



EMILY CARR UNIVERSITY RESEARCH ETHICS BOARD (ECU-REB)

ECU-REB Standard Operating Procedures

SECTION 200	Ethics Review & Monitoring
RESPONSIBILITY FOR EXECUTING THIS POLICY:	Members of ECU-REB, Research Ethics Board Coordinator
APPROVAL AUTHORITY:	Director of Research
EFFECTIVE DATE:	June 17 2014
SUPERCEDES SOP DATED:	

Purpose

The purpose of **Section 200 Ethics Review & Monitoring** is to describe in detail the ECU-REB procedures for reviewing and monitoring research ethics in order to promote consistent and accountable service.

SOP 201 – Pre-Review – The application process

- **FORM 201.1 Research Ethics Application** will be completed for project-based research, including Graduate Student research projects.
- **FORM 201.2 Research Ethics Application for Externally Approved Research** will be completed for project-based research that has already been approved by another institutional REB. Alongside this form all of the correspondence concerning the original application, including revisions, will be reviewed in the place of a full Emily Carr University research ethics application.
- Upon receipt of the application, the Coordinator will pre-read the application to determine its completeness. The applicant will be asked to provide missing documents or details as required.
- When applications are received between the scheduled review meetings, they will be pre-read by the ECU-REB Chair to determine the proportionate level of review required, based on an initial assessment of risk as well as the availability of delegated reviewers.
- If applications are received by the regular review meeting deadlines, the Coordinator will pre-read the application for completeness and schedule them for review within the review meeting. Completed applications will be circulated to ECU-REB members, one week before the review meeting.
- The following consent templates are available from the ECU-REB website for applicants to use and modify:
 - **TEMPLATE 201.3 Invitation and Consent (General)**



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- **TEMPLATE 201.4 Invitation, Consent & Assent (Minor)**
- **TEMPLATE 201.5 Media Release (General)**
- **TEMPLATE 201.6 Media Release (Minors)**
- **TEMPLATE 201.7 Internet Preamble**

SOP 202 – Ethics Review

- The process of ECU-REB ethics review will be documented in **FLOWCHART 202.1 ECU-REB Project Review**. This diagram will be circulated through the ECU-REB web site, workshops, and other communications.

SOP 203 – Approval

- Results of the ECU-REB ethics review will be communicated to applicants with the following:
 - **TEMPLATE 203.1 Approval Status Letter – “Requires Clarification”**
 - **TEMPLATE 203.2 Approval Status Letter – “Conditional Approval”**
 - **TEMPLATE 203.3 Approval Status Letter – “Conditional Approval for Course-Based Research”**
 - **TEMPLATE 203.4 Approval Status Letter – “Full Approval”**
 - **TEMPLATE 203.5 Approval Status Letter – “No Approval”**
 - **TEMPLATE 203.6 Approval Status Letter – “Exempt from Ethics Review”**
- Applicants with research funding that is pending ethics approval will apply for partial release of funds for the non-participant portion of the research using **FORM 203.6 Partial Release of Funds Request**.

SOP 204 – Post Approval

- Applicants will request amendments to approved participant research protocols by completing **FORM 204.1 Annual Review or Request to Amend Approved Research**. Requests for amendments will be accepted at any time. For multi-year research, this form will be completed at the conclusion of each year of research. At that time, it will describe the participant involvement of the previous year and any proposed changes to the research for the coming year.
- Adverse incidents will be reported to the ECU-REB as soon as possible using the **FORM 204.2 Adverse Incident Report**. The ECU-REB Chair will meet with the individuals involved in the incident, ensure a mitigation strategy is planned and implemented if



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necessary. The signed **FORM 204.2 Adverse Incident Report** will be circulated to the named individuals and the Director of Research.

- At the completion of participant research, the researcher will complete and submit **FORM 204.3 Research Ethics Completion**.

SOP 205 – Student Learning and Course-Based Research Ethics Review

- A Course-Based research ethics review process will be available for Faculty Members who instruct courses that involve participant research activities.
- Instructing Faculty Members will apply for ethics approval of their course-based participant research by completing **FORM 205.1 Course-Based Research Ethics Application**.
- When there are no changes to the instructors or to the course content, and upon the receipt of the updated documents and application, formal notice of renewed approval will be provided by the Coordinator. The Coordinator will report on renewals at the subsequent meeting with the Chair and at the subsequent ECU-REB Review meeting.
- When course-based research is expected to fit within the parameters described in **GUIDELINES 205.5 Parameters of Risk**, and upon the receipt of the updated documents and application, formal notice of approval will be provided by the Coordinator. The Coordinator will report on low risk approval at the subsequent meeting with the Chair and at the subsequent ECU-REB Review meeting.
- **FORM 205.2 Student Research Ethics Application** will be available for use, at the discretion of the instructing Faculty Members, in courses that are approved for participant research.
- **FORM 205.4 Student Research Ethics Completion** is available for the instructing Faculty Members to use within their course in order to ensure that individual and group student research records are duly assembled and stored.
- At the completion of the course, the instructing Faculty Member will complete and submit **FORM 205.3 Course-Based Research Completion**.
- The following Guideline documents are available to researchers involved in course-based participant research:
 - **GUIDELINES 205.5 Parameters of Risk in Course-Based Participant Research**
 - **GUIDELINES 205.6 Research Within Classrooms**



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- Upon request from instructing Faculty Members, the Coordinator will deliver in-classroom workshops on research ethics and research ethics review processes.
- Upon request from instructing Faculty Members, the Coordinator will generate a report on their students' TCPS2:CORE completion.
- The process of ECU-REB ethics review of course-based research will be documented in **FLOWCHART 202.1 ECU-REB Course-Based Review**. This diagram will be circulated through the ECU-REB web site, workshops, and other communications.
- The Coordinator will provide an explanation of the ECU-REB ethics review of course-based research for inclusion in the Faculty Handbook.