STANDARDS TO BE MET

1. Key Responsibilities

The key responsibilities of Bay of Plenty District Health Board (BOPDHB) and its researchers are:

1.1 Patient / consumer wellbeing
1.2 Protection of patient / consumer rights
1.3 Compliance with BOPDHB Policy
1.4 To work in accordance and acknowledge the principles of the BOPDHB (Māori Health) Strategic Plan
1.5 To safeguard BOPDHB property
1.6 The safety of all individuals on BOPDHB premises
1.7 Appropriate use of available time, funds and resources
1.8 Meeting ethical and legal standards of research.

2. Research Approval

BOPDHB approval is required before any research may begin that involves the staff, patients and consumers of BOPDHB or that is conducted on BOPDHB premises.

2.1 **Investigator Led Research – with or without funding:**

a) All research within the BOPDHB is required to have a completed BOPDHB Research Approval Application form. This forms part of the "Locality Authorisation" which used here refers specifically to the process used by the NZ Health and Disability Ethics Committees (HDECs) for ascertaining that all local governance issues have been addressed at sites participating in a research project.

b) In order to obtain Locality Authorisation, researchers must have completed steps 1-3 below:

- *Step 1: Local Consultation:*
  Consult with your local Head of Department to ensure appropriateness of study / confirm resources available.
- *Step 2: Approval Process*
  - Complete the BOPDHB Research Approval Application form. Email to the Research Proposal Coordinator.
  - Maori Consultation also required as per Guidelines.
  - Proceed with relevant Health and Disability Ethics Committee (HDEC) application, if required.
  - Online Forms Account required to complete HDEC application.
  - If HDEC application done - electronic Locality Authorisation to be performed by Head of Clinical School.

3. Approvals External To BOPDHB for Investigator led research

3.1 Relevant external approvals must be obtained prior to the commencement of research within BOPDHB.
3.2 Ethical approval of the research project must be obtained using the Online Ethics approval process (link to Online forms). Detailed information can be found (link to Ethics website)
3.3 Specific approvals may be required depending on the nature of the research. These may include (but are not limited to):

a) National Radiation laboratory approval for radiation used in research.
b) Standing Committee on Therapeutic Trials (SCOTT) approval for unregistered medicines or formulations to be used in a trial.
c) Approval from the ethics committee of the relevant academic institution.
d) Notification to Medsafe for device studies

4. Approval Internal To BOPDHB (as part of Locality)

4.1 Service Management Level

a) It is the responsibility of the relevant Service Business Leader to ensure that:
   i. All costs incurred by the BOPDHB Service in regard to the research project are included in an approved research budget (including those costs which will be incurred by contributing units e.g. laboratory) prior to recommending final approval.
   ii. All required approvals are obtained.
   iii. Research is not commenced until all required approvals have been obtained and the proposal has final authorisation to proceed.
   iv. All income and expenditure related to the research project is accounted for and any deficit or surplus of resources is managed appropriately. This is managed by the Clinical Trials Unit.

4.2 Pharmacy and Radiology

Where Pharmacy and / or Radiology are required as part of the study, application forms may need to be completed. Guidance is provided in the Research Application Form.

4.3 Final Authorisation

An email indicating approval to commence research activities will be sent once all relevant approvals and documentation has been received by the Research Proposal Co-ordinator.

4.4 BOPDHB Research Project Database

a) A data base is maintained with the Clinical Trials Unit and once final approval has been obtained all research projects are entered onto a Research Project Database and given an authorisation number. This will be managed by the Research Proposal Co-ordinator / Clinical Trials Assistant.
b) It is intended that on completion or discontinuation of the project the researcher will notify the Research Proposal Co-ordinator / Clinical Trials Assistant within one week.
c) Where Ethics approvals are required, it is the responsibility of the researcher to ensure these are submitted on time.
d) A copy of the final report or published article related to the research is retained in the BOPDHB Library if appropriate.

5. The BOPDHB Peer Review Committee

5.1 This committee was established in 2011 in response to the changes within HDEC and more responsibility being placed on researchers and DHBs to ensure the proposed research project was scientifically valid.

5.2 Committee members include: Head of Clinical School (Chairperson), Oncologist, General Surgeon, Radiologist and Research Proposal Co-ordinator.

5.3 The researcher provides a study outline / proposal or protocol to the Research Proposal Co-ordinator who forwards to the Committee along with the attached template for comments. Any additional information required is requested via the Research Proposal Co-ordinator.
5.4 The Committee are asked to respond to the proposal within 7 days and return the completed template to the Research Proposal Co-ordinator.
5.5 The Research Proposal Co-ordinator then writes a letter for HDEC confirming review process and that the protocol was approved by the Committee.

6. The BOPDHB Independent Review Board – Ethics Committee

6.1 The Committee members are the same as above.
6.2 The Committee reviews all aspects of the project and not just the scientific validity.
6.3 Once the project has been approved by the Committee and any requested changes incorporated (often not possible as the review is retrospective) a letter of ethics committee review is written and provided to the researcher.

7. Sponsored Pharmaceutical Studies:

7.1 All sponsored Pharmaceutical studies are managed by the Clinical Trials Unit, Clinical School under the auspices of the provider arm of BOPDHB.
7.2 The Clinical Trials Unit is responsible for ensuring all Ethical approvals (including locality) are obtained prior to any research be performed. See 2.1.7 Protocol 2.

8. Research Funding for Investigator led Research

8.1 Funding Closing Dates Calendar
8.2 Funding Sources

9. Integrity In Research

All research must be conducted so as to be clinically and professionally beneficial. Research activities undertaken by or on behalf of BOPDHB must be planned with honesty, co-operation and professionalism. Research considered to be potentially sensitive must be conducted with discretion and within contractual boundaries.

10. Risk Management

10.1 Research conducted by or on behalf of BOPDHB must be compatible with the clinical needs of BOPDHB patients / consumers and / or with BOPDHB's goals as a funder and provider of services, and reflect principles of good research practice.
10.2 Any contractual relationships with external companies/contractors or institutions must be conducted with the BOPDHB and not with individual employees of BOPDHB. All contractual and related documents for Investigator led research must be authorised by the Legal services via the Research Proposal Co-ordinator. For Sponsored Pharmaceutical studies, Contract and budget negotiations are managed by the Clinical Trials Unit Research Manager. All contract requirements must be fully complied with.
10.3 All individuals who are representatives of BOPDHB must comply with BOPDHB requirements and policies (including those detailed in this policy) regarding financial, liability and legislative aspects of research.
10.4 An essential qualification of the individual who is the Principal Investigator for a research project is that she or he will personally participate in the project to a significant degree. Undertaking a course in Good Clinical Research Practice (GCP)

is expected and can be done online. The Clinical Trials Unit can provide up to date information regarding this.

11. Treaty Of Waitangi

BOPDHB research activities must be consistent with the guidelines and principles contained within BOPDHB organisational framework, and per the BOPDHB Maori Consultation Guidelines.

12. Sponsored Pharmaceutical Research

12.1 BOPDHB will conduct research for outside agencies when it is convinced that the project is an appropriate BOPDHB activity, that conditions and resources are adequate, and that staff are available, competent and interested in undertaking the work.

12.2 Identification of any risks related to a specific contract is an essential component of the approval process. A Deed of Indemnity for Clinical Trials must be completed for every research project where patient injury is not covered by ACC. Site agreements and other contractual documentation must also be approved by the Clinical Trials Research Manager. BOPDHB Legal services are involved where the Standard New Zealand template for Contract and Indemnity is not used.

13. Document management and Record Retention Sponsored Pharmaceutical Studies

13.1 Alert Process

a) Subject identified by Study Coordinator as being enrolled in a Clinical Trial when Add Alert (start study) box is ticked on the Study Patient Encounter Form. This form is used by the Clinical Trials Unit to track study related visits.
b) Medical Alert details on Clinical Trial Subject Referral and Medical Alert form completed by Study Co-ordinator
c) Clinical Trials Unit administrative staff create an alert on the patient management system for the subject stating they are on a Clinical Trial, details of the study and contact methods for Study Co-ordinator and Principal Investigator
d) Clinical Trials Unit administrative staff request Health Record, or have one created. Research Subject sticker and Do Not Destroy labels are placed on the front cover of the record
e) Daily automated SQL report listing all subjects with a Clinical Trial Alert who are inpatients is emailed to Research Administrator. This report is disseminated to applicable Study Coordinator. Study Coordinator follows individual trial protocol for adverse events as required.
f) When visiting subjects who are inpatients, the Study Coordinator places a Research Subject sticker in the inpatient notes before writing in them.
g) Alert is removed from patient management system by Research Administration staff when Study Coordinator has completes Medical Alert Removal Request.

13.2 Record Retention

a) Health Records Department retain original hard copies of the patient Health Record for all Clinical Trial Subjects. These subjects are identified by the stickers on the front of the patient file.
b) The Health Records are retained or archived as per the Public Records Act.

14. Conflict Of Interest

BOPDHB staff must not engage in any activity that gives rise or may give rise to a conflict of interest between their BOPDHB activities and any other interests or obligations without appropriate disclosure and approval.

15. Academic Freedom And Publication for Investigator led research

If appropriate the BOPDHB Service should be acknowledged in any publications arising from the research and in accordance with the BOPDHB Intellectual Property policy.

16. Intellectual Property

The ownership of Intellectual Property arising from research by or on behalf of BOPDHB must be indicated in the relevant contracts or as set out in the BOPDHB Intellectual Property policy.

17. Animal Research

Proposals that include animal research will be considered, however there may be additional requirements (e.g. legislative) and / or potential sensitivities (e.g. public concern) that impact on BOPDHB. These must be clearly identified in the risk management component of the research protocol and adhere to BOPDHB best practice guidelines.

18. The Use Of Stored Body Parts / Bodily Substances For Research Purposes

It is the responsibility of the researcher to obtain informed consent and to do so in a manner which is appropriate to the patient's needs and which meets legal requirements. Time must be given to allow discussion with whānau. This process must comply with the BOPDHB policy 1.1.1 Informed Consent.

19. Financial Management Of Research Projects

19.1 Accounting Procedures

a) Research funds will be held by the BOP Clinical School Charitable Trust during the life of the research. At the completion of the research, administration and overhead costs incurred will be retained by the Trust. Any surplus is reinvested in the DHB through the Trust to further education and research unless otherwise negotiated for a specific purpose prior to a study commencing.

19.2 Staff Involvement

a) People employed by the BOPDHB to work on research or clinical trials must have a position description that reflects the research component of their role, or a contract that is specific to the research / trial, or must be seconded from their permanent position on their existing contract terms and their time recharged to the project.

19.3 Purchase Of Goods And Services

a) The same delegated authorities and procedures for the approval and purchase of goods and services, including capital expenditure, must apply to research as for any other BOPDHB expenditure. As part of the Approval process any purchases of Goods and Services must be outlined in the budget section and demonstrate that this is approved.

19.4 Asset Management

a) Equipment used in research should be treated in the same way as any BOPDHB equipment unless it is supplied under contract with a third party in which case the terms of the contract or agreement will prevail.
b) Rental for any equipment must be charged to the research RC to cover the ongoing maintenance and servicing of the equipment.
c) Any depreciation charges resulting from the purchase of these assets must be processed through the Corporate RC and therefore must not be charged to the service unit. This recognizes that there is not an organisation commitment to replace equipment at the end of its life given it was purchased for the purpose of the research project.
d) Where capital expenditure is donated to a service unit for clinical use, on completion of the research project, the service unit then assumes responsibility for asset management and costs in accordance with BOPDHB requirements.

19.5 Financial Review

a) *Investigator led studies*:
Research funds will be held by the BOP Clinical School Charitable Trust during the life of the research. At the completion of the research, administration and overhead costs incurred will be retained by the Trust. Any surplus is reinvested in the DHB through the Trust to further education and research unless otherwise negotiated for a specific purpose prior to a study commencing.

b) *Pharmaceutical Studies*:
i. All budgets are negotiated with the Sponsor and with the best information from the lead investigator in terms of recruitment. Studies will only proceed when they will deliver a surplus based on covering all costs.
ii. The Clinical Trials unit will review each study quarterly and where necessary re-negotiate with the Sponsor.

19.6 Surplus Funds

All funds from trials are managed and held by the BOP Clinical School Charitable Trust.

ASSOCIATED DOCUMENTS

- Bay of Plenty District Health Board policy 2.1.7 Research
- 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 2.1.10 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 6.1.5 protocol 1 Alerts – Medical – Allergic Responses, Adverse Reactions and High Risk Issues
- 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