Webinar: Arts-Based Approaches in Palliative Care for Symptom Management (R01)

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Partnerships

- Interagency: National Endowment for the Arts (NEA)
  — Sunil Iyengar, Director, Research & Analysis

- FOA responding to two workshops:
  - March 2011: NEA joined OBSSR, NCCAM, & NIA as part of federal interagency task force on arts & human development to request that National Academy of Sciences (NAS) convene a public workshop to focus on research challenges & opportunities in exploring relationship of the arts to health and well-being in older adults
  - August 2011: NINR hosted “The Science of Compassion: Future Directions in End-of-Life and Palliative Care”, partnering with numerous NIH partners, to examine the state of end-of-life and palliative care research, particularly in relation to clinical practice and called for substantial research efforts to develop and test effective and optimal models of end-of-life and palliative care interventions
Participating NIH ICOs

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Arts-Based Approaches in Palliative Care for Symptom Management (R01)

**Purpose:** To support mechanistic clinical studies aimed at understanding the impact of arts-based approaches in palliative care for symptom management.

**Objective:** To understand the biological, physiological, neurological, psychological, and/or sociological mechanisms by which the arts exert their effects on symptom management during and throughout the palliative care continuum.
Goal: To develop an evidence-base that could be used as a basis for the uptake of arts-based therapies in palliative care settings, among individuals across the lifespan, with wide variety of serious chronic conditions and their accompanying symptoms.
Key Points

- Intended to foster research on the potential for arts-based approaches to enhance palliative care for individuals living with multiple symptoms related to serious chronic or terminal illness.

- Designed to encourage research to determine how the specific arts intervention might be working mechanistically in managing or ameliorating patients’ serious chronic symptoms related to quality of life.
Key Points

- Term “arts” refers not only to artistic activities, but also to creative activities, such as literature, rituals, oral histories, storytelling, etc.

- Palliative care integrates and coordinates the emotional, psychological, social, and physical aspects of care with a focus on enhanced quality of life.

- Particular interest in the comparison of differences in mechanisms in male and female sample populations.
Important to Note!

- This FOA is not intended to determine efficacy or the comparative effectiveness of interventions, or to assess interventions designed to treat a particular disease state;

- This FOA will not support studies of experimental models of disease or animal studies, or fully-powered randomized clinical trials designed to test efficacy or effectiveness

  ✓ Randomization may be employed as a methodological approach to elucidate the mechanism of arts-based approaches and to meet other goals of this FOA;

- Applications proposing research in topics not identified as high programmatic priority will be considered of low programmatic priority, which will reduce the likelihood of funding.
National Institute of Nursing Research

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Appropriate compelling mechanistic clinical studies with clear rationale could include (but are not limited to):

- Developing methodologies that allow the elucidation of the underlying mechanism by which arts-based intervention may be operating, as part of integrative practices in palliative care;

- Assessing which components of arts-based integrative palliative care interventions exert an effect on QoL and functioning, for various severities and trajectories of symptom management in serious chronic conditions;
FOA Research Scope

Appropriate compelling mechanistic clinical studies with clear rationale could include (but are not limited to):

- Examining how arts-based interventions actually optimize palliative care and impact QoL by mitigating common symptoms and/or symptom clusters (such as pain, dyspnea, fatigue, stiffness, mobility disability, distress, etc.) associated with a number of serious chronic conditions.

- Examining patient-related factors (e.g., age, sex, illness, ethnoculture, etc.) that account for individual variation in responsiveness to arts-based interventions for symptomatic relief;
FOA Research Scope

Appropriate compelling mechanistic clinical studies with clear rationale could include (but are not limited to):

- Examining approaches that integrate the arts within palliative care among children, adults, and their caregivers to reduce, eliminate, or ameliorate symptoms throughout illness trajectories and determine when and how these interventions are working;

- Examining interdisciplinary intervention-based protocols that explore the mechanistic relationship between engagement with the arts and purported health-promoting and symptom-reducing outcomes within care settings.
Key Dates & Data

- R01 Research Project Grants
- Open Date (Earliest Submission Date): September 5, 2014
- Expiration Date: September 8, 2017
- Applicants may request up to $300,000 in direct costs per year
- The maximum project period is 3 years
- The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.
- Types of Applications Allowed: New, Resubmission, & Revision
- Applicants must follow the SF424 (R&R) Application Guide instructions
  [http://grants.nih.gov/grants/funding/424/index.htm#inst](http://grants.nih.gov/grants/funding/424/index.htm#inst)
To Learn More…………

- Applicants are encouraged to consult with NCCAM and NINR staff as your team develops plans for an application:
  - D. Lee Alekel, Ph.D., NCCAM Program Director
    Lee.Alekel@nih.gov
  - Lynn Adams, Ph.D., NINR Program Director
    lynn.adams@nih.gov


- For assistance with your electronic application or for more information on the electronic submission process, visit [http://grants.nih.gov/grants/ElectronicReceipt/index.htm](http://grants.nih.gov/grants/ElectronicReceipt/index.htm)
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Topics for This Afternoon

- Required registrations
- The review process
  - Administrative review
- Review criteria
- Common mistakes
- Tips
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Institutional Registrations Required Prior to Submission

- Dun and Bradstreet Universal Numbering System (DUNS)
- System for Award Management (SAM)
  - Requires renewal AT LEAST annually
- eRA Commons
- Grants.gov
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Electronic Submission Required

- Applications in response to this R01 Funding Opportunity Announcement (FOA) MUST be submitted electronically through either:
  - Grants.gov – or –
  - Peer-to-peer systems developed by some universities and third party providers
Reminder of Review Process

- Applications submitted electronically to Grants.gov
- Grants.gov sends application to NIH IMPAC II
- Applications are assigned by the CSR Division of Receipt and Referral (DRR) to IRGs and ICs
  - Applications received in response to this FOA will be reviewed at the Center for Scientific Review (CSR)
- Applications are assigned to individual Scientific Review Officers (SROs)
- SROs conduct administrative review
- SROs identify expertise necessary to review application, identify researchers with that expertise, and assign applications to them
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Common Issues in Administrative Review: Formatting

- FOA follows standard formatting guidelines
  - Margins no less than one half inch
  - Arial, Helvetica, Palatino Linotype or Georgia 11 point, no more than 15 characters per inch or 6 lines per inch
- Detailed requirements:
  [grants.nih.gov/grants/writing_application.htm](http://grants.nih.gov/grants/writing_application.htm)
More Common Issues in Administrative Review: Page Limits

- Page limits
  - Specific Aims: 1 page
  - Research strategy: 12 pages
  - Each biosketch: 4 pages
Yet more Administrative Review
Issues: Appendix

- Reviewers are not required to review appendix materials; anything that you think is critical to the application should be in the body of the application.

- Allowable materials include:
  - Manuscripts and/or abstracts accepted for publication but not yet published.
  - Published manuscripts and/or abstracts only when a free, online, publicly available journal link is not available.
  - Patent materials directly relevant to the project.
  - Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents may be submitted in the Appendix as necessary.
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Review Criteria

- This FOA uses the standard five review criteria for R01s:
  - Significance; Investigators; Innovation; Approach; and Environment.
- Note that under each of these overarching criteria are additional criteria specific for this FOA; each of the five standard criteria has new, additional language for this FOA.
Additional Criteria: Significance

- Is there a sufficient body of preclinical or clinical research of high scientific rigor to support the study rationale? Is it clear why the proposed mechanistic study is essential to advance the field of arts-based approaches in palliative care for symptom management? Is the proposed project likely to yield clear answers needed to proceed to the next step of the therapeutic development of the arts intervention as proposed in this application?
Additional Criteria: Investigator(s)

- Does the application provide strong evidence of necessary experience and expertise with the arts intervention, the study population, and the research methods to be employed? Does the investigative team have a track record of publishing the results of research previously completed? Has the investigative team successfully recruited the study population in previous clinical studies?
Additional Criteria: Innovation

- Does the proposed study have the potential to advance the field (e.g., by breaking ground for future studies in this area) even if (a) the proposed study design, methods, and intervention are not innovative, and/or (b) the results of the study indicate that further clinical development of the arts intervention is unwarranted?
Additional Criteria: Approach (1)

- If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

- Are the mechanistic hypotheses based on a sound theoretical framework? Does the applicant describe how the proposed study relates to a larger strategy for research and development on the arts intervention, and will it provide mechanistic data needed to advance that strategy?
Additional Criteria: Approach (2)

- Does the application demonstrate the feasibility of methods for developing tools for data management and study oversight, finalizing protocol documents and manuals, as well as addressing appropriate regulatory requirements (IND, IRB)? Are the outcome measures, dose/duration of study, appropriateness of inclusion/exclusion criteria, sample size, and power calculations clearly justified and explained in the application?
Additional Criteria: Approach (3)

- Is the proposed design feasible and adequate to provide interpretable results? Is the proposed timeline feasible and appropriate for the timely completion of the study (particularly regarding participant accrual goals)?

- Are the plans for recruitment outreach and are follow-up procedures to ensure data collection at stated intervals appropriate? Are the retention plans and practices described?
Additional Criteria: Environment

- Does the information provided in the application provide reasonable assurance that the target sample size can be enrolled in the timeframe proposed? Does the application document the availability of the requisite eligible subject pool in the proposed clinical center(s)? Is there documentation of the commitment of any subcontractors and consultants, as well as service agreements for personnel and facilities?
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Common Mistakes

- All key personnel should provide an up-to-date biosketch on the “new” form (look for a “Rev. 08/12” on the footer). The personal statement should address the roles and contributions the individual will make to the project.

- Applications with multiple PIs are required to have a multi-PI plan. That plan should include a justification for multiple PIs, plans for addressing disagreements between the multiple PIs.
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Tips

- Make sure your registrations are up to date (check NOW)
- Be sure you understand the goals of the FOA (if you have questions, ASK EARLY!)
- Be sure you understand and follow the review criteria
- Start work on the application EARLY
- Complicated applications with many components
  - Make sure you have everything
  - Reserve lots of time to proofread
Tips (continued)

- This FOA specifies the sorts of research team members who should provide a biosketch.

- Submit applications early – at least a few days before the deadline
  
  - This FOA requires lots of additional information. There are many criteria for the reviewers to consider under each of the standard five review criteria. Take the time to be sure that you have addressed all of the additional criteria.

  - Once the receipt date and time (5PM applicant’s local time, standard NIH receipt dates) has passed, you will be unable to make additions or corrections to your application.
This FOA goes into considerable detail about what sorts of information should be included, and what points addressed, in the application itself. For example, the PHS398 Research Plan section includes a half-page list of information which must be included in the Research Strategy section summarizing the study protocol.

Be sure to include the information and address all of the points requested in the FOA.
National Center for Complementary and Alternative Medicine
National Institute of Nursing Research
Office of Behavioral & Social Sciences Research
Office of Research on Women’s Health

Web sites: nccam.nih.gov; ninr.nih.gov;
obssr.od.nih.gov; obssr.od.nih.gov

Clearinghouse: 1-888-644-6226