



**Request for Proposal
for
Protocol for Planned Case-Control Study**

Proposal Deadline: August 22, 2025

Public Health Foundation Enterprises, Inc. dba
Heluna Health
On behalf of
California Dept of Health – Infant Botulism Treatment and Prevention Program
(CDPH-IBTPP)

HELUNA HEALTH
13300 Crossroads Parkway, North Suite 450
City of Industry, CA 91746
www.HelunaHealth.org



Request for Proposal – Protocol for Planned Case-Control Study

KEY DATES SCHEDULE

ISSUANCE OF RFP:.....August 8, 2025

CONSULTANT QUESTIONS ON RFPAugust 15, 2025 by 5:00 PM PST

PROPOSAL SUBMITTAL DEADLINEAugust 22, 2025 by 8:00 PM PST

FINAL SELECTION BY:.....August 29, 2025

DELIVERY LOCATION of Proposal:

Electronic Submissions Only Including Application Narrative and Budget

Send to: Breanna Tillman Email: BTillman@helunahealth.org

Subject Line: Company/Person Name - RFP for Protocol for Planned Case-Control Study

ANTICIPATED TERM OF SERVICE/AFTER-ACTION PROJECT:

Upon execution of contract to December 31, 2025

NOTICE: ALL QUESTIONS RELATED TO THIS RFP ARE TO BE DIRECTED TO Breanna Tillman via E-MAIL at BTillman@helunahealth.org----- no later than August 15, 2025 by 5:00 PM PST. Questions will only be accepted via email. NO PHONE CALLS PLEASE

Once the Contractor's application has been reviewed and approved, HELUNA HEALTH will draft and send a contract encompassing required activities and approved funding.

Additional documents may be required to establish the contractual agreement.



Introduction and Background:

Background:

Infant botulism is a rare but life-threatening illness that was first recognized in the 1970s in California, yet the causes remain poorly understood. Because infant botulism is extremely rare, a case-control study is the only feasible study design for identifying potential risk factors for the disease. While ideal for studying rare diseases, case-control study designs are subject to selection bias when the population at risk is dynamic and ill-defined, making the selection of controls particularly challenging. Appropriate controls in a case-control study should represent the same population from which the cases arose, i.e., if they were to become a case they should be identified as a case in the study. Caution is required to avoid over-matching cases and controls which could result in inadvertently matching an important risk factor for the disease.

Purpose, Goals and Objectives:

Purpose:

The purpose of this solicitation is for HELUNA HEALTH, on behalf of the CDPH-IBTPP, to solicit proposals from qualified contractors to award a contract for design of a case-control study protocol.

Goals and Objectives:

To design the protocol for a case-control study of infant botulism, with specific attention to: overall study design, selection of cases and controls (defining inclusion and exclusion criteria and sampling approach), mechanism of recruitment and enrollment of controls, variables and mechanisms of collection of participant data, and statistical analysis.

Scope of Work and Budget:

Service Overview:

The contractor agrees to provide HELUNA HEALTH/CDPH-IBTPP the services described herein.

This project will be conducted during the period, from date of contract execution through December 31, 2025.

Services to be Performed:

Writing the following sections of the protocol for the case-control study:



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1. Study design, Selection of cases and controls (defining inclusion and exclusion criteria and sampling approach)
2. Mechanism of recruitment/enrollment of controls
3. Variables and mechanism(s) of collection of participant data
4. Statistical analysis

Note: Sections of the protocol related to laboratory testing will be written by others (laboratory scientists)

Therefore, the contractor will:

Phase 1: The contractor shall complete and deliver the following section of the study protocol: Study design, Selection of cases and controls (defining inclusion and exclusion criteria and sampling approach)

Phase 2: The contractor shall complete and deliver the following section of the study protocol: Mechanism of recruitment/enrollment of controls

Phase 3: The contractor shall complete and delivery the following section of the study protocol: Variables and mechanism(s) of collection of participant data

Phase 4: The contractor shall complete and deliver the following section of the study protocol: Statistical analysis

Service Location:

The services rendered will be performed offsite.

Service Hours:

The services shall be provided during normal working hours, 8:00 a.m. to 5:00 p.m., Monday through Friday unless agreed upon by Heluna Health/CDPH-IBTPP and contractor.

Budget:

HELUNA HEALTH anticipates entering into an hourly/deliverable-based contract with the selected contractor. The budget amount for the period of the contract term is not to exceed an all-inclusive amount of **\$45,000**.

Reporting:

Progress Reports:

Contractor must submit progress reports and meet with the client staff on a weekly basis and as requested. The weekly reports shall detail the work performed and the goals accomplished. The report shall clearly identify completed tasks and provide information related to weekly activities. The client project manager may request that additional details be included in the report.



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Estimated Timeline

Activity	Estimated Timeline
Release of RFP	August 8, 2025
Contractor questions on RFP	August 15, 2025 by 5:00 PM PST
Proposals due from contractor	August 22, 2025 by 8 PM PST
Award to selected contractor	August 29, 2025
Contract executed	September 5, 2025
Kick off meeting with CDPH and contractor	September 15, 2025
Phase 1: Contractor provides draft plan	September 22, 2025
Phase 2: Contractor finalizes and implements plan	October 26, 2025

Proposal Requirements-Instructions:

All proposers must provide the following as part of their proposal:

- (1) **Title Page/Cover Letter or Curriculum Vitae:** Include your or your company's name, address, web site, telephone number, and primary contact person with e-mail, direct line and mobile phone numbers. The title page will be considered a cover letter, and should be signed by you OR an agent, owner or authorized officer of your company. **Maximum of 1 page in length.**
- (2) **Statement of Qualifications/Sample Work on Similar Projects:** All responses must include a statement of qualifications, experience and description of the respondent individual or firm and your/its history. The response should specifically indicate you or your firm's current and historical expertise in providing services identified in this RFP. **Maximum of 2 pages in length.**
- (3) **Technical Solution:** The Respondent shall demonstrate and describe the firm's or group's ability to accomplish the project, based on the requirements in the Statement of Work. Our ability to interpret and evaluate your ability to perform the project will factor into our decisions. The information must be stated in the budget, including justification and qualifications. **Maximum of 2 pages in length.**
- (4) **Past Performance/References or Summary:** All responses must include references from at least 3 clients, preferably clients who have utilized the contractor within the last three years. **Maximum of 2 pages in length.**
- (5) **Billing Rates and Structure:** HELUNA HEALTH anticipates entering into an Hourly/Deliverables-Based contract with selected firm or group not to exceed an all-inclusive amount of \$45,000. **Maximum of 2 pages in length**



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(6) Documents to include with application:

- Completed and signed W9 <https://www.irs.gov/pub/irs-pdf/fw9.pdf>
- Proof of General Liability Insurance Certificate

Contractor Questions on RFP

Contractor questions about the RFP must be submitted to Heluna Health no later than **August 15, 2025 by 5:00 PM PST**. Questions will only be accepted via email and should be submitted to Breanna Tillman at BTillman@helunahealth.org.