit with recommended changes (please see letter attached)

IRB Approval # _____ Committee Comments: _____