

PUBLIC JOINT CALL BETWEEN FINANCIADORA DE ESTUDOS E PROJETOS (FINEP) OF BRAZIL AND THE NATIONAL RESEARCH COUNCIL OF CANADA (NRC)

1. INTRODUCTION

In accordance with the Memorandum of Understanding signed in 04/4/2016 between the National Research Council of Canada (NRC), through the National Research Council - Industrial Research Assistance Program (NRC-IRAP) and Financiadora de Estudos e Projetos (Finep), referred to as supporting institutions, announce a call for proposals for joint R,D&I projects focusing on developing diagnostic kits for human health application.

2. OBJECTIVES

2.1 This selection aims to support projects to be carried out in cooperation between small and medium Canadian enterprises (SMEs) and Brazilian Scientific, Technological and Innovation Institutions in association with Brazilian Business Society - hereinafter referred to as "International Consortia" -, within the thematic area defined in item 3 of this Call, using grants for its execution.

3. JOINT INNOVATION PROJECTS AND THEMES

3.1 This Public Call aims to support projects that use scientific and technological knowledge for the development of diagnostic products of interest to human health.

3.2 For this call the following will be considered "products used for diagnostics": reagents, standards, calibrators, materials, supplies and instruments, as well as instructions for its use.

3.3 These products must contribute to make a qualitative, quantitative and/or semi-quantitative analysis from a sample of the human body in order to provide clinical information and are not intended to perform an anatomic, physical or therapeutic function.

3.4 Supported Activities:

3.4.1 Research and Development

Level I – Technological Development

1. Document analysis of the pre-development stage
2. Definition of a seed lot
3. Definition of the technological platform
4. Definition format and standardization of the test
5. Assessment against samples and reference panels (primary validation of sensitivity, specificity, reproducibility and stability)
6. Patent Feasibility Analysis

7. Determination of technical and economic feasibility of production

Level II – Prototype Development

1. Adequacy of Good Manufacturing Practices (GMP)
2. Obtaining pilot batches
3. Preliminary definition of kit presentation (package leaflet)

Level III – Validation

1. Validation (multicenter studies)
 - a. Sensitivity analysis
 - b. Specificity Analysis
 - c. Reproducibility Analysis
 - d. Stability analysis
 - e. Analysis of the feasibility of the operation of the kit by the target user
 - f. Preparation of Dossiers

3.4.2 Registration

1. Technical Report
 - a. Historical record of the project
 - b. Standard formula
 - c. GMP and GLP documentation
2. Previous analysis as required by the regulatory agency
3. GMP and GLP certification
4. Request registry

3.4.3. Transfer to Production

- a. Scale up
- b. Technology Transfer

3.5 The item 3.4.2 (Registration) can only be funded by Finep if at least one of the levels I, II and III of the item 3.4.1 have occurred in Brazil. NRC-IRAP will not financially support Items 3.4.2.

4. ARRANJO INSTITUCIONAL E CRITÉRIOS BÁSICOS DE ELEGIBILIDADE

PART I - RULES APPLICABLE TO ALL INSTITUTIONS



4.1 A Brazilian Scientific, Technological and Innovation Institution (ICT) is considered an entity or body of the direct or indirect public administration or a non-profit organization legally constituted under Brazilian law, with headquarters and forum in the country, stating in its institutional mission or in its social or statutory purpose, the activities of basic or applied research of scientific or technological nature or the development of new products, services or processes.

4.2 A Brazilian Support Foundation is a foundation created to support research, teaching and extension projects, institutional, scientific and technological development projects and projects to stimulate innovation of interest to ICTs, registered and accredited in the Ministry of Education and the Ministry of Science, Technology And Innovation, under the terms of Law No. 8,958 of December 20, 1994, and other relevant legislation at the state, district and municipal levels.

4.3 A Brazilian Business Society is considered a company incorporated under Brazilian law, which has its headquarters and administration in the country, focused on the production or circulation of goods and / or services, for profit, whose corporate acts are duly filed in the competent public registry;

4.4 A small and medium-size enterprise (SME) in Canada is considered a company with 500 or fewer full-time equivalent employees, incorporated in Canada.

4.5 The grants will be conditioned to technical, financial and legal analysis, approval and contracting rules of each supporting institution.

4.6 The supporting institutions will provide all necessary assistance to the international consortia during the project proposal, evaluation and monitoring phase.

5. FUNDING OF PROJECTS

5.1 NRC-IRAP will provide financial contributions to Canadian SMEs and Finep will finance Brazilian Research Institutes associated with Brazilian Business Societies. The companies / business societies eligible in this process cannot belong to the same economic group.

5.1.1 Economic Group is defined as a group of companies whose majority or effective control is exercised by the same individuals and / or legal entities.

5.2 The Canadian and Brazilian executors will receive resources from NRC-IRAP and FINEP, respectively, in accordance with their norms and laws, and the complementary resources (counterparts) must be provided by the project executors or partners themselves, when applicable.

5.3 The total volume of resources available for this call is up to R\$ 2.000.000,00 (two million Reais) from FINEP in form of grants and up to CAN\$1.000.000,00 (one million Canadian dollars) from NRC-IRAP .

5.4 Canadian SMEs may receive up to 50% of their part of eligible project costs through NRC-IRAP.

5.5 FINEP's supporting conditions are described on PART II of this document.

5.6 The number of projects to be selected for funding will depend on the number and quality of the submitted applications and the available funds. Finep's resource will be assigned successively to the projects that obtain the highest final mark based on the selection criteria until the limit of availability of these resources is reached.

5.7 Project duration should not exceed 2 years. An extension could be accepted by both countries if formally agreed by the supporting institutions.

5.8 Funding application by FINEP and NRC-IRAP will begin following the review and acceptance of the joint common proposal in phase 1. If one of the agencies denies the project, the other participant cannot have its portion of the project funded by the other agency in relation to the current call for proposals.

6. THE REVIEW PROCESS AND THE JOINT ASSESSMENT CRITERIA

6.1 The submission of applications will be performed in a 2-phase process.

6.1.1 Phase 1

The 1st step consists of submitting a joint application form which has to follow the template provided in the page of the call in Finep's website. The form must be completed in English, and the partner applicants in Brazil and Canada must submit identical forms to Finep and NRC-IRAP, respectively.

In Brazil, applicants must also submit a joint application form to Finep in Portuguese in addition to the English version.

The joint application forms must be identical, signed by the legal representatives, in Portuguese and English. The English version of the joint form must also contain the signature of the legal representative of the respective partner of the other country, and should be sent by e-mail to finepnrc@finep.gov.br and also to the following address:

FINEP – Financiadora de Estudos e Projetos
Edifício Ventura - Avenida República do Chile n. 330 - Torre Oeste - 10º andar - Centro
CEP: 20031-170 - Rio de Janeiro - RJ.

The Canadian partner must contact NRC-IRAP to receive instructions on how to send the joint application form.

The joint application forms will be joint evaluated by both agencies taking into account the advantage and added value resulting from the cooperation between the participants from the two jurisdictions (e.g. increased innovation capability, commercial leads, access to R&D infrastructure, new fields of application, market potential, competitiveness, etc.). The applicants will thereafter receive feedback according to the timetable provided in item 8, in order to apply for phase 2.

6.1.2 Step 2

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Brazilian applicants must submit the project (s) in Finep's own forms, which will be evaluated in accordance to the rules of this Call, as Finep's rules and operational policy. Canadian applicants will be notified by NRC-IRAP whether to complete NRC-IRAP funding proposal documents, under the rules of the Canadian supporting institution.

Due to their specific characteristics, rules and regulations, FINEP and NRC-IRAP will evaluate in parallel the cooperative project presented by the proponents in their respective countries.

The supporting institutions will use objective criteria associated with their evaluation methodologies, covering the following aspects: degree of innovation, scientific merit, project quality, international cooperation, potential for value creation, market potential, competitiveness, social and environmental impacts.

6.2 In addition, the following criteria must be met:

- There must be at least one Canadian SME, according to the criteria of that country and one Brazilian Scientific, Technological and Innovation Institution associated at least one Brazilian Business Society;
- The International Consortia must agree on a cooperation agreement on possible intellectual property rights and market strategy. The draft of this agreement should be presented by the Brazilian applicant for Phase 2 evaluation of this joint call. The formalized agreement will be mandatory by the time of the signature of the agreement with Finep. The draft and the final agreement shall contain the obligations of each partner (company and institution), from both countries; the country (ies) where the project will be executed; the share of each company and / or institution in the costs of the project; whether there will be other participants based in other countries and what obligations these participants will assume; the penalties in cases of breach of contract and the forums where the disputes will be settled;
- The tasks contained on the work plan should be clearly assigned to each partner as well as the resources required and allocated to implement the project;
- The submission of the proposal to only one of the supporting institutions, both in Phase 1 and Phase 2, will lead to its elimination of the process;
- In case of submission of proposals with similar content sent by the same participants, only the last proposal sent for evaluation purposes will be considered.

6.3 Besides the already mentioned criteria, Finep's assessment is detailed in PART II.

7. SELECTION PROCESS

Finep and NRC-IRAP will evaluate the proposals and the decision on the projects will be based on the evaluation criteria described in item 6.2, Phase 2. The list of selected projects will be published by Finep on its website: <http://www.finep.gov.br/> while NRC-IRAP will contact the selected Canadian companies.

8. TIMETABLE

The Timetable of the call implementation will be as follows:

Launch of the call	28 August 2017
Deadline for submitting joint application form (step 1):	27 November 2017
FINEP: Preliminary Results of step 1:	22 December 2017
FINEP: Deadline for submitting request for reconsideration of step 1:	02 January 2018
Final results of step 1:	19 January 2018
Deadline for submitting full applications (step 2):	19 February 2018
FINEP: Preliminary selection decision:*	05 April 2018
FINEP: Deadline for submitting request for reconsideration	16 April 2018
Final results of the joint selection decision	30 April 2018

* These steps apply only to Brazilian participants in Finep's evaluation process as established in PART II of this document and are not applicable to Canadian partners

9. REPORTING

The national project coordinators, both in Brazil and in Canada, should submit periodic reports to the respective party, according to the regulations established by the respective supporting institutions. All reports should describe the activities carried out, both in Brazil and in Canada.

In Canada:

The national project coordinator must submit status reports on a monthly basis to NRC-IRAP in accordance with the normal NRC-IRAP claiming process.

In Brazil:

The legal representative must submit progress reports, signed by the national project coordinator. To qualify for payments from Finep, one must also submit project account reports.

10. OMISSIONS

Situations that are not covered in this document will be evaluated jointly by members of FINEP and NRC-IRAP designated in Item 11 as national points of contact, within 10 (ten) business days of the presentation by electronic message addressed to any of the two with copy to the other.

11. NATIONAL CONTACT POINT

PART I - RULES APPLICABLE TO ALL INSTITUTIONS



In Brasil

Finep
Serviço de Atendimento ao Cliente - SEAC
Tel: +55 21 2555-0555
e-mail: seac@finep.gov.br

In Canada

NRC-IRAP
Andrew Bauder
Tel: 905-849-7441
e-mail: andrew.bauder@nrc-cnrc.gc.ca

12. MISCELLANEOUS

12.1 Each Part will cover its own administration costs from its contribution to the call unless otherwise jointly decided.

12.2 This Agreement is subject to the availability of funds in the budget of the agencies and the applicable laws and regulations of their respective countries.

12.3 For each agency the Public Call will come into force from the date of signature by their authorized representative and shall remain in force until the end of the funded projects.

12.4 The specific rules for ICT's and Brazilian Business Society are detailed on the PART II of this document. Reading this document is mandatory.

PART II - RULES APPLICABLE ONLY TO BRAZILIAN INSTITUTIONS



Detailment of the Joint Public Call between Financiadora de Estudos e Projetos (FINEP) and the National Research Council Industrial Research Assistance Program (NRC-IRAP)

Introduction

This annex is an integrant part of the Joint Call between Financiadora de Estudos e Projetos (Finep) and the National Research Council Industrial Research Assistance Program (NRC-IRAP). It aims at detailing the Joint Public Call for support Finep Brazilian Scientific, Technological and Innovation Institutions in association with Brazilian Business Society. The content of this part is only applicable to Brazilian partners. It´s full content is available in the Portuguese version of this document.