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Ethics for Evaluation

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"All human interaction, including the interaction involved in human research, has ethical dimensions. However, 'ethical conduct' is more than simply doing the right thing. It involves acting in the right spirit, out of an abiding respect and concern for one's fellow creatures."

(*The National Statement on Ethical Conduct in Human Research*)

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National Statement on Ethical Conduct in Human Research

Research Merit and Integrity

Justifiable potential benefit, appropriate methods, support, design experience and facilities

Justice

Fair for participants

Beneficence

Whether risks are justified by potential benefits

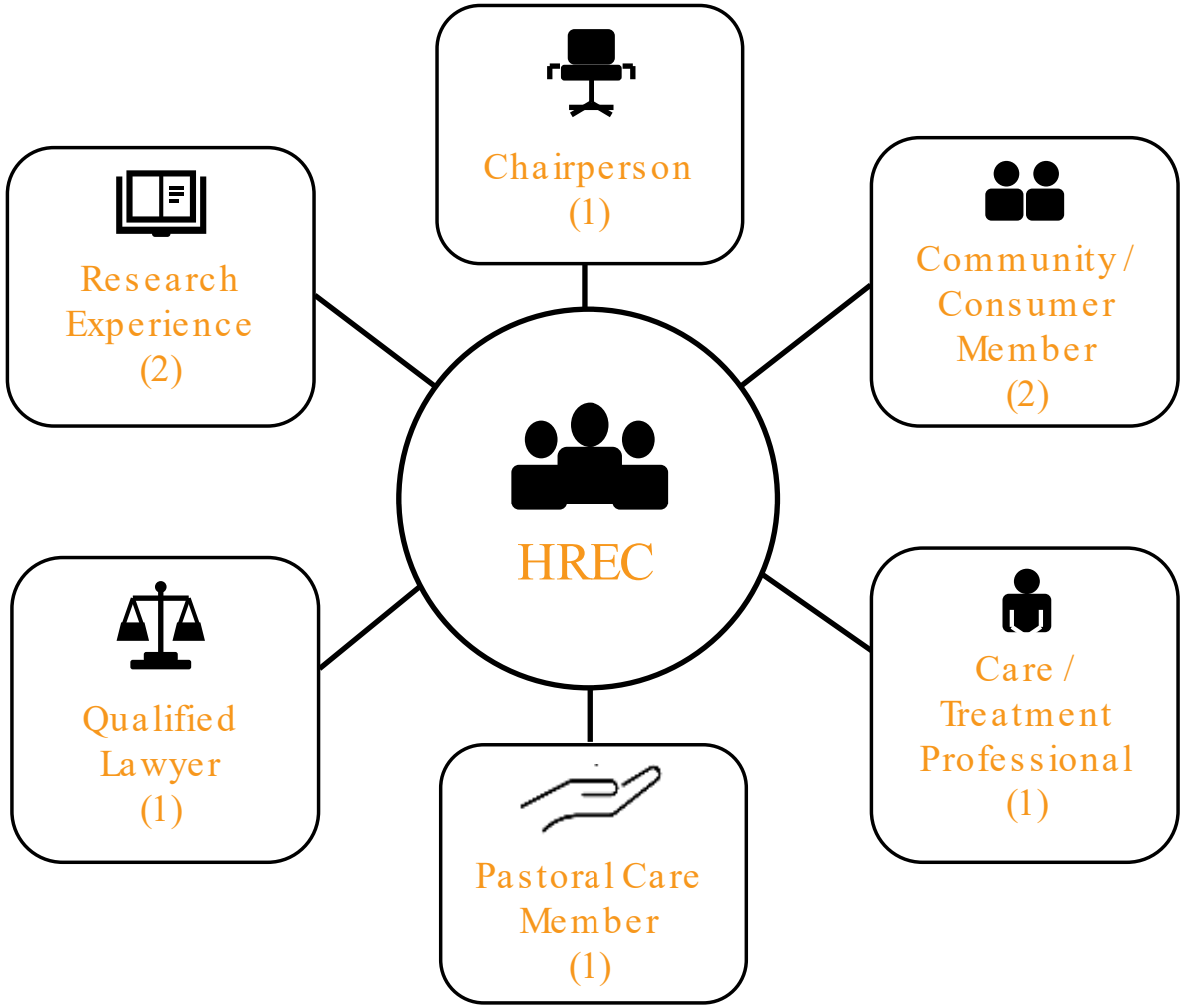
Respect

Respect for the intrinsic value of human beings

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Human Research Ethics Committee (HREC)

National Statement on Ethical Conduct in Human Research, a HREC must consist of at least 8 people.



Based on the NHMRC National Statement on Ethical Conduct in Human Research (2025), section 5.1.30

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Risk Profiles of Research - National Statement

Lower risk		**Higher risk** (Individual, group, community, societal or global)	
Minimal	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

Based on the NHMRC National Statement on Ethical Conduct in Human Research (2025), section 2.1

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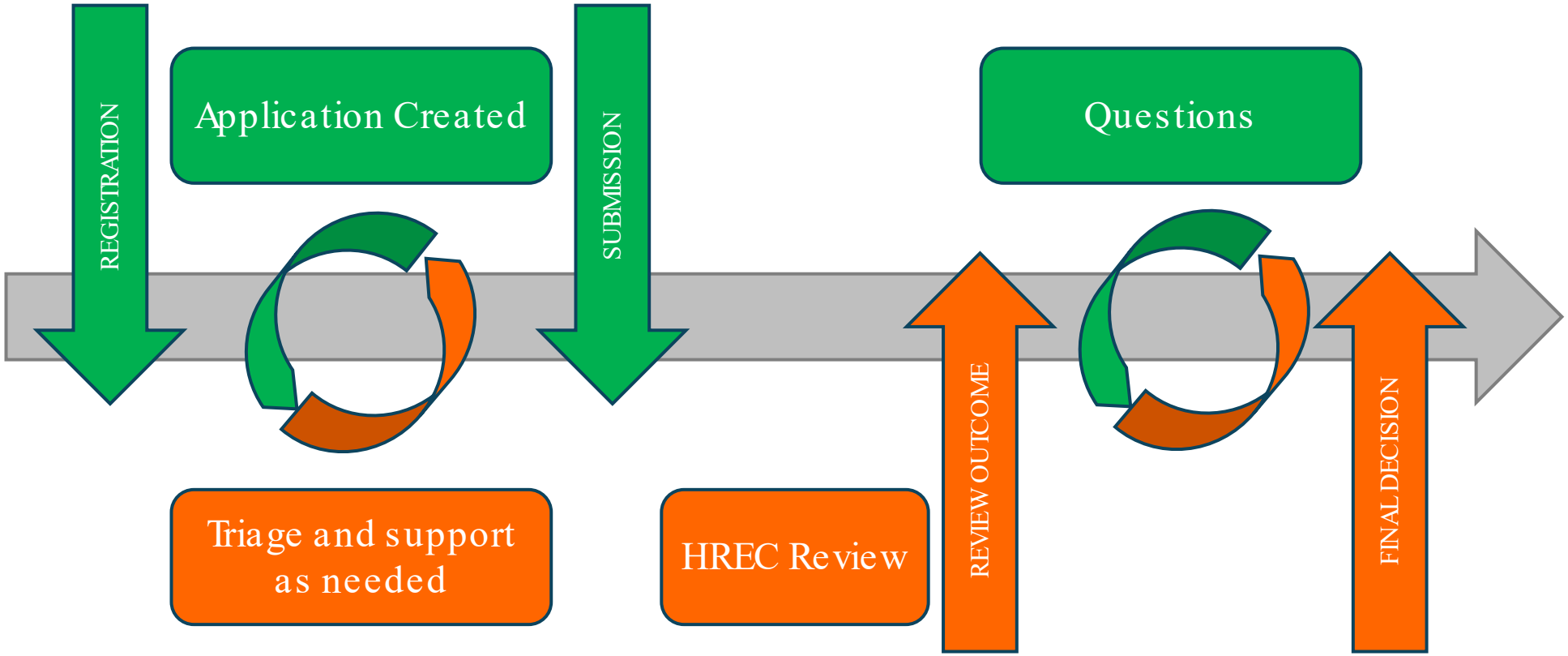
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- Private, Independent, Not For Profit
- Specialist ethics provider
- National HREC service headquartered in Adelaide
- Largest ethics provider in Australia
- Proceeds go back to the Australian research sector

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HREC Review Process



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Review of Evaluation – Common Comment Themes

- Study Proposal and Documents
- Consent
- Confidentiality
- Recruitment
- Data and AI

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Ethics Review of Evaluation – Study Proposal

Distinction between the program and the evaluation the program which is being reviewed

Clarity of project aims and **objectives**

Justification of the study and **sample size**

National Statement: 1.1 (c); 3.1.1 (c); 3.1.2 (b-c); 3.1.12; 3.1.13; 3.1.14

Adequately considered and **detail**ed proposal

National Statement: 2.1.1; 2.1.3, 5.3.1

Consider whether your proposal requires **Aboriginal and Torres Strait Islander HREC** review

National Statement: Chapter 4.7
AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research

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Ethics Review of Evaluation – Other Study Documents

Survey/Questionnaire **validation**

National Statement: 3.1.1 (c-d); 3.1.2

Include crisis **support** contact in PICF/participant documents

Relevance of participant questions

Questionnaires/ surveys need to be **provide**d

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Consent



PICF

Fully informed consent

Waiver of Consent

National Statement: 2.3.10

Opt-Out

Guidelines approved under Section 95 and 95A of the Privacy Act
Requires HREC approval

Limited Disclosure

National Statement 2.3.1-2.3.4

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Ethics Review of Evaluation – Consent

Language – should be high level and age appropriate

National Statement: 3.1.1 (e); 3.1.22 (b)

Delayed or deferred consent not ethically permissible

National Statement: 4.5.7

Advice on when/how to **access results** of the research study

National Statement: 2.2.2 (k); 3.1.69; 3.1.70

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Ethics Review of Evaluation – Consent

Information and Consent form as a single document

PICF Formatting – avoid **tick box** consent statements
(allows for some and not others to be checked)

Financial **incentives** can not be considered benefits of participating

National Statement: 2.2.10; 3.1.10; 3.1.21

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Ethics Review of Evaluation – Confidentiality

Approach for managing **confidentiality** in focus groups/interviews included in the PICF

National Statement: 1.11; 2.2.6

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Ethics Review of Evaluation – Recruitment

Consider **why** potential participants are being approached

Consider any potential for recruitment **bias**

National Statement: 2.2.9; 3.1.18

Be clear about Participant **reimbursement** amount, schedule and method

Consider potential **coercion** in recruitment strategies

National Statement: 2.2.9; 3.1.17

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Ethics Review of Evaluation – Data Management

Data **management** plan detail

National Statement: 3.1.30; 3.1.44

Language – 'data de-identification' should be changed to '**coding**' in line with the National Statement

National Statement: Chapter 3.1 Element 4

Detail for planned data **analysis**

National Statement: 3.1.2 (b-c); 3.1.44

Data coding **process**

National Statement: 1.11; 2.2.6 (f); 3.1.40; 3.1.41

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Ethics Review of Evaluation – Data Management

Patient data use and management if a participant **withdraws**

National Statement: 2.2.6 (g); 2.2.19; 2.2.20; 3.1.31

Policy for managing the use of **AI** *(when applicable)*

Future use of participant data policy

National Statement: 2.2.14

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Ethics Review of Evaluation – Data Storage and Sharing

Data **storage** and privacy policies

National Statement: 3.1.43; 3.1.44; 3.1.45

Data sharing policy and process

National Statement: 1.11; 2.2.6 (f)

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Summary

- Align your proposal with the National Statement on Ethical Conduct in Human Research
- Be clear about the scope of the ethics review (the evaluation versus the project being evaluated)
- Have clear policies and procedures for data use, storage, protection and sharing
- Be clear about consent requirements
- Have appropriate recruitment strategies
- Consider level of risk as discussed in the National Statement

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Support for Applications

- Reach out to your HREC with any questions
- Consult ‘Guidance and Resources’ on the HREC website
- Extensive resources, guidance and Bellberry team support

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