[redacted]

NOTICE OF PROPOSED PROCUREMENT (NPP)

Solicitation #: 1000210808 **Closing Date: July 31, 2019** **Time: 2:00 PM**

This requirement is for the Public Health Agency of Canada (PHAC).

TITLE:
Autopsy services for Creutzfeldt-Jakob Disease

BACKGROUND:

INTRODUCTION

Prion diseases are rare, untreatable, lethal degenerative brain disorders of humans and animals. Human prion diseases, known as Creutzfeldt-Jakob disease (CJD), evoke public health concern because of their infectious nature. In keeping with its responsibilities for national surveillance, prevention and control of infectious diseases, the Public Health Agency of Canada (PHAC) operates the Canadian CJD Surveillance System (CJDSS) with a program mandate to identify and diagnose all suspected cases of CJD in Canada, understand their causes, and continuously assess associated risks to public health. Because definitive diagnosis of CJD requires post mortem pathological examination of the brain, the CJDSS requires specialized laboratory services to conduct cranial autopsies, in which brain tissue is retrieved from patients suspected to have CJD and submitted to pathological examination.

OBJECTIVES

The program objectives achieved by the CJDSS through the contracted services are

i) definitive confirmation or exclusion of a diagnosis of CJD
ii) supporting investigations to further characterize confirmed CJD cases
iii) a pathology-based alternative diagnosis when CJD has been excluded

The key deliverable for the Contractor is submission of brain tissue harvested by autopsy from a suspected CJD patient to the CJDSS Neuropathology Reference Laboratory located at the university of Ottawa (“the Reference Laboratory”). The tissue specimens must be accompanied by patient identifiers and supporting information, including clinical case notes and pertinent laboratory reports. The materials and information must meet pre-specified criteria (detailed below) to enable the Reference Laboratory to conduct a full neuropathology examination, reach a definitive diagnosis and initiate supporting investigations, to allow the CJDSS to meet its three objectives as listed above.

SCOPE:

Reliable diagnosis of CJD for surveillance purposes requires a standardized approach as well as availability of specialized laboratory reagents, procedures and facilities. These capacities are provided by the CJDSS Reference Laboratory. The CJDSS therefore requires that the Contractor work in close collaboration with the Reference Laboratory to ensure the neuropathological examination is completed in a timely manner. The key deliverable in each case is submission of appropriate brain tissue samples and accompanying documentation to the Reference Laboratory.

In addition to confirmation or exclusion of CJD, more detailed disease characterization based on additional pathological features is performed for diagnostic, surveillance and public health purposes. To render these additional pathological and biochemical investigations technically feasible, portions of brain tissue are recovered and prepared by the Contractor in both formalin-preserved (“fixed”) and fresh-frozen forms. In addition, as the pathological abnormalities in CJD vary regionally in the brain, a thorough

examination of the entire brain is required. Specifically, one sagittally divided half of the brain must be frozen and the other half fixed, before submission to the Reference Laboratory.

ESTIMATED VALUE:

The Contractor will be paid a firm all-inclusive price per autopsy.

Bidders must identify their per autopsy firm all-inclusive rate, applicable taxes extra, for the initial contract period (contract award to March 31, 2021) and each Option Period 1-3 as follows:

	Contract Award-March 31, 2020	April 1, 2020-March 31, 2021	Option Year 1	Option Year 2	Option Year 3
Firm Price Per Autopsy	$	$	$	$	$

**Canada reserves the right to request additional information as to the proposed yearly per autopsy pricing.

CJDSS historical data determines the number autopsies estimated within a particular geographic region within Canada. Contracts will be awarded on a “first come” basis, up to the Agency’s maximum annual budget.

OWNERSHIP OF INTELLECTUAL PROPERTY:

There is no Intellectual Property in the resulting Contract.

SECURITY REQUIREMENT:
There is no security requirement associated with this solicitation.

MANDATORY REQUIREMENTS:

M1. The bidder must confirm its readiness to work with the PHAC CJDSS Surveillance Office to coordinate the autopsy process, receipt and disposition of the patient’s remains, and shipping of harvested tissues within guidelines and timelines specified in the Statement of Work, on all regular business days.
M2. The supervising neuropathologist of the bidder must be certified by the Royal College of Physicians and Surgeons of Canada, and be licensed by a Provincial or Territorial College of Physicians and Surgeons. Proof of certification must be provided upon request

SELECTION METHODOLOGY:

Bids must comply with the requirements of the bid solicitation and meet all mandatory technical evaluation criteria to be declared responsive. All responsive bids will be recommended for award of a contract on a “first come” basis, up to the maximum annual budget.

Enquiries regarding this Request for Proposals are to be submitted in writing to:

Erin Massey
Senior Procurement and Contracting Officer
Health Canada | Public Health Agency of Canada
erin.massey@canada.ca

PART 1 – INFORMATION AND INSTRUCTIONS

1.1 Standard Instructions, Clauses and Conditions

All instructions, clauses and conditions identified in the bid solicitation by number, date and title are set out in the *Standard Acquisition Clauses and Conditions Manual* (https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) issued by Public Works and Government Services Canada.

Bidders who submit a bid agree to be bound by the instructions, clauses and conditions of the bid solicitation and accept the clauses and conditions of the resulting contract.

The 2003 (2016-04-04) Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation.

1.2 Certifications and Additional Information

Bidders must provide the required certifications and additional information to be awarded a contract.

The certifications provided by Bidders to Canada are subject to verification by Canada at all times. Unless specified otherwise, Canada will declare a bid non-responsive, or will declare a contractor in default if any certification made by the Bidder is found to be untrue, whether made knowingly or unknowingly, during the bid evaluation period or during the contract period.

The Contracting Authority will have the right to ask for additional information to verify the Bidder's certifications. Failure to comply with any request or requirement imposed by the Contracting Authority will render the bid non-responsive or constitute a default under the Contract.

1.2.1 Certifications Required with the Bid

Bidders must submit the following duly completed certification as part of their bid.

1.2.1.1 Integrity Provisions - Declaration of Convicted Offences

In accordance with the *Ineligibility and Suspension Policy (*http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html), the Bidder must provide with its bid the required documentation, as applicable), to be given further consideration in the procurement process.

1.2.2 Certifications Precedent to Contract Award and Additional Information

The certifications and additional information listed below should be submitted with the bid but may be submitted afterwards. If any of these required certifications or additional information is not completed and submitted as requested, the Contracting Authority will inform the Bidder of a time frame within which to provide the information. Failure to provide the certifications or the additional information listed below within the time frame specified will render the bid non-responsive.

1.2.2.1 Integrity Provisions – Required Documentation

In accordance with the Ineligibility and Suspension Policy *(*http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html)*,* the Bidder must provide the required documentation, as applicable, to be given further consideration in the procurement process.

1.3 Applicable Laws

Any resulting contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario.

Bidders may, at their discretion, substitute the applicable laws of a Canadian province or territory of their choice without affecting the validity of their bid, by deleting the name of the Canadian province or territory specified and inserting the name of the Canadian province or territory of their choice. If no change is made, it acknowledges that the applicable laws specified are acceptable to the Bidders.

1.4 Debriefings

Bidders may request a debriefing on the results of the bid solicitation process. Bidders should make the request to the Contracting Authority within 15 working days from receipt of the results of the bid solicitation process. The debriefing may be in writing, by telephone or in person.

PART 2 - RESULTING CONTRACT CLAUSES

2.1 Security Requirements

2.1.1
Unscreened contractors must be escorted by an employee or Commissionaire at all times when visiting Government of Canada facilities.

Information which is to be used in the development of the contracted product, as reference material or otherwise made available to the contractor must be unclassified material and considered to be releasable to the public by HC/PHAC and/or The Government of Canada.

No Protected or Classified information is to be made available to the contractor, used in the production of the contracted product, or produced as a result of this contract.

2.2 Statement of Work

The contractor must perform the work in accordance with the Statement of Work in Appendix A.

2.3 Standard Clauses and Conditions

All clauses and conditions identified in the Contract by number, date and title are set out in the *Standard Acquisition Clauses and Conditions Manual (*https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) issued by Public Works and Government Services Canada.

2.3.1 General Conditions

2010B (2016-04-04) General Conditions – Professional Services (Medium Complexity) apply to and form part of the Contract.

2.3.2 Supplemental General Conditions

4008 01 (2008-05-12) Interpretation
4008 06 (2008-05-12) Safeguarding Personal Information

2.4 Term of Contract

2.4.1 Period of the Contract

The initial period of the Contract is from date of contract award to March 31, 2021 inclusive.

The Contractor hereby grants to Canada the irrevocable option to extend the period of the Contract by up to three (3) additional one (1) year period(s) under the same terms and conditions. The Contractor agrees that, during the extended period of the Contract, it will be paid in accordance with the applicable terms set out in the Basis of Payment.

Canada may exercise this option at any time by sending a written notice to the Contractor 30 days before the end date of the Contract. The option may only be exercised by the Contracting Authority and will be evidenced for administrative purposes only, through an amendment to the Contract.

2.5 Authorities

2.5.1 Contracting Authority

Name: Erin Massey

Title: Senior Procurement and Contracting Officer
Health Canada | Public Health Agency of Canada
Materiel and Assets Management Division
Telephone: 613-941-2094
E-mail address: erin.massey@canada.ca

The Contracting Authority is responsible for the management of the Contract and any changes to the Contract must be authorized in writing by the Contracting Authority. The Contractor must not perform work in excess of or outside the scope of the Contract based on verbal or written requests or instructions from anybody other than the Contracting Authority.

2.5.2 Project Authority and Technical Authority (to be identified at contract award)

The Project Authority for the Contract is:

Name: _____
Title: _____
Organization: _____
Address: _____
Telephone: ___ ____ _____
E-mail address: _____

The Project Authority is the representative of the department or agency for whom the Work is being carried out under the Contract. The Technical Authority is responsible for all matters concerning the technical content of the Work under the Contract. Technical matters may be discussed with the Technical Authority. The Project Authority and the Technical Authority have no authority to authorize changes to the scope of the Work. Changes to the scope of the Work can only be made through a contract amendment issued by the Contracting Authority.

The Technical Authority for the Contract is:

Name: _____
Title: _____
Organization: _____
Address: _____
Telephone: ___ ____ _____
E-mail address: _____

2.5.3 Contractor's Representative (to be identified at contract award)

Name: _____
Title: _____
Organization: _____
Address: _____

Telephone: ___ ____ _____
Facsimile: ___ ___ _____
E-mail address: _____

2.6. Payment

2.6.1 Basis of Payment

In consideration of the Contractor satisfactorily completing all of its obligations under the Contract, the Contractor will be paid a firm price per autopsy as specified in Annex B.

Canada will not pay the Contractor for any design changes, modifications or interpretations of the Work.

2.6.2 Method of Payment –QUARTERLY PAYMENTS

Canada will pay the Contractor on a quarterly basis (April 1-June 30; July 1-September 30; October 1-December 31; January 1-March 31) for work performed during the 3-month period covered by the invoice in accordance with the payment provisions of the Contract if:

a. an accurate and complete invoice and any other documents required by the Contract have been submitted in accordance with the invoicing instructions provided in the Contract;

b. all such documents have been verified by Canada;

c. the Work performed has been accepted by Canada.

The Public Health Agency of Canada has adopted electronic direct deposit as their method for paying invoices. Suppliers are asked to register for electronic direct deposit and to provide their account information upon request. For help with online registration, send an email to: hc.direct.deposit.requests-demande.de.depot.direct.sc@canada.ca.

2.7 Invoicing Instructions

1. The Contractor must submit invoices in accordance with the section entitled "Invoice Submission" of the general conditions. Invoices cannot be submitted until all work identified in the invoice is completed.
2. Each invoice must be supported by:

    a. A listing of the completed autopsies referencing the CJDSS Case Number conducted during the 3-month period covered by the invoice. The invoice must not contain any personally identifiable information. Note: To obtain CJDSS Case Number if missing, please contact the CJDSS team through our toll free number 1-888-489-2999

3. The original invoice must be forwarded to: hc.p2p.east.invoices-factures.est.sc@canada.ca

2.8 Certifications and Additional Information

2.8.1 Compliance

Unless specified otherwise, the continuous compliance with the certifications provided by the Contractor in its bid or precedent to contract award, and the ongoing cooperation in providing additional information are conditions of the Contract and failure to comply will constitute the Contractor in default. Certifications are subject to verification by Canada during the entire period of the Contract.

2.9 Applicable Laws

The Contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario.

Bidders may, at their discretion, substitute the applicable laws of a Canadian province or territory of their choice without affecting the validity of their bid, by deleting the name of the Canadian province or territory specified and inserting the name of the Canadian province or territory of their choice. If no change is made, it acknowledges that the applicable laws specified are acceptable to the Bidders.

2.10 Priority of Documents

If there is a discrepancy between the wording of any documents that appear on the list, the wording of the document that first appears on the list has priority over the wording of any document that subsequently appears on the list.

(a) the Articles of Agreement;
(b) 2010B 2016-04-04 General Conditions – Professional Services (Medium Complexity);
(c) 4008 01 (2008-05-12) Interpretation;
(d) 4008 06 (2008-05-12) Safeguarding Personal Information;
(e) Annex A, Statement of Work;
(f) Annex B, Basis of Payment;
(g) The Contractor's bid dated _____ (to be inserted at contract award).

ANNEX A – STATEMENT OF WORK

1. TITLE

Autopsy services for Creutzfeldt-Jakob Disease

2. SCOPE

2.1. Introduction

Prion diseases are rare, untreatable, lethal degenerative brain disorders of humans and animals. Human prion diseases, known as Creutzfeldt-Jakob disease (CJD), evoke public health concern because of their infectious nature. In keeping with its responsibilities for national surveillance, prevention and control of infectious diseases, the Public Health Agency of Canada (PHAC) operates the Canadian CJD Surveillance System (CJDSS) with a program mandate to identify and diagnose all suspected cases of CJD in Canada, understand their causes, and continuously assess associated risks to public health. Because definitive diagnosis of CJD requires post mortem pathological examination of the brain, the CJDSS requires specialized laboratory services to conduct cranial autopsies, in which brain tissue is retrieved from patients suspected to have CJD and submitted to pathological examination.

2.2. Objectives of the Requirement

The program objectives achieved by the CJDSS through the contracted services are

i) definitive confirmation or exclusion of a diagnosis of CJD
ii) supporting investigations to further characterize confirmed CJD cases
iii) a pathology-based alternative diagnosis when CJD has been excluded

The key deliverable for the Contractor is submission of brain tissue harvested by autopsy from a suspected CJD patient to the CJDSS Neuropathology Reference Laboratory located at the university of Ottawa (“the Reference Laboratory”). The tissue specimens must be accompanied by patient identifiers and supporting information, including clinical case notes and pertinent laboratory reports. The materials and information must meet pre-specified criteria (detailed below) to enable the Reference Laboratory to conduct a full neuropathology examination, reach a definitive diagnosis and initiate supporting investigations, to allow the CJDSS to meet its three objectives as listed above.

2.3. Background and Specific Scope of the Requirement

In comparison with surveillance for other infectious diseases, surveillance for CJD is labour-intensive and must cope with basic technical challenges, particularly those related to disease diagnosis. Clinical and laboratory features of CJD can vary widely among different cases of the same disease subtype, and conversely can overlap with those of other neurological or non-neurological diseases. Various medical criteria such as patient symptoms and history as well as results of supporting investigations including electroencephalography, magnetic resonance imaging, biochemical markers and DNA analysis all help to differentiate CJD from other conditions. However, definitive diagnosis of CJD continues to be based on post-mortem neuropathological examination of the brain to confirm or exclude the presence of pathologic tissue changes characteristic of CJD.

Identification and diagnosis of CJD cases for surveillance purposes, including autopsy and neuropathological examination, requires the CJDSS to closely monitor individual patients over time, in collaboration with physicians involved in their care. Medical investigation of a living patient suspected to have CJD typically proceeds over a period of weeks or months. If after these investigations have been performed CJD remains a possibility at the time of death or impending death, informed consent for autopsy and post-mortem neuropathological examination is requested by the CJDSS from the patient’s legal representative with the assistance of a collaborating health professional. Contracted autopsy services may proceed, with coordination by the CJDSS, only after this consent has been granted.

The CJDSS also arranges for transportation of a deceased suspected CJD patient’s remains to the contracted pathology laboratory for autopsy, then after completion of the procedure from the laboratory to

a funeral facility where the remains are returned to the custody of the patient's family. As arrangement of consent, autopsy and transport are all labour-intensive and time-sensitive, the Contractor is required to work closely with the CJDSS office to ensure that the procedure is completed in a timely, orderly manner consistent with the wishes of the patient's family.

Reliable diagnosis of CJD for surveillance purposes requires a standardized approach as well as availability of specialized laboratory reagents, procedures and facilities. These capacities are provided by the CJDSS Reference Laboratory. The CJDSS therefore requires that the Contractor work in close collaboration with the Reference Laboratory to ensure the neuropathological examination is completed in a timely manner. The key deliverable in each case is submission of appropriate brain tissue samples and accompanying documentation to the Reference Laboratory.

In addition to confirmation or exclusion of CJD, more detailed disease characterization based on additional pathological features is performed for diagnostic, surveillance and public health purposes. To render these additional pathological and biochemical investigations technically feasible, portions of brain tissue are recovered and prepared by the Contractor in both formalin-preserved ("fixed") and fresh-frozen forms. In addition, as the pathological abnormalities in CJD vary regionally in the brain, a thorough examination of the entire brain is required. Specifically, one sagittally divided half of the brain must be frozen and the other half fixed, before submission to the Reference Laboratory.

In light of these specialized requirements, only a small number of healthcare institutions in Canada (one in most provinces) have the necessary resources to perform CJD autopsies, including a qualified neuropathologist, trained technical staff, suitable laboratory facilities and institutional support.

3. REQUIREMENTS

3.1. Tasks, Activities, Deliverables and/or Milestones

The Contractor is required to complete the following tasks, as and when requested by the CJDSS:

Brain removal and preparation

- Following applicable institutional safety guidelines and protocols for autopsy of suspected CJD patients, the Contractor removes the entire brain from the cranium.
- The Contractor ensures one sagittally divided half of the brain is frozen promptly and stored at –85 °C and the other half is fixed in formalin (4% phosphate-buffered formaldehyde).
- If one half of the brain displays gross external abnomality, that half is fixed and the other half is frozen.
- It is imperative that the tissue remain in formalin fixative for a minimum of 2 weeks before submission to the Reference Laboratory.

Shipping of brain tissue

- The harvested tissue is shipped to the Reference Laboratory at the University of Ottawa, for diagnostic examination and storage as per the Tissue Shipping Protocol, Work Instruction #PDP-WI-003-02 (see Addendum 2).
- Both fixed and frozen tissue are shipped to the Reference Laboratory at the same time, and no later than 6 weeks post-autopsy. Fixed and frozen tissues require separate packaging, using dedicated containers provided by the CJDSS *via* the Reference Laboratory. Packaging must be performed to ensure the integrity of the tissues during transport and in compliance

with applicable regulations for public transport of human tissues.

- An individual certified in the Transportation of Dangerous Goods must package and ship the tissues. The CJDSS may require the Contractor to provide a copy of the certification, which will be stored securely on receipt.

- The brain tissue shipment must include copies of all pertinent clinical notes, preliminary autopsy report, and completed CJDSS autopsy consent form.

- The Contractor must ship tissues in such a way that they will arrive at the Reference Laboratory on a regular business day.

- As the Reference Laboratory is located in Ontario, the Contractor must remain aware that statutory holidays in this province may differ than those of their own province.

Reference Laboratory report

- The CJDSS Reference Laboratory will provide a written neuropathology report to the CJDSS. A copy of this report, addressed to the submitting pathologist under whose supervision the tissue removal was performed, will be forwarded to the Contractor by the CJDSS.

3.2. **Specifications and Standards**

The work on one CJDSS case is considered to be complete and invoiceable when both formalin-fixed and frozen brain tissues and copies of pertinent clinical notes, preliminary autopsy report and CJDSS autopsy consent form have been received by the Reference Laboratory in good order, and this receipt has been confirmed by the CJDSS.

3.3. **Technical, Operational and Organizational Environment**

All technical work is carried out under the supervision of the Contractor, in their own institution's facilities. The Contractor will be responsible for management and training of staff, including ensuring occupational safety standards are met and technical and professional certifications are maintained. All procurement and maintainance of equipment used to perform CJD autopsies and store harvested tissues is the responsibility of the Contractor.

Occupational risks can be associated with CJD autopsies, both during the autopsy procedure itself, and during handling of the harvested tissue specimens for preparation, storage and transport. The Contractor is responsible for ensuring that occupational safety requirements are met within their facility.

3.4. Method and Source of Acceptance

The work on one CJDSS case is considered to be complete and invoiceable when both formalin-fixed and frozen brain tissues and copies of pertinent clinical notes, preliminary autopsy report and CJDSS autopsy consent form have been received by the Reference Laboratory, and these materials have been confirmed by the CJDSS to have been received in good order.

3.5. **Reporting Requirements**

It is the responsibility of the Contractor to promptly notify the Technical Authority of any situation that may lead to service interruptions. In such cases the Contractor must submit a written report to the Technical Authority, describing the situation, the status of existing work at the time the report is prepared., and any negative impacts on the timely completion of the work.

4. ADDITIONAL INFORMATION

4.1. Canada's Obligations

Canada will provide to the Contractor:

- access to a staff member who will be available to coordinate activities

- other assistance or support, to provide direction and clarification as required

4.2. Contractor's Obligations
See Sections **3.1**–**3.5**.

4.3. **Location of Work, Work site and Delivery Point**
The work will take place at the Contractor's work site.

5. PROJECT SCHEDULE

5.1. Language of Work
Discussions of the work will be carried out in English or French, as agreed with the CJDSS.

5.2. Travel and Living
No travel or living expenses are required.

6. PROJECT SCHEDULE

6.1. Schedule and Estimated Level of Effort

The work is performed on a case-by-case basis, as and when required for the CJDSS.

7. APPLICABLE DOCUMENTS AND GLOSSARY

7.1. Applicable Documents

- Work Instruction # PDP-WI-003-3;
- Submission of Tissue Samples to the Canadian Creutzfeldt-Jakob Disease Surveillance System
- Best practices for the performance of a CJD autopsy

7.2. Relevant Terms, Acronyms and Glossaries

CJD: Creutzfeldt-Jakob disease
PHAC: Public Health Agency of Canada
CJDSS: Canadian CJD Surveillance System

ANNEX B – BASIS OF PAYMENT

1.1. Canada will pay the Contractor for the satisfactory performance of the agreed to services an all-inclusive firm price per autopsy as detailed below, to a limitation of expenditure of *$*_____ inclusive of all expenses, customs and duties. Applicable taxes are extra.

	Contract Award-March 31, 2020	April 1, 2020-March 31, 2021	Option Year 1	Option Year 2	Option Year 3
Firm Price Per Autopsy	$	$	$	$	$

1.2. All prices and amounts of money in the Contract are exclusive of the Goods and Services Tax (GST) or Harmonized Sales Tax (HST), whichever is applicable, unless otherwise indicated. GST or HST, to the extent applicable, will be incorporated into all invoices and progress claims for goods supplied or work performed and will be paid by Canada. The Contractor agrees to remit to Canada Revenue Agency any GST or HST paid or due.

1.3. No increase in the total liability of Canada or in the price of Work resulting from any design changes, modifications or interpretations of specifications made by the Contractor will be authorized or paid to the Contractor unless such changes, modifications or interpretations have been approved in writing by the Contracting Authority prior to their incorporation into the Work. The Contractor is not obliged to perform any Work or provide any service that would cause the total liability of Canada to be exceeded without the prior written approval of the Contracting Authority. The Contractor will notify the Project Authority in writing as to the adequacy of this sum:

a. when it is seventy five percent (75%) committed, or
b. four (4) months prior to the Contract expiry date, or
c. if the Contractor considers the funds provided to be inadequate for the completion of the Work, whichever comes first.

In the event that the notification refers to inadequate funds, the Contractor will provide to the Project Authority, in writing, an estimate for the additional funds required. Provision of such notification and estimate for the additional fund does not increase the liability of Canada.