



All investigators wishing to conduct research involving any resource of the Bermuda Hospitals Board (BHB), or under the remit of the Department of Health Research Governance Framework (2008), must submit the following documents to:

**The BHB Ethics Committee
Research Ethics Subcommittee
Email: research.ethics@bhb.bm**

1. A completed BHB Research Ethics Proposal Application Form.
2. The proposed research protocol (covering all headings stipulated in Appendix 1 of the Department of Health Research Governance Framework).
3. All forms, documents and questionnaires intended for use by research participants, including the consent form and copies of any advertisements or recruitment tools.
4. Letters or document of ethical approval from the appropriate institutional review board, if research originates from outside of Bermuda.
5. If research is to be conducted in the Bermuda Hospitals Board system, an approval letter from the relevant Programme Manager must accompany the research protocol.
6. Written letters of acceptance of the protocol from all participating agencies.
7. Letters of permission for any copyrighted material to be used in the study.
8. Outline of appropriate safety measures for any products or pharmaceuticals to be used in the research.
9. If using a study product, an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g. recent investigator's brochure, published data, a summary of the product's characteristics) is required.
10. The principal researcher should include a copy of his or her curriculum vitae.
11. A statement of all significant previous decisions by other ethical review committees, and an outline of changes made to the protocol based on those decisions.
12. A summary or diagrammatic representation (flowchart) of the protocol.
13. A statement that upon completion of the research, the primary researcher agrees to supply the BHB Ethics Committee with a summary of the outcome of the research study.
14. Publications resulting from research at or by the BHB shall acknowledge the BHB as a participating agency with a disclaiming statement that the views of the study may not reflect those of the BHB.

All applications must comply with the Department of Health Research Governance Framework (2008).



Once the BHB Ethics Committee has approved the research proposal, the final approved version should be forwarded to the Chief Medical Officer at the Department of Health for final permission to conduct the research in Bermuda.

The Ethics Committee will respond to the application in writing, no more than 4 weeks after receiving the proposed research protocol.

Please see the Bermuda Hospitals Board Policy and Procedure: Medical

Research/Clinical Trials/ Other Research Activities (2008) the Department of Health

Research Governance Framework (2008) for additional information.



BHB Research Ethics Proposal Application Form

1. Long Title of Research Study:

2. Name of Primary Researcher: _____

3. Address of Primary Researcher:

4. Telephone: _____ Mobile: _____

5. Email: _____

6. Name of Affiliated Institution: _____

7. Name of Academic Research Supervisor (if applicable):

8. Telephone: _____ Email: _____

By signing this document, I agree to abide by the requirements of the Bermuda Hospitals Board Ethics Committee regarding the initiation and completion of research, as outlined in the Application Packet for Submitting Research Proposals for Bermuda Hospitals Board Ethics Committee Approval and in the Department of Health Research Governance Framework (2008). I understand that at any point the Bermuda Hospitals Board Ethics Committee can withdraw ethical approval of this research if it is deemed that I have contravened the stated ethical requirements.

Print Name: _____

Signature: _____

Date (DD/MMM/YYYY): _____

Please attach this application to the front of the research protocol.