

Advancing Research to Optimize Medication Use Among Older Adults Pilot Proposal Guidelines (USDeN Pilot 2025-2026)

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, multimorbidity, and cognition, 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 \$30,000 in direct costs (i.e., not including 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. Applicants from all related disciplines are welcome, including but not limited to medicine, nursing, pharmacy, psychology, social work, health economics, health policy, pharmacoepidemiology. The application process involves submitting a letter of intent (LOI); these will be competitively reviewed and a subset will be invited to submit a full application.

- 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 frailty and/or Alzheimer's disease and related dementias (ADRD).
- 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
 - d) Pharmacoequity and health disparities

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 for this grant opportunity is a maximum of \$30,000 in direct costs. The combined budgeted total costs (directs plus indirects) will not exceed \$50,000 or use an indirect cost rate exceeding each organization's negotiated rate. (For example, if an institution's indirect cost rate is higher than 66.7%, please note that direct costs will need to be under \$30,000 so that the total of direct plus indirect costs does not exceed \$50,000). The possibility of funding exceeding these limits 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 the aforementioned limits 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 and will be competitively reviewed. Applicants will be notified if they are invited to submit a full application (see timeline in final section of this RFA). LOIs will be evaluated for the overall quality and impact of the proposed research questions and research plan, feasibility of conducting the proposed research within the available time and budget, engagement of stakeholders, how the proposed research will advance the investigator's career development in deprescribing science, and to a lesser extent alignment with priority areas (see section 4). It is NOT expected that research plans and stakeholder engagement activities will be fully formed at the time of the LOI. As such, it is perfectly acceptable to acknowledge uncertainties or decisions to be made between the time of the LOI submission and the final proposal, and it is expected that aspects of the research and stakeholder plans may change between the LOI and the final proposal. In other words, LOI review will focus on the big picture and not on small details.
- i) Formatting: Up to 3 pages in length, ½" margins, 11-point Arial font. Required format is as follows:
 - Page 1: Administrative Data (1 page)
 - a) Applicant/PI Name and Academic Rank (current and/or at time of award):
 - b) If Junior/Early-Stage Investigator, name of Primary Mentor:
 - c) Other Key Personnel and Project Roles:
 - d) Institution:
 - e) Project Title:
 - f) Alignment with Priority Areas (check all that apply; alignment with one or more of these areas is encouraged but not required)
 - Point-of-care tools to help clinicians, patients, and caregivers stop or reduce medications
 - Patient-important outcomes in deprescribing
 - Pharmacoequity and health disparities
 - Vulnerable populations (ADRD, multiple chronic conditions, frailty)
 - Application Summary (Up to 2 pages allowable)
 - a) Briefly describe each of the following planned components.
 - (a) Research Objectives / Aims
 - (b) Significance of the topic
 - (c) Target Population and Planned Sample Size (must include older adults)
 - (d) Target Clinical Setting(s) for Deprescribing

- (e) Research Plan/Study Design
- (f) Intervention and comparison group description (if applicable)
- (g) Stakeholder Engagement plan. (This may include descriptions of the stakeholders, methods of engagement and ways in which stakeholder feedback will inform research. Please see the RFA section 6-(b)-iii-3 for resources related to stakeholder engagement. As noted above, it is not expected that stakeholder engagement activities will be fully formed at the time of the LOI, but at a minimum general plans and directions should be articulated).
- (h) Briefly explain why it is feasible to complete this project within 1 year of funding
- (i) Describe how proposed research will advance applicant's career development in deprescribing science and what next steps this award will lead to.
- (j) If International applicant, relevance to U.S. healthcare system
- ii) Please explain requests greater than the budget cap specified above and/or requests for more than one year of funding.
- 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. Please note that USDeN is not funding quality improvement proposals.
- iv) LOI due date is **November 12, 2021 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) Full Proposals (if invited to submit after LOIs are reviewed):
- i) Formatting: A maximum of five pages (including the cover page) in length, ½" margins, 11-point 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:** Describe the aims and objectives that will determine the scope, depth and overall direction of the study. Quality improvement (QI) projects are not supported by this funding mechanism.
 - (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) **Stakeholder Engagement:** Participation from at least two stakeholder types, either in an advisory capacity or as a full member of the research team, is required unless there is a compelling case why this is not feasible or informative. Except when there is a compelling case otherwise, stakeholders must include older adults or caregivers and at

least one additional community partner, front-line clinical providers, health systems administrators or others depending on the focus of the project. (Please see https://deprescribingresearch.org/wp-content/uploads/2020/12/USDen-Stakeholder-engagement-

FAQ FINAL.pdf, https://www.pcori.org/sites/default/files/PCORI-Updated-Engagement-Plan-Template.pdf/ and https://www.pcori.org/about-us/our-programs/engagement/public-and-patient-engagement/pcoris-stakeholders for additional information on engaging stakeholders). Questions about stakeholder engagement will be addressed during the webinar for this RFA (click https://jhjhm.zoom.us/webinar/register/WN V9yXSWLkSOqoJO7B13dXXw to register and see https://deprescribingresearch.org/network-activities/investigator-development/webinars/ to access an archived recording once it has occurred). Note that this is not intended to be a daunting requirement, and we anticipate that for many investigators there will be a learning curve for how to assemble and work with stakeholder partners. Please contact us with additional questions at admin@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 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. This component should be structured in a way that is feasible within the allotted budget and project period.
- (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.
- (4) 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.
- (5) **Approach:** Describe the overall strategy, methodology, and planned analyses. If appropriate, include feasibility, preliminary studies, potential problems, and alternative strategies.
- (6) **Future Aims:** Describe how this work will lead to future research, grants, and investigator career advancement. Note that this constitutes an important part of the review process alongside other proposal components (see below).
- 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 (e.g., those with fewer than 5 years in a faculty appointment or equivalent position) 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 <u>NIH-style biosketches</u> for the PI, primary mentor (if the PI is a junior investigator), 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 should describe plans for being appointed as a faculty member or equivalent position by the time this award begins, which is likely to occur in August 2025. 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 \$30,000 in direct costs and may not exceed \$50,000 in total (direct plus indirect) costs, unless written permission has been granted otherwise.
 - (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 pilot awards section of the network website (https://deprescribingresearch.org/network-activities/grant-opportunities/). 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.
- i) 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 the U.S. and to other settings outside of the applicant's home country.
 - 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, 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 for the public about USDeN pilot grants (Visit https://deprescribingresearch.org to register and to see an archived version after the session has occurred)	October 15, 2024, 1 – 2 PM CST (11 – 12 PST)
Letters of intent (required)	November 12, 2024
Invitations sent to submit full application (after LOI review)	November 26, 2024 (or earlier)
Full application due	January 31, 2025
Awards announced	March - April 2025
Beginning of funding for selected awards (anticipated)	May - June 2025