

"Risk & Review," a tool for research ethics review

Emily Carr University promotes a high standard of ethics and integrity in research and scholarship. All university-affiliated research activities involving human participants require review and approval from the Emily Carr University Research Ethics Board (ECU-REB). Research ethics review is proportionate to the amount of risk proposed. This tool helps determine the level of research ethics review required for projects. The opinion of the ECU-REB should be sought if there is any doubt or confusion over the determination of levels or risk and review.¹

Level 1 Research - EXEMPT

If the answers to all the following questions are **Yes**, the research activity is likely **exempt** from ethics review. These activities should not be included in a research ethics application unless an explanation is necessary to understanding research activities that require review.

If any of the answers are **No**, complete the rest of the questions on the next page.

	Research Ethics Review Exemptions	Y	N	Review Level
1.	Are the activities outside of a Tri-Council definition of "research"? <ul style="list-style-type: none"> ○ Research is defined as "an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. The term 'disciplined inquiry' refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community." (TCPS2, Article 2.1) ○ Note: The TCPS2 expects the research activities for "theses or equivalent research projects involving human participants" to have research ethics review (Article 6.12). Thesis research is usually not exempt. 			Yes - Level 1 - Exempt
2.	Is the project a quality assurance or quality improvement study rather than academic research? <ul style="list-style-type: none"> ○ When organizations take up quality assurance and quality improvement studies, these are exempt from research ethics review when the activities are used exclusively for the organization's internal assessment, management, or improvement purposes; AND, when they are not considered academic research. 			Yes - Level 1 - Exempt
3.	Do the research activities involve collecting data that is already legally accessible? <ul style="list-style-type: none"> ○ Materials or data that are already legally accessible to researchers and appropriately protected by law are exempt from research ethics review. This includes the secondary use of anonymous data or previously published data or findings that are legally accessible to the researcher. (In Canada, this exemption does not apply to primary research, even if it is limited to anonymous data collection.) 			Yes - Level 1 - Exempt
4.	Do the research activities involve unobtrusive observations? <ul style="list-style-type: none"> ○ Observing people in public is exempt from research ethics review when: it does not include an intervention by the researcher; AND, when the targeted observation does not violate a reasonable expectation of privacy for that site; AND, when the research results do not reveal individuals' identity. 			Yes - Level 1 - Exempt
5.	Is the participant research outside of University employees' or students' work or roles at the University, and does not involve employees, students, or the University facilities? <ul style="list-style-type: none"> ○ Research conducted by university employees or students, outside of their university roles, is exempt from the university's research ethics review. These activities must not involve the researcher's university titles, the university name, the facilities, students, staff, or any form of communication that might be seen to indicate university support of the research. 			Yes - Level 1 - Exempt
6.	Are the participant research activities part of the initial exploratory phase of a larger participant research project? <ul style="list-style-type: none"> ○ Initial exploratory research activities are exempt from research ethics review when the activities (including interviews or observations, for example) are needed to determine the feasibility of research, establish partnerships, or to design a research proposal. Without research ethics approval results from this phase of research cannot be included in the research data or outcomes. 			Yes - Level 1 - Exempt
7.	Is this a creative practice project in which the involvement of humans is <i>not</i> a research activity? <ul style="list-style-type: none"> ○ Creative practice activities are exempt when the research does not "obtain responses from participants that will be analyzed to answer a research question" (TCPS2, Article 2.6). The TCPS2 definition of "research" (above) should also be consulted to determine if the activities qualify for the creative practice exemption. 			Yes - Level 1 - Exempt

¹ The ECU-REB is tasked with making the final determination of level of research ethics reviews. This document is only a resource to assist researchers in understanding how decisions are made, and to assist ECU-REB reviewers in decision-making.

Level 2 Research – LOW RISK

If the answers to all the questions on this page are **No**, the research is expected to be low risk, but still needs research ethics approval. In most cases, these applications will be reviewed by one reviewer and staff. With course-based research ethics approval, review of Level 2 student research is delegated to course instructors.

Level 3 Research – MINIMAL RISK

If the answers to questions **1, 2, or 3** on this page are **Yes**, the proposed research is expected to be minimal risk, but still needs research ethics approval. In most cases, these applications will be reviewed by one reviewer and staff.

Level 4 Research – BEYOND MINIMAL RISK

If the answers to questions **4, 5, 6, or 7** on this page are **Yes**, the proposed research is expected to be beyond minimal risk and needs research ethics approval. Applications for this research may require a meeting of the full board.

		Y	N	Review Level	
1.	Does the research involve other research ethics boards or protocols? <ul style="list-style-type: none"> o Partnership with schools, universities, hospitals or health authorities may require additional ethics review. Research with First Nations, Inuit and Métis peoples may be subject to specific cultural protocols and/or regional research ethics review. If any organizations or groups that have their own research ethics or research approval protocols are involved in this research, indicate Yes. 			If all are No - Level 2 – Low Risk	Yes - Level 3 – Minimal Risk
2.	Are any of the research participants unable to provide consent to research independently? <ul style="list-style-type: none"> o Note: The age of majority in BC is 19. Legal age of consent is not always required for research, but in most cases parental consent is expected for children involved in research. 				Yes - Level 3 – Minimal Risk
3.	Will in-person participant research activities take place outside of the Emily Carr University premises?				Yes - Level 3 – Minimal Risk
4.	Do the participant research methods involve testing of items subject to regulation or safety testing? <ul style="list-style-type: none"> o If items being tested present a potential harm to research participants, if an individual will be assessing them for safety prior to use in research, or if they fall within jurisdiction of other regulators like "Medical Devices Bureau", indicate Yes. 				Yes - Level 4 – Beyond Minimal Risk
5.	Does the research impact the vulnerability of individuals, groups or communities whose circumstances make them vulnerable in the context of the research? <ul style="list-style-type: none"> o If the research methods might intensify the vulnerability of the participants' circumstances, indicate Yes. 				Yes - Level 4 – Beyond Minimal Risk
6.	Do the research methods involve deception of the participants? <ul style="list-style-type: none"> o If there are any areas of the research activities which will be hidden to the participants and not disclosed in the consent materials, indicate Yes. 				Yes - Level 4 – Beyond Minimal Risk
7.	Do the participant research activities present more than minimal risk to participants? <ul style="list-style-type: none"> o If there is a probability and magnitude of possible harms to participants that is greater than those encountered in similar, everyday activities, indicate Yes. 				Yes - Level 4 – Beyond Minimal Risk

For more information, including the timing of full board reviews, contact the Research Ethics Coordinator – ethics@ecuad.ca