GenomeBritishColumbia

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Genomics Innovation Fund Guidelines

Contents

A. Introduction and Background

Since its inception in 2000, Genome British Columbia (Genome BC) has invested nearly $1.3B in over 500 genomics research projects. As genomics has progressed, Genome BC's focus has evolved as well, moving from supporting predominantly discovery research to including application and translation with an additional focus on innovation – the practical translation of ideas and research outcomes into new and improved products, services, processes, systems or social interactions.

As part of its innovation mandate, Genome BC is launching the Genomics Innovation Fund (GIF) to support the advancement of innovation projects in BC.

B. Program Objectives

The key objective of the GIF is to support the development of transformative innovation genomics projects with commercial potential. Through GIF, Genome BC aims to support technology development projects that could be game-changing and advance the field of genomics[1] with commercial potential, or new applications that could likely lead to new commercial products.

C. Program Parameters

Genome BC aims to run one intake of GIF each year, and to award funding to between four and eight applications per intake, depending on the range of projects that are submitted and the merit of the final applications.

- Maximum funding available per project is $250,000
- Project terms of 12 months are recommended. Project terms of up to 18 months will be considered if the project team can provide strong justification for the longer term. Projects will not be permitted to extend beyond 18 months.
- No co-funding is required
- Approximate funding envelope per intake will be $1,000,000 to $2,000,000

Intellectual Property

Genome BC does not take an ownership stake in project intellectual property (IP). Genome BC expects a return on its investment in projects at affiliated BC research institutions, as defined by existing agreements between Genome BC and institutional partners.

D. Eligibility

Project Eligibility:

The goal of GIF is to advance innovations enabled by omics along the Technology Readiness Level (TRL) pathway. Genome BC has adapted the TRL scale for innovations involving omics; see Appendix 1 for details.

Projects must:

a. Involve innovation in the area of omics or use omics as a means to innovate.

[1] The term genomics or omics is defined here as the comprehensive study, using high-throughput, cutting-edge technologies, of the genetic information of a cell or an organism. This includes the function of specific genes, gene clusters, their interactions with each other or the surrounding environment as well as regulation such as bioinformatics (as applied to omics), epigenomics, lipidomics, metabolomics, metagenomics, proteomics and transcriptomics.

b. Have freedom to operate (FTO) and be able to confirm FTO. FTO is the availability of the product/service to use or sell without incurring legal liability by infringing on protected intellectual property held by a third party.
c. Justify how the project will advance the innovation by at least one step along the TRL scale, and indicate a plan for how the next step(s) will be reached beyond the proposed project, and
d. Describe the potential impact (e.g., societal, environmental, economic) of the innovation and how it would be assessed. What challenge(s) does the innovation address and why is this important?

Applicant Eligibility:

The GIF aims to support innovators with academic or organizational affiliation to a BC-based entity or corporation. The Project Leader must be appointed as faculty or employed at one of the following types of BC institutions or entities:

a. Post-secondary institutions or their affiliated hospitals or research institutes
b. Laboratories or units of government departments, ministries or agencies
c. Non-governmental, not-for-profit organizations (including community or charitable organizations) with an explicit research or knowledge translation mandate
d. Industry and commercial enterprises based in BC

For Project Leaders with existing Genome BC projects, administrative requirements (e.g. reporting) must be up to date in order to apply to GIF.

Note that Genome BC will only flow funds to a BC-based entity and the funds must be spent in BC (see Appendix 3 for Financial Guidelines).

E. Equity, Diversity, and Inclusion (EDI)

Equity, diversity, and inclusion are essential to achieving excellence and the full potential of the research ecosystem. Applicants are encouraged to consider how EDI-related considerations can be integrated into their research design and practices. For reference, see the Government of Canada's Best Practices in Equity, Diversity and Inclusion in Research Practice and Design guide: https://www.sshrc-crsh.gc.ca/funding-financement/nfrf-fnfr/edi-eng.aspx

F. Process

The application process will consist of two stages:

1. Expression of Interest (EOI) to outline the project and indicate how it fits within the scope of the program
2. Application to describe the project in more detail and to provide a detailed research plan and budget

Expression of Interest:

The Expression of Interest (EOI) should be completed using the EOI form template provided by Genome BC, available on the website (www.genomebc.ca). Applicants may not submit more than one EOI to a GIF intake. Each EOI should only describe one project.

EOIs will be reviewed by Genome BC with the assistance of external experts. Genome BC's goal is to support a range of projects from different entities and sectors that align with Genome BC's strategic goals and have the potential to provide societal, environmental or economic benefits to BC. This will be taken into consideration during the EOI review process to determine which projects are selected for the application stage.

Application:

The application will provide greater detail about the planned project, including methods, activities, objectives, milestones, and a budget. Applications will be evaluated by external reviewers and Genome BC against the evaluation criteria outlined in Appendix 2. Genome BC reserves the right to decide which applications will be awarded funding and decisions will be final.

Genome BC reserves the right to modify the review process to accommodate the number of EOIs and/or applications and ensure that sufficient funds are available for subsequent intake(s).

G. Administration Following Notice of Results

The plan for disbursement of approved funds will be determined based on the specific needs of the project. The first disbursement of funds will flow to projects once all conditions for the release of funds have been met as detailed in the Notice of Results.

Funded projects will be required to provide Genome BC with updates on the project progress throughout the project term. The reporting requirements and schedule will be determined in the funding agreement.

H. Timelines

Genome BC plans to run one intake of the GIF program per year unless changes to the schedule are required. Below is a general outline of the program timeline. Visit Genome BC's website at www.genomebc.ca for information about upcoming intakes.

Approximate Date	Activity
May	Deadline for submission of Expression of Interests (EOIs) to Genome BC
June	Applicants notified of the decision for their EOI(s) Selected applicants will be invited to submit an application
August	Deadline for submission of applications to Genome BC
December	Notification of results

I. Genome British Columbia Contact

Interested applicants are encouraged to contact Genome BC for information at GIF@genomebc.ca or visit Genome BC's website at www.genomebc.ca.

Appendix 1. Technology Readiness Level (TRL) Scale

Technology Readiness Levels (TRL) are a type of estimation which can be used to assess the maturity level of a particular technology. There are nine technology readiness levels, starting with TRL 1 as the least mature and TRL 9 as commercially available. A TRL number is obtained once the description in the "Definitions of TRL Levels" table (see Table 1) has been achieved. For example, successfully achieving TRL 3 (proof-of-concept) does not automatically move the technology to TRL 4 until laboratory validation is underway.

Figure 1 Phases of Technology Readiness

Knowledge Development

TRL 1-3 is the **Research and Invention Phase** starting with initiation of scientific discovery research and ending with a proof-of-concept or feasibility model. This phase is mainly funded by public sources and work is performed in academic settings.

Technology Development

TRL 4-7 is the **Innovation Phase** which is attained once the proof-of-concept technology is ready and continues to the point where the technology has been demonstrated in an operational environment. At this stage, the technology and work may be transitioned from academia to public or private partnerships in anticipation of commercialization. It is in this phase that many new ideas going through the innovation process fail to progress. Those ideas that do succeed, can spend anywhere between 5-10 years or even longer in this phase.

Business Development

TRL 8 and 9 is the **Commercial Market Phase** in which technology has been tested, de-risked, qualified and is released into the market. Once proven, private organizations take the technology to the market and perform post-market release activities and surveillance.

Definitions of TRL Levels

Definitions and descriptions of each TRL have been adapted from multiple sources [1-7]. Below each level, comparable descriptions for genomics-related technology have been suggested.

Table 1 Definitions of Technology Readiness Levels used by Genome BC

Level	Description
TRL 1	Concept Evaluation - Basic principles observation and reporting
	• Review of scientific knowledgebase • Exploration of a technology's basic properties • Scientific findings are reviewed and assessed as a foundation for characterizing new technologies • Active review and analysis of scientific literature to identify rationale for a potential new product • Examples might include "paper studies" of a technology's basic properties
OMICS	• Literature searches and identification of existing resources (e.g. searching EST databases, SNP databases, etc.)

TRL 2	**Technology Evaluation** - Technology concept and/or application formulation
	• Study if and how a technology can produce improved outcomes compared to the *status quo*, or address an unmet need • Development of research ideas, hypotheses, experimental designs and protocols for addressing the related scientific issues • Use of computer simulation or other virtual platforms to test hypotheses • Examples are limited to analytical studies which focus on practical applications based on basic principles observed • Examples may also include screening of potential compounds or initial IP searches for patentability
OMICS	• Determining the value for sequencing a genome and planning for genome sequencing projects, such as deciding on which technology to use • Identifying potential pipeline components (i.e. for bioinformatics analysis) • Research idea, hypothesis, and experimental design generation through paper studies
TRL 3	**Proof-of-Concept Research** - Analytical and experimental critical function and/or characteristic proof of concept
	• Active R&D (research, data collection, and analysis) is initiated to test hypothesis, and a technological solution is developed • Identify what is required for a technology to meet the application's requirements • Explore prototypes, critical design features and components • Perform analytical and laboratory studies to physically validate the separate components which make up the technology • Develop standard operating protocols/procedures (SOPs) • Examples in drug development may include target and/or candidate identification, and characterization of preliminary candidate(s), including *in vitro* activity and preliminary i*n vivo* proof-of-concept (non-GLP) • Filing of IP would also be considered at this level
OMICS	• Library preparation and optimization, active sequencing, data collection (e.g. of WGS data), and running through candidate pipelines to determine the sequence and its quality, and evaluate the pipeline to be used
TRL 4	**Early-Stage Prototype Development** - Component and/or breadboard validation in laboratory environment (laboratory validation)
	• Iterative integration and testing of basic components and critical technologies (hardware and software) in a laboratory environment to establish that they will work together • Establish design and development plan, and develop a regulatory strategy • Examples include integration of *ad hoc* hardware into "low fidelity" prototypes in the laboratory • Examples also include initiation of experiments **to identify markers**, correlates of protection, assays, and endpoints for further non-clinical and clinical studies

OMICS	• Validation of WGS data and alignment using other resources such as optical maps, BAC-by-BAC sequencing, etc. to polish the sequence • Generation of a draft reference genome • Initial GWAS studies to determine if genotype-phenotype associations exist • Identification, selection and validation of relevant variants (SNPs) to be included on a panel • Assay/test method validation in accordance with the product's intended use (sample type, volume, assay components)
TRL 5	**Late-Stage Prototype Development** - Component and/or breadboard validation in relevant environment (field validation)
	• Integration and testing of basic components in a simulated environment usually involving accessing "better" testing equipment to identify potential issues • Significantly increased fidelity of breadboard technology • Begin (e.g. GLP) studies supporting regulatory requirements • Examples include drafting preliminary target product profiles, and determining properties such as shelf life, storage conditions, and packaging to ensure that anticipated use of the product is consistent with the intended use for which approval will be sought from regulatory authorities (e.g. FDA, Health Canada, CFIA)
OMICS	• Validate the genomic selection (predictive) models from GWAS to determine power of prediction • Validation of biomarkers or panels to predict organism and/or environmental status • Generation of high-quality reference genome, demonstration of the value of SNPs and arrays to obtain phenotypic data in the lab environment
TRL 6	**Simulated Environment Pilot** – System model or prototype demonstration in a relevant environment (field demonstration)
	• Final testing of representative model or prototype to provide data critical to the commercialization phase where the technology is applied • Represents a major step up in a technology's demonstrated readiness compared to TRL 5 • Regulated production, regulatory submission, and generation of clinical data • Examples include testing a prototype in a high-fidelity laboratory environment or in a simulated operational environment • Transfer or license of intellectual property by end user from academia
OMICS	• Pilot studies to confirm validity and utility of SNP panels and biomarkers in a clinical (non-laboratory) setting (e.g. early clinical trial)
TRL 7	**Operational Environment Demonstration** - System prototype demonstration in an operational environment (operational demonstration)
	• Prototype near or at planned operational system • Use of the prototype in an operational environment to understand how it performs in non-simulated testing • Requires demonstration of an actual system prototype in an operational environment (e.g., in an aircraft, in a vehicle, or in space) • Scale-up, initiation of GLP process validation • Validate assays for manufacturing quality control • Perform regulatory submissions for approval and marketing clearance

OMICS	• Utilization of reference quality genome, demonstration of the value of SNPs and arrays to obtain phenotypic data in the real world • Confirm clinical validity and utility of SNP panel and validation in a larger cohort
TRL 8	**Final Testing and Evaluation** - Actual system completed and qualified through test and demonstration (approval to market)
	• In most cases, TRL 8 represents the end of true system/product development • Technology has proven to be successful under normal operating conditions in its final form • Perform regulatory submissions of approved product to start marketing • Examples include developmental testing and evaluation of the product, or technology system in its intended use to ensure it meets design specifications
OMICS	• Product / diagnostic test is ready and approved for use for real world implementation, e.g. direct-to-consumer personal genomics testing
TRL 9	**Successful Deployment** - Actual system proven through successful mission operations
	• Market launch and post-market surveillance • Application of the technology, in its final form, in real-life "mission" conditions, such as those encountered in industry or clinical settings • Active sales and distribution, and post-marketing studies as may be required • Commence post-licensure/post-approval and post-marketing commitments, such as safety surveillance, and studies to support use of the technology/product in special populations
OMICS	• Post-commercialization and revenue generation activities • Post-market evaluation of relationships between particular genetic variations and the presence or absence of specific diseases or traits, and assessment of the interpretation of findings at a population level

Acronyms

R&D	Research and Development
WGS	Whole Genome Sequencing
GWAS	Genome-wide Association Studies
SNP	Single Nucleotide Polymorphism
IP	Intellectual Property
GLP	Good Laboratory Practice
FDA	United States of America, Food and Drug Administration
CFIA	Canadian Food Inspection Agency

Appendix 2. Evaluation Criteria

To meet the objectives of the Genomics Innovation Fund, the following evaluation criteria will be used to evaluate projects at each stage of the process.

The following categories of criteria are regarded as equally important:

A. Innovation

1. Does this project represent innovation, as defined by Genome BC? That is, the practical translation of ideas and research outcomes into new or improved products, services, processes, systems or social interactions.
2. Does this project involve innovation in the area of omics or use omics as a means to innovate?
3. Will the proposed project advance the innovation by at least one level along the TRL scale?

B. Impact

4. Is the proposed impact of the innovation well-described and achievable? Impacts may include societal, environmental or economic benefits to BC.
5. What is the significance of the proposed impact of the innovation, and how would it be measured?
6. Have the potential users/beneficiaries of the project outcomes been identified?
7. Is there a pathway and timeline for how the next step(s) will be reached beyond the proposed project?

C. Research, Management and Financial Feasibility

Research

8. Do the proposed activities have specific, measurable objectives that will support the project deliverables?
9. Are the proposed objectives, goals, milestones and critical path feasible? Milestones must be constructed as to provide objective performance metrics and should be realistically attainable during the proposed timeframe.
10. Are the necessary resources, facilities and equipment available and suitable?
11. Are the design, methods and analysis adequately developed, well integrated, and appropriate to the aims of the project?
12. Does the project include collaborators that are essential to the success of the project?
13. To what extent does the project support equity, diversity and inclusion (EDI) by having a project team that attains gender parity and includes members of under-represented groups (racialized persons, people living with different abilities, Indigenous peoples, members of the LGBTQ2S+ community)?
14. Are the plans for handling the data and biological resources (data protection, release and publication, resource sharing, etc.) appropriate?
15. Does the team have a risk management plan to mitigate potential risks (e.g., reasonable plan for sample collection or access to ensure the timely completion of the project)?

Management

16. Is the expertise and time commitment of the project team appropriate for realizing the project goals?
17. Does the project leader(s) have the demonstrated leadership and research expertise/experience?
18. Does the management plan cover project governance, accountabilities of personnel, and processes for decision making on project direction?

Financial

19. Do the budgeted costs comply with the eligible costs outlined in the Financial Guidelines (Appendix 3)?
20. Do the budgeted costs align with the proposed project plan and activities?
21. Are the financial and budgetary control processes effective?
22. Does the documentation and principal financial assumptions support the proposed budget?
23. Are the costs incurred and paid for in the Province of BC? Costs incurred in BC utilizing fee-for-service providers located outside of the province may be eligible though quotes and a strong justification must be provided.

Appendix 3. Financial Guidelines

A. Eligible costs

Eligible costs are defined as reasonable and new costs for items that directly support the objectives of the Genome BC approved project. Overhead costs are not eligible costs and as such cannot be included in the proposed budget.

The main categories of eligible costs are: 1) salaries and benefits, 2) consumables, 3) services from others, 4) general and administrative costs and 5) equipment.

Eligible costs may include the following:

1. Salaries and benefits

a. Salaries for project team members. Note that these must represent at least 0.15 FTE per annum.
b. Salaries for Project Leader or Co-leaders are eligible, unless the individual holds a salaried position that covers their activities within the project. Note that salaries for these roles will require strong justification for their inclusion in the project budget.
c. Benefit rate as charged by the host entity, not to exceed 20% of the employee's salary.
d. Salaries to support administration and coordination of the project, such as a Project Manager. These costs cannot exceed more than 5% of the total budget.

2. Consumables

a. Materials and supplies consumed as part of the project, such as laboratory reagents and supplies. For consumables utilized in most laboratories, a general rate per Full Time Equivalent (FTE) may be accepted, provided that the rate is appropriately justified in the supporting documentation.
b. Items that meet at least one of the following; 1) expendable tangible property, 2) useful life of 1 year or less, or 3) a cost of less than $2,000. For example, a $1,900 piece of equipment, such as a laptop, would be considered a consumable cost.
c. Travel for project activities only (e.g. sample collection).
d. Equipment service contracts, provided that the need for the use of the equipment is justified.

3. Services from Others

a. External costs that are conducted at arms-length and incurred based on a reasonable fee-for-service arrangement or contract.
b. Costs related to Intellectual Property protection services, such as patent registration, filing, and maintenance costs incurred during the term of the project, as long as the service is provided by a company external to the host entity, and not covered by the IP Support Fund (see Section C. Program Parameters).
c. A copy of a quote or Statement of Work (SOW) must be provided to support any individual cost that exceeds $15,000.

4. General and Administrative (G&A)

a. Reasonable general and administrative costs directly linked to the project. For example, costs for the project's communications and public outreach activities, and costs associated with scholarly publications, including fees to provide open access to the findings (e.g. costs of publishing in an open access journal or making a journal article open access).
b. G&A costs must not exceed five percent (5%) of the non-administrative costs of the project budget (calculated as total budget less administrative costs).

5. Equipment

a. Equipment is defined as any item (or collection of interrelated items comprising a system) which is used wholly or in part for the project proposed and meets all three of the following conditions: 1) non-expendable tangible property, 2) having a useful life of more than one (1) year, and 3) a cost of $2,000 or more.
b. A strong justification for the need to purchase equipment for a Genome BC project must be provided.
c. Any items of equipment over $15,000 require a copy of a quote to be provided with the application.

B. Ineligible costs

Ineligible costs include, but may not be limited to:

- Indirect costs to the project.
- Regular facility rental costs.
- The opportunity cost of using existing infrastructure.
- Costs related to the preparation and submission of an application for funding from Genome BC or any other funding agency.

Genome BC will conduct a financial due diligence review of each application and its associated budget as part of the review process to assess if costs are eligible and well justified.