Checklist for Determining Exempt Research Status

Instructions: Use this worksheet to determine whether a complete protocol application needs to be submitted for your proposed project to the Institutional Review Board. This worksheet is designed to help investigators find out whether their project constitutes human subjects research, according to the definitions provided by the federal regulations for the protection of human subjects - 45 CFR 46, posted on the Office of Human Research Protections (OHRP) website. Please fill out the information in the prescribed order to ensure accuracy. Students: Complete this worksheet with your faculty supervisor. All: Retain this worksheet for your records. **Researchers who believe that their project warrants exempt status should submit this form to the IRB/IACUC Chair at irb@elmhurst.edu**.

PROJECT INFORMATION:

Completed By: Date:

Signature of Faculty Supervisor (if applicable): Date:

Project Title:

Description of project: *Briefly describe the purpose of the research and the methods that will be implemented for data collection.*

CATEGORY A: EXEMPT STATUS:

Definition: Exempt research projects present risks so benign to the human subjects who participate in them, that the federal regulations say such projects are exempt from review. Nevertheless, given the inherent conflict of interest with a researcher designating their own project as exempt, this status must be determined by an independent board of researchers (the IRB) who ensure that the research poses minimal risks to participants. Exempt status allows researchers working on the project to amend their study materials at their own discretion. The researchers need to submit revisions to the IRB only when the revisions proposed might threaten the "exempt" status – or in other words, the revisions being made pose more than benign risk to human subjects. The primary investigator (faculty or staff) of this research is the one who makes this risk assessment. If the researcher is unsure whether study changes increase risk, please contact the chair of the IRB.

CLASSIFICATION PART A: Please check each box that applies. This ensures that you read this material and believe that your project meets the following criteria. In order to obtain exempt status, <u>all of these boxes must be checked to proceed</u>.

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

☐ 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.

☐ 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).

☐ The research does not involve subjects under the age of 18.

☐ The research does not involve deception.

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

☐ The research does not require a waiver from informed consent procedures (i.e., a consent form will be included in your procedures.

Initial here to confirm that you still believe your research qualifies as exempt:

CLASSIFICATION PART B: In order to establish that your research qualifies for exempt status, <u>at least 1 of the following criteria must apply to your research project</u>. Please check all relevant boxes:

☐ (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.

> *Example – A math instructor comparing the effectiveness of posting videos of step-by-step solutions for select homework problems online to working through select homework problems step-by-step during class time.*
> *Example – Exploring the advantages and disadvantages of a writing assignment that requires students to share their writing with their peers and receive peer feedback regularly throughout the writing process.*

☐ (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.

> *Example – A survey of Elmhurst University students on their use of the internet.*
> *Example – Interviewing local bar owners about the impact of new liquor laws on their businesses.*
> *Example – Observing how fans of opposing teams interact while watching college football games.*

☐ (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.

Example – An interview with the mayor of Elmhurst about the city's relationship with Elmhurst University.
Example – Exploring the relationship between extraversion scores (one of The Big Five personality traits) and approval ratings of members of the Illinois House of Representatives.

☐ (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.

Example – Analyzing the voting records of members of the U.S. Senate and House of Representatives on environmental issues.
Example – Analyzing human tissue samples that already existed at the time of the application and will be handled in a way that the samples cannot be linked to the subjects they came from.

☐ (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.

Category 5 research is reserved for Federal Government Research – not applicable for Elmhurst University IRB Review

☐ 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.

Example – Tasting new ice cream flavors in the cafeteria to determine which flavors to make part of Chartwells' everyday offerings.
Example – Tasting salsas to determine which is the spiciest.

Initialing here indicates that you believe your research meets all the qualifications for exempt status:

Note: The research cannot involve prisoners or be subject to FDA regulation. Children may participate but you must obtain parental consent and child assent.

If you believe that your research does NOT qualify for exempt status, please initial here:

If the project does not meet the requirements for exempt status, the researcher should submit an application for research involving Human Subjects (IRB) or Animal Subjects(IACUC).