

Criteria for Exemption from IRB Review

Institutional Review Board

There are specific criteria defined by the US Department of Health and Human Services in 45 CFR 46.101 (b) that qualify a research project for exemption from review by an Institutional Review Board (IRB). Please note that the determination of whether a research project is exempt cannot be made by the Principal Investigator; it must be made by an IRB or other official appointed by an institution. Even if a project is certified as exempt by an external IRB, it must still be approved by CVTC, as the project may still not be acceptable for other reasons.

The exempt categories of research as outlined by 45.CFR46.101(b) include:

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 item (2) 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 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.

If your research would be included in one of the previous categories as outlined by 45.CFR46.101(b), please indicate you are seeking **Exempt Determination** when completing the **Research Approval Application Form** for the Institutional Review Board. Approval by the IRB needs to be granted prior to beginning your research at CVTC. This exemption still needs to be verified and determined by an IRB official.