



Clinical Research in ALS and Related Disorders for Therapeutic Development (CReATe)

Biomarker Development/Validation: 2017 Request for Applications

The CReATe Consortium, an NIH-funded Rare Diseases Clinical Research Consortium (RDCRC), in partnership with the ALS Association, is pleased to announce this request for applications (RFA) to support the discovery and/or validation of biomarkers that are relevant to the development of therapies for patients with ALS or a related disorder (including primary lateral sclerosis [PLS], hereditary spastic paraplegia [HSP], progressive muscular atrophy [PMA], multisystem proteinopathy [MSP], and frontotemporal dementia [FTD]). Proposals to develop either wet (e.g. biological-fluid based) or dry (e.g. neuroimaging, neurophysiological) biomarkers are encouraged. Investigators submitting an application in response to this RFA may also request to use the data and/or biological samples collected by the CReATe Consortium.

Letter of Intent:

A letter of intent is required and should take the form of a single “specific aims” page that includes the title of the proposal and up to 5 key words that best characterize the nature of the proposal.

Full Application Materials:

Applications that are invited for full submission should include:

1. Title of the application
2. A 4-page application in which the first page describes the specific aims of the proposal. The application should address the significance, innovation, scientific approach, and aspects of the scientific environment that are relevant to the successful completion of the proposed work.
3. A 4-page NIH-style biosketch for the principal investigator.
4. A budget and brief budget justification.
5. Letters of support, if relevant, demonstrating the availability of required biological samples or access to the relevant clinical data.

Applications should be submitted via email to ProjectCReATe@med.miami.edu as an assembled PDF.

Biological Samples:

Investigators are encouraged (but not required) to utilize existing sample collections, such as those housed at the CReATe Biorepository (rarediseasesnetwork.org/cms/create/researchers/biorepository), Coriell Biorepository (coriell.org), or NEALS Biorepository (alsconsortium.org/for-als-researchers/neals-sample-repository/).

**Eligibility:**

Any individual with the requisite scientific training, irrespective of country of residence or origin, may submit an application in response to this RFA.

Budget:

- A maximum of \$60,000 in total costs, including both direct and indirect costs (IDCs), for a maximum period of one year, may be requested.
 - For applications funded by the ALS Association, IDCs will be limited to 10% (which must similarly be included within the \$60,000 total cost requested)

Review Criteria:

- Significance. Does the study aim to develop or validate a biomarker that is relevant to therapy development for ALS, PLS, HSP, PMA, MSP and/or FTD?
- Innovation. For discovery projects, are the aims original? For validation projects, will the proposed work advance the field in a meaningful way?
- Approach. Are the scientific methods sound? Is the study design appropriate for the intended purpose/application of the proposed biomarker?
- Investigator and environment. Is the investigator appropriately trained and well suited to carry out the proposed work? Is the institutional environment appropriately supportive of the proposed work?
- Budget. Is the budget reasonable and proportionate with respect to the proposed work?

Reporting Requirements:

Successful applicants agree to:

- Submit a protocol to the RDCRN for NIH approval if the project entails prospective enrollment of human subjects
- Present their work at an annual CReATe consortium meeting
- Appropriately acknowledge funding in presentations/publications
- Submit a final report at the end of the funding period
- Provide ad hoc and annual updates to the CReATe consortium on the progress of the work funded through this RFA.

Timeline:

RFA release: March 6, 2017

Letter of intent due: April 7, 2017

Invitation to submit full application: May 5, 2017

Full application due: June 2, 2017

Notification of award: June 28, 2017

Earliest start date of award period: July 1, 2017