

An open letter to interested candidates for the LBDA Research Center of Excellence (RCOE) Grant Award

From: Michael Koehler, CEO, Lewy Body Dementia Association
Brad Boeve, MD, LBDA RCOE Coordinating Center, Mayo Clinic

Date: August 4, 2017

Lewy body dementia (LBD) research is entering an unprecedented period of opportunity and growth, due to historic increases in federal funding for dementia research and expanding interest from industry in both LBD biomarkers and therapies. The Lewy Body Dementia Association is launching a new research program to harness opportunities like these to more rapidly advance clinical trials and the availability of safer, more effective therapies for those living with LBD.

We are building a collaborative, clinical trial-ready network of centers who can deliver outstanding clinical care to the LBD community across the United States. LBDA will devote considerable effort promoting the RCOE program and its centers to the LBD community as resources for expert clinical care. This will establish an ongoing resource of well-categorized subjects for rapid enrollment into clinical trials.

This RFA is the first step, intended to establish the network of centers and start collaborative discussions. With this request for applications, we are confident the RCOE program will serve as a foundation for future LBDA research initiatives and will attract more robust financial support from both industry and LBDA supporters. In the meantime, this award serves as token remuneration for your work in submitting the RFA and will be, we hope, the first of larger funding opportunities to come.

The Lewy Body Dementia Association, by working with all stakeholders in the research community, believes the more we work together the sooner we can make significant progress in alleviating the burdens of this terrible disease. Your grant application will add to the considerable 'sweat equity' LBDA and our Scientific Advisory Council is investing to get the RCOE program off the ground.

It is LBDA's intention that the RCOE award fosters an ongoing relationship for the benefit of all parties involved. To that end, **LBDA's Mike Koehler is eager to answer any questions you may have, prior to investing your valuable time and energy on a grant application.** You can contact him by email at mkoehler@lbda.org or by phone at (215) 822-3622.

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Request for Proposals

2017 LBDA Research Centers of Excellence (RCOE) Award

Objective: This award will form a collaboration between the Lewy Body Dementia Association (LBDA) and up to 16 academic research centers to establish the LBD Research Centers of Excellence Program. The over-arching objective is to increase access to LBD clinical care expertise and create a clinical trials-ready network of nationally-recognized research centers for trials in the Lewy body dementias (LBD)

The aims of the program are to:

- Increase access to high quality clinical care over the course of LBD
- Establish a clinical trials-ready network Increase access to support for people living with LBD and their caregivers
- Increase knowledge of LBD among medical and allied (or other) professionals
- Create infrastructure and resources to advance LBD research

Background: National research priorities for LBD, which includes dementia with Lewy bodies and Parkinson's disease dementia, were first developed in 2013 at the Alzheimer's Disease-Related Dementias (ADRD) Summit organized by the National Institutes of Health (NIH). Updated in 2016, the top priority for LBD research remains unchanged: to initiate clinical trials of new and existing therapies to address symptoms that have the greatest impact on patient function and caregiver burden in LBD.

With historic increases in federal funding for dementia research, major new investments are being made to identify LBD biomarkers. In parallel, the biotech industry is increasingly investing in the LBD market. As a result, a more robust research infrastructure is needed to facilitate nationwide clinical trials in both biomarkers and new/existing therapies.

Large scale studies require a standardized approach to patients with LBD across multiple centers of expertise and centralized and standardized data collection. LBDA's RCOE program will establish this essential foundation. The RCOE program also will act as a signpost for LBD families seeking expert clinical care, resulting in a ready set group of LBD patients across the country for rapid recruitment into therapeutic trials.

Description: This is a collaborative initiative between LBDA and 16 academic centers, one of which will serve as the RCOE Coordinating Center (see below). LBDA will promote RCOE sites nationally to the general public as academic centers with a reputation for excellence in LBD clinical care and research.

The RCOE program will function as a clinical trials-ready network. Ultimately, RCOE sites will collaborate to develop a standardized protocol and identify a centralized clinical data repository. At a later time, LBDA will issue additional awards to the centers to begin implementing the standardized protocol.

In collaboration with the Coordinating Center and the RCOE's scientific oversight and management infrastructure, LBDA will represent the RCOE sites (in part or as a whole) to industry as a network ready to conduct industry-sponsored clinical trials. LBDA will not represent any center individually.

Administrative functions to be performed by LBDA for industry-sponsored clinical trials include contract negotiation, contract signing, accounting, and legal matters. Each center will have the opportunity to decline participation in any research project due to conflicts or compliance issues prior to final RCOE commitments and signoff.

RCOE Coordinating Center: LBDA has awarded the RCOE Coordinating Center grant to Bradley F. Boeve, M.D., Mayo Clinic College of Medicine in Rochester, MN.

Mechanism of Support: Up to 15 additional centers will receive initial funding for the RCOE designation of \$4,500 total cost per year (including up to a 50% indirect rate). This award is renewable annually, pending submission and review of an annual report.

Additional Mechanisms of Support: LBDA will provide travel support to primary investigators to participate in an annual RCOE meeting. Additional funding for the RCOE program will be generated by a) successful negotiations for industry-sponsored clinical trials and b) the establishment of an Industry Advisory Council.

Eligibility Requirements: Applications may be submitted only by U.S.-based, nonprofit, academic institutions. All RCOE sites must meet the following minimum criteria:

- Primary investigator with demonstrated expertise in LBD diagnosis and clinical care
- Experience with and capacity for clinical trials
- Collaborative interaction with a local (new or existing) LBD-specific support group
- Demonstrated commitment to providing a minimum of LBD continuing medical education and continuing education for their health system medical staff and other health service providers. (i.e., 1 or 2 Grand Round sessions or 1 or 2 Lunch and Learn sessions, per year).

Center Responsibilities: At the outset responsibilities for each RCOE Center include:

- Participation in the LBDA RCOE-wide clinical research initiatives
- Utilize the institution's marketing/communications capabilities to support the RCOE program.
- Collaboration with LBDA on all centralization efforts for development, administration, marketing/communications, compliance, and legal activities
- Timely reporting on all RCOE activities and research projects as requested
- Participation in annual strategic planning meeting. The first planning meeting will take place on **December 14th, 2017 in New Orleans, LA.**

Renewal and Termination: The annual award is renewable upon submission and review of the annual report by the LBDA. Successful recruitment of study participants for RCOE-contracted clinical trials will be a point of consideration for renewals.

Should the primary investigator leave their institution during the Award year, the LBDA RCOE Award will be terminated immediately and both involved parties (investigator and institution) would need to reapply for the award.

Should the award not be renewed or terminated, any supplemental grant contractual obligations for which the LBDA RCOE is engaged must be completed by the institution thru the completion of the contract period regardless of timeframe.

Application Scoring and Review Process: LBDA will engage members of its Scientific Advisory Council and external LBD experts to perform a scientific review of the RCOE application. The final selection of all RCOE sites will include several factors, such as proposal score and geographic diversity.

Applications will be scored on the following criteria:

1. Demonstrated clinical expertise in LBD
 - a. Description of facilities, patient numbers (LBD and related disorders), staffing
 - b. Additional support services for patients and caregivers
 - c. Capacity for diagnostic testing including neuropsychological assessment, neuroimaging, and biomarker collection
2. Capacity and experience in clinical trials in LBD, dementia, and related disorders
 - a. Description of clinical trial experience
 - b. Capacity for clinical trial procedures including neuropsychological assessment, neuroimaging, and biomarker collection.
 - c. Capacity for clinical trial data management
3. Demonstrated commitment to professional and community education and family/caregiver support
 - a. Professional and lay public educational programs
 - b. LBD support group
4. Infrastructure for support of LBDA RCOE

- a. Administrative staffing
 - b. Designated administrator for administration of grant and support for annual reporting
5. Research expertise in LBD
- a. Publications on LBD and related disorders
 - b. Grant support
 - i. NIH, Foundation, Industry, philanthropy
 - c. Other related activities

Application Inquiries

All candidates are encouraged to contact Mike Koehler directly with any questions about the RFA, the role of the Center primary investigator and the application procedure.

Mike Koehler

Chief Executive Officer

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Application Timeline

- Letter of Intent requested by **August 18th, 2017**
- Application deadline: **September 5, 2017**, 11:59 p.m. Eastern
- Scientific review: September, 2017
- Announcement of RCOE Sites: October, 2017
- First annual RCOE strategic planning meeting **December 14th, 2017 in New Orleans, LA.**

Application Procedure:

A one-page Letter of Intent (LOI) is requested by **August 18th, 2017**. ([Click here](#) to download the suggested LOI.) Email the LOI to Dr. Bethany Peterson, PhD, bpeterson@lbda.org. Receipt of LOIs will be acknowledged via email by LBDA.

The RCOE grant application is due by **September 5, 2017**, 11:59 p.m. Eastern. Download the RCOE grant application and email a completed, signed copy to Dr. Bethany Peterson, PhD, bpeterson@lbda.org. Receipt of applications will be acknowledged via email by LBDA.