

GUIDELINES 202.2 *The Risk & Review Tool* – Preparing 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).

Since the level of research ethics review is proportionate to the amount of risk proposed, the following risk assessment will help you to understand the level of research ethics review that may be required for your project. Though the assessment of risk and review is ultimately determined by members of the ECU-REB, this tool will assist researchers to anticipate the level of review their project will require, based on an assessment of risk.¹ *The Risk & Review Tool* begins by explaining how some activities may be exempt from research ethics review and then it goes on to describe research activities that may be associated with a level of risk.

Risk & Review Level 1 – Research activities that are EXEMPT from research ethics review

If the answers to 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 it is necessary to explain them in an application that includes other non-exempt research activities.

	Research Ethics Review Exemptions	Y	N	Review Level
1.	<p>Are the activities outside of a Tri-Council definition of "research"?</p> <ul style="list-style-type: none"> Although ethical concerns may be present in projects that utilize research methods, the research ethics review process only applies to projects that fit the Tri-Council definition of research. The Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS2) defines "research" 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" (Article 2.1). Note: although student research may not yet be ready to "withstand the scrutiny" of a professional research community, the TCPS2 includes guidance for the review of research activities within courses that teach research methodologies and for the review of "theses or equivalent research projects involving human participants" (Article 6.12). 			Yes - Level 1 - Exempt
2.	<p>Can the project be described as a quality assurance or quality improvement study rather than academic research?</p> <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.	<p>Do the research activities involve collecting data that is already legally accessible?</p> <ul style="list-style-type: none"> Collecting materials or data that is legally accessible to researchers and appropriately protected by law is 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. Note: In Canada, this exemption does not apply to primary research, even if it is limited to anonymous data collection. 			Yes - Level 1 - Exempt
4.	<p>Do the research activities involve unobtrusive observations?</p> <ul style="list-style-type: none"> Observing people in public when it does not include an intervention staged by the researcher; AND, when the targeted observation does not violate a reasonable expectation of privacy for that site; AND, when the dissemination of the research will not enable the identification of individuals is exempt from research ethics review. 			Yes - Level 1 - Exempt
5.	<p>Is the participant research not being conducted by University employees or students, as part of their roles at the University, and is not involving employees, students or the University facilities.</p> <ul style="list-style-type: none"> Research conducted by University employees or students, outside of their roles at the University is exempt from research ethics review. This applies to activities that do not involve the use of the researcher's university titles, the university name, the facilities, students, staff, or any form of communication that might be construed as support for, or involvement in, the research by the university. 			Yes - Level 1 - Exempt
6.	<p>Are the participant research activities part of the initial exploratory phase of a larger participant research project?</p> <ul style="list-style-type: none"> Initial exploratory research activities are exempt from research ethics review when the activities (interviews, observations) are needed to determine the feasibility of research, establish partnerships, or to design a research proposal. If results from this phase of research need to be included in the research data or outcomes, research ethics approval is required. 			Yes - Level 1 - Exempt
7.	<p>Is this a creative practice project in which the involvement of humans is <i>not</i> a research activity?</p> <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" and when the results are not circulated as academic research (TCPS2, Article 2.6). 			Yes - Level 1 - Exempt

Once it is determined that the research activities require ethics review, the type of review process will be proportionate to the level of risk to participants. The following list of risks corresponds to the level of review available through the ECU-REB. If all of the answers to the “Parameters of Risk” questions are **No** the expected level of review is **Risk & Review Level 2 – Low Risk Research**. These levels are explained below.

Note: this list which has so far been called the “Parameters of Risk” is unique to Emily Carr University. Other universities or ethics boards have developed other tools or criteria for applying proportionate review processes.²

	“Parameters of Risk”	Y	N	Review Level	
1.	Does the research involve other research ethics boards or protocols? <ul style="list-style-type: none"> 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 of these organizations or groups are involved in this research, indicate Yes. 			If all are No - Level 2 – Low Risk	Yes - Level 3 – Minimal Risk
2.	Will the research participants be legally declared minors or under legal guardianship? <ul style="list-style-type: none"> The age of majority in BC is 19. 				Yes - Level 3 – Minimal Risk
3.	Will the 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 other regulation or safety testing? <ul style="list-style-type: none"> If items being tested present a potential harm to research participants, if an individual will be assess 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 target vulnerable individuals, groups or communities? <ul style="list-style-type: none"> “Vulnerability” may apply to individuals whose legal autonomy is compromised (for instance, those who are incarcerated or seeking refugee status), to socially, economically or politically isolated groups (for instance, geographically isolated indigenous communities, or people living in economically disadvantaged zones), or to people who are vulnerable to coercion due to the benefits of research (for instance, disabled people who may rely on the outcomes of research as low cost solutions to everyday predicaments). 				Yes - Level 4 – Beyond Minimal Risk
6.	Do the research methods involve deception of the participants? <ul style="list-style-type: none"> 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"> 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

Risk & Review Level 2 – Low Risk Research

If the answers to **all** of the Parameters of Risk (above) are **No**, the proposed research is expected to be Low Risk, but still needs research ethics approval. Applications for this research can be submitted at any time. In most cases, these applications will be reviewed by the Chair of the ECU-REB, and results will be available within a week of submission.

Risk & Review Level 3 – Minimal Risk

If the answers to the Parameters of Risk **1, 2, or 3** are **Yes**, the proposed research is expected to be Minimal Risk, but still needs research ethics approval. Applications for this research can be submitted at any time. In most cases, these applications will be reviewed by three delegated ECU-REB reviewers. Results will be available two to three weeks after submission.

Risk & Review Level 4 – Beyond Minimal Risk

If the answers to the Parameters of Risk **4, 5, 6, or 7** 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. The approval process could take 2-3 months. For more information, <http://www.connect.ecuad.ca/research/reb/when> .

¹ If reviewers determine a different level of risk and review than what a researcher identifies on the application, researchers will be informed of the changes and of how the change will affect the progress of the review.

² Another available tool that has been made available for health researchers is the ARECCI Ethics Screening Tool. Presented as a no-cost interactive survey, the ARECCI generates a score and category of risk to participants. It can be found here - <http://www.aihealthsolutions.ca/initiatives-partnerships/arecci-a-project-ethics-community-consensus-initiative/tools-and-resources/>