

EXEMPT RESEARCH REQUEST

WEST COAST UNIVERSITY INSTITUTIONAL REVIEW BOARD (IRB) REVIEW

Research activities are exempt from IRB oversight when the only involvement of human subjects is within one or more of specific exempt categories.

Any investigator requesting exemption of a project from IRB oversight needs to complete this form and submit it to the IRB along with a completed West Coast University IRB Application Form.

The exempt categories (listed below) do not pertain to research involving prisoners or research regulated by the U.S. Food and Drug Administration (FDA) unless that research meets the criteria for exemption described in 45 CFR 46.101(b)(c) and 21 CFR 56.104(d).

Research that otherwise could be exempt but that raises ethical concerns or requires measures to protect subjects may be moved to a higher level of review (i.e., expedited or full board review) at the discretion of the IRB.

Study activities may not be implemented until the investigator receives final written IRB notification that the exemption has been granted.

Check the appropriate category(ies) that you think qualifies your research project as exempt:

	<p>1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special educational instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. [45CFR46.101(b)(1)]</p>
	<p>2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless both of the following are true:</p> <ul style="list-style-type: none">(a) information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; and(b) any disclosure of the 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, insurability, or reputation [45CFR46.101(b)(2)] <p>NOTE: If the research involves children as participants, the research must be limited to educational tests (cognitive, diagnostic, aptitude, achievement) and observation of public behavior when the investigator(s) do not participate in the activities being observed. Research involving children that uses survey procedures, interview procedures, or observation of public behavior when the investigator(s) participate in the activities being observed cannot be granted an exemption.</p>
	<p>3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publically 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 [45CFR46.101(b)(4)]</p> <p>To qualify for this exemption, data, documents, records, or specimens must exist at the time the research is proposed.</p>

	<p>4. Taste and food quality evaluation and consumer acceptance studies:</p> <ul style="list-style-type: none">(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 [45CFR46.101()(6) and 21CFR56.104(d)]
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Principle Investigator Signature

Date