Research Human Ethics Procedure

Section 1 - Background and Purpose

(1) Research conducted with or about people or their data or tissue raises ethical considerations that govern the standards of conduct. It may also expose research participants to 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 sound 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 established policies and procedures to ensure that human research conducted by La Trobe staff and students conforms to the National Statement, other relevant legislative requirements and current best practice. The University's Human Research Ethics Committees (HRECs) are 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 Governance Policy.

Section 3 - Policy Statement

(4) Refer to the Research Governance 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 students are also expected to adhere to responsible research practices 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 the Human Research Ethics Committees (HRECs) are to ensure, on behalf of La Trobe, that all activities relating to research involving humans abides by the requirements in the National Statement and that research proposals are designed in accordance with the following values:

a. Research merit and integrity

b. Justice
c. Beneficence
d. Respect for human beings

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

(8) The HREC reviews applications for research projects and must approve only those applications that meet an ethically acceptable standard and conform to all the requirements of the National Statement.

Part C - HREC Terms of Reference

(9) The HREC Terms of Reference align with the requirements specified in the National Statement. As a sub-Committee of the Research and Graduate Studies Committee (RGSC) the HRECs reports on a regular basis to the RGSC. The Terms of Reference are publicly available on the Human Research Ethics website.

Part D - Externally Approved Projects

(10) The National Statement stipulates that institutions have a responsibility to adopt a process that eliminates any unnecessary duplication of elthical review. Accordingly, La Trobe University accepts human ethics approvals from other human research ethics committees registered with the National Health and Medical Research Council (NHMRC). Research approved by another HREC where La Trobe University researchers are involved must be registered via the externally approved projects pathway. This process is available on the Human Research Ethics website.

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

Part E - Reporting Requirements

(12) Annual Progress Reports: The Principal Investigator (PI) of an HREC approved project must submit timely Annual Progress Reports to the HREC as a condition of project approval. A PI who fails 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 (or delegate).

(13) Annual Safety Reports for clinical trials: PIs or sponsors of clinical trials must submit an Annual Safety Report which will be reviewed by the HREC (or delegate) to assess whether ongoing safety monitoring is being conducted appropriately and that the trial's safety monitoring plans are being followed and where necessary, are being adapted to take into account new findings as the trial progresses. The HREC (or delegate) may, at their discretion, request more frequent reporting of clinical trials.

(14) Final Reports: The PI of an HREC approved project 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 (or delegate)and retained by the University as an official record from the PI regarding the outcome of all research produced during the approval period.

(15) If the PI of an HREC approved project plans to leave the University or transfer to another institute, the PI must notify the Ethics, Integrity and Biosafety (EIB) team prior to their departure by sending an e-mail to humanethics@latrobe.edu.au. The PI can either nominate a different La Trobe staff member as the new PI, transfer the project to another institute or request to close the project.

Part F - Serious Adverse Events, Significant Safety Issues, Serios Breaches of Good Clinical Practice and Incidents

(16) In keeping with the conditions for ethics approval of clinical trials, the PI must immediately report any Serious Adverse Events, Significant Safety Issues, data breaches and Serious Breaches of Good Clinical Practice to the EIB team using the relevant templates on the Human Research Ethics website.

(17) For HREC approved projects that do not include clinical trials, the PI is responsible for reporting incidents using the template found on the Human Research Ethics website.

(18) Reports will reviewed immediately by the HREC Chair (or delegate), actioned accordingly and ratified by the HREC at their next meeting.

Part G - Complaints and Non-compliance

(19) 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 to the Senior Manager, Ethics Integrity and Biosafety.

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

(21) 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 the Senior Manager Ethics, Integrity and Biosafety.

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

Part H - Monitoring of HREC Approved Projects

(23) 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 EIB team.
d. Research Monitoring will be an ongoing process conducted across all research disciplines throughout each calendar year.

(24) Selecting projects for Research Monitoring:

a. Research projects will be selected for monitoring based on the following factors, including but not limited to:
    i. The classification of risk
    ii. HREC recommendations
    iii. Clinical trials where La Trobe University is the sponsor
    iv. History of safety issues, breaches of Good Clinical Practice and/or incidents
    v. Complaints
    vi. Clinical trials that require registration with the TGA

vii. Significant conflicts of interest
viii. Research led by La Trobe non-salaried staff
ix. Research conducted overseas
x. International collaborations where a research contract/agreement is involved
xi. Research that involves or heavily relies on collaborations with Aboriginal and Torres Strait Islander peoples
xii. Issues raised in annual reports
xiii. Significant number of ethics modifications, including extension requests
xiv. People in dependent or unequeal relationships
xv. Insufficient annual reporting

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. Once a project is selected for monitoring, the PI will be contacted by EIB to arrange a mutually convenient date for the Research Monitoring visit within the following month.
d. If a suitable date cannot be arranged within this timeframe, the PI must provide a letter to EIB outlining the circumstances of their unavailability and suggest a suitable alternative.
e. 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.

(25) Reporting following Research Monitoring

a. Following a Research Monitoring visit, a feedback report will be provided to the PI and the HREC within 2 weeks. This report will include:
    i. A summary of the outcomes from the Research Monitoring visit; and
    ii. Recommendations for further action or follow-up.
b. The Research Monitoring report will be discussed with the PI. The aim is to provide an opportunity for the PI to provide information to support their activities and for the EIB monitor to provide feedback and highlight any corrective actions.
c. Should the process of Research Monitoring give rise to matters that fall outside the scope of this Procedure, these will be referred to other institutional processes where appropriate.

(26) Research Monitoring follow-up:

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

Section 5 - Definitions

(27) 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 and other relevant regulations and legislation.
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. Incident: an event that impacts a project and/or participants that is not associated with a clinical trial, including but not limited to, a safety issue or departure from an ethically approved project description.
f. Low risk research: research in which the only foreseeable risk is one of discomfort.
g. Negligible risk research: research in which there is no foreseeable risk of harm or discomfort.
h. Principal Investigator: refers to the researcher primarily responsible for the conduct of the research.
i. Research 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 (2018), relevant state and federal legislation and applicable ethical and biosafety approvals.
j. Serious Adverse Event: any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.
k. Serious Breach: a breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree:
    i. the safety or rights of a trial participant, or
    ii. the reliability and robustness of the data generated in the clinical trial.
l. Significant Safety Issue: a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

Status and Details

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