Research Human Ethics Procedure

Section 1 - Background and Purpose

(1) Research conducted with or about people or their data or tissue has the potential to raise conflicts with ethical considerations. It can also expose research participants to sometimes significant risks. Human research is governed in Australia by the National Statement on Ethical Conduct in Human Research (2007) (National Statement). The purpose of the National Statement is to promote ethically good research that accords participants with the respect and protection that is due to them, and is of benefit to the wider community.

(2) La Trobe University has set in place policies and procedures to ensure that human research conducted by La Trobe staff and students conforms to the National Statement, other related legislative requirements and current best practice. The University Human Research Ethics Committee (HREC) is responsible for ensuring compliance with the National Statement by reviewing, approving and monitoring all human research conducted by La Trobe staff and students.

Section 2 - Scope

(3) Refer to the Research Integrity Policy.

Section 3 - Policy Statement

(4) Refer to the Research Integrity Policy.

Section 4 - Procedures

Part A - Regulatory Environment

(5) Human research is governed by the National Statement. In Victoria, human research also needs to comply with the requirements of state regulators, including Privacy Victoria, the Department of Health and Human Services and the Department of Justice. Researchers should consult with the legislation of other states and countries when planning to conduct research outside Victoria. La Trobe researchers and research trainees are also expected to adhere to responsible research practice as established by the Australian Code for the Responsible Conduct of Research (2018).

Part B - Role of the University Human Research Ethics Committee

(6) The primary responsibility of an Human Research Ethics Committee (HREC) is to ensure, on behalf of the institution for which it acts, that all activities relating to the National Statement on Ethical Conduct in Human Research (2007) Updated 2018 (the National Statement) and to ensure research proposals are designed in accordance with the following values:

a. Respect for human beings
b. Research merit and integrity
c. Justice
d. Beneficence

(7) In accordance with the National Statement, La Trobe has established a HREC and a Low Risk Sub-Committee. For hereon, any function of the HREC is also a function of its Sub-Committee unless stated otherwise.

(8) The HREC and its Sub-Committees review applications for projects and must approve only those applications that are ethically acceptable as defined by section 2.1.3 of the National Statement and conform to the requirements of the National Statement.

Part C - HREC Terms of Reference

(9) The HREC terms of reference comply with those specified in the National Statement. As a subcommittee of the Research and Graduate Studies Committee (RGSC) the HREC reports on a regular basis to the RGSC. The Terms of Reference are publicly available on the Ethics, Integrity and Biosafety website.

Part D - Operating Guidelines

(10) HREC operating guidelines, regarding applications, training, are displayed on the HREC website.

Part E - Externally Approved Projects

(11) The National Statement asks that duplication of ethics review be avoided. Accordingly, La Trobe University accepts human ethics approvals from other human ethics committees registered with the NHMRC and processes research approved by another HREC where La Trobe University researchers are involved. This process is available on the HREC website.

(12) The review is conducted by the HREC Chair (or delegate) in consultation with content experts if required and approvals sent for ratification to the HREC. La Trobe University reserves the right to place conditions on involvement or refuse involvement should approved proposals not conform to the requirements of the National Statement, other relevant legislation or potentially expose the University to undue risk.

Part F - Reporting Requirements to the HREC

(13) Annual Progress Reports: Principal Investigators of HREC approved projects must submit an Annual Progress Report to the HREC (or its Sub-Committee) as a condition of project approval. Principal Investigators who fail to submit a Progress Report by the due date may have their project suspended until a report has been received and reviewed by the HREC.

(14) Final Reports: All Principal Investigators of HREC approved projects must submit a Final Report within three months of the expiry date or conclusion of their project as a condition of project approval. Final Reports are reviewed by the HREC and kept by the University as an official record from the Principal Investigator regarding the outcome of all research produced during the approval period.

Part G - Serious Adverse Events, Incidents and Complaints

(15) For processes outlining Serious Adverse Events, Incidents and Complaints please refer to the HREC website.

(16) Allegations of research misconduct, including evidence of human research conducted without ethics approval, must be dealt with according to the La Trobe University Research Misconduct Procedure.

Part H - Complaints and Non-compliance

(17) The University has established a complaints and grievances mechanism for La Trobe University personnel, students and persons external to the University to allow the voicing of concerns regarding human research. Such concerns can be submitted in writing to the Senior Manager Ethics, Integrity and Biosafety.

(18) Complaints or grievances by La Trobe University personnel about decisions reached by the HREC can be submitted in writing to the Deputy Vice-Chancellor (Research and Industry Engagement) or the University Ombudsman

(19) Any unplanned impacts on human research participants or researchers outside the scope of the HREC and its Low-Risk Sub-Committees must be reported promptly to Senior Manager Ethics, Integrity and Biosafety.

(20) Allegations of breach or research misconduct, including evidence of human research conducted without ethics approval, must be dealt with according to the La Trobe University Research Misconduct Procedure.

Part I - Monitoring of HREC Approved Projects

(21) General Principles for Research Monitoring:

a. All research monitoring will be conducted in accordance with the relevant NHMRC guidelines and University policies.
b. Research monitoring will consider confidential and commercially sensitive information, conflicts of interest and align with University values.
c. Research monitoring will only be conducted by appropriately qualified and trained members of the Ethics, Integrity and Biosafety (EIB) team in collaboration with the committee chair.
d. Research Monitoring will be an ongoing process conducted across all research discipline throughout each calendar year.

(22) Selection projects for Research Monitoring:

a. Research projects will be selected for monitoring by the Chair of the appropriate governance committee, in collaboration with EIB.
b. The frequency of monitoring will depend on the degree of risk that arises from the research and should be proportionate to that risk.
c. Project selection will be based on a variety of factors, including but not limited to the following:
    i. The classification of risk
    ii. Following a complaint
    iii. Annual report
    iv. Numerous adverse events
    v. Numerous ethics amendments; and/or
d. Once a project is selected for monitoring, the Principle Investigator (PI) will be contacted by EIB to arrange a suitable date for the research monitoring visit within the following month.
e. If a suitable date cannot be arranged within this timeframe, the PI must provide a letter to EIB outlining the circumstances of unavailability and suggest a suitable alternative.
f. Once a date has been finalised, the PI will be provided with a letter detailing the time, date, duration, purpose, scope and procedure of the research monitoring visit.

(23) Reporting following Research Monitoring

a. Following a Research Monitoring visit a feedback report will be provided to the PI within 2 weeks. This report will include:
b. A summary of the outcomes from the Research Monitoring visit
c. Recommendations for further action or follow up.
d. The Research Monitoring report will be discussed with the PI. The aim is to provide an opportunity to the PI to provide information to support their activities and for the monitor to provide feedback and highlight any corrective actions.

(24) Research Monitoring Follow up

a. Where further action is indicated, the researcher will be given a reasonable time commensurate to the corrective action to be implemented to address any recommendations.
b. EIB will ensure that actions are appropriately followed up.

Section 5 - Definitions

(25) For the purpose of this Procedure:

a. Above low risk (research): research which may lead to harm, including physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage.
b. Compliance: acting in accordance with the National Statement.
c. Discomfort: a negative accompaniment or effect of research, less serious than harm.
d. Ethics: a framework in which actions can be considered as good or bad, right or wrong. Ethics is applied in the evaluation of what should or should not be done when human beings are involved in research.
e. Low risk (research): research in which the only foreseeable risk is one of discomfort.
f. Monitoring: Monitoring of research refers to the process of verifying that the research is conducted in accordance with the Australian Code for the Responsible Conduct of Research, relevant state and federal legislation, and in accordance with applicable ethical and biosafety approvals.
g. Negligible risk (research): research in which there is no foreseeable risk of harm or discomfort.
h. Principal Investigator (PI): refers to the researcher primarily responsible for the conduct of the research.

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