

# Policy For the Ethical Review And Conduct Of Research Involving Humans Within CPL

## Policy Statement

The *National Statement on Ethical Conduct in Research Involving Humans* specifies institutional responsibilities for the handling of research. Both the *National Statement* and *Australian Code* specify that the relevant ethics committee must review and monitor the conduct of research, suspend research where unforeseen risks or other ethical issues arise, conduct random audits and take action in relation to potential breaches of the principles of ethical conduct in research. This policy gives a framework for the ethical conduct of research involving humans, which confers special ethical responsibilities on both the organisation and individual researchers. CPL is committed to the highest ethical standards of research involving humans, in conformance with the *National Statement on Ethical Conduct in Human Research* issued by the National Health and Medical Research Council.

The risk factors associated with non-compliance could be summarised as:

- Exposure to potential litigation;
- Negative public commentary (in an area of increasing public, media and political interest);
- Loss of research funding or potential ability to receive funding;
- Compromising the institution's claim to being an ethical and responsible corporate citizen;
- Decreased standards of research and research training, and
- Deregistration as an NHMRC compliant Ethics Committee.

## Aim

Provide a framework for the ethical (1) assessment and (2) conduct of research at CPL.

## Objectives

CPL considers the responsibilities of the ethics committee to be an important element of the corporate vision for the organisation. In line with the National Statement on the Ethical Conduct of Human Research and the Australian Code of Conduct for Research this policy confirms that:

- 1) CPL's Terms of Reference for the Ethics Committee should be available to all staff, clients, families, carers and other relevant people;
- 2) The deliberations of the committee should be based upon the National Statement or Australian Code, as appropriate;
- 3) The policy positions that underpin the decisions of the ethics committees should be transparent and consistent;

- 4) The decisions of the committees should be communicated to applicants in a timely and clear manner, with advice on how best to resolve any outstanding matters;
- 5) The Ethics Committee strives to engage and consult with the various elements of CPL, and respond to the needs and challenges faced by researchers; and the committee provide CPL with regular reports in relation to their work; and
- 6) Provide a framework for approving, monitoring and documenting research within CPL.

## Principles

CPL endorses the ethical principles set out in the *National Statement on Ethical Conduct in Human Research*. The general guiding principles include:

- Research must have merit and integrity
- Research must be just
- The likely benefit must outweigh the risk of harm or discomfort
- Research must demonstrate respect for all human beings, their privacy & confidentiality.

## Relevant Stakeholders

- All staff, clients, carers and families associated with CPL.
- Interagency professionals (e.g., teachers, researchers, professionals).

## Research Review Framework

The Research Review Framework is outlined in the *“Procedure For Reviewing Research Projects”*

Using the Research Review Framework, projects are assessed via a risk assessment framework. Research projects will be reviewed using three levels of assessment. These are:

**Expedited Ethics Review One (E1)** - Chairperson CPL HREC

**Expedited Ethics Review Two (E2)** - Expedited Ethical Review Panels established by the CPL HREC

**Full Ethics Review Three (E3)** – CPL HREC.

Procedural Guidelines for the ethical review and conduct of research at CPL are outlined in the relevant procedure documents.

## Definition

### Research Requiring Review

“Research” .... Includes work of direct relevance to the needs of commerce industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights, and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction. It excludes routine testing and routine analysis of materials components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.

Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through:

- Taking part in surveys, interviews or focus groups;
- Undergoing psychological, physiological or medical testing or treatment;
- Being observed by researchers;
- Researchers having access to their personal documents or other materials;
- The collection and use of their body organs, tissues or fluids (e.g., skin, blood, urine, saliva, hair, bones, tumour and biopsy specimens) or their exhaled breath;
- access to their information (in individually identifiable, re-identifiable or non- identifiable form) as part of an existing published or unpublished source or database. (*National Statement on Ethical Conduct in Human Research 2023*).

### Types of Research

#### Research can include:

- Qualitative research
- The use of databanks
- Intervention research
- Human Tissue research
- Genetic research
- Stem cell research
- Pure basic research.

**Experimental or theoretical work** which is undertaken primarily to acquire new knowledge without a specific application in view and is carried out without looking for long term economic or social benefits other than the advancement of knowledge. It includes most humanities research.

#### Strategic basic research

Experimental or theoretical work which is undertaken primarily to acquire new knowledge without a specific application in view and is directed into specific broad areas in the expectation of useful discoveries. It provides the broad base of knowledge necessary for the solution of recognised practical problems.

#### Applied research

Original work which is undertaken to acquire new knowledge with a specific practical application in view. Applied research is undertaken to determine possible uses for the findings of basic research or to determine new methods or ways of achieving some specific and pre-determined objective.

### **Experimental development**

Systematic work, using existing knowledge gained from research and/or practical experience, for the purpose of creating new or improved materials, products, devices, processes or services. In the social sciences, experimental development may be defined as the process of transferring knowledge gained through research into operational programs. (*National Statement on Ethical Conduct in Human Research 2023*).

### **When is ethical review required?**

Institutions are responsible for establishing procedures for the ethical review of human research. That review can be undertaken at various levels, according to the degree of risk involved in the research. Research with more than a low level of risk must be reviewed by an HREC. Research involving no more than low risk may be reviewed under other processes as outlined in the National Statement. CPL may also determine that some human research is exempt from ethical review. A judgement that a human research proposal meets the requirements of this National Statement and is ethically acceptable must be made before research can begin and before full funding for the proposal is released.

### **When ethical review is normally not required?**

The following types of research do not require Ethics Review.

- Quality Audits
- Performance Reviews. However, performance reviews or studies that contain an element of research in addition to assessment may require ethics review.
- Client Complaint investigations.

Researchers who are unsure about whether their proposed research requires Ethics Committee Clearance should consult the Chair of the Ethics Committee or their representative.

### **Ethics and law in human research**

Human research is governed by Australian law that establishes rights for participants and imposes general and specific responsibilities on researchers and institutions. Australian common law obligations arise from the relationships between institutions, researchers and participants. Contractual arrangements may impose obligations on research funders and institutions.