



GENOMICS IN SOCIETY

Expert Panel

Integrated GE³LS Research Review Report
Appendices

September
2018



GenomeCanada

GLOBAL CHALLENGES + GENOMIC SOLUTIONS



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GLOBAL CHALLENGES + GENOMIC SOLUTIONS

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Appendix one: Glossary

ABC	Applied Genomics Research in Bioproducts or Crops Competition (2008) ¹
CIHR	Canadian Institutes of Health Research ²
GC	Genome Canada ³
GiS	Genomics in Society
GE³LS	Genomics and its Ethical, Environmental, Economic, Legal and Social aspects GE ³ LS research is defined more broadly than the GE ³ LS acronym as genomics-related research endeavors and related activities undertaken from the perspective of the social sciences and humanities, and not limited to the disciplines that make up the acronym.
GE³LS Lead	GE ³ LS Research Leader The GE ³ LS Lead is responsible for the execution and oversight of the integrated GE ³ LS research within a large-scale genomics project. Typically, this researcher works in collaboration with the Project Leader to integrate the genomics and GE ³ LS research components.
LSARP	Large-Scale Applied Research Project
NSERC	Natural Sciences and Engineering Research Council ⁴
Project Leader	Overall Research Project Leader The Project Leader is responsible for the intellectual direction of the project. In applications where the responsibility for the intellectual direction of the project is shared relatively equally between two or more individuals, there may be more than one Project Leader.
RFA	Request for Applications

¹ <https://www.genomecanada.ca/en/programs/large-scale-science/past-competitions/large-scale-research-project-competitions/competition>

² <http://www.cihr-irsc.gc.ca/>

³ <https://www.genomecanada.ca/>

⁴ www.nserc-crsng.gc.ca/

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Research Oversight Committee

The mandate of the Research Oversight Committee is to report to the Genome Centre on the progress being made by the Project and make recommendations regarding continued funding as well as to provide advice and guidance to the research team to help ensure that the Project achieves its stated objectives and milestones. Typically, each project has Research Oversight Committee members with genomics and/or GE³LS expertise. Implemented in the 2012 LSARP competition.

Scientific Advisory Board

Predecessor to the Research Oversight Committee, in place prior to the 2012 LSARP competition.

SIAC

Science and Industry Advisory Committee⁵

The Science and Industry Advisory Committee (SIAC) is a permanent committee of Genome Canada's Board of Directors. The Committee is tasked with providing advice and recommendations to the Board on:

- Emerging scientific research opportunities and challenges and potential areas for investment in genomics and Genomics in Society, including GE³LS research in Canada;
- International trends, developments and potential national and international collaborations;
- Areas of strategic social and economic importance to Canada; and
- Application of the outcomes of genomics research including commercialization, knowledge.

SSHRC

Social Sciences and Humanities Research Council⁶

User

Those able to use the information generated through research to make informed decisions on relevant issues, policies, programs and product development. Examples of user organizations could include industry and industry associations, producer organizations, government departments and regulatory agencies.

⁵ <https://www.genomecanada.ca/en/about/governance/science-and-industry-advisory-committee>

⁶ www.sshrc-crsh.gc.ca/

Appendix two: Review Methodology

Focus of the Review

The review has three core activities and three key deliverables, as summarized in the following table.

Table 1: Core Activities and Expected Key Deliverables

Core Activities	Key Deliverables
<p>Review how integrated GE³LS research has been undertaken across Canada.</p> <p>Key question: How is integrated GE³LS research defined and actioned by key stakeholders?</p>	<p>A definitional framework for integrated GE³LS research in Canada.</p>
<p>Identify examples of successes, best practices and impediments of integrated GE³LS research in large-scale research projects.</p> <p>Key questions:</p> <ul style="list-style-type: none"> • What does success look like for integrated GE³LS research, within projects and/or within competitions and in the aggregate at the national level? • What are the key indicators of best practice in developing integrated GE³LS research? • How do Genome Canada’s processes, guidelines and criteria affect selecting for success in integrated GE³LS research? 	<p>Identification of: key indicators of success; factors that contribute to the successful integration of GE³LS research; factors that may inhibit success; and strategies for removing these barriers.</p>
<p>Review outcomes from a sample of integrated GE³LS research to assess how effective they are in supporting the uptake of genomic-based applications.</p> <p>Key question: To what extent has integrated GE³LS research been effective in translating research results into practice and policy and in supporting the uptake of genomic-based applications?</p>	<p>An assessment of the effectiveness of integrated GE³LS research in contributing to the overall uptake of genomic-based applications.</p>

The review primarily focused on integrated GE³LS research funded from the Applied Genomics Research in Bioproducts or Crops Competition (2008) to the 2015 Large-Scale Applied Research Project Competition – Natural Resources and the Environment. There was one exception to this timeframe, as the peer reviewer survey was sent to members of the Full Application Review Committees for the four most recent LSARP competitions (2012, 2014, 2015, 2017).

Methodologies and Data Sources

The Review collected primarily qualitative evidence, although some quantitative data were also obtained, particularly through the survey.

The Expert Panel met several times by teleconference to review materials, assess the evidence, develop recommendations and finalize the report. The recommendations were developed in an iterative manner: using background information, including a review of prior performance evaluations as well as competition processes (such as RFAs and evaluation criteria across competitions) and the Expert Panel's expertise, and data collected from the peer reviewer survey and interviews, preliminary recommendations were drafted a few months after the Expert Panel was convened. Once all the data were collected and analyzed over the next several months, the Recommendations were refined into their final version, with the unanimous support from the members of the Expert Panel.

Case Studies and Supporting Evidence

Eight case studies⁷ were carried out, which focused on a range of funded LSARP projects and their integrated GE³LS research component. Some of the selected case studies each included both an “original” project as well as a “follow-on” project (based off the research done in the original, funded in a later LSARP competition). In two instances, both “original” and “follow-on” projects were treated together, as a single case study; in one case only the “follow-on” project was analyzed; and in two cases only the “original” projects were analyzed (their counterparts having been funded in the most recent LSARP competition, with little research undertaken to date).

The case studies included document reviews and interviews, as follows:

1. Document reviews of the project applications and reports (final reports and/or interim reports, if projects were still in progress).

Elements that were examined include: the overall project aim, the GE³LS research project aim, the GE³LS research activities, the GE³LS findings/ outputs/outcomes, the integration of the GE³LS research in the overall project, identified GE³LS research challenges, expected benefits to Canada and the role of the users.

2. Semi-structured interviews conducted separately with the nine Project Leaders/ Co-Leaders, eight GE³LS Leads/Co-Leads,⁸ four members of Research Oversight Committees and six users of the research, for a total of 26 separate individuals

⁷ One selected project was not developed into a case study because the GE³LS Lead was not available for an interview. Evidence from the project (including findings from interviews with the Project Leader and a user of the research) was used, as appropriate, in the overall analysis.

⁸ Due to availability for interviews and/or researcher succession on a project, a Project Leader or Project Co-Leader and GE³LS Lead or GE³LS Co-Lead, may have been interviewed for a case study. However, both types will be referred to as Project Leaders and GE³LS Leads unless specifically differentiated from the original Project Leaders and GE³LS Leads.

APPENDIX TWO

involved in the selected projects. Interview questions were open-ended, and the interviews primarily collected qualitative data.

Interviews focused on the approach taken to develop the integrated GE³LS research; factors affecting integration; communication and collaboration between genomics and GE³LS researchers; guidance provided by the Genome Centre(s) and Research Oversight Committees; outputs or outcomes of the GE³LS research that affected uptake of the genomics research; advantages and disadvantages of integrated GE³LS research; and, whether Genome Canada should continue to support the integrated GE³LS research model.

The following tables outline the case study characteristics.

Table 2: Summary of Case Study Interviews

	Case Study #1	Case Study #2	Case Study #3	Case Study #4	Case Study #5	Case Study #6	Case Study #7	Case Study #8
Project Leader								
GE ³ LS Lead								
Research Oversight Committee Member								
User								
Total # of Interviews (Not including the 2 interviews for the project not developed into a case study)	3	2	3	2	3	3	4 ⁹	4

Table 3: Summary of Case Studies by Competition

Competition in Applied Genomics Research in Bioproducts or Crops (2008)	2010 Large-Scale Applied Research Project Competition – Multi-Sector	2010 Large-Scale Applied Research Project Competition – Forestry and Environment	2012 Large-Scale Applied Research Project Competition – Genomics and Personalized Health	2014 Large-Scale Applied Research Project Competition – Genomics and Feeding the Future	2015 Large-Scale Applied Research Project Competition – Natural Resources and the Environment
2 case studies	1 case study	1 case study	1 case study	1 case study	2 case studies

⁹ Project Leader was also the user.

Table 4: Summary of Case Studies by Lead Genome Centres

Genome British Columbia ¹⁰	Genome Alberta ¹¹	Genome Prairie ¹²	Ontario Genomics ¹³	Genome Quebec ¹⁴	Genome Atlantic ¹⁵
2 case studies	2 case studies (1 led by both Genome Alberta and Genome Atlantic)	1 case study	2 case studies	1 case study	1 case study (led by both Genome Alberta and Genome Atlantic)

Table 5: Summary of Case Studies by Primary Sector

Agriculture	Energy	Health	Forestry
4 case studies	1 case study	2 case studies	1 case study

Genomics Enterprise Interviews

Semi-structured interviews were conducted with twelve stakeholders of the Genomics Enterprise, which included interviews with 10 Genome Centre staff (with one to two staff participating in each interview), an interview with one Genome Canada staff and an interview with one external consultant with considerable experience working with the Genomics Enterprise and the LSARPs. Interview questions were open-ended, and the interviews primarily collected qualitative data.

Table 6 outlines the breakdown of interviews by Genome Centre.

¹⁰ <https://www.genomebc.ca/>

¹¹ <http://genomealberta.ca/>

¹² <http://www.genomeprairie.ca/>

¹³ www.ontariogenomics.ca/

¹⁴ www.genomequebec.com/

¹⁵ <http://genomeatlantic.ca/>

Table 6: Summary of Genomics Enterprise Interviews

Group	# of Individuals Interviewed
Genome Canada	1
Genome Alberta	2
Genome Atlantic	1
Genome British Columbia	2
Genome Prairie	2
Ontario Genomics	1
Genome Quebec	2
External Genomics Enterprise Consultant	1
Total	12

Peer Reviewer Survey

A survey of peer reviewers (sent to 123 peer reviewers, 40 of whom responded, for a 32.5% response rate) who were members of the Full Application Review Committees for the four most recent LSARP competitions (2012, 2014, 2015, 2017) and took part in the in-person panel review process. Of these 40 peer reviewers, 29 had expertise in genomics (hereafter referred to as “genomics reviewers”) and 11 had expertise in GE³LS research (hereafter referred to as “GE³LS reviewers”). The survey focused on how LSARP peer reviewers understand integrated GE³LS research and social and economic benefits (SEB), what they understand success to look like for integrated GE³LS research, and how they think Genome Canada’s processes, guidelines and criteria affect selecting for success in integrated GE³LS research. Questions were both open-ended and closed-ended, and collected both qualitative and quantitative data.

Review of Genome Canada Documentation

Prior evaluations of Genome Canada’s performance and programs, as well as competition processes, RFAs and evaluation criteria across the competitions (from the Competition in Applied Genomics Research in Bioproducts or Crops in 2008 to the 2017 Large Scale Applied

Research Project Competition – Genomics and Precision Health) were all examined to identify (1) common themes and issues and (2) the evolution of descriptions and requirements for integrated GE³LS research.

Data Analysis

The document review helped create a detailed table of project information and was used to supplement the interviews with project teams, in terms of describing research activities and outcomes.

Interview data were aggregated according to categories of interview participants, resulting in five “lines of evidence” (Project Leaders, GE³LS Leads, users, Research Oversight Committee members and staff of the Genomics Enterprise, including Genome Canada and the six Genome Centres). These were then analyzed according to broad themes that emerged from the interviews, to address the Core Activities and Key Deliverables.

The peer reviewer survey allowed for a mixture of both qualitative and quantitative responses, the former of which were analyzed by identifying several core themes and common responses from participants. The qualitative comments from the survey often painted a more nuanced portrait than the quantitative answers.

The review of Genome Canada documentation was used to help the Expert Panel develop the recommendations in an iterative manner a few months after the Expert Panel was convened.

Limitations and Mitigation Strategies

In executing this review, the following potential challenges and mitigation strategies were considered:

Table 7: Limitations and Mitigation Strategies

Limitation	Mitigation Strategy
<p>The timing of this review to provide meaningful input into Genome Canada strategic planning processes meant that timelines for the data, analysis and report writing components of the project were tight.</p>	<ul style="list-style-type: none"> The selection of interview participants and case studies were strategically targeted with the assistance of the Genome Centres to ensure the best representation across sectors, competitions and Lead Genome Centres/geographic regions while keeping research workloads manageable with the timelines.
<p>Participation rates for the case studies varied. Originally, 12 potential case studies were selected. In three of these projects neither the Project Leaders nor GE³LS Leads were able or inclined to participate, and in one, only the Project Leader did so.</p>	<ul style="list-style-type: none"> Several attempts were made to encourage participation until adequate representation was reached across sectors, including approaching different participants on the teams and engaging the Genome Centres to facilitate contact. The partial data collected from three projects that were not developed into case studies were aggregated into the data analysis to ensure learnt knowledge was utilised. The review collected substantial documentary evidence, in coordination with Genome Canada, to help validate the findings for each case.
<p>The loss of the three potential case studies may have resulted in the loss of data on less positive experiences with projects or the competition process.</p>	<ul style="list-style-type: none"> Interview questions were devised to delve into both the successes and challenges experienced by participants and the review found that all participants were forthcoming on elements that did not work well, providing a perspective that appeared both honest and balanced. Members of the Expert Panel who have been involved in Genome Canada funded projects confirmed that the evidence is in line with their own experience. Genome Canada’s current national strategic consultation process has provided additional anecdotal evidence that supports the issues and challenges raised by the review and although this has not fed directly into this review it has validated the findings.

Limitation	Mitigation Strategy
<p>The review relied heavily on qualitative data with its inherent risks for personal perspectives and anecdotal experience</p>	<ul style="list-style-type: none"> • Saturation of information was achieved through the interviews. • Multiple lines of evidence (e.g. document reviews and surveys) were used to help validate or assess the quality of the collected data, and rigorous interviewer techniques and quality control measures were taken to review data and differentiate experience from opinion. • Genome Canada’s current national strategic consultation process has provided additional anecdotal evidence that supports the issues and challenges raised by the review and although this has not fed directly into this review it has validated the findings.
<p>The survey response rate (32%) was in line with the average rates expected of internal surveys (30 – 40%) and above average for response rates expected for external surveys (10 – 15%). The N (40) was low; therefore, statistical validation is not possible.</p>	<ul style="list-style-type: none"> • Response rates were maximized by sending reminders to participants, but the original cohort number was small, so statistical validation was not planned for this survey.

Appendix three: Peer Review Survey Results

Purpose

Genome Canada has undertaken a survey of peer reviewers who were members of the Full Application Review Committees for the 2012 through 2017 Large Scale Applied Research (LSARP) Competitions and took part in the in-person panel review process. This survey was conducted as part of a review to examine the effectiveness and value of integrated GE³LS research, specifically as part of two of the review's core activities (see Appendix Two for more details on core activities and methodologies)::

1. Review how integrated GE³LS research has been undertaken across Canada.
 - Key question: How is integrated GE³LS defined and actioned by key stakeholders?
 - Expected key output: a definitional framework for integrated GE³LS research in Canada.
2. Identify successes, best practices & impediments of integrated GE³LS research in LSARPs.
 - Key questions: What does success look like for integrated GE³LS research, within projects and/or within competitions and in the aggregate at the national level? What are the key indicators of best practice in developing integrated GE³LS research? How do Genome Canada's processes, guidelines and criteria affect selecting for success in integrated GE³LS research?
 - Expected key outputs: identification of key indicators of success and factors that contribute to the successful integration of GE³LS research, and identification of factors that may inhibit success and strategies for removing these barriers.

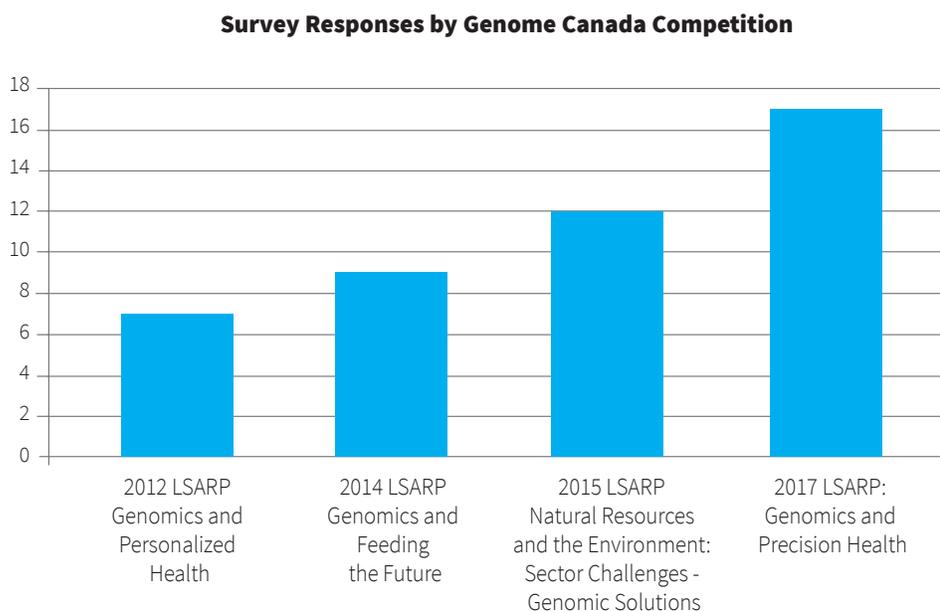
The survey shed light on what LSARP peer reviewers understand success to look like for integrated GE³LS research, how they think Genome Canada's processes, guidelines and criteria affect selecting for success in integrated GE³LS research, and how they understand the differences between integrated GE³LS and social and economic benefits (SEB), which, through anecdotal feedback, has been reported as a source of confusion by peer reviewers as well as competition applicants.

Methods

The survey was executed in December 2017 and peer reviewers from Genome Canada's 2012 LSARP competition onwards were invited to participate. The survey was sent to 123 participants with 40 responses being received, giving a 32.5% response rate. Of these 40 peer reviewers, 29 had expertise in genomics (hereafter referred to as "genomics reviewers") and 11 had expertise in GE³LS (hereafter referred to as "GE³LS reviewers").

The distribution of respondents is shown in the following chart.

Figure 4: Survey Responses by Genome Canada Competition



Summary of Results

The survey allowed for a mixture of both qualitative and quantitative responses, the former of which were analyzed by identifying several core themes and common responses from participants. The qualitative comments from the survey often painted a less clear and more nuanced portrait than the quantitative answers.

In reviewing the responses to the questions, several overarching themes became apparent:

1. Overall support for integrated GE³LS research and Genome Canada's support of it. Some did suggest that GE³LS should be optional and not required for all projects such as those focused on basic research. (Note: while the LSARPs may include an element of basic research, their focus is on applied research.)
2. There is confusion with the definition of GE³LS and its distinction from SEB.
3. The GE³LS research often feels like it is "tacked on."
4. The integration of the GE³LS research is a unique and important component of the research.

The following two parts of the report provide the responses to each question of the survey, first in summary format and then in detail including quotes from the respondents. The results are divided into four sections:

4. Definitional Considerations for GE³LS.
2. Definitional Considerations for Social and/or Economic Benefits (SEB).
3. Research Outputs and Outcomes.
4. Competition Processes.

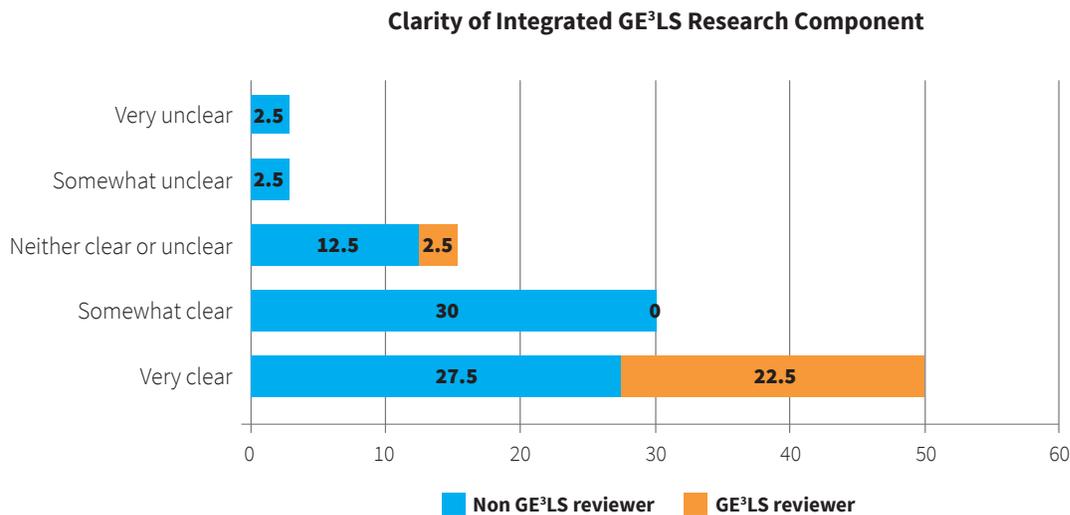
Section 1: Definitional Considerations for GE³LS

1A Part 1. As a reviewer were you sufficiently clear about what you were asked to review in terms of the integrated GE³LS component of the application?

Respondents were provided with Genome Canada’s definition of GE³LS¹⁶ as an aide memoir and asked if as a reviewer they were sufficiently clear about what they were asked to review in terms of the integrated GE³LS component of the application.

80% replied that they were somewhat/very clear. The responses from the GE³LS reviewers were predominately that it was “very clear.”

Figure 5: Clarity of Integrated GE³LS Research Component



¹⁶ The overarching objective of integrated GE³LS research is to investigate the relevant factors that will impact the advancement and application of the proposed genomics research. Projects also support collaboration between genomic scientists and GE³LS researchers in all aspects of the project (including research management and oversight). Integrated GE³LS research should be closely related to the overall project objectives, deliverables and potential social and/or economic benefits. The scope should be narrower than in large-scale GE³LS research, but the depth of the investigation must be sufficient to provide findings that can influence project direction, assist in the application and adoption of the project’s deliverables and have value to the broader sector.

1A. Part 2. If a new description for integrated GE³LS were to be developed, what should it emphasize?

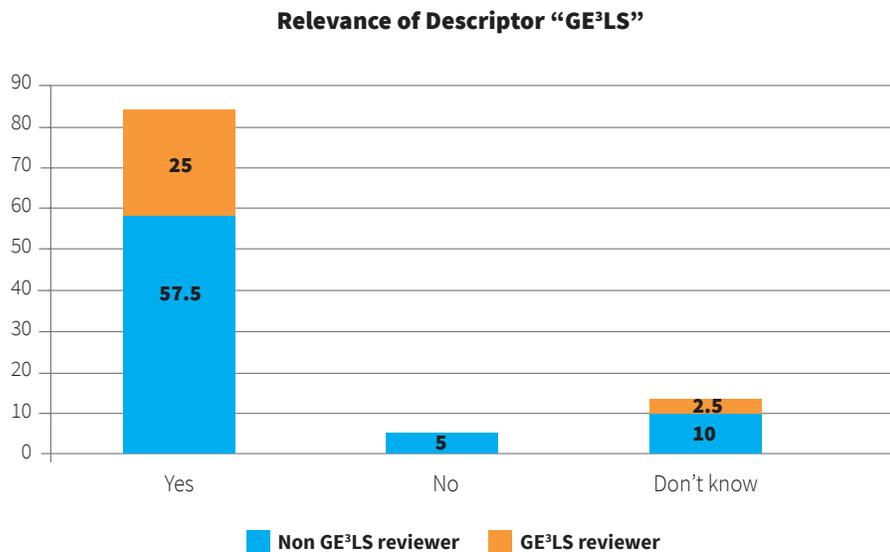
The following key themes emerged in the qualitative responses:

- 1A (i) GE³LS research should support the application of the project’s deliverables.
- 1A (ii) GE³LS research should be closely related to the overall project objectives.

1B. Is the descriptor “GE³LS” still relevant for the type of research undertaken in this arena?

82% of respondents felt that the descriptor “GE³LS” was still relevant for the type of research undertaken in this arena.

Figure 6: Relevance of Descriptor “GE³LS”



The following key theme emerged in the qualitative responses:

- 1B (i) The GE³LS acronym is clumsy but now known by the community.

1C. What other types of research do you think should come under GE³LS?

The following key themes emerged in the qualitative responses:

- 1C (i) The GE³LS remit is broad enough and no change is necessary.

- 1C (ii) There should be inclusion of education and engagement within the GE³LS remit.
- 1C (iii) There should be more focus on the applied and translational aspects of the genomics research.
- 1C (iv) Concern that the focus of GE³LS research on the applied and translational aspects of the genomics research could be to the detriment of larger more interesting questions.

Section 2: Definitional Considerations for Social and/or Economic Benefits

2A. What is your understanding of the differences between GE³LS and SEB?

Survey respondents were provided with Genome Canada's description of Social and/or Economic Benefits (SEB)¹⁷ and asked to articulate their understanding of the differences between GE³LS and SEB.

The following key themes emerged in the qualitative responses:

- 2A (i) GE³LS research meets specific research goals while SEB relates to the outcome and impact of the project as a whole.
- 2A (ii) Not clear on the difference.
- 2A (iii) Hard to measure.
- 2A (iv) Miscellaneous.

2B. What should be emphasized if a new description for SEB were to be developed?

Survey respondents were provided with Genome Canada's description of Social and/or Econ

The following key themes emerged in the qualitative responses:

- 2B (i) Tangible deliverables.
- 2B (ii) No change.
- 2B (iii) More detail on the SEB in the proposals.
- 2B (iv) Miscellaneous.

There was considerable emphasis on the need to be able to articulate and demonstrate tangibles deliverables that lead to societal change, but it was also noted by many that there is no need to change the SEB definition.

¹⁷ In the documents provided to reviewers, Social and/or Economic Benefits (SEB) are described as: The concrete deliverable(s) that will be realized by the end of the project that have the potential for subsequent translation into outcomes and/or enhanced cost-effectiveness within the sector. Eventual benefits could include, for example, adoption of a new technology or treatment, a change in practice guidelines, a change in policies, an application of an existing product/drug to a new indication. 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.

2C. How can Genome Canada better articulate the differences between GE³LS and SEB for reviewers and researchers?

The following key themes emerged in the qualitative responses:

- 2C (i) GE³LS is about research, while SEB is about outcomes.
- 2C (ii) Provide concrete examples.
- 2C (iii) GE³LS and SEB need to be integrated.
- 2C (iv) Miscellaneous.

As noted in the answers to the previous question on reviewers understanding of the differences between GE³LS and SEB, respondents could articulate that GE³LS research meets specific research goals while SEB relates to the outcome and impact of the project as a whole. Many respondents also called for more concrete examples to be provided to help clarify the difference.

Section 3: Research Outputs and Outcomes Benefits

3A. In your own words, what constitutes successful outputs in integrated GE³LS?

The following two key themes emerged in the qualitative responses:

- 3A (i) Clear integration with the objectives of the project that enhances the research as a whole.
- 3A (ii) Supporting the potential translational impact of the project.

3B. In your own words, what constitutes successful and achievable social and economic outcomes of integrated GE³LS during and following the research project?

The following four key themes emerged in the qualitative responses:

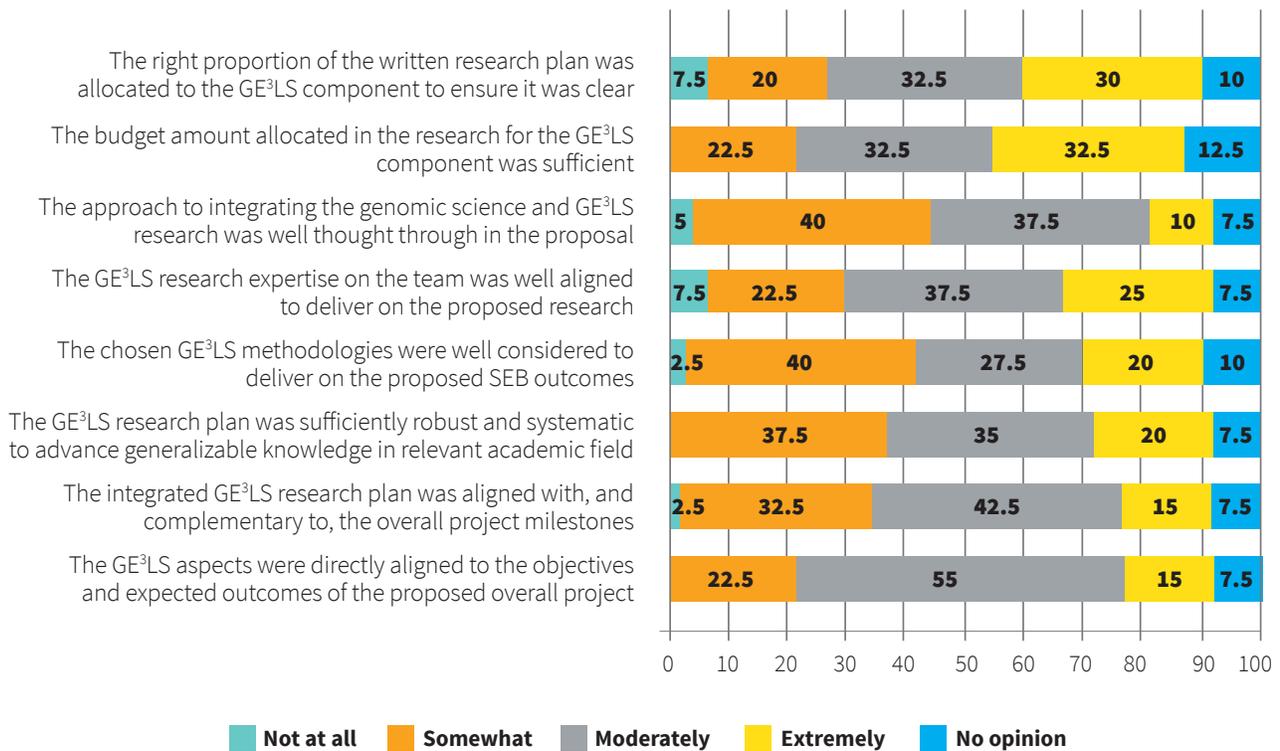
- 3B (i) Tangible benefits (both material and knowledge).
- 3B (ii) Track metrics and evidence of change.
- 3B (iii) Community engagement and awareness raising.
- 3B (iv) Unsure.
- 3B (i) Tangible benefits (both material and knowledge).
- 3B (ii) Track metrics and evidence of change.
- 3B (iii) Community engagement and awareness raising.
- 3B (iv) Unsure.

Section 4: Competition Process

4A. In thinking of the integrated GE³LS within the project/s you reviewed, how would you generally rate the following

Figure 7: Rating Integrated GE³LS Research

Rating Integrated GE³LS Research



The following key theme emerged in the qualitative responses:

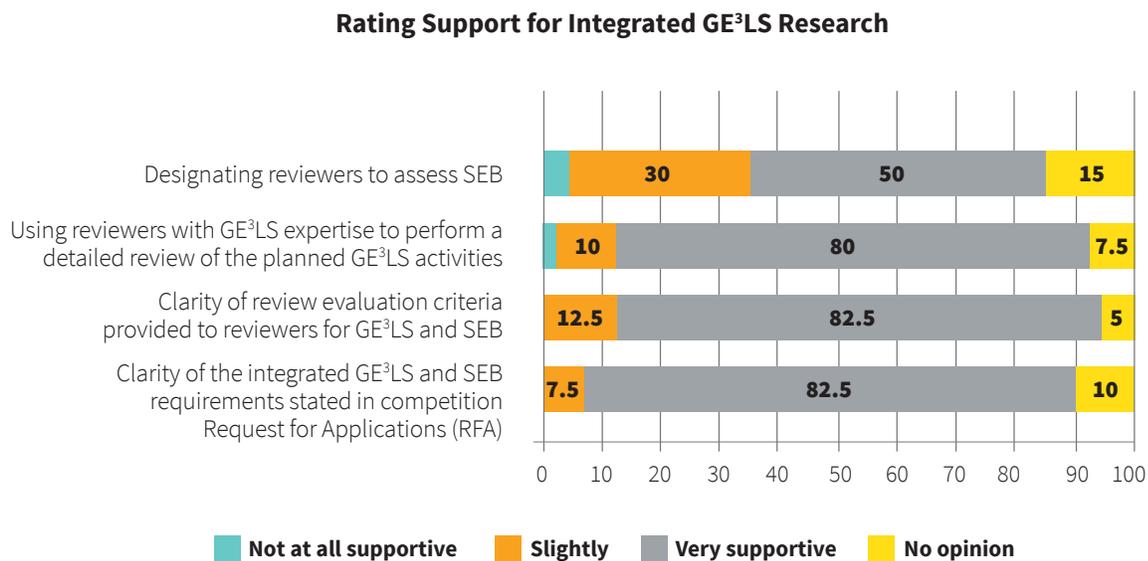
- 4A (i) The integration of the genomic science and GE³LS research varied enormously across projects.

4B. How would you rate the following aspects for supporting the development and selection of good integrated GE³LS?

82.5% felt that the clarity of the integrated GE³LS and SEB requirements stated in competition Requests for Applications (RFA) and the clarity of review evaluation criteria provided to reviewers for GE³LS and SEB supported the development and selection of good integrated GE³LS.

Given some of the previous survey responses noted above, these results could be indicative that some of the issues in developing and selecting good integrated GE³LS may lie beyond the competition process issues.

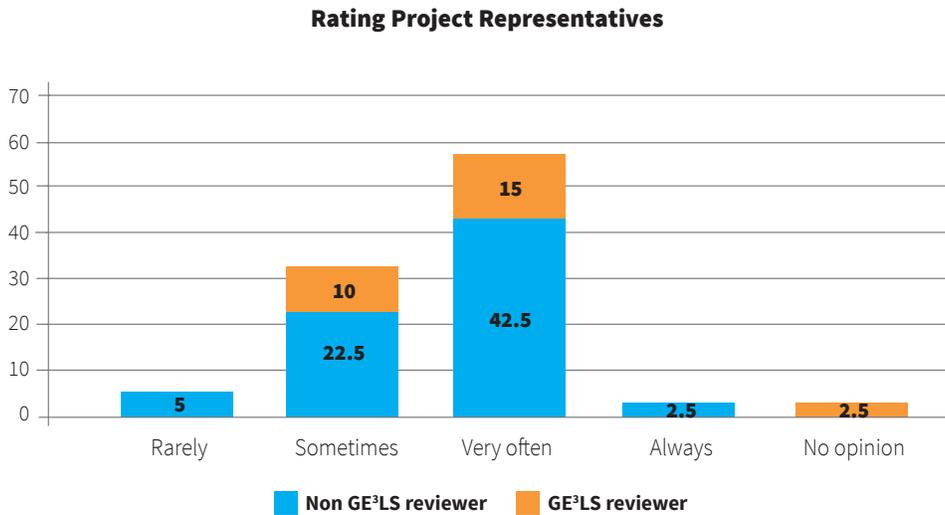
Figure 8: Rating Support for Integrated GE³LS Research



4C. Did you feel that the project representatives present at the in-person panel review were able to answer questions on the GE³LS research to the satisfaction of the review panel?

60% of respondents felt that the project representatives present at the in-person panel review were able to answer questions on the GE³LS research to the satisfaction of the review panel very often or always.

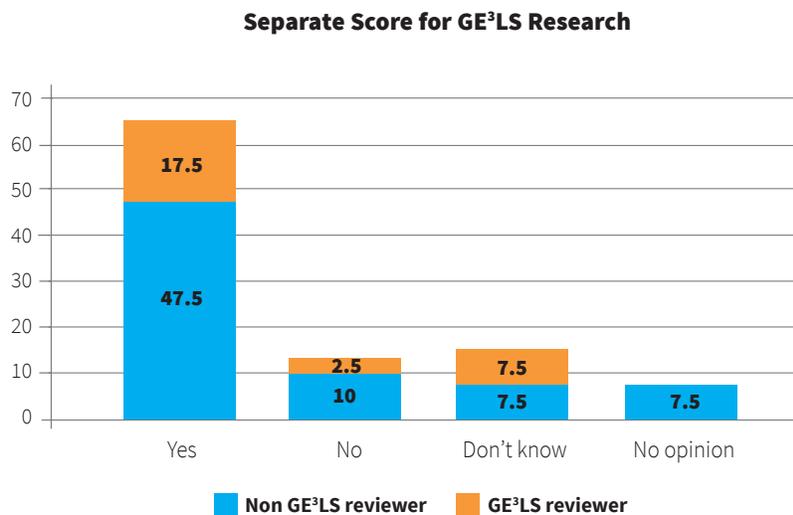
Figure 9: Rating Project Representatives



4D. Do you think there should be a separate score for the GE³LS component of the research plan distinct from the overall research plan and score for SEB?

65% of survey respondents felt that there should be a separate score for the GE³LS component of the research plan, as shown in the examples directly below (all qualitative responses are from genomics reviewers).

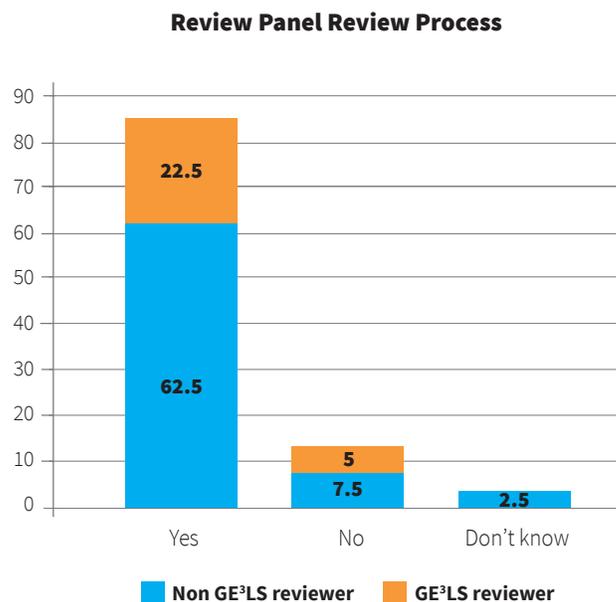
Figure 10: Separate Score for GE³LS Research



4E. Does the in-person panel review process (the Face-to-Face meeting, the presentation and Q&A) allow for an adequate review of the integrated GE³LS?

85% of survey respondents felt the in-person panel review process allowed for the adequate review of the GE³LS component of the research plan

Figure 11: Review Panel Review Process



The following key themes emerged in the qualitative responses:

- 4E (i) The review process for GE³LS is effective.
- 4E (ii) Do not always feel confident that they have the expertise to assess the GE³LS component of the project.
- 4E (iii) It was a challenge rating proposals where the integration and/or quality of the genomics research and GE³LS research differs.

4F. Suggestions for improving the in-person panel review process.

Several suggestions for improving the in-person panel review process were made by the GE³LS reviewers in the qualitative responses:

- Send the project team key points raised by reviewers in advance of the panel review so they know which GE³LS person and other team members to send to the panel meeting.

- Set up a pre-review to help focus the attention of all reviewers in the face to face meetings
- The review of integrated GE³LS could be improved by making it clear to the applicants that the GE³LS leadership be represent in the in-person team.
- Managing the time for questions and answers more closely as when pressed for time the GE³LS questions are sacrificed

Survey Data

The survey shed light on what LSARP peer reviewers understand success to look like for integrated GE³LS research, how they think Genome Canada's processes, guidelines and criteria affect selecting for success in integrated GE³LS research, and how they understand the differences between integrated GE³LS and social and economic benefits (SEB), which, through anecdotal feedback, has been reported as a source of confusion by peer reviewers as well as competition applicants.

The survey allowed for a mixture of both qualitative and quantitative responses. Qualitative answers were analyzed by identifying a number of core themes and common responses from participants. This was reviewed separately by three Genome Canada staff¹⁸ working on the integrated GE³LS review to ensure congruence.

In reviewing the responses to the questions, a number of overarching themes became apparent:

1. Overall support for integrated GE³LS research and Genome Canada's support of it. Some did suggest that GE³LS should be optional and not required for all projects such as those focused on basic research. (Note: basic research is not relevant to LSARP, which requires applied research.)
2. There is confusion with the definition of GE³LS and its distinction from SEB.
3. The GE³LS research often feels like it is "tacked on."
4. The integration of the GE³LS research is a unique and important component of the research.

Overarching Theme 1: Overall support for integrated GE³LS research; should not be required for all projects, such as those focused on basic research

Genomics reviewers:

- I think the GE³LS components are excellent additions to the proposals. My GC experience was novel and comprehensive, primarily because these aspects of novel genomics studies were included. Makes it very exciting to see research transformed into utility!

¹⁸ A Research Analyst, an Evaluation Consultant and a GE³LS Consultant.

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- I really liked the GE³LS component of the LSARP – I wish we had similar emphasis in US grant mechanisms. It really focuses the mind in terms of what the research is trying to achieve and keeps the focus on the patients. It really changed the way I view my own research and how I am formulating my own grant proposals
- I think this was a unique aspect of these grants that define it as different from what is done in the US and it is forward thinking and very valuable
- I wonder whether there could be an optional GE³LS component for projects that are more in the basic science realm
- So for basic science projects it is difficult to rank proposals based on GE³LS. Other projects that have significant non-basic research components are better suited for GE³LS analysis
- The [GE³LS] proposal is there because something needs to be included in the GE³LS section. An optional section might be an alternative

GE³LS reviewers:

- I do think it's critical that integrated GE³LS is required.

Overarching Theme 2: There is confusion with the definition of GE³LS and its distinction from SEB.

Genomics reviewers:

- There seemed to be some confusion about the GE³LS component being evaluated not as part of the research but as a social benefit
- A clearer definition of the research component of GE³LS. Is it just to apply current thinking to any potential issues or should it have a clear research focus of its own in the sphere in which it is being applied?
- Although I thought I was clear at the start of the review process, it became less clear as there were many ways of interpreting the socioeconomic requirement, all of which could to some extent be considered valid in the context of the proposals. I think the socioeconomic component should emphasize quantitative modelling of the social and economic benefits of technology uptake. (although ideally such a model would be part of an initial proposal)
- GE³LS is fuzzy - we need to clarify. Is it a requirement and if so, could it be simply a type of social or economic benefit? The GE³LS team did not seem to have the skills to assess SEB, so we found that their assessment was not useful

in the context of the overall discussion. This was frustrating for all concerned, not the least of which was the GE³LS person!

GE³LS reviewers:

- Re “Designating reviewers to assess SEB” -- this would be only helpful in conjunction with expanding on the definitions and distinctions between the GE³LS and SEB sections and intentions for them. The latter is a necessary condition for the use of such reviewers. It might make sense to also ensure that those reviewers are market and sector experts appropriate to the overall proposal, assuming that I’ve understood the distinction between GE³LS and SEB.

Overarching Theme 3: The GE³LS research often feels like it is “tacked on.”

Genomics reviewers:

- Often the GELS work we see in GC proposals is very “tacked on” and does not feel like a part of the main objective of the proposal.
- In general, the GE³LS components felt like add-ons. GE³LS researchers did not appear to have played a core role in project development (there was a feeling of teams having ‘grabbed a nearby social scientist’).
- It’s been 3 years since I participated as a reviewer, but I thought the GE³LS component seemed a bit “forced” or an add-on in some proposals.
- In many applications GELS seemed like an afterthought and it seemed like there was often not enough GELS expertise across Canada to adequately tackle the issues for all the centers.
- One could really tell when GE³LS researchers were part of the project design and when the GE³LS was simply tacked on as an afterthought.
- The issue is that sometimes certain scientific project are not prone to GE³LS studies and the proposal is just there because something needs to be included in the GE³LS section. An optional section might be an alternative.

GE³LS reviewers:

No responses.

Overarching Theme 4: The integration of the GE³LS research is a unique and important component of genomic research.

Genomics reviewers:

- I think the GE³LS components are excellent additions to the proposals. My Genome Canada experience was novel and comprehensive, primarily because these aspects of novel genomics studies were included. Makes it very exciting to see research transformed into utility!
- The GE³LS work in the end supported the research aims developing genomic-based clinical biomarkers, by providing guidelines as to how these biomarkers needed to perform in order to have a real impact. This helped guide the work of the team in selecting and validating biomarkers of interest.
- I really liked the GE³LS component of the LSARP - I wish we had similar emphasis in US grant mechanisms. It really focuses the mind in terms of what the research is trying to achieve and keeps the focus on the patients. It really changed the way I view my own research and how I am formulating my own grant proposals.
- I think this was a unique aspect of these grants that define it as different from what is done in the US and it is forward thinking and very valuable
- I think it is a significant factor in this work, and can actually inform the direction of the other proposed research

GE³LS reviewers:

- I do think it's critical that integrated GE³LS is required
- From my experience the GELS activities were generally well thought out and relevant to the research activities and outputs. At times there was good integration between GELS assessments and the research activities. One area that may be improved is the integration of the outcomes from the GELS activities into the research itself.
- GE³LS team member clearly integrated into the larger project team publications in high quality peer reviewed journals
- Further emphasis on ensuring that GELS activities are fully integrated into the project.
- Integrated GE³LS research should be closely related to the overall project objectives..." some cost effectiveness projects were hard to assess--cost effectiveness analyses arguably are "closely related" to objectives, impact

etc because high costs will restrict adoption. But this is such a truism it seems hard to see it as GE³LS. also given the long time line-- often extending beyond the funding period--how useful would results of a cost effectiveness results be

The results from the survey are presented in this document in four sections:

1. Definitional Considerations for GE³LS.
2. Definitional Considerations for Social and/or Economic Benefits (SEB).
3. Research Outputs and Outcomes.
4. Competition Processes.

Section 1: Definitional Considerations for GE³LS

1A. Part 1. As a reviewer were you sufficiently clear about what you were asked to review in terms of the integrated “integrated GE³LS” component of the application?

Respondents were provided with Genome Canada’s definition of GE³LS¹⁹ as an aide memoir and asked if as a reviewer they were sufficiently clear about what they were asked to review in terms of the integrated GE³LS component of the application.

80% replied that they were somewhat/very clear. The responses from the GE³LS reviewers were predominately that it was “very clear” (see *Figure 5: Clarity of Integrated GE³LS Research Component*).

1A. Part 2. If a new description for integrated GE³LS were to be developed, what should it emphasize?

The following key themes

- 1A (i) GE³LS research should support the application of the project’s deliverables.
- 1A (ii) GE³LS research should be closely related to the overall project objectives.

Finding 1A (i) – GE³LS research should support the application of the project’s deliverables.

Genomics reviewers:

- I would emphasize the “influence project direction, assist in the application and adoption of the project’s deliverables”.

¹⁹ The overarching objective of integrated GE³LS research is to investigate the relevant factors that will impact the advancement and application of the proposed genomics research. Projects also support collaboration between genomic scientists and GE³LS researchers in all aspects of the project (including research management and oversight). Integrated GE³LS research should be closely related to the overall project objectives, deliverables and potential social and/or economic benefits. The scope should be narrower than in large-scale GE³LS research, but the depth of the investigation must be sufficient to provide findings that can influence project direction, assist in the application and adoption of the project’s deliverables and have value to the broader sector.

- I would suggest emphasizing even more strongly that the GE³LS work should be designed to support uptake and utilization of the genomics project, especially for more applied/translational competitions

GE³LS reviewers:

No responses.

Finding 1A (ii) – GE³LS research should be closely related to the overall project objectives.

Genomics reviewers:

No responses.

GE³LS reviewers:

- Integrated GE³LS research should be closely related to the overall project objectives
- Further emphasis on ensuring that GE³LS activities are fully integrated into the project

1B. Is the descriptor “GE³LS” still relevant for the type of research undertaken in this arena?

82% of respondents felt that the descriptor “GE³LS” was still relevant for the type of research undertaken in this arena (see *Figure 6: Relevance of Descriptor “GE³LS”*).

The following key theme emerged in the qualitative responses:

- 1B (i) The GE³LS acronym is clumsy but now known by the community.

Finding 1B (i) – The GE³LS acronym is clumsy but now known by the community.

Genomics reviewers:

- Acronyms are invariably problem for those not in government.
- It’s always been a clumsy acronym, but everyone’s used to it now.

GE³LS reviewers:

- Initially I thought GE³LS was a terrible descriptor, but I have to admit the “E3” reminded me, as an economist, that there were two other “Es” to think about!

1C. What other types of research do you think should come under GE³LS?

The following key themes emerged in the qualitative responses:

- 1C (i) The GE³LS remit is broad enough and no change is necessary.
- 1C (ii) There should be inclusion of education and engagement within the GE³LS remit.
- 1C (iii) There should be more focus on the applied and translational aspects of the genomics research.
- 1C (iv) Concern that the focus of GE³LS research on the applied and translational aspects of the genomics research could be to the detriment of larger more interesting questions.

Finding 1C (i): The current GE³LS remit is broad enough and no change is necessary.

Genomics reviewers:

- think the scope is fine.

GE³LS reviewers:

- I think it's broad enough already.....
- you mean other than Ethical, Environmental, Economic, Legal and Social issues-- that's quite a lot as it is.
- It's already a pretty broader definition
- It is fairly comprehensive.

Finding 1C (ii): There should be inclusion of education and engagement within the GE³LS remit.

Genomics reviewers:

- There is a need to develop educational and engagement programs as part of the GELS remit
- In so many of the projects I've reviewed, education of non-scientists (government officials, general public, others) is one of the critical issues, but it is not directly discussed or encouraged -- perhaps for fear of being seen too much as advocacy? Education activities are often critical to translating GE³LS knowledge into SEB outcomes. I would advocate for explicit inclusion of education (GE⁴LS?)
- education of general population, maybe (outreach)

- Not sure I would suggest more research, but I do think education/outreach would be appropriate.
- I think you could emphasize engagement of end-users more in the GE³LS definition

GE³LS reviewers:

- I think it is not always clear that applicants understand what is 'research'. for example, sometimes educational programmes are included as part of GE³LS but no research questions are defined or met
- educational research BUT it MUST be research and not just an educational programme ie. the effectiveness of the educational programme should be evaluated
- Education. Ultimately if the community does not understand what we all regard as genomics and benefits it brings, there is no point continuing. This much is clear from the experiences of early products of genomics. It is clear that engaging with people and giving them time and information to understand the outcomes is positive for science. Not doing so is fatal. Good example is the way the researchers at Rothamstead in the UK engaged when their trials were threatened by anti GM activists.

Finding 1C (iii): There should be more focus on the applied and translational aspects of the genomics research.

Genomics reviewers:

- disease models for cost effectiveness cost effectiveness modeling of drugs and biomarkers
- Translation of genomics to the consumer in an ethical, safe, and useful manner.
-an emphasis on generating within projects a connectivity between the GE³LS and other components that has a REAL impact on the research performed. Some of the best proposals that I reviewed did a great job of that. Better research is performed when it has a real impact on the real world. The GE³LS components of the project help to identify what those impacts are and help direct the lab/field research in directions that will have the biggest benefit.
- It is hard to imagine a project that should not at least consider the impact on the progress of their work.

- I would suggest emphasizing even more strongly that the GELS work should be designed to support uptake and utilization of the genomics project, especially for more applied/translational competitions.
- My sense is that this should be an analysis of whether there are significant policy implications, or innovations in ethical, legal frameworks.
- Applied science that brings the fundamental research to practice should be emphasized even though it currently fits under GE³LS.
- Adoption by the research or clinical communities to become ‘state of art’ in the field (i.e., one reasonable definition of “innovation”)

GE³LS reviewers:

- GE³LS could also include evaluation of the various aspects of the ‘applied’ project approach in positioning highly-qualified persons successfully in terms of enhanced career opportunities.

Finding 1C (iv): Concern that the focus of GE³LS research on the applied and translational aspects of the genomics research could be to the detriment of larger more interesting questions.

Genomics reviewers:

- While GE³LS research was well-planned and conducted by qualified researchers, it consequently rarely tackled really interesting questions. E.g., GE³LS research tended to focus on how to maximize uptake of new genomic tools in specific geographic areas or industry sub-fields. Larger and more interesting questions about informed policy design and value-based trade-offs went unasked.
- ... but, I’ve noticed less and less risk taking and the appearance that proposed GE³LS work increasingly seems to be going back over previously plowed ground. Although the sophistication and depth of GE³LS work has improved over time, I am not at all convinced that the different GE³LS research are really paying attention to each other in a way that would enable them to synthesize greater knowledge through integrated analyses. The projects are all still highly compartmentalized and specific, and I’ve seen little effort to generalize. (Perhaps the projects end before this becomes possible? Not sure whether the depth and breadth of similar work in the social sciences permits broad syntheses as would be the case for biological studies, i.e. outcomes from the genomics work continue to knock-on and inform other biological research for many years after a project is complete.)
- Many of the Cancer grants satisfied the GE³LS requirement with economic studies. Frequently the environment and ethics were not addressed.

- It could be more encompassing along the lines of the UN Sustainable Development Goals. I'm not suggesting you go that far, but more disaggregation of the description of GE³LS could be useful.
- I think that the “economic” part should actually be pulled out and made part of the SEB section. This is what really gets the two confused. Make it GEL2S and just leave ethics and environment in with Legal.

GE³LS reviewers:

No responses.

Section 2: Definitional Considerations for Social and/or Economic Benefits

2A. What is your understanding of the differences between GE³LS and SEB?

Survey respondents were provided with Genome Canada's description of Social and/or Economic Benefits (SEB)²⁰ and asked to articulate their understanding of the differences between GE³LS and SEB. The following key themes emerged in the qualitative responses:

- 2A (i) GE³LS research meets specific research goals while SEB relates to the outcome and impact of the project as a whole.
- 2A (ii) Not clear on the difference.
- 2A (iii) Hard to measure.
- 2A (iv) Miscellaneous.

Finding 2A (i) – GE³LS research meets a specific research goal, while SEB relates to the outcome and impact of the project as a whole.

Genomics reviewers:

- GE³LS was more related to the ethical etc. issues as pertaining to the effects on either the research and/or the population/environment. The SEB was the positive benefits that might accrue from the research.
- The GE³LS evaluation was for research with specific goals; the SEB was an assessment of the outcome of the research

²⁰ In the documents provided to reviewers, Social and/or Economic Benefits (SEB) are described as: The concrete deliverable(s) that will be realized by the end of the project that have the potential for subsequent translation into outcomes and/or enhanced cost-effectiveness within the sector. Eventual benefits could include, for example, adoption of a new technology or treatment, a change in practice guidelines, a change in policies, an application of an existing product/drug to a new indication. 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.

- GE³LS has a broader focus than SEB, by including ethical and environmental issues. GE³LS provides a broader foundation upon which to build SEB-related directions for information management and for changes in policy, direction to optimize environmental management and productivity. GE³LS is information; SEB is action.
- GE³LS seems to be more focused on interdisciplinary research, whereas SEB is focused on outcomes. To some extent SEB is a subset of GE³LS, but it is important not to confuse research activity (which requires funding) with research outcomes (which is what you get at the end).
- SEB to me means: Do the scientific deliverables generate an economic and/or social impact? e.g., cost savings to health care, reduced mortality/comorbidity, potential for commercialization, quality and scale of community resources, etc. GE³LS seemed more related to a targeted study to /understand/ benefits, or how the project would be perceived (or the output/deliverables of the project), or how the output would be utilized and trying to understand the barriers to adoption of practical and clinically relevant insights.
- SEB should describe the economic and social consequences of the project, whereas GE³LS should propose a project fostering collaboration between genomic and GE³LS researchers, connected from the main theme of the project
- The SEB seems more about a big picture description of the outcome of the work; GE³LS is more of an integrated research activity that will lead to such outcome.
- GE³LS is fully integrated into the project and therefore comprises a key component of the research program; whereas, SEB relates to outcomes of a project.
- SEB speaks to general significance of the proposed research. This is analogous to our 'Significance' score in US NIH review. GE³LS is more about the details of translating the research into practice. Evaluating attitudes of practitioners and end users, looking at the economics of translation, and the ethical and legal issues related to translating the research.
- GELS is a means to the SEB end
- SEB is direct impact on the public, for example reduced cost in healthcare or improved patient outcomes. GELS is a research objective aimed to understand whether and how the proposal might impact people. They are related, but separate. E.g. a proposal could dramatically reduce healthcare costs, but if physicians are unwilling to perform the procedure or unable to implement it as is done in the research setting SEB would be high but GELS might indicate that it is not a good strategy and could point to other options.

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- GE³LS is part of the research effort, SEB are the outcomes of the research conducted. GE³LS activities enhance the benefit of the project, giving it more of an impact, leading to SEB. So, GE³LS are inputs/activities of the project and SEB are what come out the other end
- The difference in my opinion is that the SEB focuses on tangible and quantifiable outcomes whereas GE³LS develops new knowledge and understanding across a broader range of issues.
- GELS relates to the factors required to ensure the success of the project. SEB describes the deliverables if the project is successful

GE³LS reviewers:

- GE³LS involves a set of clear research aims and objectives and methods to address them; SEB are the outputs of research that may be moderators [eg. publications], intermediate [eg. improved skills or capacity] and final [eg. health gain].
- GE³LS has a component in terms of genomics, and SEB not. SEB may come from other things than genomic research.
- My understanding is that SEB is primarily focused on the potential social and economic benefits of the research and outcomes (for example a new insect resistant tomato) on the targeted or relevant sectors of society (for example farmers) and/or possibly society as a whole (for example consumers). Whereas GELS encompasses a much wider assessment of the project from an ethical, environmental, economic, legal and social perspective. GELS would look at and assess any potential economic or environmental detriments that may occur from the research, as well as any benefits. In addition, GELS would assess the legal and regulatory framework under which the project may operate to ensure full compliance. The various assessments of the research and outputs would be underpinned by an ethical evaluation highlighting any potential conflicts. GELS activities should then feed back into the other research areas to inform and shape further research activities and outputs to minimize possible adverse impacts of the research. GELS help promote cooperation and coordination among people of different disciplines. So while there is a degree of overlap between SEB and GELS, SEB is fundamentally looking at potential benefits. GELS on the other hand takes a wider perspective helping to establish norms of conduct for all areas of research.
- I see GE³LS as creating (or managing) an environment that is optimal for delivering social and economic benefit.
- Social and/or Economic benefits focuses on -- benefits. GE³LS looks at

impacts -which includes risks. SEB is not about values--about what should be the case. SEB is about what researchers think will be the case.

- The SEB are about the consequences, outcomes of the research (whether genomics or GELS). They are related but clearly separate things.
- SEB is more along the lines of near-term impact on society and economics of Canada. GE³LS can have a more broad meaning.
- GE³LS looks at the broader context in terms of the potential benefits, barriers and incentives to adoption, whereas SEB more specifically focuses on potential outcomes/impacts from the concrete project deliverables.

Finding 2A (ii) – Not clear on the difference.

Genomics reviewers:

- It was very difficult to differentiate between the two
- As noted, this was somewhat unclear. GE³LS = factors associated with implementation of genomic benefits, SEB = how findings may impact health care across Canada
- GELS reflects more of the overarching goal and/or broad structure of the research and team. SEB are two aspects within GELS and specifically addressing the deliverables proposed by the project.
- Some thoughts from an email I wrote just after the 2017 LSARP: 4. The scoring of GELS versus SEB was confusing to lots of people. I kept getting crossed up on it even though I KNEW how it was “supposed to” work. It’s very difficult for people to separate GELS which is trying to model the SEB of a project (and score it under Research) from their estimate of the SEB likely to be realized, and score the latter in the SEB category.
- These descriptions seem very similar as if the same goals are desired but said in two different ways.

GE³LS reviewers:

- This was somewhat confusing, and in several of the post-interview discussion, the panels of which I was part discussed our understanding (or lack thereof) of the distinction. As I recall, in the end we decided that one reflected the outcomes of the proposed genomic research, as opposed to the GE³LS research. This was in part based on “within the sector.” However, this also posed challenges in writing up our review/panel summaries and, from the proposals, apparently also for the [sic]

Finding 2A (iii) – Hard to measure.

Genomics reviewers:

- I think the GELS is broader and less tangible/measurable.
- SEB is clear - will this work have an outcome that is likely to create real benefits. GE³LS on the other hand is fuzzy, subjective and difficult to assess.

GE³LS reviewers:

No responses.

Finding 2A (iv) – Miscellaneous.

Genomics reviewers:

- GE³LS develops technology, SEB models benefits and routes of uptake.

GE³LS reviewers:

- GE³LS encompasses the SEB, which is a narrower criterion on which to base project benefits. Even though I am an economist who strongly believes in the power of market and non-market valuation approaches, I truly appreciate attention given to ethical (equity) and environmental aspects of research.

2B. What should be emphasized if a new description for SEB were to be developed?

The following key themes emerged in the qualitative responses:

- 2B (i) Tangible deliverables.
- 2B (ii) No change.
- 2B (iii) More detail on the SEB in the proposals.
- 2B (iv) Miscellaneous.

There was considerable emphasis on the need to be able to articulate and demonstrate tangible deliverables that lead to societal change, but it was also noted by many that there is no need to change the SEB definition.

Finding 2B (i) – Tangible deliverables.**Genomics reviewers:**

- It should emphasize the overall effects of the research and application, both the positive and possibly negative consequences and indicate why the balance is net positive.
- I think this is a very difficult area to interpret and take action on. I am an environmental microbiologist, so I would promote action to improve use/management/stabilization of environmental resources (e.g. farmer use of N and runoff to major lakes....). How does Genome Canada or the Canadian government convince local farmers to alter their practices to maintain healthy natural environments. I think it's not enough to just mention the options - there need to be incentives also.
- The importance of the impact should be highlighted and considered in the score of the SEB section. The timeline of reaping the benefit/impact should also be included in the definition/requirements.
- Acceptance by the public. A new product is useless if not adopted.
- technology development knowledge to support innovation or commercialization
- I would emphasize the “influence project direction, assist in the application and adoption of the project’s deliverable”. It seems to me that these were not clearly outlined in the proposal, and not followed as I would have expected.
- SEB should emphasize long term, significant or substantial benefit to the country, its people or the economy.
- The same organizations (Institutes) were involved in nearly all projects, which I reviewed. And the same concepts were proposed indifferently of the scope of the project itself. I think the applicants were not clear about what they should deliver.
- SEB could be altered to clarify if it's about outcomes from GE³LS. The relationship should be clearer to reviewers.
- Societal impacts in terms of definable social or economic outcomes.

GE³LS reviewers:

- More concrete so that applicants could directly address this question rather than “hypotheticals”

- I think that the current definition was appropriate and general enough to cover multiple aspects. We may also emphasize on both, the individual direct benefit and the benefit for the global population at a country level.
- I am not sure. Perhaps how the GE³LS component is research focused versus SEB as uptake of (genomics and maybe GE³LS) research focused.
- It should emphasize that the outcomes are being sought have involved a wider consultation and understanding of broader aspects encompassed by GE³LS

Finding 2B (ii) – No change.

Genomics reviewers:

- Not sure I think SEB needs to be revised, per se.
- it's fine
- I think it's fine as is. Maybe just add a short statement about how this is distinct from GE³LS (which are actual research).
- I like the current SEB description
- I felt this was clear as stated
- I like the definition as is, but personal utility could potentially be baked in - sometimes there is personal benefit to knowledge that is not easily captured in economic output in terms of life planning etc

GE³LS reviewers:

No responses.

Finding 2B (iii) – More detail on the SEB in the proposals.

Genomics reviewers:

- SEB seems clear. In the 70+ pages of the proposals, however, the SEB often just seemed like a summary of the bulk of the grant.
- a description of what the actual benefit(s) might actually be from the proposed research. Maybe put this into three time frames, such as near-term, mid-term and long-term benefits. Some projects have obvious near-term benefits, others may be much more long term. Both can be important. If that is better differentiated, it might help the reviewers make better judgments about what the actual outcomes might be. So, maybe use of the word “outcomes” might be important in this context as well.

GE³LS reviewers:

No responses.

Finding 2B (iv) – Miscellaneous.

Genomics reviewers:

- examples of well written and poorly written SEBs would be helpful
- Maybe economic and social benefits could be separated. SEB could drop the social benefits in favor of strictly scientific and economic issues and GELS could drop the economic issues in favor of the social etc.

GE³LS reviewers:

- I think the word cost-effectiveness should be dropped as this is not an output and is also confusing with the GE³LS aspect. rather than concrete can we say SMART outputs the definition could also list some example SEB health gain research capacit etc some examples have been described in published reviews of funding schemes - see SEB from the IMI programme [EU funder].

2C. How Genome Canada can better articulate the differences between GE³LS and SEB for reviewers and researchers?

The following key themes emerged in the qualitative responses:

- 2C (i) GE³LS is about research, while SEB is about outcomes.
- 2C (ii) Provide concrete examples.
- 2C (iii) GE³LS and SEB need to be integrated.
- 2C (iv) Miscellaneous.

As noted in the answers to the previous question on reviewers understanding of the differences between GE³LS and SEB, respondents could articulate that GE³LS research meets specific research goals while SEB relates to the outcome and impact of the project as a whole. Many respondents also called for more concrete examples to be provided to help clarify the difference.

Finding 2C (i) – GE³LS is about research, while SEB is about outcomes.

Genomics reviewers:

- As suggested previously (and assuming my interpretation is correct) GE³LS is aimed at looking at the overall effects including political and social questions of acceptance, while SEB should be the cost/benefit analysis. GE³LS will look at issues like public acceptance (which are not necessarily simply associated

with benefits) while SEB is more a cost/benefit analysis but not directly related to social acceptability

- I never thought that there was such a need. I thought that they were pretty clearly delineated. Otherwise, maybe emphasize that GE³LS are the inputs of the project that affect society acceptance/benefits to society, and SEB are those outcomes.
- GE³LS is information and interactions among information categories; SEB is economics and action with a plan.
- Emphasize that the SEB are the claims the applicants are making (and should be robustly supported) regarding the benefits to derive from their research. GELS work might explore social impact, but if the social impacts are something that still needs to be figured out via a research project, then they should NOT be claimed as likely benefits in the SEB section.
- As above a cleaner delineation of the issues to be undertaken in the two areas. GELS should be more sociological and SEB should be Scientific and Economic Benefits.
- I think that impact/significance better define SEB. GE³LS is simply a social/economic study associated with the scientific study that would help in its successful adoption and implementation.
- one is social and society the other is basic science or applications for industry
- GE³LS should focus on ethical study design, policy implications, and legal framework. My sense is that most of the teams did not take this seriously, particularly if the work is early. In addition, one could argue that the GE³LS is quite similar for all applications of precision medicine.

GE³LS reviewers:

- we may reconcile GE³LS and SEB by emphasizing on both aspects, the concerns or issues that may come from this new area of research and the benefits that are foreseen in terms of social and economic impact.
- SEB is primarily focused on the benefits, whereas GELS ensures that any benefit is weighed against any potential harm that GELS helps establish ethical norms of conduct and research integrity and GELS promotes understanding between different disciplines.
- Well of course this depends if my understanding of the differences in Question 5 is how GC sees it! But I think of it as creating the conditions for the social and economic benefits to be effectively delivered/ taken up/ implemented. But I also see that GE³LS has a broader role than this and I have always

thought that enhancing an understanding and acceptance of genomics is very important. I guess you could see that as part of the process of delivery of outcomes.

- I think of SEB as standard economic and social measures of project benefits (employment and income impacts; economic efficiency; social revulsion and/or acceptance of research projects and associated outcomes). To some extent there is some overlap with other aspects of GE³LS (e.g., equity as measured by income or wealth distributions), but concerns about equity and the environment goes beyond narrow economic definitions or tools. As another example, economics still struggles with projects that require large upfront costs with long-delayed benefits (e.g., climate change). GE³LS allows researchers and the granting agency to assure that topics with which economics may struggle are address using other disciplinary approaches.

Finding 2C (ii) – Provide concrete examples.

Genomics reviewers:

- give examples from reviews that staff think made the distinction correctly, give examples of statements that fit better in one category or the other
- Perhaps phrasing as “impacts of grant” vs. “studying potential impacts or barriers”; e.g. study of impacts or barriers to impact (GE³LS) vs. Actual, / tangible/ direct impacts from scientific investigations.
- perhaps use key words
- I don’t think this is a big issue - at least it wasn’t a problem in our review group. A simple asterisk note in the instructions to reviewers in the SEB and GE³LS sections would be enough.

GE³LS reviewers:

- This is a very challenging question. A section explicitly discussing the definitions of both categories and their distinction, with examples, might help. Additionally, while brevity is laudable, perhaps more lines could be allowed to elaborate on the definitions under each heading.
- Describe in bullet points what should be considered in grading each aspect of the grant.

Finding 2C (iii) – GE³LS and SEB need to be integrated.

Genomics reviewers:

- There needs to be a very strong focus on fully integrated activities and not just something that is placed to the side.
- My confusion stems from why the social and economic aspects are “pulled out” into their own section in the application as opposed to the other GELS factors like the ethics, environment and legal part. Are these factors not as important? I’d assume that all aspects should be addressed but the SEB section would give the impression of duplicating justification and importance of 2 of these topics. Maybe SEB should instead be focused on DELIVERABLES which are relevant to all of the factors in GELS.

GE³LS reviewers:

No responses.

Finding 2C (iv) – Miscellaneous.

Genomics reviewers:

- Is this a real problem? Is this a real problem being articulated by GELS researchers, or is this a complaint from scientists who have not consulted their GELS colleagues as to what it is they actually do?

GE³LS reviewers:

No responses.

Section 3: Research Outputs and Outcomes

3A. In your own words what constitutes successful outputs in integrated GE³LS?

The following key themes emerged in the qualitative responses:

- 3A (i) Clear integration with the objectives of the project that enhances the research as a whole.
- 3A (ii) Supporting the potential translational impact of the project.

Finding 3A (i) – Clear integration with the objectives of the project that enhances the research as a whole.

Genomics reviewers:

- Showing that the GE³LS work has informed other aspects of the project, and led the team closer to an impactful deliverable(s)
- Project milestones and outcomes that recognize and address the integration of science with broader societal knowledge and needs with respect to the research that is conducted.
- Showing that the GE³LS work has informed other aspects of the project, and led the team closer to an impactful deliverable(s)
- Project milestones and outcomes that recognize and address the integration of science with broader societal knowledge and needs with respect to the research that is conducted.
- Proposed approach that is: - contextual to the problems addressed in the grant - where the lead is integrated also into the science that is actually being done, to the extent that they are also knowledgeable (and that the scientific leads are, reciprocally, also knowledgeable about the GE³LS questions, objectives, and approaches).
- Clear recommendations to the research team related to programmatic directions to be undertaken in response to knowledge generated from the GE³LS activities.
- Focused research that seeks to clarify or resolve the most critical potential legal, ethical, etc stumbling blocks that might hinder an otherwise really good bit of genomics
- The best GE³LS work informs project research in unexpected and timely fashion such that research can head in new directions identified as crucial from GE³LS data. Ideally, the GE³LS knowledge should be taken up and used as a starting point for future studies, but I've seen few good examples of this.
- Collaborations; targeted projects with clear aims

GE³LS reviewers:

- A full and comprehensive evaluation of the GELS issues raised by aspects of the research activities, accompanied by coherent suggestions of how to integrate the GELS recommendations into shaping the research activities.

- Clear evidence of integration of GE³LS with the science objectives. Evidence that the GE³LS component is not just a separate set of questions running alongside but that the outcomes do in fact modify how the science is performed or applied.
- This is extremely variable and dependent upon the particular project. Successful outputs would include, but not be limited to, some evidence that the GE³LS research/researchers influenced the project direction during execution; some evidence of direct stakeholder engagement and ideally that that engagement influenced project direction during execution; peer reviewed work accepted in the appropriate GE³LS disciplinary journals; contributions to policy and/or guidance documents; et al.

Finding 3A (ii) – Supporting the potential translational impact of the project.

Genomics reviewers:

- A definitive impartial evidence base on the GE³LS aspect of the research, including mitigation and adaptation approaches where appropriate
- ability to economically define the translational impact of the genomic project being proposed
- new technology developed and route to uptake clearly articulated, with commercial partner(s) involved where applicable.
- A clear plan that would help/guide implementation and adoption of the outcome.
- Use of the data or product
- any learnings that improve the odds of adoption of novel technology
- A clear plan to either move things into the clinic, or to identify barriers, depending on the stage of the proposed research. This covers economics, legal/ethical, and social research on attitudes about adoption. I would also like to point out - the degree that the results can impact minority communities should be considered somewhere - GE³LS or otherwise. I realize the demographics of Canada are different, but this was neglected in many of the proposals. Could be evaluated under SEB as an alternative.
- The GE³LS activities complement the science and look forward to societal issues with the adoption of the results/products. Therefore the GE³LS activities would be essential for supporting the case for adoption of the new

- Validation of the genomics approaches, examples of how they may be used and incorporated into literature for the public and for the government. Also including drawbacks - it's important not to oversell the new technologies.

GE³LS reviewers:

- Successful outputs in integrating GE³LS include improved project adoption and impact relative to stated objectives, improved project design and management, and the creation of new knowledge that may be applied more universally to other projects.
- Outputs that inform the practice of scientific and clinical colleagues and assist the development of technologies that patients regard as useful.
- The translation of scientific discoveries into medical practice.

3B. In your own words, what constitutes successful and achievable social and economic outcomes of integrated GE³LS during and following the research project?

The following key themes emerged in the qualitative responses:

- 3B (i) Tangible benefits (both material and knowledge).
- 3B (ii) Track metrics and evidence of change.
- 3B (iii) Community engagement and awareness raising.
- 3B (iv) Unsure

Finding 3B (i) – Tangible benefits (both material and knowledge).

Genomics reviewers:

- The GE³LS outcomes should provide a reasonable framework in which to implement the results of the work, or directly indicate this is not acceptable, even though the science has tangible benefits. It should also provide a road map for societal information in which it may need to be involved after the completion of the science.
- Demonstrable social and economic benefits of the outputs. A clear line of sight to these benefits.
- a proposal with systematic deliverables that can be tested and evaluated - an output of deliverables that improve the current state of the art - where the clear barriers to progressed are outlined in detail and rationale is clearly described

GENOMICS IN SOCIETY

Expert Panel

- Patentable information. Start-ups. Documentable deliberative activities that can be directly linked to the project goals and outcomes.
- It really depends on the project. Some impact on clinical practice and commercialization of a technology is probably the most you can hope for. For earlier stage projects, a clear identification of the barriers for utilizing genomic information in whatever domain they are studying, and an economic case for deploying the technology.
- define if the project will have economic benefit to society if successful
- Quantitative assessment of economic and/or social benefit, and clear model for technology uptake
- Realistic deliverables; well thought out plans to accomplish these deliverables including legal, social and ethical considerations
- Clear social/economic benefits from the GE³LS driven implementation of the scientific outcome.
- Adoption of the product
- improved quality of life or economic value
- Fully successful efforts result in uptake and utilization of techniques, data and knowledge after the project is complete.
- Translation of genomics policy, ethical and legal issues to society in a meaningful way.
- The research conducted leads to new knowledge that changes the way that some aspect of society runs. For example, a new way to grow a crop, a new way to produce or evaluate a drug, etc.

GE³LS reviewers:

- a generalization of new practices that are adopted after development of new policies issued after successful outcomes of a research project.
- A full assessment of the social and economic issues with recommendations on how to mitigate any detrimental social and economic impacts, resolve potential conflicts and how these recommendations can be integrated into the research activities.
- This is extremely variable and dependent upon the particular project. Successful outputs would include, but not be limited to, some evidence of

adoption of the technologies; some analysis, such as a Sustainable Return on Investment assessment, of the project reflecting broader stakeholder assessment and cost/impact savings; potentially IP filings (if this is SEB, rather than the social and economic outcomes of the GE³LS research); et alia.

- Generating a scientific discovery that has the potential to become a commercial product.
- Improved project design leading to enhanced uptake of project outcomes that are more able to be sustained after project completion.

Finding 3B (ii) – Track metrics and evidence of change.

Genomics reviewers:

- They must be explainable in simple terms to the public, and be implemented in local regions with follow up metrics to illustrate their benefit.
- This is seldom possible within the typical report window on a completed projects (always the case for publicly supported research). Strongly recommend regular retrospective reviews 4 to 7 years out from project completion. It costs money, but I have participated in such reviews for Nordic funding agencies and the information has been very helpful in understanding what went right and what didn't. (Not that the info was always acted upon, however.)

GE³LS reviewers:

- building research capacity for Canada evidence that research has changed practice

Finding 3B (iii) – Community engagement and awareness raising.

Genomics reviewers:

No responses.

GE³LS reviewers:

- Community engagement be it social or economic is the key thing that I look for. I always want to see GE³LS outputs that build a knowledge and acceptance of genomics more broadly that just within the project. At the end of the project I ask, “will successful implementation of these outcomes address the immediate problem but in addition can they be used to raise awareness of the importance of genomics to Canada?”

Finding 3B (iv) – Unsure.

Genomics reviewers:

- The whole GELS issue is foreign to me as we don't have a similar requirement in USA grant applications so it is often not clear to me what the outcomes should be. The research descriptions make sense, but it is unclear how often those goals are reached in these grant applications.

GE³LS reviewers:

No responses.

Section 4: Competition Process

4A. In thinking of the integrated GE³LS within the project/s you reviewed, how would you generally rate the following?

- 62.5% felt the right proportion of the written research plan was allocated to the GE³LS component to ensure it was clear.
- 65% felt the budget amount allocated in the research for the GE³LS component was moderately or extremely sufficient.
- 47.5% felt the approach to integrating the genomic science and GE³LS research was moderately or extremely well thought through in the proposal (however, qualitative responses indicated that this varied enormously across projects as noted in the below quotes).
- 62.5% felt the GE³LS research expertise on the team was moderately or extremely well aligned to deliver on the proposed research.
- 47.5% felt the chosen GE³LS methodologies were moderately or extremely well considered to deliver on the proposed SEB outcomes.
- 55% felt the GE³LS research plan was moderately or extremely sufficiently robust and systematic to advance generalizable knowledge in relevant academic field.
- 57.5% felt the integrated GE³LS research plan was moderately or extremely aligned with, and complementary to, the overall project milestones.
- 70% felt the GE³LS aspects were moderately or extremely directly aligned to the objectives and expected outcomes of the proposed overall project.

See Figure 7: Rating Integrated GE³LS Research.

The following key theme emerged in the qualitative responses:

4A (i) The integration of the genomic science and GE³LS research varied enormously across projects.

Finding 4A (i). The integration of the genomic science and GE³LS research varied enormously across projects.

Genomics reviewers:

- This varied among the proposals I reviewed. Some were excellent and others were a bit disjointed.
- The proposals were a bit uneven. Some had well integrated GELS and others not so much.
- It was *really* variable how some studies did this. Some were really good - integrated, plausible, made sense, but I'd estimate that was maybe 10-20%. Most seemed ad hoc, thrown together, not integrated.
- The problem with this question is that some proposals would get the "extremely" rating and others would get the "not at all".
- The proposals from LSARP 2017 were hugely variable. There were a few really good ones amongst a preponderance of really fairly bad ones.
- The responses vary with project. Some groups had fantastic GELS while others had little to none
- this varied widely by project
- Very hard to rate - this varied widely from proposal to proposal
- The quality of the GE³LS was all over the place. In different cases I could respond 'Extremely' or 'Not at all'. The fundable proposals in our group all had very good GE³LS - I don't think they could improve on this. The 'bad' ones were just very generic, providing general issues of privacy concerns, return of results, etc. I would just encourage applicants to really tailor these to their proposal aims, instead of just filling it out with boilerplate.

GE³LS reviewers:

- its impossible to answer “generally”. Some were fantastic. Others were not.
- This section of questions is not generalizable based on my experience. The several (five or six, I believe) proposals evaluated ran the gamut from very poorly aligned and linked to extremely well aligned and linked. At least one of those I reviewed would get all “Extremely” on here, while one would get all “Not at all” and others hovered around the middle categories. At this point in time, I feel that each proposal evaluated would have the same rate on all of these categories.
- Some proposals obviously had a more integrated GE³LS component. One could really tell when GE³LS researchers were part of the project design and when the GE³LS was simply tacked on as an afterthought, or when researchers without GE³LS expertise attempted to write that section of the proposal.

4B. How would you rate the following aspects for supporting the development and selection of good integrated GE³LS?

82.5 % felt that the clarity of the integrated GE³LS and SEB requirements stated in competition RFAs and the clarity of review evaluation criteria provided to reviewers for GE³LS and SEB supported the development and selection of good integrated GE³LS (see Figure 8: Rating Support for Integrated GE³LS Research).

Given some of the previous survey responses noted above, these results could be indicative that some of the issues in developing and selecting good integrated GE³LS may lie beyond the competition process issues.

4C. Did you feel that the project representatives present at the in-person panel review were able to answer questions on the GE³LS research to the satisfaction of the review panel?

60% of respondents felt that the project representatives present at the in-person panel review were able to answer questions on the GE³LS research to the satisfaction of the review panel very often or always (see Figure 9: Rating Project Representatives).

4D. Do you think there should be a separate score for the GE³LS component of the research plan distinct from the overall research plan and score for SEB?

65% of survey respondents felt that there should be a separate score for the GE³LS component of the research plan (see Figure 10: Separate Score for GE³LS Research), also illustrated in the examples directly below (all qualitative responses are from genomics reviewers).

Genomics reviewers:

- Tough question. The risk is that a project is not going to be successful with respect to the science. In all cases if the science is successful there would likely be a huge impact. So for basic science projects it is difficult to rank proposals based on GELS. Other projects that have significant non-basic research components are better suited for GELS analysis.
- Is it too hard to use GE³LS as a separate category in each application? Should we have only GE³LS applications, or must we require GE³LS to be in each application? In my view the GE³LS was never a “make or break” component of the application, so perhaps it ought to be a “check the box” if ok. Otherwise, and action to go back and complete?
- My recommendation would be to score the GELS as part of SEB with an explicit instruction to think of SEB as two-part: the GELS component of the proposal and the likely real SEB to be had from the project. I think this is a more natural split, especially since at least the “S” benefit of many of the projects is expected to be a direct output of the GELS work. On the topic of SEB, I think there needs to be some more rigorous vetting of the SEB claims made in the proposals. Several of the ones I reviewed, and most egregiously the xxxxx proposal for which I was a Reader, made absurdly inflated quantitative claims about likely economic output/benefit of their projects. My concern is that most of the reviewers are academic scientists who are not used to evaluating such claims, and don’t necessarily immediately know how to go about pressure-testing them. Perhaps there could be some parallel process (akin to the KPMG review of the budgets) where some person/people with a business background take a pass over the quantitative SEB claims and score them. I’m not sure who would do this though. There were a few very good health economists on the proposal teams, but obviously they’d have to not participate in any of the grants to be able to do this role. Perhaps ask some of them for recommendations regarding a couple of US peers who could do that. I’d actually be willing to lead/integrate such an effort if GC thought it worthwhile to do.

GE³LS reviewers:

No responses.

4E. Does the in-person panel review process (the Face-to-Face meeting, the presentation and Q&A) allow for an adequate review of the integrated GE³LS?

85% of survey respondents felt the in-person panel review process allowed of the adequate review of the GE³LS component of the research plan (see Figure 11: Review Panel Review Process).

The following key themes emerged in the qualitative responses:

- 4E (i) The review process for GE³LS is effective.
- 4E (ii) Do not always feel confident that they have the expertise to assess the GE³LS component of the project.
- 4E (iii) It was a challenge rating proposals where the integration and/or quality of the genomics research and GE³LS research differs.

Finding 4E (i) – The review process for GE³LS is effective.

Genomics reviewers:

- Compared to the review system I am used to, the GE³LS review process was a model of openness, fairness and rigour.
- In general, the review process went well. Given that there are four panels doing the reviews it seemed the process might be uneven. At final ranking it seemed like the cancer genomic applications were favored in the review process and as a result that may have put “too many eggs” in one basket. Perhaps that is simply because cancer genomics is the “hot area” in precision medicine at this moment, but it may have left some other promising areas unfunded. How can we insure the review process is even? One large panel that does all of the interviews?
- There were a few bright spots. The GELS reviewers seemed to be much tougher and it was unclear if it is inherent in this area of research, poor GELS plans, or tough reviewers. Or all three.
- The in-person review came close to being adequate in many cases in conjunction with the written submission, but in others was clearly not. Again, this was very much proportional to the seriousness with which the research team approached the inclusion of GE³LS components and this whether they had the appropriate people in the room.

GE³LS reviewers:

No responses.

Finding 4E (ii) – Do not always feel confident that they have the expertise to assess the GE³LS component of the project.

Genomics reviewers:

- As a non-expert, I endeavored to try my best to think critically about this, and provide some feedback, but there were some cases where I didn’t feel very

confident about what was constructive, or even determining what was strong, weak, and/or not good.

- The scope of the GE³LS components were so broad (necessarily so) - I just found it difficult to keep everything in mind when reading the proposals. Maybe if the sub-components were more explicitly outlined in the proposals and the scoring criteria (although this would be more work).
- GE³LS is a difficult category because it contains so many disparate areas -- and these areas require disparate skill sets to address. I found our session focusing on ethics, counseling, and policy issues - but not in any coherent way. The GE³LS group did not have a way to engage with the other reviewers, making their contributions difficult to assess or even discuss.
- It was a pleasant surprise to see how seriously the other reviewers and Genome Canada took the effective inclusion of the GE³LS component. the GE³LS components of the proposals and the relative efficacy of the particular GE³LS component was directly reflected in funding outcomes.

GE³LS reviewers:

- The diversity of opinion about what constitutes worthwhile GEL3LS activities is the biggest challenge of the face to face meetings. It was clear to me that some reviewers on the panels had not read this section properly and were only able to comment on the genomic science aspects. a pre-review by a GE³LS expert to highlight issues would help overall.
- this review was very well managed. an achievement given all the working parts. one point- while it might seem very obvious that reviewers should come prepared with questions to ask investigators, I didn't - its hard to anticipate the appropriate level/type of question- not too broad, not too petty. Maybe its just a matter of reviewer experience.

Finding 4E (iii) – It was a challenge rating proposals where the integration and/or quality of the genomics research and GE³LS research differs.

Genomics reviewers:

- I think the biggest question we faced was how to rate proposals where the science was strong but the GELS was not. Guidance on that front for both reviewers and applicants would be helpful.
- Providing examples of strong versus weak GELS statements would be very helpful for new reviewers

- I felt several of the proposals that were given very high marks because of the proposed research did not truly integrate the GE³LS component.
- GELS is relevant, but I was disappointed that one proposal with great science went unfunded because GELS was lacking. I wondered whether there could be an optional GELS component for projects that are more in the basic science realm. Of course, it may be an institutional decision to prioritize translational research, in which case, gels requirement is warranted.

GE³LS reviewers:

No responses.

4F. Suggestions for improving the in-person panel review process

Several suggestions for suggestions for improving the in-person panel review process were made in the qualitative responses:

4F (i) Miscellaneous.

Finding 4F (i) – Miscellaneous.

Genomics reviewers:

- The [GE³LS] proposal is there because something needs to be included in the GE³LS section. An optional section might be an alternative
- I really liked the GE³LS component of the LSARP – I wish we had similar emphasis in US grant mechanisms. It really focuses the mind in terms of what the research is trying to achieve and keeps the focus on the patients. It really changed the way I view my own research and how I am formulating my own grant proposals
- Send the project team key points raised by reviewers in advance of the panel review so they know which GE³LS person and other team members to send to the panel meeting.
- Set up a pre-review to help focus the attention of all reviewers in the face to face meetings
- Managing the time for questions and answers more closely as when pressed for time the GE³LS questions are sacrificed.
- I think this was a unique aspect of these grants that define it as different from what is done in the US and it is forward thinking and very valuable

- I wonder whether there could be an optional GE³LS component for projects that are more in the basic science realm
- So for basic science projects it is difficult to rank proposals based on GE³LS. Other projects that have significant non-basic research components are better suited for GE³LS analysis

GE³LS reviewers:

- The review of integrated GE³LS could be improved by making it clear to the applicants that the GE³LS leadership be represent in the in-person team.
- I do think it's critical that integrated GE³LS is required.

Appendix four: Descriptions & Criteria of GE³LS Research in the LSARP Competitions (2008 – 2017)

Genome Canada has funded 84 LSARPs between 2008 and 2017, the scope of this review. The breakdown is as follows:

Table 9: Total Funded LSARPs, 2008-2017

Competition	Sector	Total Funded LSARPs
Competition in Applied Genomics Research in Bioproducts or Crops (2008)	Agriculture	12
2010 Large-Scale Applied Research Project Competition – Multi-Sector	Agriculture, Fisheries, Human Health	7
2010 Large-Scale Applied Research Project Competition – Forestry and Environment	Forestry, Environment	9
2012 Large-Scale Applied Research Project Competition – Genomics and Personalized Health	Human Health	17
2014 Large-Scale Applied Research Project Competition – Genomics and Feeding the Future	Agriculture	11
2015 Large-Scale Applied Research Project Competition – Natural Resources and the Environment	Forestry, Environment, Energy, Mining	13
2017 Large-Scale Applied Research Project Competition – Genomics and Precision Health	Human Health	15

The tables on the following pages provide details of the integrated GE³LS research requirements and the review criteria for these LSARP competitions. One of the key changes is how GE³LS was defined. In 2008 and 2010, GE³LS was understood as the “ethical, environmental, economic, legal and social issues” and “aspects,” respectively, related to genomics research. However, from 2012 onwards, it has been understood to stand for these words but defined more broadly, as genomics-related research endeavors and related activities undertaken from the perspective of the social sciences and humanities, and not limited to the disciplines that make up the acronym.

Changes to the wording related to GE³LS research that has changed since the prior LSARP competition is highlighted in **purple** text. **Black** text indicates no change in phrasing since the earlier LSARP competition.

Table 10: GE³LS Research Requirement Wording

GE³LS Research Requirement
<p data-bbox="321 657 881 688">2008 – Applied Bioproducts and Crops (ABC)</p> <p data-bbox="321 741 1341 953">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.</p> <p data-bbox="321 989 1349 1108">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.</p> <p data-bbox="321 1144 548 1171">This GE³LS plan should:</p> <ul data-bbox="321 1176 1317 1266" style="list-style-type: none"> • describe the objectives, milestones, expected outcomes, and the methods to be used to address the identified GE³LS issues; • integrate the GE³LS issues identified with the scientific components of the application.
<p data-bbox="321 1316 1016 1348">2010 LSARP – Multi-Sector / Forestry and Environment</p>
<p data-bbox="321 1388 1317 1444">All applicants must consider the key GE³LS aspects arising from their proposed research and develop a plan to address these aspects as an integrated component of the research plan.</p>
<p data-bbox="321 1484 946 1516">2012 LSARP – Genomics and Personalized Health</p>
<p data-bbox="321 1556 1333 1644">Genome Canada will support three modalities of GE³LS 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:</p> <ul data-bbox="321 1648 1317 1892" style="list-style-type: none"> • Integrated GE³LS 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 healthcare system, but also to ensure that discoveries are translated into patient and population benefits. Each project must include an integrated GE³LS research component. The overarching objective of integrated GE³LS research is to support collaboration between genomic scientists and GE³LS researchers throughout all aspects of research projects (including research management and oversight) that will advance knowledge and its translation; • Large-scale GE³LS research projects ...

GE³LS Research Requirement

2014 LSARP – Genomics and Feeding the Future

While genomics and its tools has the potential to have significant social and economic impact in the agri-food and fisheries/aquaculture sectors there remain potential barriers to the adoption and uptake of the outcomes from this research. In this competition, the applied GE³LS research should assist in the effective translation of research results into practice and policy, and the uptake of genomic-based applications related to food safety, security and sustainable production. GE³LS research may be conducted in two forms:

- **Large-scale GE³LS research projects:** ...
- **Integrated GE³LS research:** All other projects must include an integrated GE³LS research component. The overarching objective of integrated GE³LS research is to investigate the relevant factors affecting the advancement of the genomics research proposed and to support throughout all aspects of research projects (including research management and oversight) collaboration between genomic scientists and GE³LS researchers. Integrated GE³LS research should be closely related to the overall project's objectives, deliverables and potential social and/or economic benefits. The scope should be more targeted than in large-scale GE³LS research, but the depth of the investigation must be sufficient to provide findings that can be applied to the project, as well as the broader sector. Moreover, the nature of the research outputs should have the potential to assist in the likely successful uptake of the project's deliverables.

2015 LSARP – Natural Resources and the Environment

While genomics has the potential to have significant social and economic impact in the [natural resource sectors \(including interactions between natural resources and the environment\)](#), there remain potential barriers to the adoption and uptake of the outcomes from this research. In this competition, the applied GE³LS research should assist in the effective translation of research results into practice and policy, and the uptake of genomic-based applications [within the natural resource sectors](#). GE³LS research may be conducted in two forms:

- **Large-scale GE³LS research projects:** ...
- **Integrated GE³LS research:** All other projects must include an integrated GE³LS research component. The overarching objective of integrated GE³LS research is to investigate the relevant factors affecting the advancement of the genomics research proposed and to support collaboration between genomic scientists and GE³LS researchers throughout all aspects of the research project (including research management and oversight). Integrated GE³LS research should be closely related to the overall project's objectives, deliverables and potential social and/or economic benefits. The scope should be more targeted than in large-scale GE³LS research, but the depth of the investigation must be sufficient to provide findings that can be applied to the project, as well as the broader sector. Moreover, the nature of the research outputs should have the potential to assist in the likely successful uptake of the project's deliverables.

GE³LS Research Requirement

2017 LSARP – Genomics and Precision Health

While genomics has the potential to have significant **impact** in the **health area** there remain **barriers** to the adoption and uptake of the outcomes from this research **into the health-care system**. In this competition, the applied GE³LS research should assist in the effective translation of research results into practice and policy, and the uptake of genomic-based applications **into the health-care system**. GE³LS research may be conducted in two forms:

- **Large-scale GE³LS research projects:** ...
- **Integrated GE³LS research:** All other projects must include an integrated GE³LS research component. The overarching objective of integrated GE³LS research is to investigate the relevant factors **that will impact** the advancement **and application** of the **proposed** genomics research. **Projects also** support collaboration between genomic scientists and GE³LS researchers in all aspects of the project (including research management and oversight). Integrated GE³LS research should be closely related to the overall **project** objectives, deliverables and potential social and/or economic benefits. The scope should be **narrower** than in large-scale GE³LS research, but the depth of the investigation must be sufficient to provide findings that can **influence** project direction, assist in the **application and adoption** of the project's deliverables, **and have value to the broader sector**.

Table 11: GE³LS Research Definition Wording

GE³LS Research Definition
<p>2008 – Applied Bioproducts and Crops (ABC)</p> <p>...the ethical, environmental, economic, legal and social issues and potential implications associated with genomics research (GE³LS).</p>
<p>2010 LSARP – Multi-Sector / Forestry and Environment</p> <p>...key ethical, economic, environmental, legal and/or social aspects relevant to the genomics research (GE³LS) being proposed as part of the overall research plan. GE³LS proposals are also eligible to be submitted as large-scale projects.</p>
<p>2012 LSARP – Genomics and Personalized Health</p> <p>The acronym GE³LS 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 GE³LS activities.</p>
<p>2014 LSARP – Genomics and Feeding the Future</p> <p>Same as 2012 LSARP. In the context of this RFA, it can also include approaches from a wide range of disciplines including but not limited to: development studies, environmental sciences, food studies, geography, innovation studies, political sciences, and population studies.</p>
<p>2015 LSARP – Natural Resources and the Environment</p> <p><i>Same as 2012 and 2014 LSARPs</i></p>
<p>2017 LSARP – Genomics and Precision Health</p> <p><i>Same as 2012, 2014, and 2015 LSARPs, except for the following sentence.</i> In the context of this RFA, it can also include approaches from a wide range of disciplines including but not limited to: implementation research, health administration, health management, health services research, health technology assessment, real-world evaluation and comparative effectiveness research.</p>

Table 12: Evaluation Criteria Wording

Evaluation Criteria
2008 – Applied Bioproducts and Crops (ABC)
<p><i>Review Criteria: Scientific Criteria - Ethical, Environmental, Economic, Legal and Social Issues - GE³LS</i></p> <ul style="list-style-type: none"> 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
2010 LSARP – Multi-Sector / Forestry and Environment
<p><i>Review Criteria: Scientific Criteria - Ethical, Environmental, Economic, Legal and Social Aspects - GE³LS</i></p> <ul style="list-style-type: none"> i. Key GE³LS aspects relevant to the objectives and/or expected outcomes of the proposed project are appropriately identified and addressed ii. The GE³LS co-applicants on the team have appropriate expertise, experience, credibility, commitment and resources to effectively address the GE³LS aspects iii. The ways in which the Project Leader and GE³LS co-applicant(s) propose to communicate, collaborate and interact with one another throughout the course of the project are meaningful and effective iv. The integrated GE³LS research plan is aligned with, and complementary to, the overall project milestones and is sufficiently robust and systematic to advance generalizable knowledge in relevant academic fields v. Consideration has been given to coordinating efforts with GE³LS researchers working on similar questions in other Genome Canada-funded projects to maximize opportunities for synergies and minimize potential duplication

Evaluation Criteria

2012 LSARP – Genomics and Personalized Health

Evaluation Criteria: Research Proposal - Including Research on Ethical, Environmental, Economic, Legal and Social Aspects of Genomics (GE³LS)

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 GE³LS Research Criteria (in addition to the GE³LS aspects which are considered to be included in the criteria above)

- Does the GE³LS investigation address salient aspects of the genomics project and are the research questions directly related to the objectives and expected outcomes?
- Is the integrated GE³LS research plan aligned with, and complementary to, the overall project milestones?
- Is the GE³LS research plan sufficiently robust and systematic to advance generalizable knowledge in relevant academic fields?

Evaluation Criteria

2014 LSARP – Genomics and Feeding the Future

Evaluation Criteria: Research Proposal - Including Research on Ethical, Environmental, Economic, Legal and Social Aspects of Genomics (GE³LS)

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 and original thinking?
- To what extent is the research relevant to the end-users identified?

Research Plans

- How appropriate are the methods and approaches proposed (including handling of data and resources) in terms of the research objectives?
- How feasible is the research, given the projected resources and timelines?

Research Expertise

- How appropriate is the expertise and track record 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's GIN Nodes and/or other technology service providers)?

Specific criteria related to Integrated GE³LS research (in addition to the GE³LS aspects which are included in the criteria above):

- Does the GE³LS research address the most salient aspects of the project and is it closely related to the overall project's objectives, deliverables and potential social and/or economic benefits?
- Is the integrated GE³LS research plan closely aligned with, and complementary to, the overall project milestones? Is the GE³LS research plan sufficiently robust and systematic to advance generalizable knowledge in relevant academic fields?

2015 LSARP – Natural Resources and the Environment

Evaluation Criteria: Research Proposal - Including Research on Ethical, Environmental, Economic, Legal and Social Aspects of Genomics (GE³LS)

Evaluation Criteria

2017 LSARP – Genomics and Precision Health

Evaluation Criteria: Research Proposal - Including Research on Ethical, Environmental, Economic, Legal and Social Aspects of Genomics (GE³LS)

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?

Research Plans

- How appropriate are the methods and approaches in terms of the research objectives? **This includes but is not limited to:**
 - appropriateness of the plan to disaggregate data by sex and report sex-specific associations, if applicable
 - feasibility of the plan for handling data and resources
 - feasibility of the plan for enrollment of samples/subjects if the samples have not yet been collected
 - robustness of the power analysis and appropriate analytical plan
- How feasible is the research given the projected resources and time-lines?
- How appropriate is the plan for sharing data and resources within the project and with the wider community. Does the plan comply with Genome Canada's policies on Data Release and Sharing?

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 **supported Genomics Technology Platforms** and/or other technology service providers)?

Specific GE³LS **Research Criteria** (in addition to the GE³LS aspects which are **considered to be** included in the criteria above)

- Does the GE³LS **investigation** address salient factors that will impact the advancement and application of the **genomics research** and are the **research questions** supportive of the objectives and **expected outcomes**?
- Is the integrated GE³LS research plan aligned with, and complementary to, the overall project milestones?

Is the GE³LS research plan sufficiently robust and systematic to advance generalizable knowledge in relevant academic fields?

Appendix five: Previous Evaluations of GE³LS Research Progress

To ensure the Genomics in Society, and the GE³LS research activities in particular, are delivering on their objectives, Genome Canada must be able to identify their outcomes in a meaningful way. This includes using appropriate performance measures well suited to the nature of GE³LS research and its contributory role. Such measures would be intended not only to assess the value of past work done, but also to help guide future directions and priority areas. Assessment over the last 10 years has identified the following:

2006: An international study conducted by the European Research Area on Societal Aspects of Genomics (ERASAGE) in 2006 found Canada to be a “benchmark country” with its GE³LS research programs ranking among the most “strongly developed.”

2008: A commissioned bibliometric analysis concluded in 2008 that Canada ranks 4th overall in GE³LS research using multi-criteria rating from 1996-2007, just behind the US, UK and Denmark, and on par with Australia.

2009: An external evaluation of Genome Canada conducted by KPMG in May 2009 found that Canada’s leadership in GE³LS research had improved substantially since Genome Canada was created, from an average rating of “fair to good” prior to Genome Canada, to an average rating of “excellent.” While several federal and provincial initiatives have contributed to enhancing Canada’s leadership position in GE³LS research, most respondents believed that this change was either completely (8%), mainly (38%), or partially (23%) due to Genome Canada and the regional Genome Centres. In respect of integrated GE³LS research, the evaluation of Genome Canada revealed that 47% of respondents believed Canada has done this well or very well. Much of this enthusiasm can be attributed particularly to the international respondents who regarded Canada’s experience with GE³LS research integration as faring better than that of their own countries. International reviewers saw GE³LS research integration “*as a key defining characteristic of Genome Canada and very valuable.*” Here at home, however, some GE³LS researchers do not believe their work is as well-integrated in the science as it could be, and some genomics scientists are not fully persuaded of the added value GE³LS research brings. All concede, however, that when integrated GE³LS research works, it works well.

2014: Evidence from Genome Canada’s external Five-Year Evaluation (2014) confirms that Genome Canada contributed to reinforcing Canada’s position as a leader in the field. For instance, nearly 80% of GE³LS researchers reported that Genome Canada has effectively increased the quantity of GE³LS research in Canada, while 60% agreed it has increased its quality. Additionally, Project Leaders (52%) and Project Co-Leaders (35%)²¹ reported a higher standing of Canada in GE³LS research in 2008-2013 compared to 2002-2007 (21% for Project Leaders, 15% for Project Co-Leaders), and the proportion of Project Leaders who attributed this standing to Genome Canada is higher in 2013 than in 2009 (55% vs. 33%).

²¹ References to Project Leaders and Project Co-Leaders in the survey results refer to the **genomic** Project Leaders and Project Co-Leaders. If the survey result were garnered from GE³LS Leads and Co-Leads, the acronym appears before the abbreviation.

Moreover, bibliometric data²² show that Canada ranks third in the production of GE³LS peer-reviewed research papers worldwide and is one of the few leading countries in genome research that specializes in this area. Furthermore, while this area grew in importance both in Canada and worldwide from 1981 to 2011, Canada's growth has been slightly faster than the world's growth since Genome Canada's creation; this points to a possible direct contribution of Genome Canada to this rate. Additionally, the production of GE³LS research papers supported by Genome Canada increased significantly after they received Genome Canada funding.

Despite these successes, there appears to be significant differences of opinions among stakeholders on the most effective model to support GE³LS research in Canada in the future. On the one hand, many national and international stakeholders are highly supportive of Genome Canada's unique approach of embedding GE³LS research into all LSARPs. Examples of benefits highlighted by interview and survey participants in the Five-Year Evaluation (2014) include the following:

- It allows for consideration of GE³LS research aspects early in the lifecycle of a project. If there is no GE³LS research component with funding tied to it, GE³LS research aspects will likely not be considered in the design phase of the project and thus may not be dealt with as effectively.
- Project Leaders who are not required to address GE³LS research issues associated with their genomics research may be tempted to ignore them, which may create delays at later translational stages (e.g., commercialization of a controversial genomic technology).
- Without a GE³LS research requirement, there is also a risk that GE³LS research conducted in the context of stand-alone projects only would be disconnected from the specific GE³LS research issues faced by the genomics research.
- When incorporated properly, the multidisciplinary research resulting from the incorporation of GE³LS research can be beneficial to both science and the social sciences (e.g., a single project can result in transfer to a broader range of researchers).

On the other hand, the Five-Year Evaluation noted that interview and survey participants felt the integration of GE³LS research into genomics research has proved challenging and findings are mixed on the extent to which this integration has been a success. Not quite half of researchers across all groups (GE³LS and genomics) indicated that GE³LS research considerations have been effectively integrated into Genome Canada-funded projects. There was also a consensus among case study respondents that genomic research and GE³LS research often continues to function in silos. The term 'forced fit' was often used to describe the current situation between GE³LS and genomics research in some Genome Canada-funded

²² Genome Canada's Five-Year Evaluation (2014)

APPENDIX FIVE

projects. Interview participants frequently referred to the inherent difference of culture and perspective between social and natural sciences, which can constitute a barrier to integration, notably when trying to incorporate GE³LS research into project goals.

In this context, it is not surprising to observe that the majority of GE³LS researchers (58%) indicated that the integration of GE³LS research into all Genome Canada-funded projects was the most effective model to support GE³LS research in the future, while only a third of Project Leaders and Project Co-Leaders (30%) held that view. Even GE³LS researchers often stated that there is room for improvement and further efforts should be made by Genome Canada to build awareness and capacity in GE³LS research (e.g., increase the pool of world-class GE³LS researchers in Canada, improve networking between GE³LS researchers).

Other comparable international funders have differing approaches to GE³LS research funding. The Research Council of Norway uses a similar integrative model to that of Genome Canada, while the National Human Genome Research Institute (NHGRI) and the Wellcome Trust do not require that all funded projects incorporate GE³LS research considerations. The NHGRI reserves 5% of its funding to support Ethical, Legal and Social Implications (ELSI) research, which is not automatically integrated into biomedical-funded projects. The Wellcome Trust assesses the need for research into ethical issues on a case-by-case basis. Some international interview participants cautioned that requiring GE³LS research integration in all funded projects may lead to an inappropriate use of resources, as not all projects carry GE³LS research issues.



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