

About the lifepool project

The **lifepool** project is a collection of health and lifestyle information, clinical data and biospecimens, broadly defined as 'data'. **lifepool** is funded by the National Breast Cancer Foundation (NBCF) and is part of the NBCF National Research Resource.

The women who have contributed data to **lifepool** come from the Victorian community and have largely been recruited through BreastScreen Victoria.

Each **lifepool** participant has given informed consent for the use of her data in research into breast cancer and other womens' health issues.

Who can access the resources of lifepool

The resources of the **lifepool** project are open to researchers from a range of institutions such as Universities, Medical Research institutes, and commercial research groups such as pharmaceutical companies, subject to conditions outlined in this Access Policy. Applications from international research groups will be considered.

Each research project applying for access to this data must have approval from a duly constituted Human Research Ethics Committee or appropriate equivalent. Applications from researchers outside of Australia must demonstrate approval from a Human Research Ethics Committee or equivalent that is recognised by the Access Committee as applying similarly rigorous standards of review. **Lifepool** participants understand that the use of their data must be approved by the National Breast Cancer Foundation (NBCF) Access Committee

A key issue for Access Committee review is to ensure that the research supported by this resource fits within the boundaries of informed consent provided by **lifepool** participants.

Further information about the nature of the resource can be obtained by contacting the Manager of **lifepool**. Contact details are listed on page 4 of this policy document.

Ethical Approval

The operation of **lifepool** has been approved and is overseen by the Peter MacCallum Cancer Centre Human Research Ethics Committee. **Lifepool** will provide data to researchers who satisfy the NBCF Access Committee that their application is both ethically and scientifically appropriate.

Researchers wishing to access the resources of **lifepool** must demonstrate that their project has local HREC approval before any data is released. A copy of the Participant Information and Consent Form (PICF) under which **lifepool** resources have been collected will be supplied on request to facilitate such local HREC approval.

Review History

Lifepool Management Committee: 11 Oct 2010
18 April 2012

Lifepool Management Advisory Committee: 26 March 2012
NBCF Access Committee: 25 June 2012

Approval Process

Expression of Interest	Brief summary to be supplied. Informal discussion with lifepool project staff to determine how the resource can meet needs of research project. Data dictionary will be supplied on request
Stage 1 review	Formal submission of application for review by lifepool Access Committee (LAC) Further information or clarification may be requested from the researcher by the LAC
Stage 2 review	Application referred to NBCF Access Committee for review with recommendations & comments from LAC
Completion of Material Transfer Agreement	Issued by Peter MacCallum Cancer Centre as the Principal Institution
Data/biospecimens supplied to researcher	Cost recovery fees will apply

Expression of Interest:

The Expression of Interest (EOI) will provide a broad outline of the nature of the project, and the scope of the data request.

The EOI should be approximately 1 page in length and should be submitted to the **lifepool** Manager. The EOI should provide in 'point form' a broad outline of the research project listing aim, hypothesis and project design and a description of the **lifepool** resources required. A list of the investigators and their affiliations should be included.

The EOI is required to ensure that the request is within the scope of **lifepool** resources and could reasonably be supplied.

The EOI will be distributed to the LAC by email.

A response will be received within 10 working days in most instances. Included in the response will be an approximate quote for any relevant cost recovery charges

Full application to be considered by Access Committee in a two-stage review process:

Stage 1 Review will be conducted by the Lifepool Access Committee

Applicants must provide a detailed scientific proposal including aims, hypotheses to be tested, significance of the project and relevant background information. A detailed research plan should be provided including methods, references and a timeline for the work.

All applications should provide a detailed statistical justification for any data request

The application should include details of existing funding and any prior scientific and ethical review.

Full application form attached [Application for Access to Lifepool Resources Version 1 April 2012]

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Stage 2 Review will be conducted by the NBCF Access Committee

All application documents provided by the applicant will be forwarded for Stage 2 review along with a summary of Stage 1 findings.

Amendments to existing projects

Occasionally, existing projects using **lifepool** resources may need to make changes to the project design. Should this happen, applicants are required to submit an application for amendment to an existing project to the LAC.

The LAC will consider amendments requesting access to additional quantities of data.

Where amendment requests require different kinds of data from the original request, the LAC reserves the right to request a separate, full application

Where investigators or collaborators are being added to an existing project, the principal investigator should provide details of the role this investigator will play in the project, the institution at which the investigator will work and how the individual will use the **lifepool** data.

Amendment requests will follow the same 2 Stage Review pathway

Cost Recovery Fees

lifepool will levy charges which aim to recover some of the costs associated with collecting and processing samples and data. **lifepool** does not profit from data donated by its participants.

A full list of cost recovery charges can be obtained from the **lifepool** manager.

Responsibilities of Investigators using lifepool data

- The **lifepool** Material Transfer Agreement must be signed by all chief investigators on the project before any data is released
- **lifepool** data must only be used for the purposes described in the approved research proposal and cannot be passed on to any third party without the express permission of the **lifepool** project
- Any publication arising from use of **lifepool** data must acknowledge the **lifepool** project and the NBCF. Suggested wording for this acknowledgement will be provided by **lifepool**
- A copy of all such publications must be lodged with **lifepool**.

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- Following publication, **lifepool** requests that researchers submit the raw data generated using **lifepool** resources back to the project. This data will be available for future use by other researchers, thus enhancing the value of the **lifepool** resource.
- An annual report on the progress of research must be provided to the **lifepool** Manager by June 1st of each year in which a project is active.
- Investigators must be willing to provide information in lay terms about research which will be used to inform all **lifepool** participants about the use of their contributions
- If, during the course of a research project, results are obtained which may have important health implications for the donor, the investigator is obliged to report such results to **lifepool**, along with the study ID for relevant data sample/samples. The **lifepool** Management Committee and Peter MacCallum Cancer Centre HREC will consider the information and may refer to the investigator for more detail about the nature of the research findings. The investigator will never be given identifying details about **lifepool** participants.

Dispute Resolution

The Chair of the NBCF Access Committee will deliberate over disputed access issues.

Contact Details

Lifepool Manager can be contacted on +61 3 9656 1096
Or via email lifepool@petermac.org

Further information for researchers, as well as access application forms, can be found on the **lifepool** website: www.lifepool.org

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