

BC Generations Project

Access Policy



BC GENERATIONS PROJECT

Your time today builds a healthier tomorrow.

Version 2.0
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1. Purpose

The data collected as part of the BC Generations Project (BCGP) are a valuable resource available to researchers to pursue investigator-initiated research. Scientific knowledge is a common good and should be shared within an appropriate framework. Data-sharing is increasingly regarded as an ethical and scientific imperative for the advancement of knowledge. BCGP recognizes the importance that its data be published in peer-reviewed journals in a timely manner and be presented in scientific meetings and conferences. The purpose of this document is to establish the principles, policies and procedures by which access to BCGP databases and biosamples is sought and granted.

Collaboration amongst researchers is strongly encouraged to maximize access to and use of BCGP data and biosample holdings. Access to BCGP holdings is time-limited and for approved analyses only. Proposals will be accepted for access to questionnaire data, physical measurements data, biosample data and biosamples. Only de-identified data and biosamples will be provided to investigators. An Access Committee (AC) will review and evaluate access requests, and oversee access to BCGP holdings. During the review process, consideration will be given to the scientific merit of the project, the potential impact on Research Participants, and appropriate use of limited resources (e.g., biosamples). To encourage a broad range of research, exclusive access to any Data (see section 3 for definition) will not be permitted. Further, researchers will not receive exclusive access to an analysis or question of interest. This *Access Policy* has been developed and implemented in order to: enable informed and efficient collaboration; encourage fair, timely and transparent access to data and biosamples for high-quality research; and ensure that access is facilitated in a scientific and ethical manner.

2. Scope

This *Policy* details the various procedures and requirements for accessing BCGP holdings. BCGP is committed to sharing with the national and international scientific communities, to the principles of transparent and facilitated access to BCGP holdings by *Bona Fide* Researchers, and to rapid data release. These holdings include, but are not limited to, responses to self- and interviewer-administered questionnaires, physical measures, new variables created during analysis, biosample data, and data derived from biospecimens.

BCGP will not discriminate between access applications on the grounds of whether the Applicants are based in Canada or in other countries, or whether they are based in public or private institutions conducting scientific health-related not-for-profit research. All *Bona Fide* Researchers are invited to submit a Preliminary Access Application Form prior to grant submission followed by an *Access Application Form* when funding has been secured.

Access to BCGP's holdings will be granted for the time period specified in the *Data and Materials Distribution Agreement*. After this time, Applicants will be allowed to re-apply using the *Access Renewal Form*. Only de-identified datasets and biosamples will be released to Approved Users and there will be no exclusive access granted to any one party.

The BC Generations Project is part of a pan-Canadian initiative known as the Canadian Partnership for Tomorrow's Health (CanPath). CanPath includes prospective longitudinal cohort studies in five regions across Canada (The BC Generations Project, The Alberta Tomorrow Project, The Ontario Health Study, CARTaGENE (Quebec), and The Atlantic Partnership for Tomorrow's Health). All partner cohorts have been established and have built the infrastructure to recruit and recontact CanPath participants and collect, safeguard and store their information, measurement data and biosamples. By design CanPath is harmonized with other national studies in Canada and large cohort studies being conducted elsewhere in the world. Applicants interested in accessing data or biosamples from two or more CanPath regional studies are encouraged to visit the CanPath researcher portal (portal.canpath.ca) for access information.

3. Definitions

Access Application Form: a document completed by the Applicant when requesting access to BCGP's data and/or biosamples. It includes, among other things, the Applicant's research project, research team and the plan to ensure the security and confidentiality of BCGP's data and/or biosamples. Applicant must have funding and ethics approval. If applicant has not secured funding or ethics they may submit a Preliminary Access Application Form.

Access Committee (AC): a BCGP review committee that will approve or deny access applications and provide overall access oversight. The AC will consult the BCGP Advisory Committee, and/or the BCGP Principal Investigator regarding individual *Access Applications* as necessary. The AC will meet monthly except for the month of December.

Access Policy: this document that outlines BCGP's general principles and guidelines on access to its databases and biosamples.

Access Renewal Form: a document submitted by an Approved User one month prior to the expiration of the term associated with the use of BCGP's holdings. This *Access Renewal Form* allows the Approved User to apply for an additional term and to highlight any changes since the last application or renewal.

Aggregate Data: summed and/or categorized de-identified data that have been analyzed and placed in a format that precludes further analysis (for example, in tables or graphs) to prevent the chance of revealing an individual's identity, (individual records cannot be reconstructed). A minimum cell size of 5 is required to release Aggregate Data to decrease the likelihood of indirectly identifying individuals. While personal health information may be used to create Aggregate Data by specifically designated personnel at BCGP, once created, Aggregate Data do not include personal health information.

Ancillary Study: an external approved project that involves BCGP participant re-contact.

Applicant: a Canadian or International *bona fide* researcher conducting research relevant to the BCGP and who is applying for Data and/or Biosamples from BCGP.

Approved Institution: the host institution with whom the Approved User is affiliated for the

purpose of the research project outlined in the *Access Application Form* and who has signed the *Data and Materials Distribution Agreement*.

Authorized Institutional Representative: an individual who will act as the representative of the Approved Institution in the *Data and Materials Distribution Agreement* or the *Service Agreement*. The Authorized Institutional Representative is determined by the institution but must be in a position to legally bind their Institution.

Approved User: an Applicant who is approved by the Access Committee for access to BCGP's Data and/or Biosamples or to conduct an Ancillary Study. A single research project involving multiple institutions will require each institution to sign a *Data and Materials Distribution Agreement*.

BCGP Advisory Committee: The purpose of the BCGP Advisory Committee is to provide strategic advice and direction to the BCGP Leadership Team (Principal Investigator and Managerial Team) on issues relating to governance structures, policies and procedures, and issues of sustainability and long-term funding.

Bona Fide Researcher: an authentic researcher from a legitimate research or clinical institution.

BC Cancer: an agency of the Provincial Health Services Authority, provides a province-wide, population-based cancer control program for the residents of British Columbia. The mission of BC Cancer is to reduce the incidence of cancer, to reduce the mortality rate of people with cancer and to improve the quality of life of people living with cancer. This includes conducting research into causes of, and cures for, cancer. See www.bccancer.bc.ca

British Columbia Generations Project (BCGP): a not-for profit research platform facilitating research in cancer and in other chronic diseases. The BCGP is a Program of BC Cancer. See www.bcgenerationsproject.ca.

Biosamples: biological samples such as red blood cells, serum, plasma, DNA from buffy coat or saliva, and urine with associated preanalytical data from a unique, but not directly identifiable, individual made available to Approved Users in accordance with the *Data and Materials Distribution Agreement*.

Coded (De-identified) Data: data for which identifiers have been removed and replaced by a code.

Data and Materials Distribution Agreement (DMDA): a signed agreement between the Approved User, their Institution(s) and BC Cancer (in respect of the BCGP). It outlines the terms and conditions of access to BCGP's data and biosamples, and must be signed before these data and/or biosamples can be transferred. The Agreement legally binds its signatories.

Derived Data: any and all data generated from or based upon the use of BCGP data and/or BCGP biosamples. Data is at the level of the individual participant or sample aliquot.

Effective Date: the date when all parties (i.e., BC Cancer in respect of the BCGP, the Approved User and Approved Institution) have signed a *Data and Materials Distribution Agreement*.

Holdings: are coded(de-identified) data and biosamples associated with unique, but not directly identifiable, individuals.

Open-Access Datasets: publicly accessible aggregate data that cannot reasonably be combined to produce a dataset unique to an individual.

Preanalytical Data: information related to the standard operating procedures, equipment specifications, reagents used, storage conditions, and quality assurance details of BCGP biosample collection, processing, and storage. This does not include any BCGP data related to Research Participants or BCGP-derived data.

Preliminary Access Application Form (PAA): an application for interested users of the BCGP data and/or biosamples holdings who are in the grant application phase and seek a support letter. PAAs are reviewed for limited feasibility and impact assessment. An access budget will also be provided.

Re-Identify: the process of linking de-identified data to a Research Participant.

Research Participants: individuals who have consented to participate in the BCGP and have provided data and/or biosamples.

Service Agreement: a signed agreement between the Approved User, their Institution(s) and BC Cancer (in respect of the BCGP). It outlines the terms and conditions of BCGP providing Ancillary Study support. The Agreement legally binds its signatories.

Significant Changes: changes that modify the accuracy and scope of the initial information provided by the Applicant in the *Access Application Form*.

4. Access to BCGP Holdings and Resources

The data collected or generated by BCGP will be made available to public and private institutions that conduct not-for-profit scientific research. Requests to access individual-level BCGP data or biosamples for non-research related uses, including by law enforcement bodies or governmental agencies, will be resisted within the limits of the law. Exclusive access to BCGP's Data will not be granted to any party. Multiple Access Requests for overlapping initiatives may be approved by the Access Committee (AC) when the request does not include the analyses of biosamples. The AC will help to identify overlapping initiatives in the proposed study and those studies already under review, started or completed. In the case of overlapping studies, the Applicant will be notified that a similar access request was received to promote collaboration between researchers. The AC will offer suggestions for combining similar proposals and will prioritize *Access Applications* if multiple overlapping biosample requests are received.

Approved Users will be given access to BCGP's data and/or biosamples for the period specified in the *Data and Materials Distribution Agreement* with the possibility for subsequent renewals. Time-limited exclusive access will be granted to investigators collecting additional data, physical measurements and/or biosamples from Research Participants as part of an approved ancillary study.

The data and biosamples may not be used for any purpose other than for the approved research project outlined in the *Data and Materials Distribution Agreement*. The Approved User must inform the BCGP Access Committee of any changes to the research project or status for continued approval. This is to be done through the reporting mechanism described in Section 6f. Approved changes may require an amendment to the *Data and Materials Distribution Agreement*.

All Derived Data must be returned to BCGP upon completion of the study. This includes all analyzed BCGP data, analysis results from biosample measurements, and all new data generated via an Ancillary Study. Biosample data must include both initial (raw) and final (analyzed) data. The data will be used to enrich the content of the BCGP database as noted in section 10 of this Access Policy. To help others interpret the data accurately the characteristics of the dataset needs to be clearly defined. To assist in this manner, BCGP has adopted the CanPath Derived Data Reporting Templates (portal.canpath.ca). The template is to be used by Approved Users to present the dataset's quality parameters and is to be returned with the derived data. As the templates are designed to capture universal information common to multiple methodologies, additional information may be requested by BCGP as assessed on a project-by-project basis. BCGP recommends that all sample measurements follow good laboratory practices and that the Derived Data Reporting Template be reviewed and experiments planned accordingly to capture the requested variables.

5. Privacy of Participants

The BCGP will uphold the rights of its Research Participants by respecting their consent and by protecting their privacy as well as the confidentiality of their data and biosamples. Approved Users accessing BCGP data and/or biosamples will also assume these obligations (see *Data and Materials Distribution Agreement*).

The Approved User shall agree to store, manage and use biosamples and data from BCGP's holdings in strict confidentiality. In doing so, all reasonable efforts to maintain the security and confidentiality of the biosamples and data, including any copies thereof, are to be employed. The Approved User may not disclose, transmit or transfer biosamples or data to unauthorized individuals. The Approved User shall retain control of the transferred biosamples and data at all times, as delineated in the *Data and Materials Distribution Agreement*.

When requesting access to BCGP biosamples and data, Applicants and co-applicants from other institutions must confirm that reasonable security measures are in place. Their plan to secure biosamples and data should be detailed in the *Access Application Form*.

Only coded (de-identified) biosamples and data will be provided to the Approved User by BCGP. The Approved User must not attempt to re-identify any individual participants of BCGP by any means. If the Approved User involuntarily identifies a participant, this constitutes a privacy breach and the BCGP must be notified immediately.

6. Data and Biosamples Access Documents

a. Preliminary Access Application Form

Applicants seeking a letter of support for grant submission are directed to submit a Preliminary Access Application Form. This will initiate a limited feasibility and impact assessment review of your research proposal and provide you with a budget estimate and support letter. Final decision concerning access to BCGP research data and/or biosamples will require a formal access application, a detailed feasibility review and a review through BCGP Access Committee.

b. Access Application Form

In order to receive access to BCGP Data or biosamples, an Applicant will need to complete the *Access Application Form*. This application will undergo a detailed feasibility and impact review assessment by BCGP managerial staff followed by submission to the Access Committee (AC) for review and evaluation.

c. Access Renewal Form

The *Access Renewal Form* is to be used by Approved Users who currently have access to BCGP data and/or biosamples and who wish to extend this access beyond the approval period. The *Access Renewal Form* must be submitted a minimum of two months prior to the project end date identified in the *Data and Materials Distribution Agreement*. Upon approval by the AC, the *Data and Materials Distribution Agreement* will be appended.

d. Data and Material Distribution Agreement Biological Transfer Agreement

A legally binding document signed by the Approved User(s) and their institution(s) prior to being given access to the holdings.

e. Final Project Report

Once an approved research project has ended, Approved Users must submit a *Final Project Report* to the AC. This Report requires a summary of the research findings and includes details as specified in the *Data and Materials Distribution Agreement*. Individual record derived data must be returned, if not already done so, with the Final Project Report.

f. Unanticipated Event/Significant Change Report

An *Unanticipated Event/Significant Change Report* must be completed and submitted to the AC if unanticipated events and/or significant changes occur during an approved research project that may have an impact on the study data, that impact the ability of the Approved User to achieve the research goals, or that represents a significant change to the information initially provided in the *Access Application*.

7. Applications and Review Process

a. General Procedure

Applications for Data, biosamples and/or future contact of BCGP participants will follow the procedure outlined here. Investigators who wish to develop a proposal for access to the BCGP resource are strongly encouraged to review the available summary data on the BCGP website www.bcgenerationsproject.ca/researchers/bc-generations-project-open-access-data-information/ and contact the BCGP Research Manager if they have questions. If the Applicant chooses to proceed with requesting a letter of support for grant submission, the Applicant will complete and submit a *Preliminary Access Application Form* to the BCGP Research Manager. The BCGP Research Manager will forward the Applicant a letter of confirmation of feasibility including: (a) acknowledgement of receipt of request; (b) confirmation that the BCGP has the proposed study data variables and/or biosamples; (c) confirmation that data and/or biosamples may be made available to the Applicant pending submission of the *Application Form*, a detailed feasibility and impact assessment review, and approval from the AC, (d) an estimate of the cost.

Once funding and Research Ethics Board approval have been secured, an *Access Application* must be submitted. Applications will be checked for completeness by the BCGP Research Manager and then forwarded to members of the BCGP research team for a feasibility and impact assessment review. All feasible applications and associated documentation will be scientifically reviewed by the AC. External bodies may be consulted at the discretion of the AC to evaluate the proposal.

If the AC proposes changes or has questions, the Applicant will be notified by the BCGP Research Manager. Any requested changes will be accompanied by reasons and resubmission will be permitted. If research proposal is approved, the BCGP Research Manager will notify the Applicant of the AC approval and forward a copy of the *Data and Materials Distribution Agreement* to the now Approved User(s). The Approved User(s) and the Approved Institution(s) will be required to sign the *Data and Materials Distribution Agreement*. Once the relevant agreements have been signed by all parties, and the access fee has been paid, the BCGP Research Manager will then notify the BCGP Data Centre and BCGP Biorepository to prepare the data/biosamples. The Approved User(s) will then be granted access to the approved data and biosamples for the time specified in the *Data and Materials Distribution Agreement*. All approved projects will be listed on the BCGP website www.bcgenerationsproject.ca/impact/approved-studies/.

Investigators will have exclusive access to any additional data obtained during analysis for an agreed period of time specified in the *Data and Materials Distribution Agreement*. Once this time period has elapsed, the analyzed data including derived data will become part of the BCGP database, even if the results have not yet been published. Data will be made available as per the BCGP data holdings access procedures.

b. Ancillary Studies Requiring Participant Contact

BCGP Research Participants have consented to be approached for future studies and/or biosamples. Applicants may submit a *Ancillary Study: Request For Recontacting Participants Form* for studies that require the collection of additional information through questionnaires, measurements, or biosamples. However, no Research Participants are to be approached by the Applicant directly. For approved ancillary studies, BCGP staff will contact participants to

determine their interest in participating in the Approved User's study. Interested participants will be directed to contact the Ancillary Study should they wish to participate or seek additional information. The Ancillary Study will provide a list of participants to BCGP staff.

Applicants proposing Ancillary Studies will provide the BCGP with all data collection instruments (e.g., questionnaire, medical records abstraction form) and/or a description of the additional measurements or biosamples that will be collected, and informed consent documents developed for the Ancillary Study. The consent form for the Ancillary Study will be jointly developed by the Approved User and BCGP, and must clearly stipulate that it is ancillary to the BCGP and participation in the Ancillary Study is not required for continued participation in the BCGP. The contact email/letter will be developed with and sent by BCGP.

Approved User(s) will have exclusive access to any additional data or biospecimens that they have collected for an agreed period of time following data collection and cleaning. This time period will be determined when completing the *Service Agreement*. Once this time period has elapsed, **new data collected as part of an ancillary study, as well as all derived data or test results, will become part of the BCGP database.** This data will be available to other researchers as per the BCGP data holdings access procedures.

c. Requests for Access to Biosamples

Some Research Participants will have provided biosamples such as blood or urine. These samples constitute a highly valuable but finite resource. Applicants are required to submit a Preliminary Access Application Form followed by an Access Application Form once funding and ethics are secured. Applicants are strongly encouraged to identify robust analysis methods that use the smallest amount of biosamples for the biomarker(s) of interest.

Priority for studies requesting biosamples will be given to studies that are novel and exhibit scientific excellence as determined by the AC. In order to efficiently manage and maximize use of the samples, however, the following criteria will also be considered:

1. First makes use of samples from those participants with the most available samples;
2. Use previously-thawed samples whenever possible;
3. Use the smallest sample volume possible; and
4. Can be integrated with other studies to conserve samples or minimize freeze-thaw cycles.

In order to conserve samples and/or minimize the number of thawing and re-freezing cycles, BCGP may choose to coordinate the dissemination of samples for several approved studies.

This may result in a delay of the provision of samples following approval of an *Access Application Form*. This will be discussed with the applicant at the time of study approval before the *Data and Materials Distribution Agreement* is signed.

d. Requests for Linked Data

Applicants requesting access to data holdings at Population Data BC in addition to BCGP data will be required to complete Population Data BC's Data Access Request (DAR) application

process. Access to this linked data will require the approval of all data stewards (including BC Cancer) following standard Population Data BC policy.

Access to BC Cancer Registry data may be co-requested with the BCGP Access Application. Applicants are to request the BC Cancer Registry DAR from the BCGP Research Manager.

e. Criteria for Review

All *Access Application Forms* submitted will be assessed by the AC, for the following:

1. Clarity, novelty and scientific excellence of the proposed research plan
2. Compatibility of the proposed research to the vision and ultimate goal of the BCGP;
3. Experience and qualifications of the applicant investigator and co-investigators;
4. Demonstration of adequate resources to complete the proposed study, and to protect integrity/security of data and/or biological samples;
5. Adequacy of the Applicants' and the Host Institutions' processes regarding privacy and confidentiality;
6. Potential impact on future uses of the data and/or biological samples held by the BCGP;
7. Potential to enrich the BCGP data and/or biological sample repositories;
8. Potential for harm to BCGP from the additional recontact of participants (for ancillary studies).

f. Access Committee (AC)

The AC will act in an oversight and monitoring capacity. The AC will review *Access Application Forms*, and make decisions to approve, reject or request additional information about an *Access Application Form*.

g. Resubmission Process

There are two situations where resubmission is possible. Firstly, when the AC decides that the application requires additional information, the Applicant will be allowed to resubmit his/her *Access Application Form* with the necessary information, documentation, and/or approvals.

Secondly, resubmission is possible after the refusal of the *Access Application Form*. The Applicant shall resubmit a new *Access Application Form* which should address the comments relayed by the AC.

The BCGP Advisory Committee will provide advice to the AC in the case of a dispute. The decision of the BCGP Advisory Committee is final.

8. Confidentiality of Research Projects Submitted

All information on research projects submitted to BCGP will be kept confidential except as otherwise indicated in this *Policy*. Note, as BCGP is a member of the pan-Canadian Study, Canadian Partnership for Tomorrow's Health, BCGP may share limited information within CanPath for the purposes of reporting regional interest in the resource. In the event that a regional access request overlaps with other CanPath requests, additional communication may occur within CanPath to properly facilitate the request. Once access to BCGP data holdings is

granted, the following information will be added to a publicly available registry created by BCGP:

- Title of the research project accepted;
- Name(s) of the Investigator(s) involved,
- Name(s) of the Institution(s) involved;
- Start Year;
- A lay summary of the scientific abstract submitted by the Applicant.

9. Publication Policy

Approved Users of BCGP's data are strongly encouraged to publish their research results so as to benefit both the scientific community and the general population. Approved users are to follow the publication policy posted on the BCGP website (www.bcgenerationsproject.ca/researchers/requesting-data-and-biosample-access/).

10. Posting Derived Data

BCGP recognizes the scientific importance of improving the depth and breadth of its database. In order to achieve this goal, Approved Users accessing BCGP holdings are required to submit Derived Data to the BCGP after a period of time negotiated between the Approved Users and the AC and specified in the *Data and Materials Distribution Agreement*. Derived Data will be made available by BCGP to other Approved Users that have successfully applied for access to BCGP's data through the established procedures. This will allow future investigators access to enriched data and enable them to build upon previous research.

The need to protect intellectual property (e.g. patents) or pre-publication results may result in corresponding constraints on public disclosure of derived data. In such a situation and where the provided timeframe is not sufficient, the Approved User may apply to the AC for an extension.

11. Intellectual Property

The objective of the BCGP is to maximize public benefit from data collected by the BCGP and its collaborators. Accordingly, BCGP Data will remain as accessible as possible. Therefore, Approved Users and their host Institution agree not to make intellectual property claims on BCGP's primary data, but may choose to obtain intellectual property rights on subsequent innovations and downstream discoveries arising from such data.

Approved Users are strongly encouraged to follow the *Guidelines for the Licensing of Genetic Inventions* (www.oecd.org/dataoecd/39/38/36198812.pdf) adopted by the Organization for Economic Co-Operation and Development (OECD). Approved Users are expected to implement licensing policies that do not impede further research; see also the U.S. National Institutes of Health's document on *Best Practices for the Licensing of Genomic Inventions* (www.ott.nih.gov/policy/genomic_invention.html).

12. Archiving or Destruction of Data and Residual Biosamples

After the approved research project is completed and the results are submitted for publication and/or the data have been used for the purpose for which use was approved, the Approved User will be permitted to archive any transferred data for peer review and audit purposes for a maximum of 5 years. Alternatively, an Approved User may destroy the transferred data immediately or after a period of time with the agreement of BCGP. In either case, a plan for archiving or destruction of data must be submitted to the BCGP Research Manager and this will be specified in the *Data and Materials Distribution Agreement*. Biosamples will be destroyed or returned to BCGP as per the terms specified in the *Data and Materials Distribution Agreement*.

13. Compliance

The Approved User and the Approved Institution shall comply with the *Access Policy* (as amended from time to time), the *Data and Materials Distribution Agreement* and any renewals thereof, any requirements set out by the BCGP Access Committee and/or the BCGP Advisory Committee as well as any applicable requirements of BC Cancer and all applicable laws and regulations in regard to the subject matter of this *Access Policy*.

The Approved User shall report any deviation from full compliance with the *Access Policy* and *Data and Materials Distribution Agreement* using the *Unanticipated Event/Significant Change Report*.

In case of failure to comply with the provisions of this *Access Policy* or *Data and Materials Distribution Agreement*, BC Cancer in respect of the BCGP shall take such measures in its discretion as it deems necessary to deal with such non-compliance, including termination of the *Data and Materials Distribution Agreement* and legal action against the Approved User and Approved Institution, including a claim to recover damages.

14. Financial Conditions

BCGP will supply data and biosamples as well as contacting research participants for ancillary studies on a cost-recovery basis. An estimated cost can be provided after review of the Preliminary Access Application Form. The final amount will be determined by the AC and will be specified in the *Data and Materials Distribution Agreement* or *Service Agreement*. **Approved User is financially responsible for the provision and return of derived data and/or biosamples to BCGP.**

15. Amendments to this Policy

This *Access Policy* will be reviewed at least every two years, or more frequently as needed. Amendments to this *Access Policy* must be approved by the BCGP Advisory Committee. In case of amendments to this *Access Policy*, a new version will be posted to the BCGP researcher website (www.bcgenerationsproject.ca/researchers/requesting-data-and-biosample-access/).