Writing a Human Research Ethics Application

National Statement [1]	Activity /Document	Consideration	Outputs
Merit and Integrity 1.1 – 1.3 (p. 6) **Element 1** 3.1.1 – 3.1.11 (p. 26-28)	Preliminary Activities 1. Need for research. 2. Literature Review 3. What is the research question? 4. How will research be funded?	• Meet with consumers /stakeholders. • What are research gaps? • What is the methodology to be used. • Researcher availability	• Literature review • Recruitment Plan • Finance requests
Merit and Integrity 1.1 – 1.3 (p. 6)	Gather research team	• Skills • Credentials • Roles	• Project Plan • Gantt chart • CVs
Risk 2.1 (p. 12-15) **Beneficence** 1.6 – 1.9 (p. 11) **Respect** 1.10 – 1.13 (p. 11)	Protocol	• Project Description • Sample size (statistician?) • Review of all risks • Data collection instruments • How is data to be analyzed?	• Detailed protocol which includes risk assessment and risk mitigation; data collection instruments; analytical methods including software to be used.
Justice 1.4 (p. 10) **Element 2** 3.1.12 – 3.1.21 (p. 28-30)	Recruitment	• Catchment • Inclusion and exclusion criteria • Is recruitment fair?	• Recruitment Plan • Translational text • Recruitment emails/flyers and advertising • Social media texts/post
Beneficence 1.6 -1.9 (p. 11) **Element 3** 3.1.22 – 3.1.38 (p. 30-32)	Participant Information Sheet	• How will you explain the research to participants in an easy-to-read format? • Is there a ready to use template? • Explain how consent is free from coercion. • Will participants be reimbursed for expenses outlaid?	• Participant Information Sheet – child/parent or guardian? Interventional / non-interventional • All research contact details. • Full disclosure of any conflicts of interest

[1] National Statement on Ethical Conduct in Human Research 2023

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Consent 2.2 – 2.3 (p.16-22) **Element 3** 3.1.22 – 3.1.38 (p. 30-32)	Participant Consent Form	• Is there an opportunity to withdraw or withdraw data? • What does consent mean to a participant? • Is there consent for future use of data?	• Consent Form including consent for images; biospecimens.
Element 4 3.1.39 – 3.1.42 (p. 32-35)	Research Instruments	• What data is being collected and how?	• Survey instruments. • Spreadsheet of tests to be performed. • Validated tools e.g. Quality of Life Scale, Pain scale etc.
Element 4 3.1.43 – 3.1.61 (p. 35-38)	Data Management Plan	• How will confidentiality be maintained throughout the research? • How will data be secured? • How will data be de-identified? • Who is the data custodian? • Who will have access to the data?	• Research data management plan. • Trial registration if required.
Justice 1.5 (p. 10) **Element 5** 3.1.62 –3.1.67 (p.38-39)	Participant Feedback	• How will participants be provided the research findings?	• Presentation or email
Element 6 3.1.68 – 3.1.71 (p. 40)	Dissemination Plan	• What is the publication plan? • What is the plan to disseminate findings amongst consumers/stakeholders?	• Peer reviewed publications • Open access • Conferences • Consumer /Stakeholder networks.
Element 7 3.1.72 –3.1.73 (p. 41)	Post Project	• What are disposal and retention of data requirements including consent forms? • Governance reporting requirements • Will there be extended monitoring of participants?	• See Data management plan. • Complete all registry requirements. • Provide final HREC reports. • Inform relevant funding bodies of outcomes.

National Statement [1]	Activity /Document	Consideration	Outputs
Responsibilities of researchers 5.3.1 – 5.3.12 (p.97-98)	Ethics Application	• Allow time. • Know HREC Meeting dates. • Understand review processes: HREC; low risk; Quality Assurance; exemption. • Refer to guidance documents. • Plain language • Write for participants.	• Application submission

Resources:

1 NHMRC Ethical Issues and Resources:

https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources

2 The University of Queensland: Human Research Ethics

https://research-support.uq.edu.au/resources-and-support/ethics-integrity-and-compliance/human-ethics/ethics-application

3 Queensland Health: Research Ethics and Governance

https://www.health.qld.gov.au/system-governance/policies-standards/health-service-directives/research,-ethics-and-governance

4 Health Translation Queensland: Research Ethics Processes

https://healthtranslationqld.org.au/resources/research-ethics-and-governance/research-ethics

Human Research Ethics Application (HREA)

All ethics submissions, including new applications, amendments, exemptions, ratifications, adverse event and annual reports are made through UQ's MyResearch system. The HREA within My Research has the following sections:

1. Introduction and Acknowledgement
2. Assessment Pathway SQ1 – 7
3. Project Overview Q1.1 – 1.8
4. Project Team – List Members of Research Team
5. Project Team Details – Contact details and role
6. Disclosure of Interest
7. Restrictions (on publication)
8. Evaluations (Scientific Merit)
9. Location (multi-site)
10. Methods – creates further questions depending on methods selected
11. Participant Specific
12. Project Details
13. Recruitment
14. Consent (alternative to consent)
15. Risk
16. Benefit
17. Data and Privacy
18. Generate HREA document.
19. Upload attachments.
20. Select review pathway.
21. Declaration
22. Generate HREA – Submission

Information on using the system is available in the MyResearch Training Hub.