RESEARCH

POLICY STATEMENT

Bay of Plenty District Health Board (BOPDHB) acknowledges the contribution research makes to health promotion and clinical treatment options. It supports research as a normal part of its operation within the parameters set out in this policy and related protocols and where consistent with the organisation's strategic goals.

All research activities undertaken by, or on behalf, of the BOPDHB must meet ethical and legal standards for research and meet internal requirements.

PURPOSE

The purpose of this policy is to set out BOPDHB's requirements relating to undertaking and/or participating in research projects at BOPDHB.

It is the intention of BOPDHB to develop and maintain a role in health research within the region. One of the key factors in meeting this objective will be a strong commitment by the organisation to support and promote diverse research and the individuals who undertake the research.

This policy applies to all clinical and non-clinical research requiring ethical approval undertaken by, or on behalf of BOPDHB. Refer to Appendix A of this document for further information on research versus audit.

EXCLUSIONS

None.

REFERENCES

- Charitable Trusts Act 1957
- Code of Health and Disability Services Consumers' Rights 1996
- Convention on Rights of The Child 1993
- Health Act 1956
- Health and Disability Commissioner Act 1994
- Health and Safety at Work Act 2015
- Health Information Privacy Code 1994
- Health Practitioners Competence Assurance Act 2003
- Health Research Council Act 1990
- Human Rights Act 1993
- Human Tissue Act 2008
- Injury Prevention, Rehabilitation and Compensation Act 2001
- New Zealand Public Health and Disability Act 2000
- New Zealand Bill of Rights Act 1990
- Official Information Act 1982
- Privacy Act 1993
- Public Records Act 2004

- The Principles of the Treaty of Waitangi
- Ministry of Health. Operational Standard for Ethics Committees. 2014
- Ministry of Health. Consent in Child and Youth Health: Information for Practitioners. 1998
- Health and Disability Ethics Committee
- Online Ethics https://nz.ethicsform.org/SignIn.aspx
- Medsafe NZ. Guideline on the Regulation of Therapeutic Products in New Zealand. Part 11: Clinical Trials – Regulatory Approval and Good Clinical Practice Requirements. 2015
- Health Research Council of New Zealand. Guidelines for Researchers Involving Māori. 2010
- Health Research Council. Guidelines for Approval of Ethics Committees (Approval Guidelines). 2012

ASSOCIATED DOCUMENTS

- Bay of Plenty District Health Board policy 2.1.7 protocol 1 Research – Standards and Responsibilities
- Bay of Plenty District Health Board policy 2.1.7 protocol 2 Research – Approvals Process
- Bay of Plenty District Health Board policy 1.1.1 Informed Consent
- Bay of Plenty District Health Board policy 2.1.6 Clinical Ethics
- Bay of Plenty District Health Board policy 2.1.8 New Clinical Interventions
- Bay of Plenty District Health Board policy 2.1.10 Intellectual Property
- Bay of Plenty District Health Board policy 2.4.6 protocol 0 – Interest – Conflict of Interest
- Bay of Plenty District Health Board policy 2.5.1 Health Information Privacy
- Bay of Plenty District Health Board policy 2.5.2 Health Records Management
- Bay of Plenty District Health Board policy 3.4.1 Asset Management
- Bay of Plenty District Health Board policy 3.5.1 Capital Expenditure
- Bay of Plenty District Health Board policy 3.5.7 Product Evaluation
- Bay of Plenty District Health Board policy 3.5.8 Purchasing
- Bay of Plenty District Health Board policy 6.1.5 protocol 1 Alerts – Medical – Allergic Responses, Adverse Reactions and High Risk Issues
- Bay of Plenty District Health Board policy 6.3.9 Body Parts and Tissues
- Bay of Plenty District Health Board Form FM.A11.1 Alert - Medical
- Bay of Plenty District Health Board Form FM.C12.1 Code of Confidentiality
- Bay of Plenty District Health Board Form FM.R11.1 Research Approval Application

Appendix A: Research versus Audit

Research	Audit
May involve experiments on humans, patients or volunteers	Never involves experiments on healthy volunteers or patients as volunteers
Is a systematic investigation which aims to increase the sum of knowledge	Is a systematic approach to the peer review of l care and / or processes in order to identify opportunities for improvement and to provide a mechanism for bringing them about
May involve allocating patients randomly to different treatment groups	Never involves allocating patients randomly to different treatment groups
May involve a completely new treatment	Never involves a completely new treatment
May involve extra disturbance or work beyond that required for normal clinical management	Never involves disturbance to the patients
May involve strict selection criteria to patients with the same condition before they are entered into the research study	May involve patients with the same problem being given different treatment, but only after full discussion of the known advantages and disadvantages of each treatment. The patients are allowed to choose freely which treatment they get