

## **RFA-HL-20-030:Regenerative Medicine Innovation Project (RMIP) Investigator-Initiated Clinical Trials (UG3/UH3 - Clinical Trial Required)**

Letter of Intent: September 18, 2019

Application: October 18, 2019

Maximum total project period: 5 years

### **Description:**

The National Institutes of Health (NIH) participating Institutes and Centers, in coordination with the U.S. Food and Drug Administration (FDA), seek highly meritorious clinical trial applications proposing to explore and enable the development of safe and effective regenerative medicine (RM) interventions using adult stem cells.

Of particular interest are projects using RM products that have undergone appropriate product development and pre-clinical studies and have demonstrated readiness to advance into clinical trials. This FOA seeks Phase I and beyond clinical trial applications that present a strong scientific rationale for the proposed clinical trial and a comprehensive scientific and operational plan.

Before the time of award and if applicable, successful applicants must obtain an Investigational New Drug (IND) authorization or Investigational New Device Exemption (IDE) approval to administer the product to humans.

Due to the complex nature of requirements in this FOA (e.g., 1:1 matching funds, resource sharing), applicants are strongly encouraged to communicate with the appropriate NIH Scientific/Research Contact and review online Frequently Asked Questions (FAQs) prior to submitting an application. Staff will be able to advise applicants in determining if their research meets the requirements and objectives of this FOA.

### **Scientific/research contact for NIDCD:**

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