





<u>Clinical Re</u>search in <u>A</u>LS and Related Disorders for <u>The</u>rapeutic Development (CReATe)

Biomarker Development/Validation: 2021 Request for Applications

The CReATe Consortium, an NIH-funded Rare Diseases Clinical Research Consortium, in partnership with the ALS Association, is pleased to announce this request for applications (RFA) to support the discovery and/or validation of biomarkers for 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]). Priority will be given to those projects that are focused on developing biomarkers of disease mechanism and that might be relevant to the development of therapies. Proposals to develop either wet (e.g. biofluid 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.

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 total costs, for a period of one year, may be requested.
- The \$60,000 limit is inclusive of indirect costs that are capped at 10%.

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: April 6, 2021

Letter of intent due: May 7, 2021

Invitation to submit full application: June 4, 2021

Full application due: July 30, 2021 Notification of award: August 30, 2021

Earliest start date of award period: September 1, 2021