

# IRB Form 1

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## Checklist for Human Subjects Research that is Exempt from IRB Review

Before performing Human Subjects Research at Lehigh Carbon Community you must read and understand Lehigh Carbon Community's Guidelines for Human Subjects Research.

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Name of Principal Investigator: \_\_\_\_\_

Title of Principal Investigator: \_\_\_\_\_

Title of Research Project: \_\_\_\_\_

Signature of Principal Investigator: \_\_\_\_\_

Date: \_\_\_\_\_

If this is student research it requires a faculty or staff sponsor.

Name of Sponsor: \_\_\_\_\_

Title of Sponsor: \_\_\_\_\_

Signature of Sponsor: \_\_\_\_\_

Date: \_\_\_\_\_

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# IRB Form 1

Use the following checklist to ensure that your research is exempt from IRB review:

**Part A (all items must apply).** Put a check mark near all items that apply to your research.

1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.

2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3. The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4. The research does not involve subjects under the age of 18, **except** as they are participating in projects that fall under categories 1, 3, 4, and/or 5 in Part B. Category B 2 studies that include minors should be submitted for expedited or full review (see IRB Form 2, Part B, 4 b, for guidelines).

5. The research does not involve deception.

6. The procedures of this research are generally **free of foreseeable risk** to the subject.

7. The research does not require a waiver from informed consent procedures.

**Part B (at least one item should apply).** Put a check mark near all items that apply to your research.

1. Research conducted in established or commonly accepted educational settings and involving normal educational practices (e.g., research on regular and special education instructional strategies, research on 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, where information is recorded anonymously (i.e., so that the human subject cannot be identified, directly or indirectly through identifiers linked to the subject). [NB: All survey/interview/observational research in which elected or appointed public officials or candidates for public office serve as subjects is exempt, whether or not data collection is anonymous.]

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources must be either publicly available

or the information must be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).

\_\_ 4. Research (including demonstration projects) conducted by or subject to the approval of federal department or agency heads, and designed to study, evaluate, or otherwise examine (i) public benefit or service programs (e.g., social security, welfare, etc.); (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.

\_\_ 5. Research involving taste or food quality evaluations or consumer acceptance studies, where the tested products are wholesome foods without additives, or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the U.S. Department of Agriculture.