



Guidelines and Evaluation Criteria

Competition in Applied Genomics Research in Bioproducts or Crops



GenomeCanada

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Genome Canada is a not-for-profit corporation dedicated to developing and implementing a national strategy in genomics and proteomics research for the benefit of all Canadians. By means of **investments of \$840 million** to date from the Government of Canada, Genome Canada has become the primary funding and information resource relating to genomics and proteomics in Canada and has established six Genome Centres across the country (Atlantic, Québec, Ontario, Prairie, Alberta, and British Columbia).

1 OBJECTIVES OF GENOME CANADA

Genome Canada's mandate is to develop and implement a national strategy in genomics and proteomics research for the benefit of all Canadians. It is committed to increasing Canada's position among the world leaders in genomics¹ research in key areas such as health, agriculture, environment, forestry, fisheries and technology development. It is also committed to a leadership role on the ethical, environmental, economic, legal and social issues and potential implications associated with genomics research (GE³LS), and to communicating with Canadians on these and other issues.

Genome Canada will fulfill its mandate through its five national objectives²:

1. the development and establishment of a coordinated national strategy for genomics research to enable Canada to become a world leader in areas such as health, agriculture, environment, forestry and fisheries;
2. the provision of leading-edge technology to researchers in all genomics-related areas through regional Genome Centres across Canada, of which there are currently six, one each in British Columbia, Alberta, the Prairies, Ontario, Quebec, and the Atlantic;
3. the support of large-scale genomics and proteomics research projects of strategic importance to Canada, by bringing together industry, governments, universities, research hospitals and the public;
4. the assumption of leadership in the area of ethical, environmental, economic, legal, social and other issues related to genomics research (GE³LS), and the communication of the relative risks, rewards and successes of genomics research to the Canadian public; and
5. the encouragement of investment by other persons in the field of Genomics research.

2 BACKGROUND

Genome Canada funds large-scale genomics research proposals in the areas of health, agriculture, environment, forestry, fisheries, new technology, and GE³LS. To ensure that

¹ The term genomics research is used to cover the study of the genes and their functions, namely genomics, proteomics, genotyping, sequencing, bioinformatics and other related fields of research (as per the definition stated in Genome Canada's Funding Agreement signed March 29, 2007).

² Genome Canada's Funding Agreement signed March 2008

research projects of the highest calibre are funded, projects are selected by international experts through a rigorous review of their scientific, management and financial plans. Central to Genome Canada's strategy is ensuring that the GE³LS issues related to the research and potential benefits for Canada are addressed as an integrated component of each proposal.

With its partners, Genome Canada has funded **115 large-scale** research projects and science and technology (S&T) platforms with a total investment to date of over **\$1.6 billion**. A list of approved large-scale projects and S&T platforms is available on Genome Canada's web site at **www.genomecanada.ca**.

Genome Canada's strategy to ensure the effective management and monitoring of its funded research projects and S&T platforms has been to establish six Genome Centres across Canada, in British Columbia, Alberta, the Prairies, Ontario, Québec, and the Atlantic region. These Centres facilitate access to leading-edge technology for researchers, support project development, management and fundraising, and provide opportunities for public outreach programs at the regional level. **Contact information for each Centre is presented in Appendix A.**

In 2006-07, Genome Canada launched a new initiative by inviting the scientific community to join with stakeholders and identify Strategic Research Themes through a Position Paper Process. Fifty-seven Expressions of Interest were received and assigned to themes by the international members of Genome Canada's Science and Industry Advisory Committee (SIAC). The communities involved selected theme leaders who managed the process, which led to the submission of eleven position papers in July 2007. These papers were subjected to an international peer review and two position papers, in the areas of Bioproducts, "*Securing Canada's future bio-based economy through genomics*" and Crops, "*Crop genomics for a healthy Canada*", were recommended to the Board of Genome Canada for inclusion in Genome Canada's Strategic Research Portfolio and budget submission to Industry Canada for 2007-2008.

3 REQUEST FOR APPLICATIONS (RFA)

3.1 Purpose

The purpose of this RFA is to solicit large-scale research projects focusing on the application of genomics research in the areas of bioproducts and crops, as defined in section 3.2. Proposals concerning the ethical, environmental, economic, legal and social aspects of genomics research (GE³LS) in these strategic areas can also be submitted as a large-scale project(s). Funding for this competition is subject to Bill C-50, the *Budget Implementation Act, 2008*, becoming law.

3.2 Research Scope

3.2.1 Bioproducts—Securing Canada's Future Bio-Based Economy through Genomics

The production of bioproducts provides an opportunity for Canada to meet environmental targets, and contribute to the Canadian economy. In addition, research in this area offers the

possibility of addressing the growing gap between the supply and demand of petroleum and concerns regarding greenhouse gas emissions. Research projects, which are sought under this theme are those that employ high-throughput genomic, proteomic, metabolomic and allied approaches to understand and manipulate the underlying biological processes exploited in the production of economically viable and environmentally sustainable bioproducts.

Projects may address any issue that falls within the general scope of this topic, but applications in the following three areas are especially welcomed:

1. **Feedstock Optimization:** Significant work is required to ensure that the right feedstock is available at the right places and at the right prices to support a rapidly expanding Canadian bioproducts and biofuels sector. The challenges to Canada involve both the optimization of feed stocks for the diversity of Canadian climatic regions, and the optimization of feedstock traits for industrial applications.
2. **Microorganisms for Sustainable Processing Technologies:** Research is needed to accelerate the identification, development and optimization of enzymes and microorganisms for use in the bioproducts sector, including the production of biofuels, biochemicals, and biomaterials, and the extraction and production of high-value bioactive compounds.
3. **Value Added-Bioproducts:** Investigation is needed with regard to the development of processes whereby low or negative value biomass residue from one industrial process is transformed into higher value bioproducts. Closely related is the need to identify high-value compounds from biological sources, which can anchor and make the production of a much larger range of bioproducts viable.

3.2.2 Crops—Crop Genomics for a Healthy Canada

The health of Canadians and the economy has been significantly improved through investments in plant research. Canada has demonstrated the strength and capacity of its plant science research with the creation of canola, and the breeding of cereals and pulse crops that thrive in harsh environments. Canadian innovations in plant breeding and genetic discovery have delivered improved human and animal health and created wealth both domestically and internationally. Canada's agricultural producers and manufacturers are the third largest food products exporters in the world. Employing high-throughput genomic, proteomic, metabolomic and allied approaches, the research will foster an improved understanding of systems that govern plant growth, development and performance. Funded projects will cultivate a comprehensive understanding of the genetic and physiological factors that contribute to the underlying biological processes of Canadian crops using genomics tools.

Crop Genomics for a Healthy Canada will build on Canadian industrial and scientific capacity, keeping Canada at the forefront of discovery in this area, and creating new economic opportunities for Canadians.

Projects may address any issue that falls within the general scope of this topic, but applications in three specific areas are especially welcomed:

1. **Basic Plant Genomics:** research to expand our knowledge of plant genomics.
2. **Application of Plant Genomics:** investigations aimed at improving human and livestock health, and the security and safety of the food supply.
3. **Agriculture and Food Production Sustainability:** an exploration of how genomics can be applied to reduce the environmental footprint of the agricultural sector through reduced water, fertilizer and pesticide use, resulting in improved sustainability.

4 COMPETITION

Genome Canada will support large-scale research projects, of three (3) or four (4) years in duration, which focus on the application of genomics research in the areas of bioproducts and crops or GE³LS issues related to these strategic areas. Genome Canada is seeking proposals that are of a scale and scope that they cannot currently be funded at internationally competitive levels through other mechanisms. In order to maximize the effectiveness of Genome Canada to advance genomics research in Canada the sharing of resources and expertise between Centres is encouraged. Large-scale projects from one Centre may require the S&T platforms available in other Centres. Similarly, researchers from across Canada, and from other countries, may collaborate on large-scale projects in order to share technology, knowledge, GE³LS expertise and resources. Genome Canada strongly encourages and supports such arrangements, where appropriate.

5 APPLICATION AND EVALUATION PROCEDURES

5.1 General Instructions

Eligible applicants, including those from industry³, academic institutions, research institutes and government laboratories⁴, must submit their application through one of the six Genome Centres (see Appendix A). Each Centre will ensure that applications satisfy Genome Canada's evaluation criteria as defined in Appendix B.

5.2 Ethical, Environmental, Economic, Legal and Social Issues Related to Genomics Research (GE³LS)

All applicants must consider the GE³LS issues arising from their proposed research and develop a plan to address these issues. Genome Canada recognizes that GE³LS issues can **both limit and enhance** research, and that attention to **both types of issues** are worthy of focus by investigators. While applicants must describe how they intend to anticipate and address GE³LS issues that may raise obstacles for completing their research (such as economic impediments, ethical concerns, legal or regulatory barriers), applicants should also consider describing how their research may contribute to a better understanding of GE³LS issues and, in so doing, maximize the overall benefits from their research.

^{3&4} Scientists working in Industry³ or Federal laboratories⁴ may be co-applicants³ on an application but may not receive Genome Canada funds for activities to be carried out in Industry or in a Federal laboratory, with the exception of costs that are incurred based on a reasonable fee-for-service arrangement or contract.

The plan to address the GE³LS issues should incorporate strategic input from one or more individuals with expertise in the field(s) relevant to the GE³LS issues identified. The individuals providing this advice may be a co-applicant, collaborator, or member of an advisory committee and should be engaged early in the development phase of the project.

This GE³LS plan should:

- describe the objectives, milestones, expected outcomes, and the methods to be used to address the identified GE³LS issues; and
- integrate the GE³LS issues identified with the scientific components of the application.

5.3 Benefits for Canada

All applications must describe, with supporting evidence, the potential benefits for Canada and outcomes of the research proposed that will be realized within five (5) years from the end of the project. Potential benefits could include: a) job creation and economic growth in Canada, b) development of a product or service, c) an impact on society, quality of life, better health, and a cleaner environment, d) knowledge generation or translation, e) potential licenses and/or new start-ups or f) the creation of new policies. The applicants must include a plan, which explains how they will transfer, disseminate, use, and/or apply the potential deliverables from the research to realize the benefits within five (5) years from the end of the project. Where appropriate, for example when new products and/or services will be developed, a clear commercialization process, which includes IP management and ownership, technology transfer and benefit sharing, must be described. In preparing the benefits section, applicants should seek input from one or more individuals with expertise in the relevant field(s).

5.4 Requirement for Technology Services from Others

Each application for support of a large-scale project must include a detailed description of all outsourced technology services that will be required, including those from Genome Canada-supported S&T Platforms. The leaders of large-scale projects should work with their Genome Centre and Genome Canada's Technology Development Consultant to determine the technologies required for the proposed research and how best to satisfy these requirements. The request for services must be described in the research proposal and further detailed in the *Services from Others* sheet of the budget form. The application must include a letter from the service provider in support of the request, which includes a description of the service(s) to be provided, unit costs, number of units required, personnel requirements, data analysis requirements, and other relevant details. Genome Canada-supported S&T platforms have been established to provide technologies and expertise to the projects and avoid duplication of effort across the country. For information on the Genome Canada-supported S&T platforms refer to the Genome Canada website www.genomecanada.ca.

5.5 Handling of Data and Resources

5.5.1 Data and Resource Management

Each application must include clearly defined policies and plans for managing the data and resources generated by the project.

5.5.2 Data Analysis

Each application must include a clear plan for the analysis of the data. The plan must include:

i) a diagram showing the data flow for the information created by all project components; ii) a description of the data flow. The data flow has to reflect the workflow in the overall project; iii) a description of the computer analysis strategies for the data; iv) a plan for the long-term preservation (archiving) of the analysis results and, where appropriate, raw data; and v) a description of personnel requirements needed to realize the data analysis.

5.5.3 Data and Resource Sharing

The project must comply with Genome Canada's policy on Data Release and Resource Sharing (Appendix C). A strategy for sharing of data and resources within the project and with the wider scientific community (after initiating appropriate protection of any intellectual property) must be provided. Projects dealing with personal data must also provide their strategy for handling privacy and confidentiality issues.

5.6 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 immediately for further information on their process.

April 1, 2008	Announce the Request for Applications (RFAs) and release the Guidelines and Evaluation Criteria
May 2, 2008	Deadline for Letters of Intent (LOIs) to Genome Centre
May 20, 2008	Deadline for Letters of Intent (LOIs) to Genome Canada
Late May 2008	Review of LOIs for eligibility; and invitation for full applications
June 2008	Information sessions
August 29, 2008	Deadline for full applications to Genome Centre
October 3, 2008	Deadline for full applications to Genome Canada
November 21, 2008	Deadline for receipt of outstanding co-funding documentation
Early December 2008	Review of applications
January 2009	Decision by Board of Directors of Genome Canada
February 2009	Notification of Award
July 2009	Deadline for applicants to be in a position to receive funding

5.7 Letters of Intent

A letter of intent (LOI) stage will be used to evaluate the potential proposals for eligibility and responsiveness to this RFA. Each LOI must be submitted on the form available at www.genomecanada.ca.

Applicants must submit an LOI by **May 2, 2008** to their lead Genome Centre. The Genome Centre will work with the applicants to help them develop their final LOI for submission to Genome Canada. The Genome Centres will require the final LOI in advance of submission to Genome Canada. The deadline for submission of the final LOIs to Genome Canada is **May 20, 2008**. LOIs submitted in the absence of the support of one of the Genome Centres, (i.e., signature of the President & CEO) will NOT be accepted.

Genome Canada in collaboration with the Genome Centres will review the LOIs for eligibility and responsiveness to the RFA. LOIs that do not fulfill the programmatic criteria (outlined in Appendix B) will NOT be invited to submit an application.

The LOI process will also be used to identify potential synergies between applications from researchers across the country. If synergies are identified, the respective applicants will be contacted in a confidential manner to determine if there is any interest in engaging with the other researchers.

The LOI process will also provide guidance to Genome Canada in the selection of reviewers for the peer review process. Applicants will be invited to submit the names of potential reviewers not currently residing and working in Canada and with whom the applicants have no conflict.

5.8 Application for Funding of a Large-Scale Project

An application for funding must be submitted to the Genome Centre by August 29, 2008 for review prior to its submission to Genome Canada on or before **October 3, 2008**. The application must address the evaluation described in Appendix B and be presented on the *Applied Genomics Research in Bioproducts and Crops* application form and budget form, which will be available at www.genomecanada.ca.

5.9 Review Process

To ensure that the objectives of Genome Canada are met, each proposal will be assessed against the scientific, financial and management criteria as outlined in Appendix B. For any application to be considered for funding a threshold of excellence for each category must be exceeded. A limited amount of funding has been allocated to this competition. There are no funding quotas for each theme; **funding decisions will be based on excellence regardless of the theme.**

A multidisciplinary committee of international members with scientific, management and financial expertise will review the applications submitted for both themes. The committee will evaluate the scientific, management and financial aspects of each application taking into consideration the evaluation criteria presented in Appendix B. To assist the committee, written reports may be solicited from external peer reviewers for each proposal and forwarded to the committee members in advance of the meeting. The international review committee will

meet with and interview representatives from each project through a reverse site visit mechanism.

The review committee will offer recommendations and advice, including budget recommendations, to the Board of Directors of Genome Canada. The Board of Directors will make the final decision on which applications to fund, regardless of theme. Following the decision, applicants will be provided with a written evaluation of the strengths and weaknesses of their application and the decision of the Board.

Genome Canada may adjust the evaluation process where warranted by the complexity of the proposals or other relevant factors. Any adjustments will be rapidly communicated through Genome Canada's website and through the Genome Centres.

6 PROJECT MANAGEMENT AND OVERSIGHT

6.1 Project Manager

All Genome Canada funded projects must have a dedicated project manager within the project. The project manager should be responsible for coordinating administrative and reporting requirements and, supporting the scientific enterprise of the project.

6.2 Science Advisory Boards

All Genome Canada funded projects must have a Science Advisory Board (SAB) to provide advice and guidance to the research team to help ensure that the project achieves its stated objectives and milestones. The membership of the SAB must be completely independent from the project with no real or perceived conflicts and be composed of experts who will work with the project to maximize the successful outcome of the project.

While projects are not required to submit details with respect to their SAB implementation plan and membership at the time of application; these must be approved by Genome Canada before funds can flow to the project.

Genome Canada is currently developing guidelines related to the membership, mandate and terms of reference for Science Advisory Boards of Genome Canada funded projects. These will be made available on the Genome Canada website.

7 INTERIM REVIEW

Genome Canada will undertake an interim review of each approved project, within approximately two years from the Notice of Award. As one of the methods used in the oversight and accountability of Genome Canada funded projects, the interim review will evaluate i) the progress of the research, including GE³LS; ii) the research team's ability to achieve the approved objectives; iii) the changes in research direction (made or proposed); iv) the progress towards ensuring the benefits for Canada will be realized within five years from the end of the project; and v) the financial and management aspects of the project, including an assessment of financial expenditures in relation to achieved outcomes and the status of the co-funding. The results of interim review will be used to determine whether funding should be continued, reduced or cancelled.

Each project leader will submit a progress report through their Genome Centre. The progress report will be reviewed by an International Science Review Committee (ISRC), who will provide a detailed evaluation of a project's progress and provide feedback and advice to the Project Leader(s), the Genome Centre. Generally, as part of the interim review, there will be a face-to-face meeting between the ISRC and the Project's representatives. The review will take into consideration the timeframe during which the project research has been ongoing. The review will also be used to provide advice regarding alternative approaches and avenues to strengthen the project. Requests for additional funds will not be considered. The results of interim review will be submitted to the Board of Directors of Genome Canada for consideration. The Board will make the final decision on whether or not to continue funding a project.

8 FUNDING

Genome Canada will fund up to 50% of approved eligible costs for new or incremental research activities that are an integral part of the Genome Canada approved project. It is the responsibility of the Genome Centre, working with the applicants, to secure the remaining 50% of the funding from other sources. Funding for this competition is subject to Bill C-50, the *Budget Implementation Act, 2008*, becoming law.

8.1 Eligible Costs

Eligible costs are defined as reasonable and incremental costs for items that directly support the objectives of the Genome Canada approved project. Budgets must **NOT** include items for which funding has already been approved from other sources, unless the request for funding of those items was specifically made to support activities in the Genome Canada project and meets all other eligibility criteria. Genome Canada funded expenses must be incurred after the Notice of Award (NOA) to be considered as eligible costs. However, there may be cases where expenses covered by co-funding that are incurred up to six (6) months prior to the NOA could be considered as eligible costs.

Eligible costs may include the following:

- i. Salaries:
 - salaries and benefits for the team members (note that salaries of researchers or senior management who are currently funded by their respective organizations are **not** considered eligible costs). Genome Canada will accept actual benefit rates as charged by the host institution;
 - the actual cost of release time from teaching and clinical duties, if supported by a letter from the host institution;
- ii. operating costs;
- iii. costs related to the general maintenance of research infrastructure, to be used for carrying out the proposed project;
- iv. support for research into GE³LS aspects of the project;
- v. costs related to the development of the plan to realize benefits for Canada, including patent filing costs;
- vi. costs for the communications and public outreach activities related to the project;
- vii. research infrastructure within Canada. As defined in the *Funding Agreement between Genome Canada and the Government of Canada*, research infrastructure

means equipment, specimens, scientific collections, computer hardware or software, information databases, communications linkages and intangible property used or to be used primarily for carrying on the project, including housing and installations essential for the use and servicing of the items listed above. This includes reasonable rental and renovation costs for existing buildings and facilities, essential for the use of those items listed above. The cost of new buildings or facilities, the opportunity cost of using existing infrastructure and the cost of major renovation are **not** eligible costs;

- viii. reasonable and low administrative costs (for example, travel for project team members, costs associated with a project's SAB, publication costs, website maintenance, office expenses, costs associated with preparation for interim review and of final reports). Administrative costs must not exceed five percent (5%) of the non-administrative costs of the budget. Note: costs associated with patenting are allowed under (v) above and should **not** be included as part of the administrative costs; and
- ix. inflation rate costs:
 - inflation for salaries, not to exceed 2.2% percent of total salary and benefits, for salary expenditures in years 2 to 4 of the project;
 - note that inflation cannot be applied to consumables, equipment, general & administrative or services from S&T platforms.

Payments to foreign persons, for example investigators' salaries, are not considered eligible costs for Genome Canada, however, costs that are incurred based on a reasonable fee-for-service arrangement or contract are considered eligible.

8.2 Co-funding

Genome Canada requires that at least 50% of the requested funding for eligible costs must be obtained through co-funding from other sources. At the time of application a well-developed and feasible co-funding plan must be provided; however, in order to release funds the project must demonstrate a firm commitment for at least 75% of the co-funding for eligible costs of the project and a well-developed and feasible plan for securing the remaining 25% of co-funding. Genome Canada reserves the right to withdraw its funding for any approved project if there is a substantial change in the co-funding status of the project.

8.2.1 Eligible Co-funding

- i. Co-funding must be applied for on or after the date the results of the Strategic Research themes were announced, i.e., October 1, 2007, and must be for eligible costs specifically requested in the Genome Canada budget (see Eligible Costs, Section 8.1) in order to be considered as an eligible co-funding source for the purpose of this competition.
- ii. Genome Canada considers any of the following possible co-funding sources, which may be Canadian or foreign, as acceptable:
 - Institutional funds, trust funds, or foundations
 - Departments and agencies of the federal government (e.g., Agriculture and Agri-Food Canada, Environment Canada, Canada Foundation for Innovation).

There are exceptions. The following agencies are **NOT** considered as eligible co-funding sources: Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council, Social Sciences and Humanities Research Council, and tri-agency programs (e.g., the Networks of Centres of Excellence, Centers of Excellence for Commercialization and Research, and the Canada Research Chairs)

- Departments and agencies of provincial and municipal governments
 - Firms and corporations
 - Voluntary organizations
 - Individuals
 - Venture capital or other investment funds.
- iii. Cash contributions as co-funding are preferred. However, in-kind contributions, defined as non-cash eligible budget items, which can be given a cash value, may be considered as co-funding if:
- the value can be reasonably determined and supported by documentation from the supplier; and
 - the expenditure represents an item that would otherwise have to be acquired with cash; however, this excludes the cost of pre-existing facilities or equipment (i.e., budgets cannot include the opportunity cost of space or equipment);
- iv. The value of previously existing IP transferred to a project is NOT considered eligible co-funding unless it is a contribution by a supplier of IP (e.g., software license that would otherwise have to be acquired from a third party supplier). Such items must be supported by appropriate documentation from the supplier's head office.
- v. Suppliers' discounts are not considered eligible co-funding.

8.2.2 Documentation Required to Support Co-funding

The full application must include complete documentation to support the proposed co-funding. This may be in the form of a letter of commitment or an agreement defining the terms and conditions. In addition, the project must provide a description of how the co-funding will directly support the objectives of the Genome Canada project. In all cases, the co-funder must explicitly acknowledge the use of the funds to co-fund the Genome Canada project.

The following provides specific examples of documentation required, depending upon the co-funding source, or type:

- From a funding agency, a copy of the full application, project summary, detailed budget and notice of award (if applicable). Note that documentation must clearly demonstrate that funding is being used for eligible costs included in the budget of the Genome Canada approved project.

- Other organizations, including industry, charities, and philanthropic organizations:
 - Documentation and supporting information that clearly demonstrates the organization's level and terms of the commitment to the project. Appropriate documentation could include but is not limited to a Board Resolution, and/or, a letter from the CEO, legal counsel or Corporate Secretary.
 - Appropriate and reasonable documentation supporting the financial viability and the ability to deliver on the co-funding. Depending on the organization involved and the level of funding being committed, documentation could include:
 - a full set of the organization's most recent audited financial statements, including the Auditors Report, a Balance Sheet, Income Statement, Statement of Cash Flows and Notes to the Financial Statements;
 - in the case where the audited statements are more than three months old a full set of the organization's financial statements (prepared within three months prior to the application) including a Balance Sheet, Income Statement, Statement of Cash Flows and Notes to the Financial Statements.
 - any other information or documentation (e.g., press releases announcing significant new financing, cash flow projections etc.) that provides support to the organization's financial viability and ability to fulfill its co-funding commitments.

- In-kind contributions should include a clear rationale and calculation of how the value was determined (including documentation to support all assumptions, price lists, quotes from suppliers, letters supporting same, etc.). All in-kind contributions must be auditable by outside experts and clear explanations are required if there are any discrepancies between the value outlined in the co-funding document and the budget.

9 ADMINISTRATION

9.1 Project Readiness

All applicants must demonstrate that they will be in a position to receive Genome Canada funding within six (6) months from notification of award (see Conditions for Release of Genome Canada Funds, Section 9.2). Genome Canada reserves the right to withdraw its funding for any approved project that has not met the conditions for release of funds within six months from notification of award.

9.2 Conditions for Release of Genome Canada Funds

The following are the minimum requirements to allow for the initial disbursement of Genome Canada's contributions:

- i. Signed agreement between Genome Canada and the Genome Centre.
- ii. Signed agreements (or MOUs) between the Genome Centre, the lead organization, the applicants and the major co-funding partners that establishes the resolution of major areas, such as, contributions, IP ownership and management, data and resource sharing and release, a commercialization process, project

management, the role of the SAB, funding term, termination policy, financial policies, quarterly reporting of expenses and co-funding status etc. The agreements or MOUs must be in compliance with the agreement between Genome Canada and the Genome Centre. Although Genome Canada funds will flow to the lead organization once an agreement has been signed and other conditions are met, in order for Genome Canada to release funds for other organizations, within which research will be conducted, agreements with those organizations must be in place.

- iii. A letter signed by the CEO and legal counsel of the Genome Centre confirming to Genome Canada that: all agreements have been signed and are in compliance with the agreement between Genome Canada and the Genome Centre; all other conditions for release of funds have been met; and funds will flow to the project upon receipt of funds from Genome Canada.
- iv. Budget, and GANTT chart (showing the project milestones and expected outcomes), as approved by the Board of Directors of Genome Canada.
- v. Appropriate certification for projects involving human subjects, human stem cells, animals, biohazards, radioactive materials or possible effects on the environment. Certification must be obtained specifically for the research approved for funding by Genome Canada. In order to release funds to an organization Genome Canada will accept a letter from the appropriate officials at the organization confirming that:
 - i) the organization will ensure that any research carried out with funds from Genome Canada will respect all of the certification requirements for the research;
 - ii) the institution will not flow funds to an investigator until all certifications for the research to be undertaken are satisfied; and
 - iii) the institution will provide Genome Canada with copies of all certifications obtained during the term of the project.
- vi. SAB membership and implementation plan that complies with Genome Canada's guidelines.
- vii. A clearly defined policy and plan for data release, sharing of resources created by the project and publication of results. The project must comply with Genome Canada's policy on Data Release and Resource Sharing (Appendix C) and must ensure that their policy is maintained and updated to stay in line with the accepted international standards, as they evolve.
- viii. Secured co-funding (received or firmly committed) amounting to a minimum of 75% of the co-funding for eligible costs and a well-developed and feasible plan for securing the remaining 25% of co-funding.
- ix. Meet other conditions that may be set by the Board of Directors of Genome Canada.

9.3 Management of Funding

- i. The agreement between Genome Canada and the Genome Centre will reference financial commitments from other persons, and specify cash flow statements.
- ii. As the needs and circumstances of each Centre, the researchers and partner organizations may differ; the contracts between these partners will be negotiated individually and need not be identical, but should apply the same general

underlying principles as defined in the agreement between Genome Canada and the Genome Centres. Genome Canada's share of the funding for approved projects will flow from Genome Canada to the Centres. The Genome Centres will manage (e.g., disburse, monitor and report on) the funds for the project.

- iii. If co-funding is secured by way of a binding agreement, and funds can be shown to be available to meet the co-funder's obligations, Genome Canada's contributions can be adjusted to accommodate the timing of the expected receipt of funds from co-funding partners. However, where co-funding sources are not secured, Genome Canada's contribution will be based on 50% of the approved quarterly budget up to the maximum amount approved by the Board.
- iv. Genome Canada will provide funding up to the approved quarterly contribution, a quarter "in advance", subject to receipt of quarterly reports of expenditures (from both Genome Canada and co-funding sources). Subsequent quarterly advances may be adjusted to account for any unused funding.
- v. The financial status of co-funding must be reported on a quarterly basis.

9.4 Accountability and Reporting

Funded projects will agree to submit to the Genome Centre on a regular basis, information and data as prescribed by the Centre in terms of timing, format and content, which will allow for the on-going assessment and monitoring of the performance of projects. It is the responsibility of the investigator leading the project to participate in this process.

9.5 Final Reports

Within three (3) months of the completion of the projects, each project will be required to submit to its Genome Centre a final report that includes a description of the accomplishments of the project relative to the approved objectives.

Should any additional requirements or restrictions be placed on new funds received for this competition, Genome Canada will be obliged to ensure that the contracts between Genome Canada and the Genome Centres reflect these conditions and that the guidelines for this competition are modified, where necessary, to allow compliance with them.

Should Genome Canada's policies be revised either during the application process or thereafter, it is the obligation of the project team to ensure that they are in compliance with the revised policies.

APPENDIX A - CONTACTS

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APPENDIX B - EVALUATION CRITERIA

Proposals, which are submitted to Genome Canada, are evaluated through a rigorous independent peer review process to assess their scientific merit and to ensure that sound financial and management practices are implemented. Excellence and innovation at the very highest of international standards must be demonstrated for funding to be awarded.

Evaluation of applications will be a two step process: Letters of intent will be assessed for programmatic eligibility. LOIs that do not fulfill the programmatic criteria will NOT be invited to submit a full application. Full applications must not only satisfy the programmatic criteria but also the scientific, management and financial criteria. *N.B:* The descriptors which follow the criteria below are not all-inclusive.

A Programmatic Criteria

Projects submitted to this competition must:

- i. Have a genomics or proteomics focus or study the GE³LS issues associated with the strategic areas
- ii. Be of a scale and scope that the research could not currently be funded at internationally competitive levels through other mechanisms
- iii. Address one of the targeted areas as outlined under the research scope (section 3.2).

B Scientific Criteria

1. *Quality of the Research*

- i. The importance and originality of the proposed investigation(s) and expected results
- ii. The appropriateness of the proposed methods and data analyses
- iii. The feasibility of the proposed methodology and likelihood of achieving the stated milestones and objectives within the proposed timeframe
- iv. The demonstration that the project is coordinated, integrated and inclusive
- v. The quality of the scientific environment in which the research will be undertaken
- vi. The demonstration of how the proposed research compares to research that is being conducted by other groups regionally, nationally and internationally
- vii. The demonstration of how the proposed research fits into the international genomics or proteomics contexts
- viii. The international relevance and impact of anticipated results and the potential for Canada to further develop its capacity for innovation and as a world leader in the area
- ix. The demonstration that the research to be carried out builds on or optimizes existing Canadian strengths and expertise in genomics or proteomics and/or fits within a unique Canadian niche

2. *Quality of the Research Team*

- i. The appropriateness of the applicants' expertise to conduct the proposed research

- ii. The quality of the applicants' recent productivity, track records and their contributions to the field of genomics or proteomics

3. *Handling of Data and Resources*

The quality of the plans for:

- i. Data and resource management
- ii. Data analysis
- iii. Data and resource sharing

4. *Training of Highly Qualified Personnel (HQP)*

- i. The quality and appropriateness of the proposed training program and training milieu
- ii. The demonstration that plans are in place to ensure that an adequate number of HQP are available to meet the needs of the proposed research

5. *Collaborations and Partnerships*

- i. The quality and appropriateness of proposed or existing collaborations
- ii. The effectiveness of the strategy for forming partnerships and collaborations with others

6. *Ethical, Environmental, Economic, Legal and Social Issues - GE³LS*

- i. The depth of analysis of relevant GE³LS issues
- ii. The appropriateness of the plan to address GE³LS issues
- iii. The relevance of the issues identified to the research project
- iv. The level of integration of the GE³LS plan with the overall research project
- v. The inclusion of the appropriate GE³LS experts in the proposed research
- vi. The level of interaction with other GE³LS projects and programs

7. *Benefits for Canada*

- i. The potential impact of the results on society, quality of life, health and the environment
- ii. The plan for knowledge generation and translation and the creation of new policies
- iii. The demonstration of how anticipated results will contribute to job creation, economic growth, development of a product, service or licences and the creation of start-ups
- iv. The quality of the plan to transfer, disseminate, use, and/or apply the potential deliverables to realize the benefits within five (5) years
- v. The effectiveness of the proposed plans for commercialization, technology transfer and the handling of intellectual property (where applicable) which addresses:
 - i. Relevant management versus ownership issues
 - ii. A plan to share benefits with others
 - iii. The expected outputs in terms patents to be filed
 - iv. The costs of patent filing and protection
- vi. The potential for use or commercialization (where appropriate) of the anticipated results and the extent to which the proposed research will further the development of new methods, perspectives and/or technology.

C Management Criteria

1. The quality of the management plan, and the administrative/ organizational structure:
 - i. The composition of the proposed management team, recruitment plan, role of key personnel and committees, frequency of meetings, etc.
 - ii. The appropriateness of management team member accountabilities
 - iii. The mechanism of communicating within the project, with the Genome Centre(s) and collaborators/partners and the strategy to coordinate activities
 - iv. The method of making the research results accessible to the scientific community
 - v. The ability to manage a multi-disciplinary, multi-institutional, national and/or international team
2. The mechanism for making critical decisions regarding the overall research direction:
 - i. The manner in which go/no-go decisions will be made
 - ii. The mechanism for evaluating research progress
 - iii. The process for making strategic decisions when a consensus cannot be reached
 - iv. The discussion of key challenges and plans to address them
3. The use of S&T platform(s) and other technologies:
 - i. The appropriateness of the service provider and/or technology chosen
 - ii. The effectiveness of proposed arrangements with the service provider and/or technology chosen
4. The effectiveness of the proposed plans to deploy human resources, equipment and infrastructure throughout the duration of the project, including the initial ramp-up period
5. The plan to secure appropriate certification for research involving human subjects, stem cells, animals, biohazards, radioactive materials or for research which may have an impact on the environment
6. The effectiveness of the proposed communications and knowledge dissemination strategy, which may include:
 - i. An overview of media relations, public outreach and education activities
 - ii. Plans to participate in public forums and presentations
 - iii. Promotional activities (e.g., advertising, website creation)

D Financial Criteria

1. ***Budget/Control Processes***
 - i. The eligibility of budgeted costs as defined in section 8.1
 - ii. The alignment of budgeted costs with the proposed research
 - iii. The clarity of links between budget items and sources of funding
 - iv. The potential overlap with other projects
 - v. Evidence of a relationship between budgeted costs and potential benefits of the proposed research

- vi. The reasonableness of the budgeted costs and justifications
- vii. The appropriateness of principal financial assumptions
- viii. The appropriateness of planned financial and budgetary control processes including mechanisms for authorizing purchases, making payments and adjusting the budget
- ix. The realism of estimates for space requirements, renovation plans (where applicable) and time period associated with the project ramp-up (e.g., recruiting, purchasing, installing new equipment, etc.)
- x. Evidence that potential difficulties encountered throughout the course of the project have been considered in appropriate depth and contingency plans have been established

2. Co-Funding

- i. The feasibility of the proposed co-funding plan, i.e., likelihood of being able to secure at least 75% of the co-funding for eligible costs at time of the release of funds.
- ii. The compliance with eligible co-funding guidelines in section 8.2
- iii. The appropriateness of supporting documentation (e.g., letters of commitment, signed agreements from co-funding sources, quotes from suppliers, grant applications to other funding agencies, confirmation of grants received, etc.)
- iv. The demonstration of a relationship between the proposed co-funding and the objectives of the project

APPENDIX C - GENOME CANADA'S DATA RELEASE & RESOURCE SHARING POLICY (Dated July 1, 2005)

Policy Principle

Genome Canada is committed to the principle of rapid data release and sharing of unique resources to the scientific community. This principle is similar to policies adopted by other organizations such as the National Human Genome Research Institute (NHGRI), the International HapMap Project, and the Gordon and Betty Moore Foundation in the USA, and The Wellcome Trust in the UK.

Genome Canada-funded projects must follow the data release and resource sharing principles of a "community resource project", defined as "a research project specifically devised and implemented to create a set of data, reagents or other material whose primary utility will be as a resource for the broad scientific community."¹

The data release and resource sharing policy is intended to accelerate the work of all users towards the timely development of products that will benefit humankind by providing users with access to the output of Genome Canada funded projects.

Publication is a primary vehicle for data release, and as such, Genome Canada expects all funded researchers to publish their findings in a timely manner.

This policy was established by Genome Canada's Science and Industry Advisory Committee and approved by Genome Canada's Board of Directors on June 17, 2005 for application to all projects funded by Genome Canada after July 1, 2005.²

Data Release and Resource Sharing Methods

- Publishing
- Patents
- Researcher's publicly and freely accessible sources (e.g. website)
- Data Archives (e.g. GenBank, EMBL, etc.)
- Open Source Archives (sourceforge.net)
- Depositing into Strain Collections (e.g. ATCC)

When making data available, researchers cannot place limits on questions posed or methods used, nor require co-authorship as a condition for receiving data.

Timeframe for Data Release

Data sharing should occur in a timely fashion. Genome Canada expects data to be released and shared no later than the acceptance for publication of the main findings from any datasets generated by a project. For large datasets that are collected over several discrete time periods

¹ The definition of "community resource project" was developed at a meeting held on January 14-15, 2003 in Fort Lauderdale, Florida. The report on the conclusions of the meeting, "Sharing Data from Large-scale Biological Research Projects: A System of Tripartite Responsibility", can be found at http://www.wellcome.ac.uk/doc_wtd003208.html. The amended release policy of the NHGRI adopts this definition for the Project (www.genome.gov/10506537).

or phases, it is reasonable to expect that the data be released in phases as they become available or as main findings from a research phase are published. However, at the conclusion of a project, all data must be released without restriction.

Resource Sharing

Projects funded by Genome Canada must also address sharing of resources generated by projects such as unique biological specimens and computer programs designed to analyze datasets. Biological reagents such as unique strains should be deposited into repositories such as ATCC and computer programs designed to analyze large datasets should be made available to others through the use of license agreements that adhere to “open source” principles (see for example, <http://www.opensource.org/>).

Proprietary Data

Issues related to proprietary data can also arise when others provide co-funding with corresponding constraints on public disclosure. Genome Canada recognizes the need to protect patentable and other proprietary data; however data must be released no later than the date that patents (including provisional patents) have been filed. Permission to delay release of data beyond this date must be obtained in writing by Genome Canada, which will use independent advisors to evaluate the request when appropriate.

In addition, non-disclosure agreements between sponsors and researchers should not be unduly restrictive and must allow publications within a defined and reasonable period of time.

Privacy Concerns

Protecting the rights and privacy of human subjects should be the first priority of a researcher. Investigators, Institutional Review Boards, and research institutions have an obligation to protect participants’ rights and confidentiality. However, data sharing is possible without compromising these efforts because identifiers can be removed from data. In addition, data sharing agreements can be used to restrict the transfer of data to others and to require that data be used only for research purposes.

International Data Repositories

The following table provides examples of databases where various data types or unique resources produced by Genome Canada-funded projects may be deposited. Note that the following is not an exhaustive list.

Data type/Resource	Database
DNA, RNA, Protein, EST, STS, HTG Sequences	DDBJ/EMBL/GenBank
Gene expression data	Gene Expression Omnibus (GEO) SAGEmap
SNPs	dbSNP
Proteomics ¹	Not yet established (Researcher’s website)

² Prior to funding all new projects after July 1, 2005, Genome Canada will review the investigator's proposed data release plan to verify that it conforms to Genome Canada policy and funds will not flow until an acceptable plan has been approved and incorporated into the terms of award. Genome Canada will monitor adherence to this policy by funded researchers through a variety of mechanisms including interim review.

Protein structures	PDB
Interactions	IntAct/BIND
Software code	SourceForge.net/ http://gchelpdesk.ualberta.ca/
Biological strains	ATCC
Metabolomics	Not yet established (Researcher's website)
Publications	PubMed Central

⁵ Standards in proteomics are fluid but authors should adopt best practices such as the ontology based mzXML file format schema (<http://tools.proteomecenter.org>). When standardized databases emerge, researchers must deposit data into these databases.

Open Access Publications

Final manuscripts are an important record of the research funded by Genome Canada and open access to these publications is paramount. In order to foster open access to journal articles, Genome Canada expects funded researchers to deposit a digital copy of their published manuscript and any appropriate supplementary information into PubMed Central (PMC), NIH's digital repository for biomedical research. Six months after the study's publication (or sooner if the publisher agrees) the manuscript will be made freely available to the public through PMC. If the publisher requests, the author's final version of the publication will be replaced in the PMC archive by the final publisher's copy with an appropriate link to the publisher's electronic database.

References

Data Access Policy for the International HapMap Project (July 30, 2003)

<http://www.hapmap.org/cgi-perl/registration>.

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http://www.wellcome.ac.uk/doc_wtd003208.html.

Data Sharing Policy and Implementation Guidance. Gordon and Betty Moore Foundation. (January 2005)

http://www.moore.org/docs/GBMF_Data_Sharing_Policy_Impl_Guide_v4.pdf.

NIH Data Sharing Policy. (March 2003)

http://grants2.nih.gov/grants/policy/data_sharing.

Enhanced Public Access to NIH Research Information. (September 2004)

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-064.html>

International Database References

Data type	Database	Host institution	URL for submission
DNA, RNA and Protein Sequences	DDBJ/EMBL/GenBank ¹	NCBI	http://www.ncbi.nlm.nih.gov/Genbank/submit.html
EST sequences	DDBJ/EMBL/GenBank	NCBI	http://www.ncbi.nlm.nih.gov/dbEST/how_to_submit.html
STS sequences	DDBJ/EMBL/GenBank	NCBI	http://www.ncbi.nlm.nih.gov/dbSTS/how_to_submit.html
HTG sequences	DDBJ/EMBL/GenBank	NCBI	http://www.ncbi.nlm.nih.gov/projects/HTGS/subinfo.html
Gene expression data	GEO	NCBI	http://www.ncbi.nlm.nih.gov/geo/
SNPs	DbSNP	NCBI	http://www.ncbi.nlm.nih.gov/SNP/
Interactions	IntAct/BIND	NCBI, EBI / BIND	http://www.ebi.ac.uk/intact/ / http://www.bind.ca
Proteomics	Various tools	ISB	http://tools.proteomecenter.org
Software code	Sourceforge	SourceForge.Net	http://sourceforge.net
Publications	PubMed Central	NCBI	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=Pmc
Biological strains	ATCC	ATCC	http://www.atcc.org/
Human gene nomenclature	HGNC	HUGO	http://www.gene.ucl.ac.uk/nomenclature
Mouse gene nomenclature	MGI	JAX	http://www.informatics.jax.org/mgihome/nomen/index.shtml

¹ DDBJ, EMBL, and GenBank are equivalent databases, all part of the International Nucleotide Sequence Databases Collaboration, and submitting to any of these is the same as submitting to GenBank. It is most convenient for Canadian scientists to submit to GenBank, but scientists are free to submit to any of the three databases