LIMITED SUBMISSION: National Institutes of Health – Botanical Dietary Supplements Research Centers (BDSRC) (U19 Clinical Trial Optional)

****PLEASE NOTE: ONE (1) PROPOSAL FROM TUFTS MAY BE NOMINATED****

DEADLINES:
Tufts Internal Email of Intent Deadline: February 26th by noon
Sponsor Deadline: April 15, 2019

For those interested, please send an email of intent to the Limited Submissions Team at limitedsubmissions@tufts.edu informing us of an intention to apply. EOI’s received after the deadline will not be considered. The email of intent must include:

1. The name of the solicitation,
2. The name of the Principal Investigator, and any co-PI's,
3. A 2-3 sentence description of the proposed project.

Should the number of interested applicants exceed the number allowed by the funder, an internal selection process will be conducted by the Office of the Vice Provost for Research, and candidates will be notified to submit internal application materials. All candidates will be notified of results. NB: Successful applications must include official notification from the Limited Submissions Team in order to submit. For more information, please see http://viceprovost.tufts.edu/resources/funding/limited-submissions/

PROGRAM PURPOSE:
• This Botanical Dietary Supplements Research Centers (BDSRC) will support transdisciplinary collaborations focused on producing critical data to inform the optimal design of future clinical trials of orally consumed, complex botanical dietary supplements for which there are rigorous but not definitive preliminary data.

PROGRAM REQUIREMENTS:
• The preliminary data provided by responsive applications must support a reproducible, physiologically and mechanistically plausible, and statistically and clinically significant effect on, or relevant to, human biological or cognitive/behavioral, objectively measured resilience.
• Applications in which a purified phytochemical is the main focus will be considered nonresponsive.
• Each BDSRC will be required to include a Botanical Research Core and two research projects that all synergize with each other, and will, separately and together, provide information that will fill in the most critical gaps in the existing body of data relevant to the optimal design of a future clinical trial of the effects on human resilience of orally consumed, complex botanical products.
• A body of rigorous and compelling evidence must be presented which is consistent over a range of research approaches and/or distinct preclinical and/or clinical models, that supports the likelihood of seeing the hypothesized effect in humans, indicates the proposed intervention(s) are unlikely to expose trial participants to inappropriate risks, and is sufficient to inform and justify design of the trial protocol, such that if the completed trial fails to provide evidence of the hypothesized effect, it is difficult to blame that failure on those design decisions.
• Please see RFA at link below for details on botanicals of interest and excluded research areas

ELIGIBILITY: No agency restrictions; please follow Tufts PI eligibility policies

AWARD INFORMATION: Budgets are limited to $1.2 million annually for a period of up to five years


NOTE: Program announcement instructions supersede instructions delivered in this document.