Pilot Innovation Fund Guidelines

A. Introduction and Background

Since its inception in 2000, Genome British Columbia (Genome BC) has invested over $1B in genomics research and built a globally significant genomics research cluster in British Columbia. As genomics[1] have progressed, Genome BC's research focus has evolved as well, moving from predominantly discovery to one of application and translation.

A key pillar of Genome BC's 2020-2023 Strategic Plan is to support innovation, with a goal of 10% of Genome BC's funding allocation being directed to innovation projects. For the purposes of this plan, Genome BC defines innovation as the practical translation of ideas and research outcomes into new or improved products, services, processes, systems or social interactions.

B. Program Objectives

The key objective of this Pilot Innovation Fund is to test our approach to fund a diverse set of innovation projects. Based on this pilot, Genome BC will develop and launch a longer-term Innovation Funding Program in support of its innovation strategy.

This pilot will leverage external experts and Genome BC's program development capacity to facilitate our development of the approach and parameters for the longer-term Innovation Funding Program. Applicants are expected to provide feedback on the program and process to enable co-creation of the longer-term innovation program by providing feedback, responding to surveys, agreeing to attend a program review workshop and/or other input mechanisms Genome BC may use to develop its Innovation Funding Program.

C. Program Parameters

Genome BC aims to support between four and six projects through this pilot, depending on of range of projects that are submitted and the merit of the final proposals.

- Maximum funding available per project is $250,000
- Maximum project duration is up to 12 months
- No co-funding is required

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.

IP Support fund

Genome BC recognizes that IP decisions and activities have associated costs. Projects awarded through this pilot will have access to additional funding to support IP activities to

[1] Genomics is the science that aims to decipher and understand the entire genetic information of an organism (i.e. plants, animals, humans, viruses and microorganisms) encoded in DNA and corresponding complements such as RNA, proteins and metabolites. For the purpose of this plan, genomics is defined broadly and includes genomics, proteomics, metabolomics, transcriptomics and other related disciplines.

advance their innovation. The scope of this support and eligible activities will be determined on a case-by-case basis with the awarded projects during the project term.

D. Eligibility

Project Eligibility:

The goal of the Pilot Innovation Fund 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. This pilot is focused on advancing research from the proof-of-concept research level (TRL 3) to the innovation phase (TRL 4-6), and/or from the innovation phase into the business development phase (TRL 7-9).

Projects submitted to this pilot must:

a. Involve innovation in the area of omics or use omics as a means to innovate,
b. Have freedom to operate (FTO) and be able to confirm FTO,
c. Have a TRL of at least 3 at the beginning of the project, based on Genome BC's scale (see Appendix 1),
d. 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
e. Describe the potential impact (e.g. societal, environmental, economic) of the innovation and how it would be assessed. What challenge does the innovation address and why is this important?

Applicant Eligibility:

This Pilot Innovation Fund aims to support a wide range of projects to help inform the development of our longer-term Innovation Program. Therefore, this pilot is open to all 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.

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 details).

E. Process

The application process will consist of three stages:

- Expression of Interest (EOI) to outline the project and indicate how it fits the scope of the pilot.
- Pitch to clarify the project.
- Proposal to describe the project in more detail and provide a final research plan and budget.

Genome BC's goal is to support a range of projects from different entities and sectors, at different stages on the TRL scale and with different types of impact. This will be a factor during the EOI review process to determine which projects are selected to invite to the pitch

stage. Depending on the number of applicants invited to the pitch stage and the size of the projects, the success rate for applications invited to the pitch stage is estimated to be 30-40%.

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 submit more than one EOI if they have multiple projects to propose. Each EOI should only describe one project.

EOIs will be reviewed by Genome BC with the assistance of external experts, and final selection will be done by external experts and GBC leadership. If an applicant has submitted more than one EOI as the Project Leader, Genome BC may decide, at their discretion, to only invite one of the projects to proceed to the pitch stage.

Pitch:

Teams that are selected to proceed after the EOI stage will be invited to pitch their project to a panel including external reviewers and Genome BC management. The main purpose of the pitch it to clarify the project and identify areas that the team should address in the proposal. Teams will be provided with feedback from the panel following their pitch. If the project is not deemed eligible or competitive at the pitch, the team may not be invited to submit a proposal.

Proposal:

The proposal will provide greater detail about the planned project, including methods, activities, objectives, milestones and a budget. It will also provide an opportunity for teams to address any critiques or concerns raised during the pitch stage. Proposals will be evaluated by external reviewers and Genome BC. Genome BC reserves the right to make the final funding decisions and decisions will be final.

F. Administration Following Notice of Results

Genome BC aims to launch these pilot projects a quickly as possible after the teams have been notified of the results. To that end, applicants and their institutions/organizations will be expected to help facilitate rapid completion of any funding conditions, including approval of funding agreements.

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. Note that Genome BC intend to use this pilot fund as a learning opportunity to help us develop a longer-term Innovation Funding Program, so a high level of engagement with funded teams in expected.

G. Timelines

Date	Activity
July 2021	Launch of Pilot Innovation Fund (PIF)
September 1, 2021	Deadline for submission of Expression of Interests (EOIs) to Genome BC

October 1, 2021	Applicants notified of the decision for their EOI(s) Applicants selected to continue will be invited to the pitch stage
October 19, 2021	Teams pitch project to Genome BC and reviewers
October 22, 2021	Pitch results and feedback provided to teams
November 17, 2021	Deadline for submission of Proposals to Genome BC
December 20, 2021	Notification of results

H. Genome British Columbia Contact

Interested applicants are encouraged to contact Genome BC for information:

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Further information is available on the Genome BC website (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

Sources

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4. https://www.ic.gc.ca/eic/site/ito-oti.nsf/eng/00849.html
5. https://elevatetechfest.com/blog/technology-readiness-levels-2/
6. https://www.medicalcountermeasures.gov/federal-initiatives/guidance/integrated-trls.aspx
7. https://ustar.org/grant-programs/tap-technology-acceleration-program/life-science-trl

Appendix 2. Evaluation Criteria

To meet the objectives of this Pilot 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 (from a starting position of at least TRL 3)?

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

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 disabilities, 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.
    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, to a maximum of $10,000 per year (pro-rated for part years) in total costs for projects.

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.

Ineligible costs include, but may not be limited to:

- Individuals already being paid a salary through their host entity (i.e. if one is receiving a salary through their organization, they cannot be paid twice with Genome BC funds)
- 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 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.