

Proposal ID No.: _____
(Assigned by IRB)

NEUMANN UNIVERSITY
Aston, Pennsylvania
Request for IRB Screening for an Exemption

Preamble:

Neumann University requires that research involving human subjects under the direction of Neumann University faculty staff and students, using any University facility or property, externally funded or not, regardless of location or research site, must be submitted to the Neumann University Institutional Review Board (IRB) for review and approval.

This requirement is in compliance with the Federal policy as stipulated in the DHHS regulations for protection of human subjects, 45 CFR 46. The involvement of human subjects in your research will not be permitted until Neumann University IRB has reviewed and approved the research protocol and forms.

No Neumann University faculty, staff or students may conduct human subject research without obtaining IRB approval (Screening for an Exemption, Expedited Review, Full Review applications).

Section A:

Principal Investigator Information

Name and title of Principal Investigator

Mailing Address:

Telephone: _____

Email Address: _____

Name and title of Co-Investigator:

Mailing Address:

Telephone: _____

Email Address: _____

Faculty Advisor (If Student Project): _____

Department/Division: _____

Telephone: _____

Email Address: _____

Section B:
Project Title:

Section C:
Exemption Criteria Checklist:

Exemption Categories Allowed Under 45 CFR.46.101(b)

_____ (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.

_____ (2) 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) 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 (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) 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 [Federal] 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 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.

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Section D:
Project Description

Please provide a description on the following: (Attach description to this Form)

1. List the research objectives
2. Explain the project design
3. Explain the characteristics of the human subject population
4. Describe the plan for recruitment of the subjects
5. Describe the research procedures (especially pertaining to human subjects)
6. Describe any potential risk and how these risks will be minimized (especially on how participants' confidentiality will be protected)
7. Provide a justification for the category of exemption under which you are applying
8. Indicate whether you intend to publish or present the results of the project and their venues, if any
9. Provide a copy of the instruments that will be used in the project (cover letter, consent form, survey questionnaire, interview questions)
10. Explain who will have access to the data and the deposition of the data

Section E:

1. I understand that the research will not be initiated until written approval is secured from the IRB.
2. If the research protocol changes in such a way that the basis for exemption no longer conforms to the criteria of exemption, a new request for review will need to be submitted.
3. If an exemption is not granted, the Principal Investigator will submit either an Expedited Review or Full Review request to IRB and to secure a written approval from IRB before the initiation of the project.

Principal Investigator Signature: _____ Date: _____

Faculty Advisor (for student project) Signature: _____ Date: _____