Peter MacCallum Cancer Centre
St Andrews Place
East Melbourne Victoria
Locked Bag 1 A'Beckett Street
Victoria 8006 Australia

Phone +61 3 9656 1111
Fax +61 3 9656 1400
ABN 42 100 504 883

www.petermac.org

Locations
East Melbourne
Bendigo
Box Hill
Moorabbin
Sunshine

Peter Mac
Peter MacCallum Cancer Centre
Victoria Australia

PETER MACCALLUM CANCER CENTRE HUMAN RESEARCH ETHICS COMMITTEE [EC00235]
ETHICAL APPROVAL

HREC Reference No: HREC/16/PMCC/2
Peter Mac Project No: 16/10
HREC Approval Date: 9 June 2016

Project Title: Psychosocial Aspects of Genomic Testing for Breast Cancer Risk

Coordinating Principal Investigator: A/Prof Bettina Meiser

I am pleased to advise that the above project has **received ethical approval** from the Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC). The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Research Involving Humans (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

Ethical approval for this project applies at the following sites:

Site
Peter MacCallum Cancer Centre
Royal Melbourne Hospital
Monash Hospital
Austin Hospital
Cabrini Hospital

Approved Documents
The following documents have been reviewed and approved:

Document	Version	Date
Appendix A - Protocol	4	27 April 2016
Appendix B - Questionnaire One	2	27 April 2016
Appendix C - Questionnaire Two	2	27 April 2016
Appendix D - Questionnaire Three - Receivers	2	27 April 2016
Appendix E - Questionnaire Three - Decliners	3	27 April 2016
Appendix F - Study Invitation Letter	2	29 March 2016
Appendix G - Participant Information Sheet and Consent Form	3	27 April 2016
Appendix H - Response Sheet	1	18 January 2016
Appendix I – Educational Pamphlet	2	29 March 2016
Appendix K - ViP Study Receivers Interview Guide	1	18 January 2016

Appendix L - Cover letter for Questionnaires	1	22 January 2016
Appendix N - Form for Withdrawal of Participation	1	22 January 2016

Noted Document	Version	Date
Appendix J - Consultation Report	1	18 January 2016
Appendix M – Study Flowchart	1	22 January 2016
Appendix O – List of measures selected for study and corresponding questionnaires	2	27 April 2016

Governance Authorisation

Governance Authorisation is required at each site participating in the study before the research project can commence at that site. You are required to provide a copy of this HREC approval letter to the principal investigator for each site covered by this ethics approval for inclusion in the site specific assessment application.

Conditions of Ethical Approval

- You are required to submit to the HREC:
  - An Annual Progress Report (that covers all sites listed on the approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the HREC.
  - A comprehensive Final Report upon completion of the project.
- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009*.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005)(ARPANSA Code).

Please note: Template forms for reporting Amendments, Adverse events, Annual/Final reports, etc. can be accessed from: https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials or www.petermac.org/research.

The HREC may conduct an audit of the project at any time.

Yours sincerely,

Namita Mazzitelli
Ethics Coordinator
Ethics Committee Secretariat
T: 9656 1699
E: ethics@petermac.org