

Evaluation of Cancer Outcomes Barwon South West (ECOBSW) Registry

ECOBSW Data Collection- Data Access, Publication and Privacy Policy

Preamble

The following policy defines how data can be obtained from the Evaluation of Cancer Outcomes Barwon South West (ECOBSW) Registry. This policy includes the criteria, conditions, and limitations for data access and procedures to be followed when requesting data access. The outlined procedures have been put in place to protect against potential breaches of privacy as well as to ensure appropriate ethical integrity and scientific merit of proposals using ECOBSW data.

Overview of ECOBSW

The ECOBSW Registry collects information from participating hospitals in the Barwon South West region of Victoria about the treatment and outcomes of cancer. In brief, a minimum data set of variables, including personal and clinical information, processes of care and outcomes such as recurrence and mortality on each eligible patient are collected. The information collected in ECOBSW will be used to understand cancer outcomes and quality of cancer care provided in health services across the Barwon South West region. This data will also provide detailed information to support service planning and research in our region.

ECOBSW registry is managed by a Management Committee and is governed by a Steering Committee including experts from oncology (medical, radiological, surgical), biostatistics, health policy, ethics and administration. The Steering Committee also includes consumer representation. The Management Committee additionally uses the advice and independent review services of mutually agreed upon research experts from outside ECOBSW registry (outlined in application process section) when considering the scientific merit of applications seeking to use ECOBSW registry data.

ECOBSW registry sits within the Barwon South Western Regional Integrated Cancer Service (BSWRICS) which is located at the Barwon Health (Data Custodian). ECOBSW registry collects data from, and provides support and structured feedback, to participating hospitals, performs analyses and produces reports in conjunction with BSWRICS Annual Report.

The ECOBSW registry Management and Steering Committees oversee appropriate access to data held by the ECOBSW registry for the purposes of research or service planning initiatives across health services in the region. Such research requires approval from a Human Research Ethics Committee (HREC) which is registered with the National Health and Medical Research Council (NHMRC) for use of the data within the proposed research application.

Confidentiality of Information

Information held by ECOBSW registry is confidential. The procedures for making a request for de-identified information and identifying data (personal information) are outlined in the sections below.

Data Access Statements

Researchers with appropriate research questions and resources can apply to access ECOBSW registry data. Researchers provided access will be expected to utilise appropriate data security measures. The ECOBSW registry Steering Committee serves to provide timely, equitable and appropriate access to data without due administrative burden. In return for this service applicants must demonstrate:

- The purpose of the project, relevance and importance of the project
- The research methods to be employed (i.e. sample size, selection criteria.)
- The feasibility of the project.
- Details as to how the information provided by the ECOBSW registry will be used (e.g. publications).
- The methods of ensuring the retention of confidentiality of patient information in both the short and the long term.
- The names of those connected with the project that will have access to the data.
- The potential risks and benefits to study subjects/participants/department.

Types of research requests:

Most requests for data fall into four categories:

1. Level 1 - non-identified aggregate data which are already in the public domain. Such data requests do not pose a risk of patient confidentiality and release of information may be provided on demand and do not require separate ethical approvals. E.g. breakdowns of numbers and rates of cancer by tumour stream, age and sex.
2. Level 2 - re-identifiable individual case record information- these files would not contain name, address, or date of birth information but may include data elements that either singly or collectively may identify an individual e.g. country of birth, postcode and age group
3. Level 3 - files containing individually identified case record information
4. Level 4 - files contain individual, record-level data with personal identifiers, to be used for research purposes involving direct patient or family contact.

Application Process

All requests for data must be made in writing to [chair of management committee email address] by completing the ECOBSW Registry Data Request Form along with the following documents (if applicable):

- Covering letter
- Data request form
- Ethics approval from institution or recognised body (NHMRC registered HREC) *only for level 2-4 data requests*
- Signed Confidentiality Form

Covering Letter

The covering letter should be addressed to the Cancer Data Analyst, ECOBSW registry Management Committee. This letter should give a brief outline of the project and what you intend to do with data from the ECOBSW database.

Data Request form

The Data Request form, Data Dictionary, Data Quality statement are available on request from ECOBSW registry Management committee [margaret.rogers@barwonhealth.org.au].

Before applying for data, you are encouraged to check with ECOBSW registry for availability and any limitations that may be applicable.

Review Process

1. Low-risk levels of data requests (1) will be forwarded to the ECOBSW registry Management Committee for a rapid initial review for final approval or rejection
2. High-risk levels (level 2-4) of data requests will be forwarded to the ECOBSW REGISTRY Steering Committee. As the group meets quarterly, there will be a proviso to review data requests in out of session meetings to expedite the review process. In such instances quorum will be achieved if at least 4 members agree to release data. These requests will be coordinated by the ECOBSW Cancer Data and Information Analyst. Decisions for data usage will be the responsibility of the Steering Committee. Decisions will be based on research merit, data availability, technical feasibility or complexity of project resource availability and competing projects.
3. If a member of the ECOBSW registry Steering Committee is making the request, they will abstain from the decision making process. This will ensure potential conflicts of interest are avoided. In the event of conflict arising as a result of the deliberations of the ECOBSW registry Steering Committee, the group will seek adjudication from a mutually agreed upon team of research experts from outside ECOBSW registry. The outcome of these deliberations will be considered final.
4. The Management Committee will provide the applicant with details of outcome of the Steering Committee's decision.
5. Upon approval, the applicant will be provided with contact details regarding arrangements for the release of data.
6. Adjustments to approved applications may be made. If the adjustment is covered by the HREC approval submitted in the original application, it will be considered an extension to an application and the changes submitted to the Management Committee. Where the adjustment involves the submission of a new HREC approval, a new application must be submitted.
7. Most internal planning projects will be supported with only minimal charge for data extraction; however access fees may be applied at the discretion of the ECOBSW registry Steering Committee.

Data request level	Data request form	Cancer Data analyst sign off	Independent approval from an NHMRC registered HREC	ECOBSW Data Governance Group
1	✓	✓	✗	✗
2	✓	✓	✓	✗
3	✓	✗	✓	✓
4	✓	✗	✓	✓

Terms and Conditions

The ECOBSW registry Management Committee will provide the specified information to the researcher on receipt of a signed User Agreement undertaking to:

- Use the information only for the research purpose stated in their application,
- Store the information in a secure manner and only for an agreed time period related to the purpose of the research,
- Not provide the information to any other person other than an associate researcher nominated in the application,
- Not seek to identify individual patients by any process, including by attempting linkage with another data set.

- Any publication, presentation or other uses, for which the data requested will be used, will correctly attribute the origin of the data.

Authorship/Publication

The ECOBSW Registry supports an environment of honesty, integrity, accuracy and responsibility in the dissemination of the findings of scientific research.

Users of the ECOBSW registry data have a responsibility to their colleagues and the wider community to disseminate a full account of their research as broadly as possible.

- If data from the ECOBSW registry is the primary source for a report or publication, the ECOBSW Management requires notification prior to publication or presentation and reserve the right to review and comment in a timely manner.
- It is a condition of use of ECOBSW Registry data that the source of the data is acknowledged, along with a statement that the analysis and interpretation are those of the author, not the ECOBSW Registry.

The authors would like to acknowledge the Evaluation of Cancer Outcomes Barwon South West Registry for providing the data.

Privacy restrictions

- Data shall remain private and shall only be disclosed to authorised parties in accordance with the requirements of applicable legislation, Commonwealth Privacy Act 1988, Information Privacy Act 2000 (Victoria) and the Health Records Act 2001.
- The Commonwealth Privacy Act 1988 impacts on release of some forms of data. In particular, individually identifiable data will not be released without ethics approval.
- Data is released for the specific purpose set out in the Data Request Form; use for any other purpose is not permitted without prior approval by the ECOBSW registry Management Committee.

References

The Cancer Council Victoria Victorian Cancer Registry Arrangements for access to data and the recruitment of subjects for research. Retrieved 9 November 2012 from Cancer Council Victoria website: http://www.cancervic.org.au/downloads/cec/VCR_data_access_08.pdf

Contributors

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