Purpose: This FOA is intended to foster mechanistic research on how arts-based approaches might enhance palliative care in managing multiple symptoms related to quality of life (QoL) in individuals living with serious chronic or terminal illness.

- Mechanism refers to the biological, physiological, neurological, psychological, and/or sociological manner by which the arts exert its purported effect(s) on selected outcomes.
- The term “arts” refers not only to artistic activities, but also to expressive and visual arts and creative activities, such as narrative, literature, rituals, oral histories, storytelling, etc.
- The intent of palliative care is multifaceted and includes relieving the myriad of disease-related symptoms (such as pain), mitigating the impact of co-morbidities, and enabling a positive influence on the course of illness. Palliative care integrates and coordinates the emotional, psychological, social, and physical aspects of care with a focus on enhanced QoL. Throughout the course of illness, a team approach composed of a variety of practitioners is used to achieve this end – to prevent suffering by managing stressful clinical complications and improving the patient’s sense of well-being.
- Symptoms involve a complex array of symptoms that accompany serious chronic illness, such as pain, stress, anxiety, fatigue, etc.

Background: Participating NIH institutes, centers, and offices (ICO) are interested in determining how the arts might enhance palliative care to manage symptoms broadly defined in individuals with serious, chronic illness or condition(s), by providing care for individuals across the lifespan, including those from diverse populations.

NCCAM provides research support for a broad spectrum of complementary health approaches, with the goal of developing foundational evidence for further research. Complementary and integrative arts-based approaches have shown some promise in relieving symptoms, and may prove beneficial in enhancing palliative care for individuals living with serious chronic or terminal illness. Integrative therapy may be an effective model for palliative care because of the potential advantage of combining the arts with conventional approaches to ameliorate symptoms.

NINR supports research to assist individuals, families, and healthcare professionals in managing the symptoms of life-limiting conditions and planning for end-of-life decisions through increased understanding of the complex issues, processes, and choices underlying end-of-life and palliative care across the lifespan. NINR is particularly interested in research that addresses strategies to minimize physical or psychosocial burden and better maintain the health of caregivers of individuals who require palliative or hospice-related end-of-life care.

The ORWH ensures that research conducted and supported by the NIH adequately addresses women’s health issues. This FOA is pertinent to ORWH’s mission because ORWH recognizes that women suffer disproportionately from serious chronic conditions and palliative care for family members often falls upon women caregivers. ORWH is particularly interested in the differences in mechanisms between male and female sample populations.

The OBSSR mission is to stimulate behavioral and social sciences research throughout NIH and to integrate these areas of research more fully into others of the NIH health research enterprise, and as such is committed to developing funding initiatives to further areas that lend themselves to this mission.

This initiative will encourage research to elucidate the mechanism of arts-based approaches designed to enhance palliative care in individuals with a wide variety of serious chronic conditions and their accompanying symptoms.
Special Review Criteria: Arts-Based Approaches in Palliative Care for Symptom Management

Reviewers should consider the usual NIH review criteria, but in addition should consider the following special review criteria in determining scientific merit for each application:

**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?

**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?

**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?

**Approach**
- 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?
- 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?
- 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?

**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?