

Institutional Review Board
Exempt Status Determination

CATEGORIES OF RESEARCH CONSIDERED EXEMPT

Research activities involving human subjects in the following categories may be determined to meet exempt status criteria by the North Shore Community College Institutional Review Board or its authorized representative. The principal investigator/project director is authorized to recommend the protocol for exemption; however, the NSCC IRB will make the final determination based on the application provided by the principal investigator to the Institutional Review Board. Please cite the appropriate exemption number on this application form. Questions about whether a research activity may meet exempt status determinations for human subject research can be directed to the IRB Contact at 978.762.4000 ext 5496..

The federally-approved Categories of Exemption found in 45 CFR 46.101(b) (exceptions are noted below¹) 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, 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 at or below the level found to be safe by the U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

¹The preceding exemptions do NOT apply if (a) deception of subjects may be an element of the research; (b) subjects are under the age of eighteen; (c) the subjects may encounter more risk than they may experience in daily life; or (d) any vulnerable populations are subjects of the activity.

Research that meets the criteria for exempt status 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.

Application for Exempt Status Determination

Submit documents electronically to lrubin@northshore.edu or in hard copy to: Math/Science 201B
NSCC, 1 Ferncroft Road, Danvers, MA 01923

Title of Research Project:

Principal Investigator/Project Director**:

Phone _____ Email address _____

Co-investigator/Student Investigator:

Phone _____ Email address _____

Co-investigator/Student Investigator:

Phone _____ Email address _____

Anticipated Funding Source:

Projected Duration of Research: _____ months _____ Projected Starting Date: _____

Other organizations and/or agencies, if any, involved in the study:

Check box for Exemption Category applied for under 45 CFR 46.101(b): 1 2 3 4 5 6

SUMMARY: Please include the following information.

Description of the purpose of the research

Description of the participants you intend to use for the research

The location(s) of where the research will be conducted

The procedures/methods to be used for data collection and whether any identifying information will be collected

How subjects will be recruited

How data will be protected and disposed of, and who will have access to the data.

If applicable, attach an Informed Consent Form and any additional materials to be used in the project (e.g. survey instruments, questionnaires, recruitment flyers or brochures, etc.).

PRINCIPAL INVESTIGATOR ASSURANCES AND SIGNATURE:

I will submit any additions or changes in procedures in the protocol to the IRB for written approval prior to these changes being implemented. If there is any change in risk, I am aware that I may need to apply for a different approval status from the IRB.

Once the project has begun, I will communicate any problems involving the use of human subjects to the IRB Chair.

I will retain the informed consent documents for a period of three years after the project.

I (and all associated investigators) have completed the required human subject research training and our certificates are on file or have been sent to the IRB Chair.

Principal Investigator Signature

__/__/__
Date

Co-Investigator/Student Signature

__/__/__
Date

Printed Name of PI

Printed Name of Co-PI/Student

**Please attach to this page a statement of researcher qualifications including a current resume/C.V. for each participating researcher.