

PROCUREMENT SERVICES

PERSONAL SERVICES CONTRACT (PSC) REQUEST FOR PROPOSAL (RFP)

REQUEST DATE:	March 5, 2025
DUE DATE & TIME:	March 21, 2025 at 2:00 PM EST
SPEED TYPE:	OGMB240095
DEPARTMENT NAME:	Anatomical Sciences and Neurobiology
DEPARTMENT CONTACT:	Denise Hand (denise.hand@louisville.edu)
CONTRACT ADMINISTRATOR:	Lauren Wieners
CONTRACT ADMINISTRATOR EMAIL:	Lauren.Wieners @louisville.edu

SERVICE REQUESTED (brief description)	Device regulatory consultant services.
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EMAIL PROPOSALS TO:

UNIVERSITY OF LOUISVILLE
ATTN: PROCUREMENT SERVICES, SERVICE COMPLEX BUILDING
LOUISVILLE, KY 40292

CONTRACT ADMINISTRATOR NAME: Lauren Wieners

EMAIL : lauren.wieners@louisville.edu

THE BOTTOM PORTION OF THIS FORM IS TO BE COMPLETED BY THE VENDOR AND SUBMITTED WITH PROPOSAL

Equal Employment Opportunity – All parties must be in compliance with executive order 11246 of September 24, 1965 as amended by executive order 11375 of October 13, 1967.

STATEMENT OF NON-COLLUSION AND NON-CONFLICT OF INTEREST

I hereby swear (or affirm) under penalty for false swearing as provided by [KRS 523.040](#):

- That attached Request for Proposal has been submitted without collusion with, and without any agreement, understanding or planned common course of action with, any other vendor of materials, supplies, equipment or services described in the Request For Proposal designed to limit independent competition.
- That the proposer is legally entitled to enter into the contract with the University of Louisville, an agency of the Commonwealth of Kentucky, and is not in violation of any prohibited conflict of interest, including those prohibited by the provisions of [KRS 45A.325](#), to [45A.340](#), [45A.990](#), [164.990](#), and [164.821](#) (7).
- That I have fully informed myself regarding the accuracy of the statements made above.

SIGNATURE:		PRINT NAME	
FIRM NAME:		ADDRESS:	
PHONE:		CITY, STATE, ZIP CODE:	
EMAIL:		WEBSITE:	

REQUEST FOR PROPOSAL COMPONENTS

1. SCOPE OF SERVICES:

This RFP is seeking regulatory consultant services. Services will be to assist a principle investigator with understanding the necessary steps for obtaining FDA approval or clearance for a medical device that is being developed to provide non-invasive neuromodulatory stimulation. Additional services will be advising on best-actions for the device development process from the regulatory perspective. The consultant will also provide letters of support to accompany grant applications and will prepare FDA filings as appropriate. The consultant will also assist with preparing IRB documents as appropriate.

2. INFORMATIONAL BACKGROUND:

Services will be provided for the University of Louisville Department of Anatomical Sciences and Neurobiology and the Kentucky Spinal Cord Injury Research Center. Requested services are required because a research grant has been awarded to conduct research that will support development of a novel neuromodulatory device. Advice and guidance from a regulatory consultant are required to best meet the goals of that research grant and receive others.

Necessary characteristics include:

- Thorough understanding of the regulatory approval and clearance process for MedTech devices
- Significant experience educating basic science researchers in the regulatory aspects of the device development process
- Significant experience working with MedTech startup companies
- Significant experience working with neuromodulatory devices and systems (invasive, implanted, non-invasive, etc.)
- Significant experience guiding companies and/or researchers with how to merge their needs for developing intellectual property with the regulatory process
- Pricing that is attractive and feasible for grant-funded academic research
- Highly flexible schedule and ability to be highly-responsive to contractor needs and timelines

3. REQUIRED PROPOSAL SUBMITTALS:

a. Proposed Cost:

- i. Fee – detailed fee that includes all costs (potential examples include, but are not limited to, below)
 1. (Hourly rate) x (hours worked)
- ii. Travel Expenses – how will this be approved, invoiced, etc. (provide a maximum allowed amount)
NOT ALLOWED
- iii. Other Expenses – administrative expenses, materials/supplies, postage (provide a maximum allowed amount)
NOT ALLOWED
- iv. Expenses associated with governmental fees for FDA filings are to be pre-approved by the contract administrator. The consultant is not under obligation to file if the university does not agree to pay the necessary charges. In such a case, the consultant is still entitled to invoice for consultant services requested and provided. (I.e., the consultant is not supposed to file without approval of the university. If they do so without approval, and incur filing fees, the contractor is not obliged to pay the fees, but is still obliged to pay for the services the consultant provided and that the contractor requested)

- b. Milestones are not required at this stage, but commitment to availability and responsiveness within the contract is required. Service provider must be willing and able to provide product within 2 weeks of a formal request for discrete services.
- c. Demonstrate experience and expertise with submission of resume(s) of service providers past work

4. METHOD OF AWARD:

Cost:	50%
Experience:	45%
Timeframe:	5%
TOTAL	100%

5. DESIRED CONTRACT PERIOD:

Desired contract start and end dates are March 2025 through January 2027.

NO SERVICES ARE TO BE PROVIDED PRIOR TO THE START DATE INDICATED ON THE FULLY EXECUTED PSC (sample provided).

6. QUESTIONS:

All questions regarding this RFP are due by **March 11, 2025, at 12:00 PM** Eastern Standard Time and are to be emailed to Lauren Wieners at Lauren.Wieners@louisville.edu. Answers to all questions submitted in writing before the deadline above will be issued as an addendum to this solicitation and posted at [University of Louisville Active Bids and RFPs](#).

7. COMMUNICATION: All communication with the University regarding this solicitation shall ONLY be directed to the Contract Administrator indicated on the first page of the solicitation. **Failure to do so may result in disqualification of submitted proposal.**