Practical Incorporation of Stakeholder-Informed Ethics into Research Funding Decisions

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ABSTRACT

Research funding has been criticized as biased against novel initiatives and lacking diversity, which leads to further disparities. Patient and stakeholder engagement could support research that goes beyond traditional paradigms and increases diversity. However, best practices to engage stakeholders in research, including funding decisions, continue to be developed. We report on the implementation of stakeholder input in two federally funded initiatives, one that seeks to advance research reducing disparities, and the other seeks to advance deprescribing research. Overall, the review process includes stakeholders as decision makers and supports their efforts through group discussion and other activities. Reconciling stakeholder input that may differ from scientific peer review is a challenge within the decision for funding. Lessons learned include balancing stakeholder and scientific assessments and including guidance on stakeholder engagement to grant awardees.

KEYWORDS: stakeholder engagement; research funding; best practices

Introduction: For 2022, the National Institute on Aging (NIA) reported a budget request of over $4 billion to fund its mission, which includes "develop[ing] strategies to improve the health status of older adults in diverse populations" and "disseminating information to . . . advocacy, community, and older-adult support organizations." [1] Implicit in these goals is an ethical concern addressing the inclusion of under-represented community members and stakeholders as a response to historical, social practices that exploited underserved/under-represented communities and exacerbated their disenfranchisement and lack of control.[2] Despite this ethical concern, achieving diverse racial/ethnic representation, both of investigators as well as of research subjects, remains critical to improve the impact of research on overall health; unfortunately our knowledge of how best to achieve this remains elusive despite decades of initiatives.[3-5] And as the 2022 NIA budget request suggests, addressing this gap through funding is among the strategies being tried to improve diversity in research, although how best to engage stakeholders in funding is also a gap. The goals of this paper are to describe how two different NIA-funded initiatives have partnered with various stakeholders to review pilot grants for research funding, and discuss challenges as well as lessons learned, thereby adding to the knowledge base which may improve the diversity of research and the applicability of research findings.

Stakeholder inclusion is especially important to research in aging and deprescribing (the process of dose reduction or stopping of medication that may no longer be of benefit), which has been increasing in recent years.[6-10] Patient and other stakeholder involvement can improve the study design to enhance the relevance of study findings of older adults around deprescribing, for example, by addressing whether older adults are resistant to the idea of reducing medication.[8,11] Furthermore, stakeholder engagement can result in findings that are more attuned to the needs of specific populations.[6]

Patient-centeredness and inclusion of the community member as a stakeholder have been critical to advancing deprescribing efforts, even as stakeholder engagement has not been a pillar of traditional approaches to medical research.[6] In fact, balancing stakeholder feedback into assessments of research, as in funding decisions, is an area of great interest and little data.[2] Even as research increasingly comes to include an element of stakeholder engagement, commentators have noted that some engagement initiatives are only minimally implemented, as if to "check a box" for engagement, without investing significant resources.[12] Ensuring that stakeholder input is

central to funding decisions and not a superficial part of the review, has been a focus of both research organizations discussed in this paper. Furthermore, although stakeholder engagement has shown promise in advancing the application of research when implemented successfully, the term "stakeholder" has sometimes been used too loosely, or with too much of an emphasis on financial stakeholder as opposed to patients.[13] A more rigorous definition of stakeholder has been delineated by the Patient-Centered Outcomes Research Institute (PCORI). PCORI defines stakeholders in various roles, including patients and those with direct lived experience of illness or injury who would be affected by health research or policy, but also those with professional experience in a given health topic, such as clinicians, payers, hospitals and health systems. [PCORI] We follow PCORI in defining stakeholder broadly, while noting that in any given research problem or policy initiatives, stakeholder constituents may be differently affected and may have unequal access to being able to advocate for their interests.

Organizational Structure and Approach to Stakeholder Reviews of Research Proposals

The University of California Los Angeles (UCLA) Resource Center for Minority Aging Research/ Center for Health Improvement of Minority Elderly (RCMAR/CHIME) is a research center funded by the National Institute of Health/National Institute on Aging (NIH/NIA). RCMAR/CHIME is administratively housed in the Division of General Internal Medicine and Health Services Research at UCLA David Geffen School of Medicine. Working alongside sister RCMAR centers across the nation, RCMAR/CHIME's mission is to help reduce health disparities between minority and non-minority older adults. The focus of the work at RCMAR/CHIME is on training and mentorship of under-represented minority junior-level faculty who will advance their careers by conducting research with minority older adults.

The RCMAR/CHIME Research Education Core manages the annual selection process of proposed pilot-study projects. The UCLA Clinical and Translational Science Institute (CTSI) provides co-funding for selected projects. The Research Education Core relies upon input from the Community Liaison Core to inform the selection of pilot projects.

With an overarching mission of increasing the relevance, reach, and impact of the supported research, the RCMAR/CHIME Community Liaison Core (CLC) facilitates academic-community partnerships for RCMAR/CHIME-supported projects. This CLC manages an eighteen-member

(approximate) Community Action Board (CAB) composed of key leaders representing a diverse group of stakeholders across the aging service network in greater Los Angeles. Stakeholders provide feedback and expert input on all aspects of the research projects (especially but not limited to recruitment and retention of minority older adults), participate as study co-investigators when appropriate. Any member of the review team, scientific or stakeholder, who is a co-investigator on a proposed project, will recuse themselves from evaluating the project with which they are associated.

Like RCMAR/CHIME, the United States Deprescribing Research Network (USDeN) is funded by the NIH/NIA. It is organized into four cores (Investigator Development Core, Pilot and Exploratory Studies Core, Stakeholder Engagement Core, and Data and Resources Core). The goal of USDeN is to develop and disseminate evidence about deprescribing for older adults, and in doing so to help improve medication use among older adults and the outcomes that are important to them.[14] USDeN's development of evidence includes investigator development initiatives, such as a junior investigator training intensive, as well as grants to fund pilot studies, grant planning, and collaboration grants.

The USDeN Stakeholder Engagement Core (SEC) helps bring stakeholder perspectives and principles to stakeholder engagement across the range of activities conducted by USDEN, including webinars, educational programming, and mentoring early-career investigators. Along with the Pilot and Exploratory Studies Core, the SEC undertakes reviews of pilot and grant planning grant applications. The SEC review is independent of the peer-review undertaken by scientific experts conducted under the auspices of the Pilot Core.

The USDeN Stakeholder Engagement Core includes a council of stakeholders, currently ~14 individuals, including patients and caregivers, as well as stakeholders in health systems, insurance and payors, advocacy organizations, governmental agencies, and academic institutions. Stakeholders meet quarterly to review funded research in progress and inform ongoing USDeN activities; one of these meetings annually is devoted to reviewing the applications for funding in the coming year. Both RCMAR/CHIME and USDeN require applicants for funding to describe a plan for engaging stakeholders. USDeN provides specific instructions along with links with further information on stakeholder engagement in its description of the application process,

stipulating as required: "[p]articipation from at least one stakeholder, either in an advisory capacity or as a full member of the research team, is required."[15] These plans are assessed as a key part of the proposal by all grant reviewers, but the scoring and assessment made by stakeholder review is especially prioritized.

Stakeholder Roles and Impact

In both RCMAR/CHIME and USDeN, one of the most important contributions stakeholders make is their participation in the annual Request for Proposal pilot proposals review and selection process. For RCMAR/CHIME, personal and professional experience/background are rooted in community-based organizations that serve minority populations; USDeN stakeholders may come from other types of partnership. The stakeholders' real-world lens brings understanding and insight into how relevant and beneficial a potential study may or may not be to improve the health status of those in the communities they serve. Stakeholders vary in years of experience and familiarity with the health system, for example, one stakeholder was a caregiver with several years of caring for her husband before he passed away, another has worked for years at a non-profit advocacy organization for health issues related to older adults. Regardless of experience, all stakeholders help to educate as well as assist researchers during both the pre-pilot and awarded pilot phase.

Stakeholders encompassing a variety of roles, from direct personal experience with health challenges, to researchers, payers and hospital administrators and clinicians were initially recruited through personal connection with the initial core of researchers at both RCMAR and USDeN. Attention to the type of stakeholder also influenced recruitment, with RCMAR and USDeN both prioritizing recruiting people with diverse perspectives. Recruitment has also come from within the stakeholder group itself, as stakeholders suggest people they know to replace them, once their terms as stakeholders ends. At times stakeholders who have been included on funded projects become partners in the grant funding review process. Stakeholders have also been recruited by potential stakeholders clicking on a link on the website. A community-based stakeholder has also helped to plan and edit this manuscript.

Stakeholder feedback has impact on research funding decisions. During one review round for USDeN one proposal was regarded as scientifically sound but was not funded because the

stakeholder review found this project's stakeholder engagement plan unacceptably in adequate. Feedback from the review process also led USDeN to place descriptions of the requirements for stakeholder engagement in proposed project in a more prominent place in the grant application.

Community partners/stakeholders work with the research team at several different stages of the research process. In the case of RCMAR/CHIME, researchers present ideas for a project to the entire group of community partners, generating discussion and specific input from the community partners. For example, one RCMAR scholar was very interested in the issue of examining "low-value care" i.e. health care that is unlikely to provide benefit and could be harmful. Community partners felt strongly that the term "low-value care" was inappropriate. Several made the important point that patients and providers may have very different opinions around what is "valuable." Based on this input, the researcher substantially revised his grant proposal, and invited 2 community partners to join the research team as funded investigators on the project. The grant was funded and the community partners continued to meet regularly with the rest of the research team to finalize the research design, interpret results, draft the poster presentation for a national meeting, and write a manuscript that is currently under review at a medical journal.

Grant Review Mechanism

The review process at both RCMAR/CHIME and USDeN follows similar but not identical processes. (**Table 1**) In both centers, stakeholders are asked to read applications and complete a standardized review form that includes both closed and open-ended response sets.

One of the most significant differences between the centers' stakeholder review processes is that RCMAR/CHIME stakeholders conduct a formal review of the Letters of Intent (LOIs), while at USDeN, the LOIs are reviewed by network leaders and staff and the USDeN stakeholders are instead asked to review full proposals. With USDeN, proposals that score very poorly in the scientific review are occasionally not reviewed by stakeholders. Neither organization presupposes scientific literacy of stakeholders; a plain language summary of each proposal is required.

RCMAR/CHIME Process

The stakeholder review process at RCMAR begins with ~4-6 stakeholders independently reading and reviewing each 2-page LOI application and completing an 8-question drop- down online questionnaire with Likert scale responses (strongly disagree, disagree, neutral, agree, strongly agree) pertaining to RCMAR areas of priority. These include asking whether the proposed project addresses an area that is important to minority older adults, whether the project is appropriately conceived to achieve its stated aims, and whether the community stakeholder level of involvement is appropriate. Their independent review also includes free text fields to assess strengths and weaknesses and add any other specific comments. Stakeholders then send their reviews via an electronic review form to RMCAR/CHIME staff, who then collate the reviews and into a summary, which is sent to the RCMAR/CHIME CLC Community Outreach Director (CR). That director then prepares an overall summary which is distributed back to the full team of reviewers.

All stakeholders then meet via phone or video conference to review each application and discuss their reviews. This meeting brings stakeholders together in active, in-depth conversation. It is an opportunity to talk through proposed study topics, weigh value of studies in under-resourced communities, and revisit recommendations for applicants. Stakeholders are invited to comment on any aspect of the research, but they most commonly raise issues around cultural and linguistic considerations, role of caregivers and family members involved in health care of older adults. Equally significant is the partner's organizational capacity to conduct a year-long study without disturbing daily service operations to clients.

After stakeholders review the LOIs, their comments are synthesized by the RCMAR administrator, and presented to RCMAR/CHIME leaders at their monthly meeting, where they decide which applicants to invite to submit full proposals. For applicants who are invited to submit full applications, the input from the stakeholders is explicitly included with the invitation letter, with the expectation that the applicant will incorporate stakeholder input into their full application.

USDeN Process

At USDeN, scientific review by 2 independent reviewers reduces the overall number of applications to 12-16 full applications which are then reviewed by 2 stakeholders each. One of

the faculty core leaders also reviews and ranks each full application alongside the stakeholders. USDeN stakeholders also are asked to respond to criteria specific to stakeholder engagement. The review rubric consists of scores for "Overall Engagement Score," "Meaningful Engagement," "Adequate Descriptions of Stakeholders,"" and "Settings and Methods." Stakeholder reviewers are asked to comment on whether the stakeholders' overall engagement was evident, that the proposed project was likely to lead to the appropriate involvement of stakeholders to answer a meaningful research question, and whether selected stakeholders and engagement goals intersected with the proposed study aims and objectives.

USDeN accessibility for a variety of stakeholder reviewers frequently pointed out instances of lack of clarity on who a stakeholder and a research subject were. Stakeholders reviewed the investigator's ability to bring a good team together, how often the investor would be meeting with the stakeholder within the proposed timeline, how professionally diverse and inclusive the stakeholders were, and how the stakeholders' credentials could contribute to the proposed project. While USDeN stakeholder reviewers were instructed to focus on the stakeholder engagement plan in their reviews, many also commented on other aspects of the research plan that did not pertain to stakeholders. This was neither discouraged nor celebrated, given the range of research training the stakeholder reviewers had and the importance of not sending a message that this level of research review was expected from everyone.

Reviews conducted by SEC members are entered into REDCap, which is a secure web application for building and managing online surveys and databases. The SEC team accesses REDCap to extract reviewer scores and comments which are then compiled into a summary sheet distributed to all reviewers prior to an all-council zoom meeting. Proposals are ranked according to an average score of three independent reviewers based on the "Overall Engagement Score."

The USDeN all-council stakeholder review meeting is very similar to the RCMAR/CHIME review meeting. Each proposal is discussed in turn; discussion begins with presentation of the scores from the 2 scientific reviewers and the stakeholder review score; each scientific reviewer and a representative of the stakeholder core then briefly present the strengths and limitations of

the proposal, and then it is opened to full study section discussion. As part of these discussions, SEC core leaders and other discussants recognize that stakeholder engagement is a new competency for many investigators, and so reviewers do not necessarily expect that every successful applicant will have a wonderful stakeholder engagement plan. Rather, USDeN considers both the strength of the plan as presented and makes a global assessment of the investigators' attempts to bring in stakeholder perspectives, recognizing that USDeN can work with them over the course of conducting their pilot award to improve their stakeholder engagement plan and skills. This is accomplished by having pilot awardees meet with stakeholder core leaders over the course of their award to refine and troubleshoot their stakeholder engagement activities. Reviewers may decide to alter their original scores based on the discussion. The process concludes with each study section panelist giving each proposal a single score reflecting its overall quality, which includes both its scientific merit and the strength of its stakeholder engagement plan. The overall review processes of both organizations are summarized in **Figure 1**.

Challenges

Implementing robust stakeholder review into scientific grant decisions faces challenges of both process and content. Perhaps the biggest challenge to ensuring meaningful stakeholder input on the review, is process-related, how to address the situation when the stakeholders and the scientists differ in their rankings of a proposal, and center leadership struggles with how to juggle competing scores in final funding decisions. Occasionally, a proposal will receive a high stakeholder review but a low scientific review. In these situations, the scientific review has always taken precedence because both centers affirm peer-review as an important mechanism to ensure scientific rigor and reliability. Neither center has ever selected a pilot proposal for funding that was felt to lack scientific rigor, even if stakeholders felt it addressed an important area and/or had a well-thought-out stakeholder engagement plan. For USDeN, when a large number of grants are received, those lacking in scientific merit are eliminated prior to stakeholder review, out of consideration of burden. Balancing the time commitment of review with providing a thorough stakeholder review on as many grant proposals as possible continues to be a process challenge. Considering the time commitment and workload of reviews, we have

not required stakeholders to comment on the review in general, though striking the balance between eliciting a review with no limitations on scope of feedback, and enabling non-specialist reviewers to comment on proposals continues to be a consideration in the review process. There have been occasions in both centers when the stakeholders rated a study poorly, but the scientific reviewers rated the project highly; in some of these cases, the project was funded with close oversight. Or, as mentioned above, one scientifically sound proposal was not funded due to a weak stakeholder engagement plan.

Initially at USDeN, only those proposals that scored in the best ~2/3 were discussed at the all-council review meeting, but recently this has been changed, so that proposals likely to be funded, based on both scientific and stakeholder scores, are discussed. For example, a proposal on the cusp of being discussed based on its scientific score may be promoted to discussion if it gets a strong stakeholder score, or triaged to not being discussed if the stakeholder score was poor. USDeN continues to assess how best to balance the rigors of a detailed review with accessibility for a variety of stakeholder roles.

Over time, both centers have implemented processes to try to prevent these discrepancies in ratings. At USDeN, the SEC's stakeholders and leaders worked closely with the Pilot and Exploratory Studies Core leaders to revise the explicit instructions in the request for proposals to clarify how necessary the stakeholder engagement component of the application was. Lack of clarity in instructions is a content-related barrier to implementation that affects the implementation process. To address this content-related deficiency, potential applicants were referred to resources to learn how to create strong stakeholder engagement, including webinars posted on the USDeN website.

Another content-related challenge to ensuring ethical stakeholder input on the grant selection process is that stakeholders can differ in their opinions about what constitutes excellent stakeholder engagement and/or how much detail should be expected on an application that has yet to be funded. One USDeN reviewer stated that they reserved their highest ranking for proposals with the clearest data on stakeholders, for example identifying stakeholders by name and qualifications, but also whether roles and tasks were stated as well as hours spent on the

reviews. Other stakeholder reviewers feel that it is an imposition on community partners to expect too much commitment from them prior to funding. Despite these occasional differences in views, there is a consensus among stakeholder reviewers, however, the applications that fail to budget resources for community partners are considered unacceptable. Continuing to refine and articulate criteria for good stakeholder engagement continues to be a content-related challenge in our review process.

Lessons Learned

Through working with stakeholders, both RMCAR and USDeN have striven to improve the review for funding and implemented changes based on how challenges were addressed. In addition to the modifications in procedures described above, we have implemented several other improvements in our review processes that we feel have improved our ability to incorporate ethical stakeholder input on research project selection meaningfully. For a process-oriented example, in early years of USDeN, the scientific reviewers used a 9-point rating scale which was more detailed than the 3-point scale the SEC reviewers used in evaluating the grant proposals. Applying the same 9-point scoring scale in both sets of reviews greatly improved the ease of communication of SEC ratings to the scientific reviewers. As noted above, clarifications in instructions that respond to stakeholder feedback have also been important in continuing to better implement stakeholder engagement in research funding decisions.

Prior to the last five years, RCMAR/CHIME stakeholders (CAB members) were asked to review full proposals during the selection process rather than LOIs. It was later decided that feedback would be most beneficial at the Letter of Intent (LOI) phase of the process so that feedback could be incorporated early on. Although USDeN continues to conduct its stakeholder review on the full proposals, both organizations recognize that both education on stakeholder engagement and assistance in planning and implementing stakeholder engagement may be needed. Anecdotally, some stakeholder core members have been told by researchers that they lack the skills to recruit and engage stakeholders.

Discussion

We have described the procedures developed over several years in which two NIH/NIA centers have successfully incorporated meaningful stakeholder input into selecting research awards. Learning from these procedures may be of value to other research centers striving to address the ethical concern that understands the inclusion of under-represented stakeholders as a response to historical social practices that exploited underserved communities and exacerbated their disenfranchisement and lack of control.[2]

The efforts reported in this manuscript cannot fully overcome decades of under representation within research initiatives. These two NIA-funded research organizations have provided practical approaches to evolve the grant review process. The peer review process has been criticized as lacking reliability and validity as it is based on the review of too few reviewers, along with the critiques noted above related to race-based disparities in funding and the privileging of established research approaches over novel approaches.[16-18] Medical research itself can engender suspicion, with some surveys showing that African American respondents are more concerned with the possibility of harmful experimentation in medical research and lower overall trust in medical professionals and medical care.[19-21] Trust requires participants to put themselves in a dependent relationship with a medical researcher, and the extent to which someone is comfortable ceding their autonomy in the setting of research will be highly dependent on a participant's past experience. Early and enduring stakeholder-informed processes should help achieve greater engagement and impact.

Conclusion

Conveying identified considerations around the involvement of stakeholders in research can strengthen an application, provide clarity, make it more competitive, and enhance the potential for successful impact. RMCAR/CHIME and USDeN are both engaging in iterative approaches to optimizing stakeholder engagement in research funding decisions. Because research funding bears an ethical imperative that harm is minimized and benefits must be increasingly distributed to exploited and underserved communities, we seek to continue to improve the process of meaningful stakeholder engagement and governance of research.

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Table 1. Characteristics of RCMAR/CHIME and USDeN Review Processes

	RCMAR/CHIME	**USDeN**
Funding Opportunities (e.g. duration, amount)	Annual 1-year pilot awards co-funded by UCLA CTSI. Funding range: up to $55,000	Annual awards for 1-year pilot studies, grant planning, and collaboration grants. Funding range: up to $60,000
Stage of Stakeholder Review	Letter of Intent, with no specific instructions to focus specifically on stakeholder engagement	Prior to proposal, webinar on stakeholder engagement for potential applicants. Full proposal, with instructions to focus on the stakeholder engagement component of the application.
Review Format	Questionnaire, followed by group discussion (phone or zoom)	Questionnaire, followed by group discussion (zoom)
Stakeholder compensation	Approximately $50 per hour	Approximately $50 per hour

Figure 1: Overall Review Processes Including Stakeholder Review

RCMAR/CHIME

Letter of intent reviewed by 2-4 stakeholders, using 8 question questionnaire

RCMAR/CHIME stakeholder engagement staff present stakeholder findings to Community Outreach Director

Community Outreach Director reports stakeholder feedback to full team of reviewers

Full team of reviewers choose invited applications; invited applications must incorporate and address feedback from stakeholders

USDeN

Full application is reviewed by 2-3 stakeholders using a rubric and inputted in a database

The database collates ranked reviews combining rubric scores in an overall engagement score

All stakeholders convene as a group and discuss applications, creating a short list of recommended applications; reviewers may change their scores based on discussion

All council review meets to make funding decisions; stakeholder core leaders present stakeholder feedback along with scientific core leaders