

Advancing Research to Optimize Medication Use Among Older Adults

Grant Planning Proposal Guidelines (USDeN GPP 2023-2024)

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. Grant planning proposal 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. This mechanism is intended for investigators conducting planning activities for a large, funded research proposal. Investigators wishing to conduct pilot and exploratory studies should consult the RFA for Investigator Initiated Proposals, which will fund pilot and exploratory awards.

- 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 grant planning activities leading to research designed to expand the quality, quantity, and translational impact of deprescribing initiatives targeting older adults. Funding will be provided to support initial development activities that will lead to a multi-site clinical trial or larger-scale research project.
- **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 topics and methodologies: 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. For this funding cycle, priority areas include the following, although applications on any topic related to deprescribing in older adults are welcome:
 - a) Deprescribing in a variety of care settings, such as home health and hospice
 - b) Point-of-care tools to help clinicians, patients, and caregivers to stop or reduce medications
 - c) Patient-important outcomes in deprescribing

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, to implementation science.

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. 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 <u>admin@deprescribingresearch.org</u> (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): An LOI is required.
- i) Formatting: 1 page in length, 1/2" 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 research aims and approach. It is fine if these elements change between the LOI and the final proposal.
- iii) Indicate if the proposal is applicable to the priority area of deprescribing among older adults with multiple chronic conditions.
- iv) Include a description of planned stakeholder engagement. This may include descriptions of the stakeholders, methods of engagement and ways in which stakeholder feedback will inform research. Please see the proposal section below for online resources related to stakeholder engagement.
- v) Requests for funding above the standard budget cap should be listed here and also separately communicated via email to <u>admin@deprescribingresearch.org</u>
- vi) 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. Please note that USDeN is not funding quality improvement proposals.
- vii) LOI due date is **January 4, 2023 11:59 PM (PST)**. Please submit through a web-based portal on the pilot awards section of the network website (https://deprescribingresearch.org/network-activities/grant-opportunities/).

b) Proposals:

- i) Formatting: A maximum of five pages (including the cover page) in length, ¹/₂" margins, 11point Arial font
 - (1) Please note that a reference list does not count toward the five-page application limit.
- ii) Cover page (one page)
 - (1) Project title
 - (2) Principal investigator(s)' Name(s) and Title(s)
 - (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 in this order:
 - (1) Study aims: Detail the study aims, significance, and approach of the multi-site clinical trial or larger-scale study this planning will foster. Describe all grant planning activities,

such as the development of study design, creation of research materials and establishment of the research team.

- (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) Funding: Summarize potential funding mechanisms for the planned larger research initiative and the timeline for submitting applications to these institutions.
- (4) Outcomes: Describe how this work will lead to publications, future grants and investigator's career advancement
- (5) Stakeholder Engagement: Participation from at least one stakeholder, either in an advisory capacity or as a full member of the research team, is required. Stakeholders may include patients, caregivers, front-line clinical providers, health systems administrators and leaders, or others depending on the focus of the project. (Please see <u>https://deprescribingresearch.org/wp-content/uploads/2020/12/USDen-Stakeholder-engagement-FAQ_FINAL.pdf</u>, <u>https://www.pcori.org/sites/default/files/PCORI-Updated-Engagement-Plan-Template.pdf</u> and <u>https://www.pcori.org/about-us/our-programs/engagement/public-and-patient-engagement/pcoris-stakeholders</u> for additional information on engaging stakeholders). Questions about stakeholder engagement will be addressed during the webinar for this RFA (see <u>https://deprescribingresearch.org/network-activities/investigator-development/webinars/</u> for how to attend the webinar and to access an archived recording once it has occurred). 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 grant planning process—including development of study design, creation of research materials and establishment of the research team.
 - (c) Detail how selected stakeholders and engagement goals intersect with study aims and objectives. Detail how stakeholders were/will be recruited and selected.
 - (d) Include a budget compensation plan that outlines how stakeholders will be compensated for their time and efforts.
 - (e) 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.
- (6) 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, methodologies, or intervention(s) to be developed. Note whether the application addresses the priority areas outlined above (see Section (4) "Research topics and methodologies"). 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.
- (7) Approach: Describe the overall strategy, methodology, and planned analyses. If appropriate, include feasibility, preliminary studies, potential problems, and alternative strategies.

- (8) Future Aims: Describe how this work will lead to publications, future grants and investigator's career advancement.
- iv) Required Supplemental Documents (Does not count toward the 5-page limit):
 - (1) Include a half-page description of the proposed grant planning activities and the envisioned study they will lead to using lay terminology geared toward non-researchers and the general public and its relevance to stakeholders.
 - (2) This mechanism is typically most appropriate for established investigators. Junior investigators must include a brief (<=1 page) supplemental mentoring plan and a letter of support from a primary mentor. These can be separate one-page documents or combined into one, single-page document. 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) Submit NIH-style biosketches (using the current NIH format) for the PI, primary mentor (if the PI is at a junior level) and any additional investigators being paid by the grant. Please ensure that each biosketch includes position/title, education/training, personal statement, positions/honors, and contributions to science.
- v) Faculty status at beginning of award period: Any fellows and post-docs who are a PI on the proposal should describe plans for being appointed as a faculty member by the time this award begins, which is likely to occur in August 2022. Any possibility of moving between institutions should also be described. This description should include the support that will be available for the proposed research at the new institution.
- vi) Interdisciplinary research teams are encouraged.
- vii) 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 (i.e., brief paragraph outlining what work will be done under the proposed project and who will do it)
 - (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 grant planning awards section of the network website (<u>https://deprescribingresearch.org/network-activities/grant-opportunities/</u>). 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. Applications in the priority areas listed in Section (4) (page 1 of this RFA) are encouraged, but a focus on these areas is not required.

- e) These funds come from the National Institute on Aging and are administered by NCIRE. Please provide the information below to your grants specialist, if needed.
- Type of Institution: NCIRE is a public, nonprofit institution exempt under Section 501(c)(3) of the IRS code. Institutional Name and Address: Northern California Institute for Research and Education 4150 Clement Street, Mail Code: 151 NC, San Francisco, CA 94121-1545. County: San Francisco County. Congressional District: CA-012. Main Telephone Number: (415) 750-6954. Fax Number: (415) 750-9358.

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) (<u>https://www.sam.gov/SAM/</u>) and have a Dun and Bradstreet Universal Numbering Systems (DUNS) number (<u>http://fedgov.dnb.com/webform</u>).
- b) Principal Investigator
 - i. Applicants must hold a doctorate degree (MD, PhD, PharmD 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 about this mechanism. (Visit <u>https://deprescribingresearch.org</u> to register and to see an archived version after the session has occurred)	October 21, 2022, 1 – 2 PM CST (11 – 12 PST)
Letters of intent (required)	January 4, 2023
Full application due	January 27, 2023
Awards announced	Early May 2023
Beginning of funding for selected awards	August 2023