

Advancing Research to Optimize Medication Use Among Older Adults Investigator Initiated Proposal Guidelines (USDeN IIP 2020)

The U.S. Deprescribing Research Network is a collaborative research network with the overall goal to support development of investigators studying deprescribing for older adults and to catalyze a range of high-quality, clinically impactful research in this area. The challenges of excessive medication use, medication-related harms, and values-driven decision-making are especially pressing for older adults, particularly those with multiple chronic conditions. Solutions to these challenges require attention to geriatric principles, including (but not limited to) clinical complexity and multimorbidity, transitions across multiple providers and sites of care, older adults' values and priorities, and the shifting balance of medication benefits and harms in late life. Our overarching aim is to expand the quality, quantity, and translational impact of deprescribing research. Pilot grants up to \$60,000 in total costs (direct plus indirect funds) for a one-year period will be awarded to applicants seeking to further research efforts in this field as detailed in the following sections.

- 1) Background: Deprescribing is an essential component of safe and effective health care for older adults. Even with the most intensive efforts, it is difficult to prevent older adults from being started on medications that may cause more harm than benefit. In addition, medications that were once helpful for older adults may no longer be advisable to continue, either because the person has developed adverse effects, or because their clinical conditions, overall health, and/or goals of care may have changed since the medication was first prescribed.
- 2) Research Objectives: This funding opportunity is for studies designed to expand the quality, quantity, and translational impact of deprescribing research targeting older adults. Funding will be provided primarily, but not exclusively, to junior investigators whose studies provide key preliminary data, proof of concept, or developmental work that provides a clear pathway to future, larger-scale studies.
- 3) Population of interest: The study must focus on deprescribing efforts impacting older adults and may include an emphasis on patients with multiple chronic conditions, including those with special vulnerabilities, such as dementia.
- 4) Research Methodology: Research is needed in a broad range of areas which include, but are not limited to, delineating the clinical outcomes of deprescribing, identifying behavioral and communication techniques that can constructively engage patients on this topic, determining the effectiveness of deprescribing interventions, and addressing the needs of underserved groups. Different study designs are needed to answer these questions from pilot research that may lead to future clinical trials, to observational studies, to in-depth qualitative evaluation.
- 5) Funds available: Maximum period of performance is one year. The anticipated total award (directs + indirects) for this grant opportunity is a maximum of \$60,000. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. The combined budgeted total costs will not exceed \$60,000 or use an indirect cost rate exceeding each organization's negotiated rate. The possibility of funding exceeding \$60,000 or a period greater than one year may be considered with special permission; initiate such a request as early as possible through an email to admin@deprescribingresearch.org

(further instructions will follow). Only those with prior approval may submit a budget greater than \$60,000 or request a period greater than one year. Within these guidelines, please request the amount needed to perform the proposed pilot study. More than one application is permitted from the same institution but not from the same individual(s).

6) Application and Submission Information:

- a) Letters of Intent (LOIs): LOIs are optional but strongly encouraged especially when, in special circumstances, requesting greater than the budget cap specified above or more than one year of funding.
 - i) Formatting: 1 page in length, ½" margins, 11-point Arial font
 - ii) Include members of the proposed research team (including who will serve as PI), and a brief synopsis of your planned engagement of stakeholders, research aims, and approach. It is fine if these elements change between the LOI and the final proposal.
 - iii) If you require specific guidance from USDeN core members about the appropriateness of your project for this funding mechanism, how to engage stakeholders, or other topics, please contact us at admin@deprescribingresearch.org and also state any outstanding queries within your LOI.
 - iv) LOI due date is **February 10, 2020,11:59 PM (PST)**. Send to: admin@deprescribingresearch.org

b) Proposals:

- i) Formatting: A maximum of five pages (including the cover page) in length, ½" margins, 11-point Arial font
- ii) Cover page (one page)
 - (1) Project title
 - (2) Principal investigator(s)' Name and Title
 - (3) Organization/Institution Name
 - (4) Institution Address (including zip +4), phone and email
 - (5) DUNS number
 - (6) Congressional district
 - (7) Total Requested amount (directs + indirects)
 - (8) Names, titles, and institutions of mentor(s), collaborator(s)/co-investigator(s), and/or consultant(s) on the project
- iii) Must include the following sections:
 - (1) Study aims: Describe the aims and objectives that will determine the scope, depth and overall direction of the study.
 - (2) Significance: Describe the importance of the problem to be addressed, relevance to deprescribing in older adults, and description of the population and/or community to be served.
 - (3) Innovation: Explain how the application addresses important gaps in knowledge or challenges and/or seeks to shift current shortcomings in deprescribing as an essential component of safe and effective health care for older adults including any novel concepts, approaches or methodologies or intervention(s) to be developed. Innovative approaches for community/stakeholder engagement should also be highlighted in this section if applicable, with more specific details provided in the stakeholder engagement section.
 - (4) Approach: Describe the overall strategy, methodology, and planned analyses. If appropriate, include feasibility, preliminary studies, potential problems, and alternative strategies.
 - (5) Future Aims: Describe how this work will lead to publications, future grants and investigator's career advancement.

- (6) Stakeholder Engagement: Participation from at least one stakeholder, either in an advisory capacity or as a full member of the research team, is required. Below are some expectations and guidance on engaging stakeholders, recognizing that different projects will benefit from different types of involvement and the extent of that involvement. Stakeholders may include patients, caregivers, front-line clinical providers, health systems administrators and leaders, or others depending on the focus of the project. Questions about stakeholder engagement will be addressed during the webinar for this RFA (see https://deprescribingresearch.org for how to attend the webinar and to access an archived recording once it has occurred). Please contact us with additional questions at admin@deprescribingresearch.org. Please also visit our website at https://deprescribingresearch.org. Please also visit our website at https://deprescribingresearch.org.
 - (a) Include a detailed description of your stakeholder(s) including how they relate to the study topic in terms of their organizational affiliation (if applicable), background and relevant experience, motivation for participating, and projected activities
 - (b) Describe how you will incorporate meaningful engagement with one or more stakeholders or stakeholder groups that informs some aspect of the research process—including topic selection, study design, conduct of research, and/or final dissemination of results
 - (c) Detail how selected stakeholders and engagement goals intersect with study aims and objectives
 - (d) Include a timeline of stakeholders' expected study-related activities along with information about planned compensation for their involvement, which should be further specified in the budget plan/justification pages.
 - (e) Detail the proposed settings and methods for stakeholder engagement
- iv) Required Supplemental Documents (Does not count toward the 5-page limit):
 - (1) Include a half-page description of the proposed study using lay terminology geared toward non-researchers and the general public and its relevance to stakeholders.
 - (2) Junior investigators must include a brief (<=1 page) supplemental mentoring plan and a letter of support from a primary mentor. Include the following details in your mentoring plan:
 - (a) Name, title and institutional affiliation of the primary mentor
 - (b) Relationship between the junior investigator and mentor
 - (c) How the mentor's experience overlaps with the study aims
 - (d) Resources this mentor has committed to the researcher during the potential award year
 - (e) Formal, planned interactions with mentor during the award year
 - (3) NIH-style biosketch for all investigators that includes position/title, education/training, personal statement, positions/honors, and contributions to science. Please also include a simplified, one-paragraph summary for stakeholders.
- v) Interdisciplinary research teams are encouraged.
- vi) Budget Forms
 - (1) Special note: The total budget must comprise both direct and indirect ("F&A") funds. Indirect costs should be charged by the recipient's institution at that institution's federally negotiated rate. Foreign organizations may charge an F&A rate of no more than 8% of modified total direct costs. Please work with your local grants management office early in the process of preparing your grant budget to clarify budgeting of direct and indirect dollars, keeping in mind that the total budget may not exceed \$60,000.
 - (2) Scope of work
 - (3) Detailed budget summary, including any expenses allocated to stakeholder involvement.

- (4) Budget justification
- (5) Other required documents
 - (a) Subrecipient commitment form (if applicable)
 - (b) F&A rate agreement letter
- c) Please submit all materials as one PDF document through a web-based portal on the pilot awards section of the network website (https://deprescribingresearch.org). If you encounter any issues with the submission process, please email admin@deprescribingresearch.org
- d) Proposals will be reviewed and scored based on innovation, scientific rigor, feasibility, investigators, potential to lead to future larger-scale work, stakeholder engagement, and relevance to aging.

7) Eligibility Criteria:

- a) Institutions
 - i. Eligible institutions include colleges, universities, medical or nursing schools, or other fiscally responsible organizations.
 - ii. Proposals may be submitted by non-US institutions, but such proposals must articulate how the proposed research applies to settings outside of the applicant's home country, including to the US.
 - iii. Prior to submitting an application, applicant organizations must be registered with System for Award Management (SAM) (https://www.sam.gov/SAM/) and have a Dun and Bradstreet Universal Numbering Systems (DUNS) number (http://fedgov.dnb.com/webform).

b) Principal Investigator

- i. Applicants must hold a doctorate degree (MD, PhD, or equivalent)
- ii. Applicants must hold a faculty, research scientist, or equivalent position at an eligible institution by the start date of the award.
- iii. Applicants from under-represented racial and ethnic groups as well as individuals with disabilities are strongly encouraged to apply for funding

8) Key Dates:

Application FAQ session, an informational webinar for the public about USDeN pilot grants (Visit https://deprescribingresearch.org to register and to see an archived version after the session has occurred)	January 7, 2020, 2-3 PM EST (11-12 PST)
Letters of intent (optional)	Monday, February 10, 2020 11:59 PM (PST)
Full application due	Monday, March 9, 2020 11:59 PM (PST)
Awards announced	June 1, 2020
Beginning of funding for selected awards	August or September 2020