

Advance Contract Award Notice (ACAN)

19-58018

Legal, Ethical, Social, and Policy Dimensions of Somatic Gene and Engineered Cell Therapies

1. Advance Contract Award Notice (ACAN)

An ACAN is a public notice indicating to the supplier community that a department or agency intends to award a contract for goods, services or construction to a pre-identified supplier, thereby allowing other suppliers to signal their interest in bidding, by submitting a statement of capabilities. If no supplier submits a statement of capabilities that meets the requirements set out in the ACAN, on or before the closing date stated in the ACAN, the contracting officer may then proceed with the award to the pre-identified supplier.

2. Definition of the requirement

With a commitment to renewing its research programs, the National Research Council (NRC) has developed a challenge program in the area of health, and specifically, in gene and engineered cell therapy. The challenge program will provide seven years of support for developing disruptive technologies to enable affordable gene and engineered cell therapies for chronic diseases and rare genetic disorders affecting Canadians. The NRC, with its wide ranging and multidisciplinary expertise and capabilities in the science of cell and gene therapy, and in technology transfer, will work with stakeholders and collaborators to help unify the value chain for gene and engineered cell therapy from discovery to commercialization.

In support of this program, the NRC requires assistance in assessing the legal/regulatory, ethical, social, and policy (LESP) dimensions specific to the approvals and use of somatic gene and engineered cell therapies. A better understanding of the LESP dimensions of somatic gene and engineered cell therapy will enhance the NRC's ability to anticipate challenges and successfully navigate the Canadian ecosystem for developing, regulating, commercializing, and delivering gene and engineered cell therapies.

These therapies hold much promise for treating rare genetic disorders as well as chronic diseases such as cancer. These therapies also raise a number of challenges including regulatory barriers, fairness in access to treatment, social acceptance, post-market surveillance, patient safety, and the sustainability of business models.

The following questions will be the focal point for the project and define the central scope of the assessment:

Main question

What are the key legal/regulatory, ethical, social, and policy challenges specific to the approval and use of somatic gene and engineered cell therapies in Canada?

Sub-question

In particular, what are the affordability and accessibility challenges specific to the approval and use of somatic gene and engineered cell therapies in Canada?

Drawing from Canadian and international examples, particularly those with healthcare systems similar to Canada, NRC wishes to hear what are some of the promising approaches for overcoming these main challenges.

To answer this charge, the assessment should focus on LESP issues specific to the approval, delivery and reimbursement of somatic gene and engineered cell therapies and to their post-market adoption and use

3. Criteria for assessment of the Statement of Capabilities (Minimum Essential Requirements)

Any interested supplier must demonstrate by way of a statement of capabilities that it meets the following requirements:

- Extensive** experience on evaluating the best available evidence on particularly complex issues where the science may be challenging to understand.
- Vast knowledge* of current Canadian programs, policies.
- Extensive** experience in outreach activities on public policy issues such as panels or roundtables with key stakeholders in the science community, including postsecondary institutions, researchers.
- Extensive** experience convening experts from across Canada and abroad to evaluate the best available evidence on complex scientific topics of public interest.
- Extensive** experience in developing policy papers pertaining to the following subject matter; health, indigenous and northern affairs research, public safety, science technology and research innovation.
- Extensive** experience in working with the federal government;
- Extensive** experience in overseeing strategic Canadian policy development and communication processes;
- Ability to engage with multiple stakeholders from diverse fields such as academia, public administration and industry;
- Ability to provide services in both official languages;
- Strong credibility and existing relationships with the post-secondary research community.

* **Vast knowledge** is defined as thorough understanding of a topic, including the perspectives of different stakeholders and associated political, economic social and technical considerations. This understanding would normally be obtained through substantial research, stakeholder outreach and first-hand experience.

****Extensive experience** is defined as a minimum of 4 years of experience of which one is within the last year.

4. Applicability of the trade agreement(s) to the procurement

This procurement is subject to the following trade agreement(s):

- Canadian Free Trade Agreement (CFTA)
- Canada-Chile Free Trade Agreement (CCFTA)
- Canada-Colombia Free Trade Agreement (CCoIFTA)
- Canada-Honduras Free Trade Agreement (CHFTA)
- Canada-Korea Free Trade Agreement (CKFTA)
- Canada-Panama Free trade agreement (CPanFTA)
- Canada-Peru Free Trade Agreement (CPFTA)
- World Trade Organization - Agreement on Government Procurement (WTO-AGP)
- North American Free Trade Agreement (NAFTA)

5. Justification for the Pre-Identified Supplier

The nature of this work requires complete objectivity. Informing on Canadian decision making policies without force or coercion is important to public confidence and the integrity of the federal departments involved.

Soliciting bids on the open market invites unreasonable risks in maintaining objectivity within the process.

The Council of Canadian Academies (CCA) is a not-for-profit organization, funded and created by the federal government with the sole purpose of convening the best experts in their respective fields to assess the evidence on complex scientific topics of public interest to inform decision-making in Canada.

Public perception of the NRC conducting work of this nature by anyone other than the CCA would be damaging to Canada's ability to preserve this source of supply.

6. Government Contracts Regulations Exception(s)

The following exception(s) to the *Government Contracts Regulations* is (are) invoked for this procurement under subsection:

6 (d) – Only person is capable of performing the work.

7. Ownership of Intellectual Property

Canada will retain ownership of any Foreground Intellectual Property arising out of the proposed contract.

8. Period of the proposed contract or delivery date

The proposed contract is from July 2019 to July 2020. The National Research Council reserves the right to extend for two additional one-year periods.

9. Cost estimate of the proposed contract

The estimated value of the contract, is \$359,115.00, plus HST.

10. Name and address of the pre-identified supplier

Council of Canadian Academies
180 Elgin St. #1401, Ottawa, ON K2P 2K3

11. Suppliers' right to submit a statement of capabilities

Suppliers who consider themselves fully qualified and available to provide the services described in the ACAN may submit a statement of capabilities in writing to the contact person identified in this notice on or before the closing date of this notice. The statement of capabilities must clearly demonstrate how the supplier meets the advertised requirements.

12. Closing date for a submission of a statement of capabilities

The closing date and time for accepting statements of capabilities is July 23, 2019 at 14:00 hrs. EDT

13. Inquiries and submission of statements of capabilities

Inquiries and statements of capabilities are to be directed to:

Melody Ellis - Senior Contracting Officer
National Research Council
Bldg. M-58, 1200 Montreal Rd, Ottawa, ON
Telephone: 613-993-4461
Email: melody.ellis@nrc-cnrc.gc.ca