

BCCA Research Committee Operation Procedure Document

Version	Date	Reason/Comments/Approvals
1.0	May 2021	Document Ratified at Steering Committee Meeting
1.1	5 November 2021	Updated acknowledgement section.

BCCA Research Committee Operation Procedure Document:

This document sets out the operating procedures regarding data requests to access the Binational Colorectal Cancer Audit database.

All data requests can be lodged using the data request application form available on the BCCA website bowelcanceraudit.com/data-access; Upon receipt, the request will be forwarded to the Research Committee (a sub-committee of the BCCA Operations Committee). Applications will be reviewed on a case-by-case basis by the Research Committee and they will make recommendations to the BCCA Operations Committee for approval. They may request further information, seek evidence of appropriate ethical approvals, co-opt specialist members for advice or provide other feedback.

Once approved, researchers should liaise with the BCCA Project Manager to access data, discuss format and timelines. A fee may be charged to cover costs in meeting the request and this will be discussed prior to data extraction.

1. DATA REQUESTS CATEGORIES:

- A.** Requests from health professionals submitting data to BCCA
- B.** Requests from health professionals not submitting data to BCCA
- C.** Requests from industry/government/other e.g. private hospitals

A. REQUESTS FROM HEALTH PROFESSIONALS SUBMITTING DATA TO BCCA

All data requests will go up on the BCCA website.

De-identified BCCA data is available to those contributing data (users) and those affiliated with users for research purposes. Contributing users are required to show an ongoing contribution to the database. Data access contribution guidelines are published on the BCCA website.

Consultants (i.e. Health professionals/specialists) who agree to make their deidentified data accessible for research will also be able to access other users' deidentified data. Data is deidentified by patient, surgeon, and site. Consultants who do not want their deidentified data included for others to access for research will not be able to access other consultants' deidentified data for their own research.

Each consultant may submit one research application for data access at a time. Once that project is complete additional submissions may be made. The manuscript draft should be provided to BCCA for review prior to first submission. The Principal Investigator should provide brief 6 monthly updates. If a project is not completed within one year, permission for data access will be withdrawn and this data and research question will be made available for other researchers. An investigator may apply for a six-month extension stating the reason for the request. Project extension requests can be emailed to the Project Manager bcca@cssanz.org and may be granted with the Research Committee approval. The Research Committee may review extension requests via email.

Each unit may submit up to three research applications for data access at a time. A unit may not submit a research application for data if one of the unit's approved research projects is still ongoing after 12 months of data provision unless an appropriate explanation has been provided.

Data will be approved and provided for the specifically identified project only. A unit/consultant must not go outside the scope of their original proposal.

Data is only released when ethics approval for the project is provided.

The source and treatment of the data should be made clear in the “Methods” section. Preferably the abstract (and keywords if applicable) should also contain “Binational Colorectal Cancer Audit” which would allow for searching Audit publications.

The Research and Operations Committee may provide advice on the research question. Authors should have contributed substantially to the conception and design of the study, the acquisition of data, or the analysis and interpretation; drafted or provided critical revision of the article.

Manuscripts must be submitted to the Research Committee for approval prior to submission for publication.

Any material or manuscript to be published using BCCA data must contain appropriate acknowledgement of BCCA. See **item 3** Acknowledgement of BCCA.

B. REQUESTS FROM HEALTH PROFESSIONALS NOT SUBMITTING DATA TO BCCA

All data requests will go up on the BCCA website.

Individuals who are not contributing data to BCCA may request data for research or audit activity purposes. Surgeons undertaking treatment for bowel cancer patients are encouraged to contribute to the database. These data requests apply mainly to health care professionals other than surgeons undertaking bowel cancer surgeries such as epidemiologists, gastroenterologists and clinical researchers interested in screening.

Requests may include de-identified data, aggregate data, or data analysis/reports. All requests will be considered and assessed on a case-by-case basis.

The Research and Operations committee will determine whether or not a request will be approved.

Requests will be approved, and data/reports provided for the specifically identified project only and researchers must not go outside the scope of their original proposal.

De-identified data, aggregate data, or data analysis/reports are not released until ethics approval for the project is provided.

Any material or manuscript to be published using BCCA data must contain appropriate acknowledgement of BCCA. See item 3 Acknowledgement of BCCA.

A fee will be charged to cover the costs in meeting the data request.

C. REQUESTS FROM INDUSTRY/GOVERNMENT/OTHER e.g. private hospitals

Requests from private organisations, state and federal government will be considered under this category.

These are considered on their merits provided they follow the following principles:

- The use of the data should be in the public good and to the benefit of BCCA
- The data is completely deidentified by site, clinician, and patient
- The work required to extract the data is fully re-imbursed
- Notwithstanding the financial support, that the BCCA have the resources to provide the requested information

All requests will be considered and assessed on a case-by-case basis.

Only Aggregate data or reports will be provided.

Any material published using BCCA data must contain appropriate acknowledgement of BCCA. See item 3 Acknowledgement of BCCA.

A fee will be charged based on a contract agreement with agreed deliverables. The fee will be determined on a case-by-case basis.

2. RESEARCH COMMITTEE OPERATING PROCEDURE

A. REQUESTS FROM HEALTH PROFESSIONALS SUBMITTING DATA TO BCCA

A research application will be forwarded to Research Committee members via email as soon as the proposal is received.

All proposals are assessed by the Research Committee to determine:

- whether the proposal is feasible in terms of data availability, ethical and data privacy constraints
- whether the proposal duplicates the work of other investigators
- whether the consultant/site data entry is optimal
- The scientific merit of the proposal and make suggestions about possible improvements, if applicable

Committee members are expected to respond within two weeks. A reminder will be sent to Committee members who do not respond after two weeks and are expected to respond within one week.

If One committee member's response is missing and there are unanimity agreements among the remaining Committee members, the Research Committee can recommend sign-off by the Operations Committee.

A Committee member can comment in a discussion but cannot vote on their own project.

If a site data entry is sub-optimal, the research request will be referred to the Operations Committee for comments; and the Project manager will inform the researcher that the data entry at the site is sub-optimal and that the research request will be referred for review by the Operations Committee.

Research application is assessed by Research Committee members via email.

- I. If Research Committee members unanimously approve a project, the Research Committee recommends sign off by the Operations Committee.
- II. If all Research Committee members are unanimously in agreement but think there is potential controversy with the data request, the data request will be referred to the Operations Committee for further discussions.
- III. If Research Committee members do not unanimously agree about a project, the data request will be referred to the Operations Committee for further discussions.

B. REQUESTS FROM HEALTH PROFESSIONALS NOT SUBMITTING DATA TO BCCA

A request will be forwarded to Research Committee members via email as soon as the proposal is received.

All requests be considered and assessed on a case-by-case basis.

All requests are assessed at the Research Committee meeting and added as an agenda item for discussion at the Operations Committee meeting. The Research Committee may recommend sign off at the Operations Committee if members unanimously approve the project.

A fee will be charged to cover the costs in meeting the request and will be discussed at the Operations Committee meeting and with the researcher prior to data extraction.

C. REQUESTS FROM INDUSTRY/GOVERNMENT/OTHER e.g. private hospitals

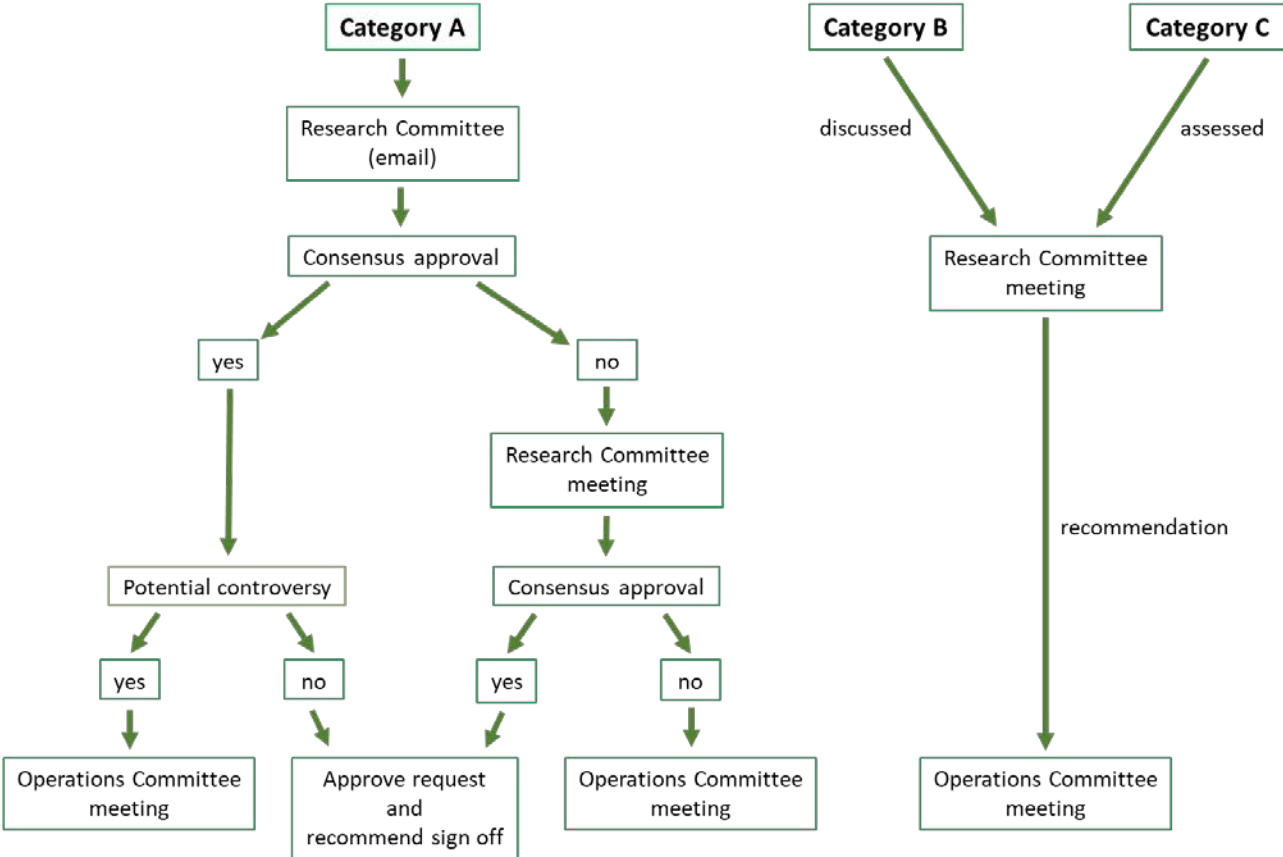
A request will be forwarded to Research Committee members via email as soon as the proposal is received.

All requests be considered and assessed on a case-by-case basis.

All requests are discussed at the Research Committee meeting and added as an agenda item for discussion at the Operations Committee meeting. The Research Committee will make recommendations to the Operations Committee on requests from industry/government/other groups (eg private hospitals).

A fee will be charged based on a contract agreement with agreed deliverables. The fee will be determined on a case-by-case basis.

Figure 1: Data Request Review Procedure



3. BCCA DATA ACKNOWLEDGEMENT

The BCCA should be acknowledged in any publication where the primary data source is provided by the Audit.

The suggested acknowledgement is:

The Binational Colorectal Cancer Audit (BCCA) is a collaborative project that collects data from public and private health services in Australia and New Zealand. *BCCA is endorsed by CSSANZ, RACS, GSA, NZAGS and MOGA.* The data in this publication are only available with the cooperation of all the participating sites, participating clinicians, and by approval of the BCCA Governance Committees. Guidelines have been applied to its use. The authors extend their thanks to all collaborators for the provision of the data. The reporting of these data are the responsibility of the authors and should not be seen as an official interpretation of the BCCA.

All publications using BCCA data should make clear the source and treatment of the data in the methodology section. Preferably, the abstract (and keywords if applicable) should also include "Binational Colorectal Cancer Audit", which would allow searching for audit publications.

Where BCCA data, figures or reporting are reproduced, or BCCA Quality Reports are used outside a unit's own quality reporting, permission should be sought via the BCCA Project Manager and when approved should be acknowledged with the following statement or similar:

"Reproduced with kind permission from the Binational Colorectal Cancer Audit."

Copies of publication/presentations should also be submitted to BCCA for our records.