

CANADIAN NUCLEAR RESEARCH INITIATIVE HEALTH PROGRAM GUIDELINES

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CNL's Canadian Nuclear Research Initiative for Contract Research Organization Overview

Canadian Nuclear Laboratories' (CNL) Canadian Nuclear Research Initiative-Health Program (CNRI-H) is a program to support collaborative Radiopharmaceutical Discovery, Toxicology and Pre-clinical Testing research, delivered as services of a Contract Research Organization (CRO) projects with third-party proponents in Canada. The goal of the program is to accelerate the discovery, development and approval of targeted radiopharmaceuticals in Canada.

Annually, CNRI-H will issue a call for proposals (CFP), and CNL will enter into joint R&D projects based on the results of a review of these proposals. The objective of CNRI-H is to make CNL's technical capabilities and expert knowledge available and accessible to the Radiopharmaceutical community in order to provide CRO services to them with the technical support required to progress radiopharmaceutical development in Canada.

The benefits of these joint R&D projects will be shared between CNL and the applicant. Work will begin as early as April 2022 and can continue until March 2024.

1.1 Focus Areas

A CFP will be issued annually as part of the CNRI-H program. The 2021/22 CNRI-H CFP emphasizes low technology readiness level work to support technology development in order to accelerate development and approval of novel radiopharmaceuticals in Canada. The focus areas for the 2021/22 CNRI-H CFP are listed in Table 1.

Table 1: CNRI-H 2021/22 Call For Proposals Focus Areas

	Topic	Focus Areas within Topic
1	Targeted Delivery Systems	<ul style="list-style-type: none"> New delivery systems for targeted radiopharmaceuticals, i.e. targeted alpha therapy (TAT) <i>In vivo</i> evaluation of targeted therapy efficacy Validation of delivery systems for targeted therapies
2	Toxicology	<ul style="list-style-type: none"> Evaluation of targeted isotope therapy or Radio Immuno Therapy (RIT) toxicity <i>in vivo</i>
3	Pre-clinical Testing	<ul style="list-style-type: none"> Validation of targeted isotope therapy or RIT efficacy for new targets / new applications Pre-clinical evaluation targeted therapies

1.2 Potential Award Details

Annually, CNL will enter into a series of jointly funded R&D projects that will utilize S&T services from CNL to progress radiopharmaceutical development in Canada. Projects must be within the CNRI-H program focus areas, and are expected to be carried out by CNL staff. Subcontracts with other performing organizations may be included in the scope, but will not be eligible for fund sharing and will only be included at CNL's discretion. Cost share ratios will be defined by CNL, with CNL contributing at most 50% of the commercial cost of the project. CNRI-H award is allocated on a project by project basis, and is not awarded directly to the successful proponent. Any changes to agreed upon project scope after an agreement is finalized must be approved by both CNL and the proponents.

2. PROPOSAL REVIEW CRITERIA

2.1 Proposal Requirements

1. The CNRI-H program is intended to support joint research projects. CNL will contribute by providing access to CNL staff and facilities. CNL will not provide cash directly to applicants, or sub-contractors.
2. CNL will define a proponent contribution between 50% - 80% of the commercial value of the project based on the following factors: the value the research to CNL, the technology readiness level (favouring earlier TRL work) and whether the proponent has received previous CNRI-H awards.

Example CNRI-H Cost Share Calculation

$$\text{Proponent Cost Share (\%)} = \frac{\text{Proponents' Financial Contribution to CNL (\$)}}{\text{Total Cost of Work Completed using CNL Staff and Facilities(\$)}}$$

Note: In-kind contributions will not be considered as part of the cost share calculation, however they will be considered during final project selection.

3. For the 2021/22 CNRI-H call for proposals, projects must be complete by 2024 March 31. Projects that extend beyond 2024 March 31, will not be considered.
4. Work is to be performed at CNL by, or in cooperation with, CNL staff. Applicants may receive access to CNL facilities and/or laboratories when deemed necessary for the project.
5. Proposal must include at least one industry partner¹.

2.2 Proposal Benefits

1. Proposals must align with at least one of the focus areas listed in the call for proposals.
 - a. Applications that include several focus areas in support of multiple objectives are welcome.
2. Proposal must create lasting value for CNL. This could be in the form of knowledge and/or technology development that CNL can leverage for future work.
3. Proposal must progress radiopharmaceutical development in Canada.
4. Proposal must provide a benefit to Canada. This benefit does not need to be fully realized at the end of the project. However, the proposal must clearly explain how the project supports a longer term goal for progressing radiopharmaceutical development in Canada.
5. In-kind contributions must be clearly defined, identifying what is being offered and how it will benefit the project. An estimated dollar value must be provided.

2.3 Project Scope

1. Research goals of the applicant should be clearly defined with specific deliverables and target timeline.
2. The proposal must outline expected working arrangements between CNL and the applicant. For example, will CNL staff work in cooperation with applicants' staff? Will work be carried out at one of CNL's sites or somewhere else?
3. Project scope must be achievable within the project budget and available resources².

¹ An industry partner is defined a private sector entity directly involved with the development and commercialization of radiopharmaceuticals.

² The initial project plan, including cost and resource requirements, will be set by CNL for proposals that have passed the technical

3. CANADIAN NUCLEAR RESEARCH INITIATIVE AGREEMENT

A CNRI-H agreement is a collaborative agreement that allows CNL and applicants to optimize their resources, share technical expertise in a protected environment, access intellectual property emerging from the effort, and advance the commercialization of radiopharmaceuticals.

3.1 Finances

Applicants must provide research funds as per the cost share requirement; but may also make in-kind contributions such as personnel, services, facilities, equipment, intellectual property or other resources. CNL will manage the project and may provide personnel, services, facilities, equipment, intellectual property or other resources. CNL will contribute by providing access to CNL staff and facilities; CNL will not provide cash directly to applicants.

3.2 Terms and Conditions

A standard set of terms and conditions has been established for the CNRI-H initiative. These terms and conditions can be found in Appendix A of this package.

3.3 Publications and Reports

The applicants agree to produce the following deliverables, in conjunction with CNL, as part of the joint research project:

- An initial abstract suitable for public release;
- A final report, upon completion or termination of this agreement; contents to be agreed upon at the start of the project.

The parties agree to secure pre-publication review from each other wherein the non-publishing party shall provide written objections to be considered by the publishing party within 15 days of notice.

4. CNRI-H PROGRAM TIMELINE

Date	Descriptions
November 30, 2021	CNRI-H 1 st call for proposals opens.
January 15, 2022	Deadline for proposal submission.
February 15, 2022	CNL selects proposals to proceed to negotiations.
April 2022	Final review and signing of agreements.
May 2022	Successful agreements announced and work begins.
September 2022	Next CNRI-H CFP is expected to be announced.

5. CNRI-H APPLICATION GUIDELINES

The total proposal is to be no more than eight pages in length. It should include the following five sections.

1. Abstract (200 words)
 - a. The abstract should be written in plain language, suitable for inclusion in a media release. It should include a description of the research project, target outcomes, and the benefit for CNL and Canada.
2. Alignment (up to 1 page)
 - a. Describe how the project aligns with one or more of the identified focus areas.
3. Impact (up to 1 page)
 - a. Define the key problem that is to be addressed through this project and its significance.
 - b. Describe how this project will progress radiopharmaceutical development in Canada.
4. Project Scope (up to 5 pages)
5. Define the research goals of the applicant, include specific deliverables and target timeline.
 - a. Identify the applicant project team, including names and expertise. Explain how the applicant project team will work with the CNL project team.
 - b. To the extent possible, identify the facilities, capabilities and expertise required to complete the scope of work.
6. Budget (up to 1 page)
 - a. Identify an approximate total budget for the project.
 - b. Identify monetary and in-kind contributions separately.
 - c. Note that in-kind contributions will not be considered as part of the matching calculation.

From the proposals that pass the technical review, CNL will select a set of proposals to proceed to negotiations. Through negotiations, CNL will work with proponents to draft a project plan in response to the CNRI-H proposal. This project plan will include scope, budget, cost share, and deliverables.



APPENDIX A CNRI-H TERMS AND CONDITIONS

Dated this _____ day of _____, 20_____.

BETWEEN:

Canadian Nuclear Laboratories Ltd. (“CNL”)

AND

[Name] (“Proponent,” and together with CNL, the “Parties”)

WHEREAS:

CNL has initiated the Canadian Nuclear Research Initiative Health Program (“**CNRI-H**”) to support collaborative radiopharmaceutical contract research projects, in order to accelerate the development and licensing of novel radiopharmaceuticals to benefit the health of Canadians, in accordance with the Program Description found at <https://www.cnl.ca/health-science-2/cnri-health>;

The Proponent is interested in procuring services from CNL under the terms of the CNRI-H program;

The Parties hereby agree as follows:

1. **Contract Documents; Order of Precedence; Notice**

- 1.1. CNL and the Proponent into this Contract upon the date first set out.
- 1.2. The Contract shall consist of (i) these terms and conditions; (ii) any change orders executed by the Parties under the Terms; (iii) the scope of work attached as Exhibit A hereto (the “**SOW**”); and (iv) any other attached appendices (collectively the “**Contract**”). Any conflict or inconsistency between the provisions of the Contract shall be resolved in the order listed above. Inclusion of any Proponent proposal, in whole or in part, is limited to incorporating the descriptions and specifications contained therein to the extent they do not otherwise conflict with prior Contract documents. Supplementary terms issued by CNL in addition to these Terms shall have equal priority with the Terms, unless the terms expressly state they take priority over the Terms.
- 1.3. Any notices, consents, approvals or other communications required under this Contract (“**Notice**”) shall be in writing and delivered to the other Party at the address set out in this Contract. Delivery may be by courier, email, or personal delivery. Delivery of the Notice shall be effective on the Business Day delivered, where “**Business Day**” means 9 am to 5 pm ET any day Monday to Friday on which banks are generally open for non-automated business in the City of Ottawa, Ontario, Canada.

2. **Schedule, timing**

- 2.1. For the purposes of this Agreement, time is not of the essence.
- 2.2. CNL will make commercially reasonable efforts to perform the Services according to the schedule described in the SOW, but the Parties agree that the schedule may be impacted by, among other things, limited access to unique CNL resources.

3. **Work**

- 3.1. CNL agrees to provide those goods (“**Materials**”) and/or supply those services (“**Services**”) as identified in the SOW, and shall provide to the Proponent those items defined in the SOW as deliverables under this Contract (the “**Deliverables**”), in accordance with this Contract and materially conforming to the specifications set out herein (“**Specifications**”).
- 3.2. The Work will be performed by CNL in accordance with (i) CNL’s Quality Assurance process, and (ii) good industry practice. The parties acknowledge that the Work is highly experimental in nature and CNL takes no responsibility for any warranty on the Services, including for fitness for a purpose.



4. Change to Services

- 4.1. If a change in the Services is proposed or required, Proponent shall provide a notice describing the proposed change in the Services to CNL. CNL may, at its sole discretion, present a method of adjustment and the adjustment of the Schedule, if any, for the proposed change in the Services. Any increases in SOW which are agreed to by CNL, other than minor adjustments to the Services, shall be payable by the Proponent at CNL's full commercial rates.

5. Payment

- 5.1. The payment for the Work are as set out in the SOW, based on a budget prepared by CNL established with CNRI-H time and material rates. Unless otherwise specified in the SOW, CNL will invoice the Proponent monthly. Payment of all undisputed amounts is due net thirty days from the date of invoice, in Canadian dollars via wire transfer. All prices and rates are exclusive of all taxes.
- 5.2. CNL will provide the Proponent notice when the Work performed has, at CNRI-H time and material rates, reached approximately 80% of the budget provided to Proponent. CNL will cease to perform any Work once the budget has been reached, unless CNL, in its sole discretion, elects to continue performing Work. Any Work requested by the Proponent in respect of the SOW once CNL's time and material costs have reached the budget shall be at CNL full commercial rates.
- 5.3. CNL will stop performing the work, and may terminate the Contract, if the Proponent becomes bankrupt, insolvent, has a receiving order made against it, or if CNL has not been paid within 60 days from the date of an invoice.

6. Force Majeure

- 6.1. Neither Party shall be deemed to be in breach of this Contract where its failure to perform or its delay in performing is due wholly or in part to a cause beyond its reasonable control. The time for performing an obligation under the Contract shall be extended for a period of time at least equal to the period of delay resulting from such a cause, and if applicable an adjustment to the Contract Price shall be as determined by CNL, in its sole discretion.
- 6.2. When the performance of an obligation is delayed by at least sixty (60) consecutive Days due to a force majeure event and the Parties have not agreed upon a revised basis for performing the obligation then either Party may terminate the Contract.

7. Intellectual Property Rights

- 7.1. The following terms used in this Article shall have the meaning set out below:
 - a. **"Background Intellectual Property"** – Means intellectual property that is required to practice or make use of the Deliverables, but which does not form part of the Deliverables themselves.
 - b. **"Intellectual Property"** – means any information or knowledge of an industrial, scientific, technical, commercial, artistic or otherwise creative nature relating to the Services, including but not limited to any inventions, designs, methods, processes, techniques, know-how, show-how, models, prototypes, samples, experimental or test data, reports, drawings, plans, specifications, or software.
- 7.2. Each Party shall retain all its Intellectual Property provided to the other, utilized or otherwise employed in the course of this Contract.
- 7.3. All Intellectual Property specifically listed as part of the Deliverables created by CNL as part of the Services performed under a Contract and paid for by the Proponent shall vest in and be the property of the Proponent, and the Proponent hereby grants to CNL a royalty-free, perpetual, non-exclusive, world-wide and irrevocable license to use the Intellectual Property in the Deliverables created by CNL for its internal use, in furtherance of its business operations.
- 7.4. Where CNL Background Intellectual Property is required to practice or make use of the Deliverables, CNL hereby grants, to the extent it has the right to do so, a sublicense to Proponent to use such Background Intellectual Property, to the extent required to practice or make use of the Deliverables. CNL shall have no obligation to procure rights to Background



Intellectual Property for the purpose of sublicensing those rights to the Proponent. If CNL is unable to provide a license for such Background Intellectual Property, it will endeavor to advise Proponent of the relevant restrictions, but will not be liable should Proponent use the Deliverables without first obtaining a license for the required Background Intellectual Property.

7.5. Any Intellectual Property created by CNL in performance of the Work which is not listed as a Deliverable, or which is incidental to the SOW, shall vest and be the property of CNL, and CNL hereby grants to the Proponent a royalty-free, perpetual, non-exclusive, world-wide and irrevocable license to use such Intellectual Property for its internal business purposes.

8. Indemnification, Limitation of Liabilities

8.1. Proponent shall indemnify CNL from and against any and all losses, claims, damages, liabilities, costs and reasonable expenses resulting from a demand, claim, lawsuit, action, or proceeding arising out of or in connection with the Proponent's use of or reliance upon any Services or Deliverables.

8.2. Notwithstanding anything contained in this Contract to the contrary, in no event shall either Party be liable for incidental, special, exemplary, punitive, consequential or indirect damages (including lost profits or lost revenues) of any Indemnified Party, as a result of or arising from a Contract, regardless of whether such liability arises in tort, contract, breach of warranty, indemnification or otherwise, and the Parties agree that they shall not assert or claim any such damages. In no event shall the liability of CNL and its personnel and/or subcontractors for damages arising out of or in connection with this Contract, whether in contract, tort (including negligence), strict liability or otherwise, exceed the actual amount paid by the Proponent under this Contract.

9. Confidentiality

9.1. The following terms used in this Article shall have the meaning set out below:

- a. **"Confidential Information"** – means all information (in any medium) relating: (i) to this Contract and clearly marked as "Confidential", "Protected-Sensitive" or "Proprietary" or with a similar legend indicating its confidential nature, or when disclosed orally, has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within fifteen (15) Days from oral disclosure at the latest as confidential information by the Disclosing Party, whether communicated to a Party before or after entering into this Contract in connection with the negotiation, creation or performance of this Contract; and (ii) all other such marked information exchanged with or accessed by a Party under or in contemplation of this Contract respecting, comprising, describing, embodying or incorporating, without limitation, information respecting either Party's business, properties, Proponents, employees, finances, operations, products or services, technical data, research, business or financial information, plans or strategies, forecasts, business practices, operations and procedures, or services pertaining to either Party or their Proponents provided that Confidential Information shall not include information which:
 - i. Was known to the receiving Party prior to the disclosure thereof by the Disclosing Party, and such information was not subject to a prior obligation of confidence;
 - ii. Was or is publicly available, or becomes publicly available other than through a breach of a confidentiality obligation by the Receiving Party;
 - iii. Is disclosed to the Receiving Party by a third party without an obligation of confidence in respect of the disclosed Confidential Information; or
 - iv. Is independently developed by the Receiving Party without reference to the Confidential Information.
- b. **"Disclosing Party"** – means, with respect to the disclosure of Confidential Information, the party who makes such disclosure and to whom such Confidential Information is, or is deemed to be, confidential or proprietary;



c. **“Receiving Party”** – means, with respect to disclosure of Confidential Information, the Party who receives such disclosure;

- 9.2. Confidential Information shall be kept in trust and strict confidence by a Receiving Party and stored using reasonable security measures that are not less than the same security measures used by the Receiving Party for the protection of its own confidential information of a similar kind.
- 9.3. Without the express written consent of the Disclosing Party, a Receiving Party shall not use any Confidential Information except in the performance of its obligations under a Contract, provided however that CNL may disclose Confidential Information to: (i) Atomic Energy of Canada Limited (AECL); and (2) to its personnel and/or subcontractors who have assumed confidentiality obligations no less stringent than those herein Confidential Information and only as necessary for the performance of the Services by such personnel and/or subcontractors.
- 9.4. If a Receiving Party, or any of its directors, officers, employees, agents, representatives or advisors, is required by law or Government Authority to disclose Confidential Information, then such Receiving Party will, if permitted by law, provide the Disclosing Party with prompt notice to that effect in order to allow the Disclosing Party to seek one or more protective orders or other appropriate remedies to prevent or limit such disclosure. If such protective orders or other remedies are not obtained, the Receiving Party will disclose only that portion of Confidential Information which it is required to disclose.
- 9.5. A Receiving Party shall take all actions and will cause its personnel and/or subcontractors to take all actions as are necessary to preserve the confidentiality of the Confidential Information and shall promptly notify the Disclosing Party in the event of disclosure of Confidential Information in breach of this Contract.
- 9.6. Notwithstanding anything to the contrary, and upon direction of the Disclosing Party, the Receiving Party shall either: (i) promptly deliver to the Disclosing Party, at the Disclosing Party’s expense; or (ii) promptly destroy (or in the case of electronic data permanently delete), and confirm in writing such destruction or deletion, all Confidential Information, provided that the Receiving Party shall be entitled to retain one (1) copy of the aforementioned material for archival and/or legal purposes only.
- 9.7. CNL, through its relationship with AECL, is subject to the Access to Information Act (R.S., 1985, c. A-1). CNL will use reasonable commercial efforts to safeguard the confidentiality of any information identified by the Proponent as confidential but will not be liable in any way whatsoever to the Proponent if such information is disclosed as required by Applicable Law.

10. Publication

- 10.1. The Parties agree that publicity is an important component of the CNRI-H program and commercialization of radiopharmaceuticals generally, but this must be balanced against the need to protect Intellectual Property rights and confidentiality.
- 10.2. Upon execution of this Agreement, the Parties will jointly prepare a public release, broadly describing the goals of the project and the nature of the work being performed, and naming the Parties.
- 10.3. Each Party shall be entitled to obtain such publicity as it considers necessary relating to the subject matter herein, provided that any press releases and other material (including electronic material) shall be approved as to form and content by each Party in writing. The Non-Publishing Party’s name and logo may not be used without written permission.

11. General

- 11.1. Successors and Assigns. The Contract shall enure to the benefit of and be binding on and enforceable against the Parties and, where context so permits, their respective successors and permitted assigns. Neither Party may assign any of its rights



or benefits under a Contract, or delegate any of its duties or obligations (other than as expressly permitted herein), except with the prior written consent of the other Party.

11.2. **Governing Law.** The validity, construction and interpretation of this Contract shall be in accordance with the laws of Ontario and the federal laws of Canada applicable therein.

11.3. **Governmental Regulations.** Each Party shall at all times and at its own expense: (a) strictly comply with all applicable Laws now or hereafter in effect, relating to its obligations under this Contract; (b) pay all fees and other charges required by applicable Laws; and (c) maintain in full force and effect all licenses, permits, authorizations, registrations and qualifications from all applicable governmental authority to the extent necessary to perform its obligations hereunder.

11.4. **CNL and Proponent agree that until such time as all regulatory requirements have been obtained, including all necessary approvals of any regulatory or research ethics board concerned, no work requiring such regulatory or ethics approvals shall commence (excepting any preliminary preparations which are not restricted by such requirements). For greater certainty, provided that the appropriate Party is reasonably pursuing the required approvals, any delay in obtaining such approvals shall not be considered a default or breach by either CNL or ABC.**

11.5. **Export.** The Parties acknowledge that the Services may be subject to export control laws and regulations of Canada, the U.S. or other relevant countries. Where Export issues or processes are addressed in the SOW, the Parties will take such steps as the SOW may provide, but only as long as those specified steps are not contrary to the applicable law. Certain Services may also be subject to regulation by the Controlled Goods Directorate (CGD) of Public Works and Government Services Canada, in accordance with the Defence Production Act (Canada) (DPA) and the Controlled Goods Regulations adopted pursuant to the DPA (CGR). The Parties shall use reasonable efforts to determine whether or not the Services may contain, use, or require items or technology subject to the DPA or CGR (a "Controlled Item"). In the event that a Controlled Item is identified to be used in the Services, then the Parties shall comply with all applicable Canadian, US, and International export control laws and regulations. In the event that any required approvals, clearances, and/or export or import authorizations cannot be obtained or maintained (or there IS an extraordinary, significant delay in obtaining them), CNL shall notify Customer as soon as practical.

11.6. **Relationship between the Parties.** The Parties are independent contractors, and except as and to the extent expressly provided in a specific Contract, neither this Contract nor any Contract is intended to nor shall be construed so as to constitute either Party as the partners, agent, trustee, employee, employer, joint venture or representative of the other Party for any purpose, or to create any relationship of partnership agency, trust, employment, joint venture or any other fiduciary or other relationship similar to any of the foregoing.

11.7. **Entire Agreement.** This Contract constitutes the entire agreement between the Parties regarding the subject-matter herein, and may be amended only in writing by the Parties.

11.8. **Amendments and Waiver.**

- a. No agent, employee or other representative of either of the Parties has the authority to make any promise, agreement or representation not incorporated into this Contract and no promise, agreement or representation shall bind the Parties unless so incorporated.
- b. Failure by either Party to exercise any of its rights, power or remedies hereunder or its delay to do so does not constitute a waiver of those rights, powers or remedies. The single or partial exercise of a right, power or remedy does not prevent its subsequent exercise or the exercise of any other right, power or remedy.
- c. No waiver of any right, power or remedy is effective unless made in writing and signed by an authorized representative of the waiving Party.



The Parties have executed and delivered this Contract, by their duly authorized officers, effective as of the date first set out above.

Canadian Nuclear Laboratories Ltd.

[Proponent]

Per:

Per:

Peter D'Amico
Director, Business Development

Name

Per:

Per:

Name

Name

Address:

Address:

286 Plant Road
Chalk River, ON K0J 1J0

