GenomeCanada

Request for Applications
2012 Large-Scale Applied Research Project Competition

Genomics and Personalized Health
A Genome Canada – CIHR Partnership

1. Overview

Genome Canada, in partnership with the Canadian Institutes of Health Research (CIHR), is seeking proposals for large-scale research projects which focus on the application of genomics[1] in the area of Personalized Health. Through this partnership Genome Canada will implement an important element of its Strategic Plan (2012-2017) and CIHR will launch its Personalized Medicine Signature Initiative. This strategic partnership will build on the complementary mandates of Genome Canada and CIHR and provide an opportunity to maximize the effectiveness of the research communities, infrastructure and resources supported by both organizations.

In the context of this competition Personalized Health can be seen as a more evidence based approach to decision making both with regards to health maintenance and disease interventions. There is a spectrum of activities that span what is referred to as the molecular medicine continuum from health maintenance and disease prevention, through early detection, to treatment of disease and disease prognosis (see Fig. 1). This approach relies upon an increasing knowledge of the underlying risk factors, causes, and mechanisms of disease pathogenesis as well as an understanding of the influence of environment, behaviour and lifestyle on the onset and outcomes of the disease state.

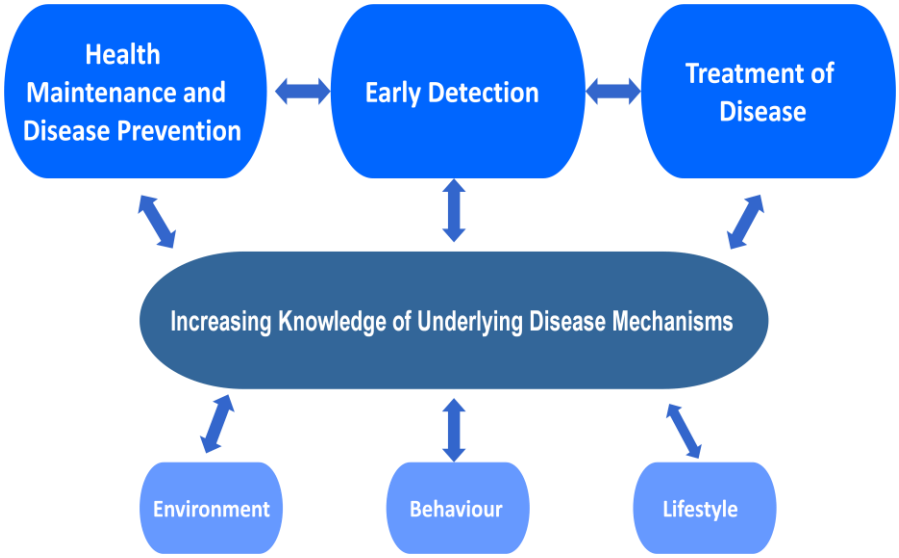

Fig. 1. The Molecular Medicine Continuum

[1] The term genomics is defined here as the comprehensive study, using high throughput technologies, of the genetic information of a cell or organism, including the function of specific genes, their interactions with each other and the activation and suppression of genes. For purposes of describing Genome Canada's mandate it also includes related disciplines such as bioinformatics, epigenomics, metabolomics, metagenomics, nutrigenomics, pharmacogenomics, proteomics and transcriptomics.

Under this Request for Applications (RFA), genomic and GE^{3}LS[2] activities can be targeted to any part of the continuum but must demonstrate their potential to contribute to a more evidence-based approach to health and their potential to improve not only the cost-effectiveness of the health-care system, but also to ensure that discoveries are translated into patient and population benefits. In order to maximize the effectiveness of this RFA in advancing genomics research and its application in Canada, sharing of resources and expertise through inter-regional or international collaboration is encouraged at all levels.

2. Objectives

The 2012 Large-Scale Applied Research Project Competition in Genomics and Personalized Health aims to support projects that will demonstrate how genomics-based research can contribute to a more evidence-based approach to health and improving the cost-effectiveness of the health-care system.

In the application, applicants must demonstrate how their proposal holds a high potential for attaining concrete deliverables by the end of the funding period that will have clinical utility and/or practical applicability in as short a time as possible. Proposals that make a strong case that significant social and/or economic benefits will be realized within a short time-frame after the end of the four-year project are particularly encouraged.

To ensure that the objectives of the RFA are met, all applications must address the evaluation criteria established for the competition, i.e., research, socio-economic benefits, management and financial (see Appendix 1). Only those proposals demonstrating the highest degree of overall excellence will be funded.

3. Parameters of the Competition

- There is up to $67.5 million available for this competition with the Government of Canada providing $40 million through Genome Canada and up to $22.5 million through CIHR. An additional $5 million is available from the Cancer Stem Cell Consortium (CSCC).
- At least 50% of the requested funding for eligible costs for each project must be obtained through co-funding from other sources.
- Genome Canada, CIHR and CSCC will invest a maximum $5 million in an individual project (please note, however, that with the maximum investment from Genome Canada, plus co-funding that can exceed $5 million, a total investment of more than $10 million per project is possible).
- In keeping with Genome Canada's mandate to invest in large-scale research, projects requiring less than $1 million from Genome Canada, CIHR and CSCC will not be considered unless very well justified.
- Successful individual projects will be awarded funding for a term of up to four years.

4. GE^{3}LS

Genome Canada will support three modalities of GE^{3}LS research activities, two of which will be included in this RFA and a third that will be launched in a follow-up competition. Within this RFA this approach includes both:

[2] The acronym GE^{3}LS stands for "Genomics and its Ethical, Environmental, Economic, Legal and Social aspects". However, it should be understood broadly as genomics-related research endeavors and related activities undertaken from the perspective of the social sciences and humanities. Therefore, it is not strictly limited to disciplines that make-up the acronym but rather encompasses all those that rely on quantitative and qualitative methodologies to investigate genomics in society, and help establish a basis to inform applications, practices and policies. Moreover, in the context of this RFA, genomics-related research emanating from scholars in health sciences and related fields such as health administration, health management, health services research, health technology assessment, real-world evaluation and comparative effectiveness research, etc., would be considered GE^{3}LS activities.

- **Integrated GE^{3}LS** research that is directly related to the overall project's potential to contribute to a more evidence-based approach to health and improving not only the cost-effectiveness of the health-care system, but also to ensure that discoveries are translated into patient and population benefits. **Each project must include an integrated GE^{3}LS research component.** The overarching objective of integrated GE^{3}LS research is to support collaboration between genomic scientists and GE^{3}LS researchers throughout all aspects of research projects (including research management and oversight) that will advance knowledge and its translation;
- **Large-scale GE^{3}LS research projects** that investigate in an innovative and comprehensive manner significant challenges and/or opportunities in achieving the objectives of the RFA. It is expected that large-scale GE^{3}LS projects would demonstrate active engagement with the genomics scientific community in the planning of the research and its conduct. This may entail sustained interactions with other large-scale projects and/or their integrated GE^{3}LS components; and,

Following the funding decisions on this current competition, a **future targeted funding opportunity** will be launched that could result in the funding of one or more projects and/or consortia that will work closely with the previously funded GE^{3}LS projects (integrated and large-scale) funded under the current funding opportunity. The goals of this subsequent opportunity would be to: promote networking amongst funded GE^{3}LS projects; identify and address overarching research questions; optimize synthesis of all the GE^{3}LS research efforts to facilitate the translation into practices and/or policies; and, identify and address the gaps in GE^{3}LS efforts that may require additional research attention. This targeted opportunity will be developed after consultation with key stakeholders.

5. Eligible Research Areas

To be eligible for this competition, proposals must:

- include genomics approaches as essential components in terms of importance to the overall outcomes of the project;
- address personalized health in humans; and,
- be of a scale and scope such that they are able to address challenges requiring a genomics approach, be internationally competitive and have the potential for major impact.

Projects must be sufficiently advanced such that the outcomes of the research are tangible and include concrete deliverables with clinical utility and/or practical applicability that will allow for subsequent translation into the health-care system. For example, studies requiring patient samples would normally be expected to have access to these samples in place, including appropriate human subject approval, at the time the project is to be initiated in order to produce concrete deliverables by the end of the four-year project.

This RFA provides an opportunity for research teams to propose large-scale projects that would be part of even larger national and international research initiatives (e.g., epigenome, human microbiome, human proteome, rare diseases), as long as other eligibility criteria are met.

Projects that propose clinical assessments of new drugs are not eligible although clinical assessment of companion diagnostics to enable existing drugs to be used in new indications as well as clinical validation of biomarkers are eligible.

NOTE: Studies whose major focus is the health of organisms other than humans are not eligible. Projects using non-human model systems that have direct applicability to human health could, however, be eligible for this competition.

While this RFA must address genomics and personalized health in humans, it is not limited to any particular research area or disease. The types of applied studies that would be eligible, potential deliverables and integrated GE^{3}LS projects include, but are not limited to, the following:

- Development of molecular markers that can inform dietary or behavioural choices in disease prevention strategies and the related understanding of how these choices may be presented to, understood, and be acted upon by, individuals;
- Development of monitoring diagnostic tools for screening programs for diseases and investigation of relevant regulatory pathways and/or relevant policies and practices that would accelerate the integration of new diagnostic tools in Canadian laboratories;
- Development of molecular markers to monitor disease progression and/or response to treatment and studies that would result in development of best practices for addressing related psycho-social implications for patients and families;
- Development of biomarker panels to stratify patients so that more targeted treatments can be offered that address the molecular pathology of the particular disease;
- Development of computational methods that will enable translation of genomic discoveries to the clinic and studies that would result in recommendations for facilitating the uptake of electronic health records by clinicians; or,
- Pharmacogenomic approaches to improve safety and efficacy of existing drugs resulting in an eventual label change for an adverse drug reaction, and related regulatory oversight.

The types of large-scale GE^{3}LS studies and deliverables include, but are not limited to, the following:

- Studies, including economic modeling, to assess more comprehensively the social and economic benefits that are derived from genomics research and its integration into the health-care system;
- Studies relying on methods such as health technology assessment, comparative effectiveness (including cost-effectiveness, clinical utility, and/or real-world effectiveness studies) or health outcome assessments related to the integration of genomics-based practices or technologies, including risk stratification, new diagnostic and screening tools, and associated therapeutic modalities, as well as studies into the understanding across health-care practitioners and segments of the Canadian population of these practices or technologies, to inform decision-making by governments or other stakeholders;
- Research related to the evidence-base available to accelerate the production of genomics knowledge that will inform clinical care, including questions related to data collection, harmonization, transfer, as well as access to and use of clinical data, and related privacy issues;
- Studies of provincial and federal policy and regulatory regimes that would provide guidance for the translation of genomics research into applications, including questions related to IP, genomics-based product approval, liability, as well as policy issues related to regimes and interventions that affect public health genomics;
- New frameworks, models and tools for resource allocation decision-making and priority setting regarding coverage decisions (including reimbursement levels) for genomics-based practices, technologies (including diagnostic tools), and medicines;
- Research on the impacts of premature entry of biomarkers into the health care system (e.g., on health care utilization and cost, patient safety, etc.) as affected by factors including, but not limited to, maturity of evidence base (e.g., clinical validity and utility), regulatory policies, consumer demand and commercialization; or,
- Research leading to frameworks and models for improving the appropriate engagement and participation of the public, patients, and/or service users in health care decision-making related to genomics-based treatments and practices.

6. Socio-Economic Benefits

All applications must describe, with supporting evidence, the deliverable(s) that will be realized **by the end of the project.** Deliverables must have clinical utility and/or practical applicability in as short a time as possible

and lead to social and/or economic benefits for Canada in terms of contributing to a more evidence-based approach to health and a more cost-effective health-care system. These benefits could include, for example, adoption of a new technology, a change in clinical practice guidelines, an application of an existing drug to a new indication, or a reduction in the number of adverse drug reactions. In addition, there could be other positive impacts on society, the economy (e.g., development of products with commercial potential), quality of life, or the environment.

Applications must include a plan which explains the next steps of how the deliverables from the research will be transferred, disseminated, used, and/or applied to realize the socio-economic benefits. Applicants must also include a rationale (including an economic component) explaining how the outcomes of the project will potentially contribute to a more evidence-based approach to health and a more cost-effective health-care system. Once funded, project teams will have to further elaborate this plan so as to provide a more substantive business case at the time of interim review that will describe the path forward to ensure the proposed deliverables and benefits are realized in the stated timeframe and within the approved budget.

Socio-economic benefits should be attainable within as short a time as possible after the end of the four-year project, appropriate for the area of research. Proposals that make a strong case that significant benefits will be realized within a short time-frame after the end of the project are particularly encouraged and, all else being equal, will have an advantage in the review process.

See **Appendix 1** for more details on all review criteria.

7. End-User Engagement

All projects must clearly demonstrate end-user engagement in the development and execution of the research plan in order to help ensure receptor uptake and clinical utility or practical applicability of the research. “End-users” in the context of this RFA can be defined as those who are able to use the information generated through research to make informed decisions on issues such as health practices, policies, programs and product development. Examples of end-user organizations include health-care authorities, patient groups and companies (e.g., molecular diagnostic, pharmaceutical and/or biotech companies). Examples of the types of individuals who could represent end-user organizations on the project team include health-care practitioners, health-care administrators and decision-makers in the public and private sectors.

End-users must be clearly integrated into the project team in the form of a project team member, collaborator and/or member of the management team. Co-funding would clearly demonstrate end-user interest in the project’s potential deliverables, although it is not a requirement for an end-user organization to contribute to the co-funding required. In addition, the project’s Science Advisory Board should include one or more individuals with expertise in transforming the deliverables of the research into socio-economic benefits.

8. Competition Time Lines

Requests for support of projects must be submitted to Genome Canada through a Genome Centre. The competition timelines outlined below include both Genome Canada and Genome Centre deadlines. Please contact your regional Genome Centre for further information on their process.

January 24, 2012	Launch of Request for Applications (RFAs) and release of competition Guidelines and Evaluation Criteria
February 27, 2012	Registration due date - Genome Centres
March 2, 2012	Due date for eligible registrations – Genome Canada

March 5, 2012	Applicants notified by Genome Centres of eligibility of Registration
April 10, 2012	Deadline for Pre-Applications to Genome Centres
May 14, 2012	Deadline for Pre-Applications to Genome Canada
July 6, 2012	Applicants notified of results of Pre-Application
August 20, 2012	Deadline for full applications to Genome Centres
October 1, 2012	Deadline for full applications to Genome Canada
Late-November 2012	Review committee meets (including meetings with applicants)
Early December 2012	Decisions by Genome Canada and Partners
Mid-Late December 2012	Notification of Decision

9. Application Process

Genome Canada will work with its partners, CIHR and CSCC, throughout the competition process. Applicants are required to apply for funding through their regional Genome Centre. The application process is comprised of three steps: Registration, Pre-Application and Full Application.

9.1. Registration

A brief **Registration** form will be used to provide early guidance on elements such as who is applying, what they are planning to do, research areas, expected deliverables, approximate budgets and suggested reviewers. This will allow for screening for eligibility by the Genome Centres and facilitate the early selection of reviewers for the peer review process. Information from eligible Registrations (i.e., name of project leader(s), lead institution, title of project, research areas and keywords) will be posted on the Genome Canada Website to facilitate the identification of areas of potential synergy between applications from across the country so that applicants could consider engaging with other researchers on a common project. This will also make possible the exchange of required information between project teams and Genome Canada's Science and Technology Innovation Centres.

9.2. Pre-Application

For the **Pre-Application,** applicants will be asked to submit a short description of the following:

- the proposed research, including an integrated GE^{3}LS research plan,
- expected deliverables of the research;
- the potential socio-economic benefits of the research;
- how the team will engage end-users in the project; and,
- high level management and financial (including budget and proposed co-funding) sections.

Individuals with the appropriate expertise will evaluate the Pre-Applications focussing on the quality of the research plan and the potential for socio-economic benefits, but also taking into consideration the management and financial plans. The proposals will again be checked for eligibility to the program. Only the most competitive Pre-Applications will be invited to submit full applications. It is expected that approximately 30 pre-

applications will proceed to the full application stage. Information from approved pre-applications (i.e., name of project leader, lead institution, title of project, research areas and keywords) will be posted on the Genome Canada Website to further facilitate the exchange of required information between project teams and Genome Canada's Science and Technology Innovation Centres.

9.3. Full Application

Those applicants successful at the Pre-Application stage will be asked to submit a full application. Full applications must address the evaluation criteria established for the competition, i.e., research, socio-economic benefits, management and financial. A final check for eligibility will be carried out. A multidisciplinary committee of experts, with expertise in assessing the research, socio-economic benefits, management and financial criteria will be established to review applications. The review committee will meet with and interview representatives from each project through a face-to-face meeting. Only those proposals demonstrating the highest degree of overall excellence will be funded. Further details of Genome Canada's application processes and selection criteria can be found in the **Guidelines for Funding Large-Scale Genomics Research Projects.**

The evaluation processes may be adjusted where warranted by the complexity of proposals received or other relevant factors. Any changes will be rapidly communicated through Genome Canada's website and through the Genome Centres.

10. Co-Funding

Genome Canada, CIHR and CSCC require that at least 50% of the requested funding for eligible costs for each project be obtained through co-funding from other sources. The Genome Centres, working with the applicants, are responsible for securing co-funding. Co-funding for this competition must be for new or incremental research activities that are an integral part of the Genome Canada approved project. Co-funding must have been applied for on or after **June 6, 2011** and must be for eligible costs specifically requested in the Genome Canada budget form in order to be considered as an eligible co-funding source. On a case-by-case basis, funding applied for before the specified date may be considered eligible co-funding if these funds are specifically re-directed towards the project approved through this RFA. See the **Guidelines for Funding Large-Scale Genomics Research Projects** for more details.

11. Partnerships and National Co-Funding Opportunities

11.1. Partnerships

To enhance its program in genomics and personalized health, a strategic partnership has been established between Genome Canada CIHR and the CSCC on this RFA. To be eligible for CIHR and CSCC partnership funding applicants must satisfy the requirements for the competition as outlined in the RFA as well as any additional requirements put forth by the partner organizations. For more details on these funding opportunities, please see **Appendix 2.** and **Appendix 3.**

CIHR is the Government of Canada's agency for health research. CIHR's mission is to create new scientific knowledge and to catalyze its translation into improved health, more effective health services and products, and a strengthened Canadian health-care system. Composed of 13 Institutes, CIHR provides leadership and support to more than 13,000 health researchers and trainees across Canada. Partnership on this RFA provides an opportunity to maximize the effectiveness of the research communities, infrastructure and resources of both Genome Canada and CIHR. CIHR's participation in this competition marks the launch of CIHR's Personalized Medicine Signature Initiative http://www.cihr-irsc.gc.ca/e/43627.html

CSCC is a not-for-profit organization founded in 2007 by a group of Canadian funding agencies to support international collaboration on a promising new front in the fight against cancer, i.e., research on cancer stem cells, which direct the growth of the many kinds of tumours. Partnership on this RFA provides an opportunity for funding in the area of cancer stem cell research.

11.2. National Co-Funding Opportunities

A number of co-funding opportunities associated with this competition are available to researchers located anywhere in Canada. Information on these opportunities can be found at **National Co-Funding Opportunities.**

12. Contacts

Karen Dewar	Genome Canada	(613) 751-4460 ext 111	kdewar@genomecanada.ca
Shelley King	Genome Atlantic	(902) 421-5646	sking@genomeatlantic.ca
Catalina Lopez-Correa	Genome Québec	514 398-0668 ext 203	clopez@genomequebec.com
Klaus Fiebig	Ontario Genomics Institute	(416) 673-6583	kfiebig@OntarioGenomics.ca
Reno Pontarollo	Genome Prairie	(306) 668-3576 (204) 975-7740	rpontarollo@genomeprairie.ca
Gijs Van Rooijen	Genome Alberta	(403) 503-5230	vanrooijen@genomealberta.ca
Gabe Kalmar	Genome British Columbia	(604) 637-4374	gkalmar@genomebc.ca

Appendix 1. Evaluation Criteria

Proposals submitted to Genome Canada are evaluated through a rigorous independent peer review process to assess their research merit and potential for socio-economic benefits for Canada as well as to ensure that sound management and financial practices are implemented. Excellence and innovation at the very highest of international standards must be demonstrated for funding to be awarded.

Eligibility Criteria

Each proposal will be reviewed for eligibility at every stage of the application process. The following criteria will be used.

Does the proposal:

- respond to the objectives of the Genome Canada competition;
- include genomics approaches as essential components in terms of importance to the overall outcomes of the project;
- address personalized health in humans; and,
- possess a scale and scope such that it is able to address challenges requiring a genomics approach, be internationally competitive and have potential to have a major impact?

If considered eligible, the proposal will be reviewed using the criteria described below.

Review Criteria

The review criteria fall into three categories:

1) Research Proposal;
2) Socio-Economic Benefits for Canada; and
3) Management and Finance

Note that the descriptive phrases which follow the criteria below are not all-inclusive.

1. Research Proposal

Including Research on Ethical, Environmental, Economic, Legal and Social Aspects of Genomics (GE^3LS)

- Research Context and Originality
  - To what extent does the proposed research lead, extend and/or complement national and international work in the area?
  - To what extent does the proposed research reflect creative, original thinking?
  - To what extent is the research relevant to the end users identified?
  - Do the expected research outcomes have the potential of contributing to a more evidence-based approach to health and improved cost-effectiveness of the health-care system?

- Research Plans
  - How appropriate are the methods and approaches (including handling of data and resources) in terms of the research objectives?
  - How feasible is the research given the projected resources and time-lines?

- Research Expertise

- How appropriate is the expertise of the research team in terms of realizing the research goals?
- How well will different types of expertise be integrated?

- Research Support
  - How suitable are the available facilities, equipment and services (including services to be provided by Genome Canada Science and Technology Innovation Centres (STICs) and other technology service providers)?

- Specific GE^{3}LS Research Criteria (in addition to the GE^{3}LS aspects which are considered to be included in the criteria above)
  - Does the GE^{3}LS investigation address salient aspects of the genomics project and are the research questions directly related to the objectives and expected outcomes?
  - Is the integrated GE^{3}LS research plan aligned with, and complementary to, the overall project milestones?
  - Is the GE^{3}LS research plan sufficiently robust and systematic to advance generalizable knowledge in relevant academic fields?

2. Socio-Economic Benefits for Canada

- Deliverables
  - To what extent have the applicants identified appropriate deliverables in terms of their potential to have clinical utility and/or practical applicability?
  - What is the probability that the deliverables will be achieved by the end of the funding period?

- Expected Benefits
  - How significant are the anticipated benefits described in the proposal in terms of their potential of contributing to a more evidence-based approach to health and improved cost-effectiveness of the health-care system?
  - Will the benefits be realized within a short time-frame after the end of the project?

Note: All else being equal between two proposals, the one which makes a stronger case for benefits to be achieved sooner will be assessed more favourably.

- Strategy for Realizing Benefits
  - How persuasive is the strategy set out by the applicants for realizing benefits from their research?
  - How strong is the plan for knowledge translation and development of benefits, i.e., how well does the plan explain the next steps of how the deliverables from the research will be transferred, disseminated, used, and/or applied to realize the socio-economic benefits?
  - How convincing is the rationale (including an economic component) explaining how the outcomes of the project will potentially contribute to a more evidence-based approach to health and a more cost-effective health-care system?

- Expertise for Realizing Benefits
  - How appropriate is the expertise of the team that will further develop and implement the strategy for realizing benefits?
  - To what extent are likely end-users involved in the project and the strategy to realize benefits?
  - If the strategy includes commercialization, to what extent has appropriate technology transfer expertise been included?

- How strong is the expertise assembled to ensure appropriate attention to ethical, environmental, economic, legal and social factors in the process of realizing benefits?

3. Management and Finance

- Management Plans and Expertise
  - How well does the management plan cover project governance, accountabilities of personnel, and processes for decision-making on research direction and strategy for realizing benefits?
  - Has the team identified the appropriate types of expertise required and role for their Science Advisory Board (SAB)? **NOTE** that applicants should not have individuals named at the application stage and if they have this does not convey any advantage in the review process.
  - How realistic is the project schedule given the likely need to "ramp-up" activities at the front end?
  - How convincing is the management plan in terms of coordination of current and future partnerships?
  - How appropriate are the plans for making the research results accessible to the research community?
  - How good are the proposed arrangements with a STIC or other technology service providers to ensure appropriate and timely collaboration?
  - To what extent do the project leaders have experience in managing large-scale projects involving research and the application of results?
  - How good are the plans to ensure that an adequate number of highly qualified personnel (HQP), both support personnel such as technicians and trainees such as post-doctoral fellows, are available to meet the needs of the proposed research through recruitment and/or training?

- Budget and Expenditure Controls
  - How reasonable is the proposed budget in terms of the anticipated level of effort and deliverables?
  - To what extent does the proposal provide assurance that expenditures from a funded project would be closely and critically monitored?

- Financing from Co-Funders
  - To what extent is the proposed co-funding plan well-documented, eligible and feasible?
  - Does the proposed co-funding directly support the objectives of the project?
  - How strong is the likelihood that the project will be able to secure at least 75% of the co-funding for eligible costs at time of the release of funds?

Appendix 2. Partnership with the Canadian Institutes of Health Research (CIHR)

Description

Genome Canada and the Canadian Institutes of Health Research (CIHR), through its Personalized Medicine Signature Initiative, will jointly support research projects in the area of genomics and personalized health, using the 2012 Large-Scale Applied Research Project Competition in Genomics and Personalized Health.

Background

CIHR is pleased to announce a strategic partnership with Genome Canada to collectively advance the Personalized Health Research agenda. CIHR's participation in this competition marks the launch of the CIHR Personalized Medicine Signature Initiative and advances all three of the initiative's stated objectives:

1. Develop an evidence base on how to assess and, where appropriate, integrate innovative diagnostics (including laboratory diagnostics and medical imaging) into health policy and practice.
2. Stimulate the discovery, validation, and translation of biomarkers, targets and genomic signatures for risk prevention and for diseases, which have the potential to promote strategies for prevention as improve the outcomes of therapeutic interventions by selecting tailoring of treatment choices to individual patient and disease characteristics
3. Foster the development and validation of diagnostics based on such biomarkers, targets and genomic signatures, and of innovative devices for the application to patient practice

This strategic partnership provides an opportunity to maximize the effectiveness of the research communities, infrastructure and resources of both Genome Canada and CIHR. Genome Canada funded researchers provide leadership in large-scale applied genomic research projects and Genome Canada funded Science and Technology Innovation Centres (STICs) allow access to world leading Centres applying genomic and other "omic" technologies to scientific problems. CIHR brings access to their extensive health research community with expertise in health economics, health services and health policy, clinical epidemiology and clinical trials, clinical and basic research as well as existing and prospective biobanks.

CIHR's participation in this competition represents the first in a series of funding opportunities to be launched under the CIHR Personalized Medicine Signature Initiative. A key research priority area underscoring the CIHR Personalized Medicine Signature Initiative focuses on real world, evidence-based, comparative effectiveness of biomarkers and new or existing tools and technologies. This focus aims to create an evidence-base for new or existing biomarkers, tools and technologies, based on analytical validity (whether a test accurately identifies a genetic variant or biomarker), on clinical validity (whether a genetic variant, biomarker, or test accurately predicts the presence of disease or risk of disease), on clinical utility (whether a test will lead to an improved health outcome as well as the risks and benefits of the test), and on comparative effectiveness (helping to inform health care decisions by providing comparative evidence on the effectiveness, benefits, and harms of different treatment options).

Funds Available

- CIHR has allocated up to $22.5 million to fund individual projects on a 1:1 funding basis with Genome Canada to deliver on the CIHR Personalized Medicine Signature Initiative and will support both types of research projects (large-scale applied genomics research projects and large-scale GE^{3}LS research projects) in targeted research areas as outlined in the table below.

- CIHR is committed to providing a minimum of $20 million on a 1:1 funding basis with Genome Canada in support of research projects above the funding cut-off line and will fund research projects that do not align with its targeted research areas if required to meet this minimum commitment.

CIHR's financial contributions for this initiative are subject to availability of funds. Should CIHR funding levels not be available or are decreased due to unforeseen circumstances, CIHR reserves the right to reduce, defer or suspend financial contributions to grants received as a result of this funding opportunity. CIHR retains the option of funding research projects in full (with the required co-funding from other sources) that align with its targeted research areas that are in the fundable range but below the Genome Canada cut-off line. However, this would only be done once CIHR has fulfilled its $20 million commitment, so it is unlikely to occur unless additional funds become available from CIHR during the competition process and sufficient co-funding is also available from other sources.

Eligible Research Areas:

Applications must be in the area of Genomics and Personalized Health and address all the eligibility criteria as outlined in RFA.

Eligible Research Areas	Level of Investment
A. Large-scale GE^{3}LS projects	• $4.5 million
CIHR Institute of Cancer Research (CIHR-ICR), CIHR Institute of Genetics (CIHR-IG) and CIHR Institute of Health Service and Policy Research (CIHR-IHSPR): CIHR-ICR, CIHR-IG and CIHR-IHSPR will consider partnering on one or more large-scale GE^{3}LS projects (including genomics: utility, clinical and comparative effectiveness). More specifically: • CIHR-IG will consider partnering on applications investigating any subject relevant to the mandate of CIHR • CIHR-ICR will consider partnering on applications where the results of the projects are generalizable to the fields of cancer research and personalized medicine • CIHR-IHSPR will consider partnering on applications relevant to IHSPR's mandate, focused on genomics: utility, clinical and comparative effectiveness	• $2.5 million is available from CIHR-IG • $1.5 million is available from CIHR-ICR • $0.5 million is available from CIHR-IHSPR
B. Large-scale genomics projects	• $18 million
CIHR Institute of Cancer Research (CIHR-ICR): CIHR-ICR will consider partnering on individual large-scale research projects relevant to personalized medicine research strategies that will have broad impact on either prevention, accurate diagnosis, targeted validation and intervention, or patient stratification for control of cancer. It is anticipated that teams will be multi-disciplinary and multi-provincial (i.e., involving sites in more than one province) in nature.	• $2.5 million

CIHR Institute of Cancer Research (CIHR-ICR): Through the **CIHR Breast Cancer Initiative (CBCI)**, CIHR-ICR will consider partnering on individual large-scale research projects relevant to personalized medicine research strategies on either prevention, accurate diagnosis, target validation and patient stratification for control of breast cancer. Research projects may include real-world evaluation of new technologies with existing approaches, and/or coordinated integration of technologies into health care services.	• $2.5 million
CIHR Institute of Genetics (CIHR-IG): CIHR-IG will consider partnering on individual research projects focused on the following areas: rare diseases; epigenetics/epigenomics; computational biology; systems biology; synthetic biology; and complex genetics. In addition, projects in the area of rare diseases must comply with International Rare Diseases International Research Consortium principles and guidelines that will be available shortly.	• $2.5 million
CIHR Institute of Infection and Immunity (CIHR-III): CIHR-III will consider partnering on individual large-scale research projects determined to be relevant to **CIHR-III strategic initiatives** in the following priority areas: transplantation; antimicrobials resistance; inflammation; human microbiome; clinical auto-immunity; preparing for and responding to emerging threats; and vaccines.	• $2.5 million
CIHR Institute of Musculoskeletal Health and Arthritis (CIHR-IMHA): CIHR-IMHA will consider partnering on individual large-scale research projects that are determined to be relevant to CIHR-IMHA's **research priority areas** plus the following: • Genetic and environmental factors relating to causes and treatment of musculoskeletal, oral and skin diseases • Development, use and accessibility of new technologies ("omics") for the study and treatment of inflammation in MSK, oral and skin diseases (i.e., systems biology/systems physiology approaches)	• $2.5 million
CIHR Institute of Neurosciences, Mental Health and Addiction (CIHR-INMHA): CIHR-INMHA will consider partnering on individual large-scale research projects aligned along two themes: the application of genomics to patient stratification to minimize side effects of pharmacotherapies in the treatment of mental health; and advancing the understanding of links between epigenetics and brain health including embedded epigenetic GE^{3}LS research.	• $3.0 million
CIHR Institutes of Cancer Research (CIHR-ICR), Circulatory and Respiratory Health (CIHR-ICRH) and Aging (CIHR-IA): CIHR-ICR, CIHR-ICRH and CIHR-IA will consider partnering on a large-scale research project that integrates multimodality medical imaging with 'omits technologies' in the area of personalized health relevant to all three Institutes' priorities. Any successful project must include the following four components: • A multi-modality, multi-disciplinary approach that combines	• $2.5 million

imaging expertise from the fields of oncology, cardiology and neurodegeneration in old age (Alzheimer's disease and related dementias)
- The ability to correlate imaging methodologies quantitatively with "omic" methodologies required to support clinical decisions.
- Evaluation of existing and new biomarkers that demonstrate clinical relevance in disease diagnosis, monitoring therapeutic response, or patient stratification leading to customized care.
- Assessment of clinical utility of research outcomes in multi-centre clinical trials

CIHR Guidelines, including Eligibility, Allowable Costs and Conditions of Funding

The general guidelines of each of the participating partner agencies must be followed, See the CIHR Partnership Funding Opportunity for a complete listing of all CIHR guidelines and the associated details.

Relevancy Review

CIHR will have access to the complete pre-application submitted to Genome Canada to conduct a relevance review to assess the alignment of an application with the specific research priority areas as outlined in the table above, prior to the review of the pre-application.

Contact Information at CIHR
For questions on CIHR funding guidelines and the competition process contact:

Carole Chow
Program Delivery Coordinator
Canadian Institutes of Health Research
Telephone: 613-948-2903
Email: Carole.chow@cihr-irsc.gc.ca

For questions about this initiative and research objectives contact:

Alison Hosey, PhD
Associate, Institute Strategic Initiatives
CIHR Institute of Cancer Research
Telephone: 613-954-1965
Email: Alison.hosey@cihr-irsc.gc.ca

Stephanie Robertson, MA
Assistant Director
CIHR Institute of Genetics
Telephone: 613-954-0533
Email: Stephanie.roberston@cihr.gc.ca

Maude Ruest
Senior Projects Officer
CIHR Institute of Health Services and Policy Research
Telephone: 514-398-5736
Email: mruest.ihspr@mcgill.ca

Appendix 3. Partnership with Cancer Stem Cell Consortium

Description
Cancer Stem Cell Consortium (CSCC) will partner with Genome Canada to support up to one large scale research project in the area of cancer stem cells as part of Genome Canada's 2012 Large-Scale Applied Research Project Competition on Genomics and Personalized Health.

Background
CSCC is a not-for-profit organization founded in 2007 by a group of Canadian funding agencies to support international collaboration on a promising new front in the fight against cancer - research on cancer stem cells, which direct the growth of the many kinds of tumours. Current members include: Genome Canada, the Canadian Institutes of Health Research, the National Research Council, the Michael Smith Foundation for Health Research, the Canada Foundation for Innovation, the Ontario Institute for Cancer Research and the Stem Cell Network.
Cancer stem cells represent an exciting and promising avenue for cancer research as their presence, in many malignancies studied so far, may explain the ability of tumours to proliferate, metastasize and survive traditional chemotherapy and radiation treatments. The ability to extract, culture and expand cancer stem or progenitor cell populations is central to advancing research and to enabling a rigorous investigation of the potential of cancer stem cells as targets for new, more specific, therapeutics.

To be eligible for CSCC funding, applications must be focused on the study of cancer stem cells with the goal of developing cancer stem cell based therapy or biomarkers with the specific aim of improving cancer treatment. Proposals must also address the eligibility criteria as outlined in the RFA.

Funds Available

The Cancer Stem Cell Consortium (CSCC) will contribute up to $5 million to Genome Canada's 2012 Large-Scale Applied Research Project Competition on Genomics and Personalized Health to support the highest ranking cancer stem cell research project which falls above the Genome Canada cut-off for fundable applications.

Approval of funding for the Partnered Project will be obtained by Genome Canada's Board of Directors and the CSCC Board of Directors.

Relevancy Review

CSCC will have access to the pre-applications submitted to Genome Canada to conduct a relevance review to assess the alignment of an application with the specific research priority area prior to the submission of the full application. Only teams who have been deemed eligible by the CSCC will be considered for this partnership funding.

Contact:
Cindy L. Bell, Ph.D.
Interim Executive Director, CSCC
Email: cscc@genomecanada.ca
Phone: (613) 751-4460 ext 118