Request for Applications
Pilot and Exploratory Studies Award

Program Description

One of the major barriers to the growth of the field of palliative care is the lack of innovative pilot projects that generate essential foundational evidence that can be implemented in practice to address suffering due to serious illness. The lack of pilot data necessary to successfully obtain large extramural funding is a particular barrier to early-career investigators seeking to obtain their first independent award (i.e., the K to R transition) and mid-career researchers seeking to sustain their careers or seeking to explore new research avenues. The overarching objectives of the **Advancing the Science of Palliative Care Research across the Lifespan (ASCENT) Consortium** are to promote the development of a palliative care research workforce and to build the evidence base for palliative care across the lifespan and a range of populations. The ASCENT Consortium requests applications to provide funding, guidance, and support for pilot and exploratory studies that lay the groundwork for larger, more comprehensive, externally funded groundbreaking studies and trials. The ASCENT Consortium is requesting applications for the 2025 funding cycle of the ASCENT Pilot and Exploratory Studies Award Program. Letters of Intent (LOI) are due by October 15, 2025. If invited to apply based on LOI review, Pilot and Exploratory Studies Applications will be due by January 14, 2026.

This request for applications (RFA) is limited to applications that support palliative care research for seriously ill patients and their caregivers in the below priority areas. Proposals may employ a range of research methodologies including but not limited to: clinical trials (as defined by the NIH), observational studies, secondary data analyses, health services research, qualitative research, and mixed methods research.

1. Improving communication between health care teams and persons with serious illness and their caregivers across the lifespan and across settings.
2. Developing and/or evaluating novel care delivery models addressing the needs of people with serious illness and their caregivers across the lifespan.
3. Assessing cost, quality, access, use, and outcomes of palliative care for people with serious illness and their caregivers across the lifespan.
4. Developing and/or using new methodological approaches (e.g., causal inference, trial design, incorporating artificial intelligence) or measures (e.g., pain, depression, spiritual distress) in palliative care research.
5. Improving pain and other physical (e.g., dyspnea, disability, cognition), psychosocial (e.g., depression, anxiety, loneliness), or spiritual (e.g., loss of meaning, existential distress) concerns of people with serious illness and their caregivers across the lifespan.

Note: The limited time and budget provided by this Consortium RFA constrains the types of clinical trials that can be proposed to activities related to creation of an intervention or preliminary testing (feasibility/acceptability) of an already developed intervention, which is NIH Stage Model Stage I. It is unlikely that the duration and budget of these awards would be sufficient for a high-quality fully powered efficacy trial (Stage II). **Applicants proposing a clinical trial are strongly advised to consult the ASCENT Consultation Program, which will include office hours and guidance to help you prepare, after your LOI has been administratively reviewed. Consultation is available for those applicants who are invited to submit a full proposal.**

Award Information

Each pilot and exploratory study must not exceed a direct cost of **$250,000 per year for a maximum duration of 2 years**. For example, smaller pilot studies may have a direct cost of $100,000 and a duration of 1 year, while larger exploratory studies may have a direct cost of $250,000 per year and a duration of 2 years.

Please note the following budget guideline update for indirect costs: If applicable, applicants are required to use their federally negotiated rate agreement as stated in NIHGPS7.4: Reimbursement of Facilities and Administrative Costs. If your organization does not have a federally negotiated rate, you may use a de minimis rate of 10%.

The budget should include support for salary, research activities, and funds for attending the ASCENT annual scientific meeting. Awards are not renewable.

Eligibility

To be eligible for the ASCENT Pilot and Exploratory Studies Award, applicants must meet the following requirements:

- Applicants must hold a clinical, research, or health-professional doctorate degree (MD, PhD, DO, DSW, DPH, PharmD, ND, or equivalent).
- Applicants must have a full-time faculty, research scientist, or equivalent position at a college, university, medical or nursing school, health care system/setting or other fiscally responsible organization within the United States with Principal Investigator status by the time of the award start date.
- Applicants must be citizens or permanent residents of the United States.
- Applicants must be able to commit to participation in ASCENT-supported periodic online and annual in person meetings.
- Applicants cannot simultaneously apply for both an ASCENT Research Scholar Award and Pilot and Exploratory Award in the same grant cycle.

Although investigators at all stages of their career are invited to apply, funding priority will be given to qualified and promising early-career investigators who are seeking their first large independent research grant (e.g., K to R transition) and mid-career investigators seeking to obtain a second large research grant to sustain their careers or exploring new research avenues. Applicants uncertain about their eligibility are strongly advised to contact ASCENT administration before preparing an application.

The number of awards will depend on the awarded budgets for meritorious applications. Applications are open to investigators from a range of disciplines across varied institutions and geographic locations focused on varied patient populations. This includes populations with disproportionately higher palliative care needs and/or challenges accessing palliative care services as defined by NIH (see also NIH-Designated Populations with Health Disparities).

Grantee Requirements

Each recipient of an ASCENT Pilot and Exploratory Studies Award, as a condition of accepting the award, will agree to the following:

- To attend (virtually) periodic training and works-in-progress presentations
- To budget for and attend (in person) the Annual ASCENT Scientific Meeting in the Washington, DC, metro area each year during their award period.
- To present results of their ASCENT-funded research at the required annual meeting and once-annually in virtual works-in-progress sessions
- To prepare annual progress reports for each year of funding and a final report at the conclusion of the award period
- To complete brief, interim, 6-month milestone surveys querying progress, barriers, and ASCENT core training program engagement for the duration of the award
- To include standardized ASCENT funding acknowledgement and disclosure in presentations, publications, and other dissemination activities
- To follow all applicable NIH policy and compliance requirements including, but not limited to, ClinicalTrials.gov registration, NIA's Clinical Research Operations and Management System reporting, and use of the ASCENT data management and sharing plan including, where feasible, the quantitative and qualitative data repositories.
- To respond in a timely matter to requests to participate in ASCENT Consortium evaluation activities when requested during and for 1 year following the award

How to Apply

Online application forms and complete instructions for the ASCENT Pilot and Exploratory Studies Award are available on the ASCENT website at ascentpalliativecare.org. Applications must be submitted electronically via ASCENT application portal by the close of business (5:00 PM PT) on the specified deadline date.

The ASCENT Pilot and Exploratory Studies Award has a two-step application process:

STEP 1: Eligible candidates are required to complete online an application and upload a letter of intent (LOI) along with their biosketch using the current NIH format, no later than October 15, 2025, at 5:00 PM PT. The LOI should not exceed 800 words and should briefly describe the applicant's previous experience, research plan, how the proposed research will lead to a future large study/grant, and how the applicant will utilize ASCENT core resources. Plans to utilize the ASCENT Cores (i.e., Design Core, Measurement Core, Population-based Data Core, and Engagement Core) are recommended (not mandated) for all applications. Applicants who meet eligibility requirements and whose research focus is in an ASCENT priority area will be invited for full proposals.

STEP 2: If an applicant is selected for further consideration, they will be asked to submit a full proposal no later than January 14, 2026, at 5:00 PM PT. Applicants will have access to the ASCENT Lab, our Consultation Program, which includes office hours and information about available resources.

Full Proposal Preparation

The format of the full application is based on an NIH R21 award and will include all items and sections outlined below. Applicants should follow the NIH font and format specifications (i.e., font size of 11 points or larger; single-spaced; no more than 15 characters per inch; no more than 6 lines per inch, and at least one-half inch margins for all pages) and should include a page number and the applicant's name

on each page. The Applicant's Biosketch and Letter of Intent are all submitted during Step 1 of the application process, while the remaining documents are submitted in Step 2.

1. **Biosketch** | Upload biosketches for the Principal investigator(s) and any key personnel in the current NIH format.
2. **Project Abstract** | Provide a concise statement of no more than 300 words describing the proposed project.
3. **Lay/General Audience Summary** | Describe your study in no more than 300 words using consumer-friendly, jargon-free, and abbreviation-free terms.
4. **Specific Aims (maximum 1 page)** | State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. Succinctly describe how the proposed research will lead to a future large study/grant and how the applicant will utilize ASCENT core resources.
5. **Research Plan** (maximum 6 pages) | The research plan should follow the NIH font and format specifications (i.e., font size of 11 points or larger; single-spaced; no more than 15 characters per inch; no more than 6 lines per inch, and at least one-half inch margins for all pages), and should include a page number and the applicant's name on each page. The following sections must be included:
    a. Significance
    b. Innovation
    c. Research Design and Methods
    d. Protection of Human Subjects (if applicable and not included in page limit)
    e. References (not included in page limit)
6. **Protection of Human Subjects (if applicable).** See below for details.
7. **Budget & Budget Justification** | Applicants should follow the online directions on the ASCENT website for how to submit the budget for their proposed project. Project expenses should be in accordance with the ASCENT budget guidelines and justified.
8. **Letters of Support** | Attach a single file with all letters of support, including any letters necessary to demonstrate the support of Senior/Key Personnel and Other Significant Contributors included in the grant application. For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per budget period anticipated.
9. No appendices will be accepted.
10. No supplemental materials will be accepted after the deadline unless requested by staff for administrative purposes or when needed for the reviewers.
11. Adherence to all NIH research requirements (e.g., Form I, Financial Conflicts of Interest, Data and Safety Monitoring Board) is expected.
12. NIA will determine whether a Safety Officer or Data and Safety Monitoring Board are required. If a clinical trial is proposed, the applicant will be required to adhere to the ASCENT Data and Safety Monitoring Plan and utilize the ASCENT appointed Safety Officer or Data and Safety Monitoring Board.

Protection of Human Subjects

If the research involves human subjects, applicants must provide a section immediately following the research plan that addresses:

1. **Risks to Human Subjects**
    a. Describe and justify the proposed involvement of human subjects in the work outlined in the Research Strategy section.

   b. Describe the characteristics of the subject population, including their anticipated number, demographics, and health status, if relevant, in alignment with NIH Policy on Inclusion of Women and Minorities as Subjects in Clinical Research
   c. Describe and justify the sampling plan, including retention strategies and the criteria for inclusion or exclusion of any subpopulation.
   d. If relevant, explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
   e. If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, provide details about all planned interventions such as dose, frequency, and administration.

2. **List any collaborating sites where human subjects research will be performed and describe the role of those sites and collaborating investigators in performing the proposed research**. Explain how data from the site(s) will be obtained, managed, and protected.
3. **Sources of Materials**
   a. Describe the research material obtained from living individuals in the form of specimens, records, or data.
   b. Describe any data that will be collected from human subjects for the project(s) described in the application.
   c. Indicate who will have access to individually identifiable private information about human subjects.
   d. Provide information about how the specimens, records, and/or data will be collected, managed, and protected, as well as whether any individually identifiable private information will be collected specifically for the proposed research project.
4. **Potential Risks**
   a. Describe all the potential risks to subjects posed by participation in the research (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects.
   b. Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research. When alternative treatments or procedures are possible, the rationale for the proposed approach should be clear.
5. **Recruitment and Informed Consent**
   a. Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
   b. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and plans for obtaining consent from a legally authorized representative for adult subjects not able to consent.
6. **If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent document(s) need not be submitted unless subsequently requested the ASCENT program.**
7. **Protections Against Risk**

a. Describe planned procedures for protecting against or minimizing all potential risks identified, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.
b. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.
c. Where appropriate, describe plans for handling incidental findings that may be uncovered as a result of the research, such as incidental findings from research imaging, results of screening tests, or misattributed paternity.

8. **Potential Benefits of the Proposed Research to Human Subjects and Others**
    a. Discuss the potential benefits of the research to participants and others.
    b. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.
    c. Please note that financial compensation of subjects should not be presented as a benefit of participation in research.
9. **Importance of the Knowledge to be Gained**
    a. Discuss the importance of the knowledge to be gained as a result of the proposed research.
    b. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.
10. **All studies involving human subjects will need a single IRB plan consistent with the ASCENT Consortium sIRB policy indicating whether they will use their institution's sIRB or will require use of University of Colorado's (CU) sIRB.** Regardless of which IRB is used, CU as the ASCENT prime site is considered a site for the sIRB given the nature of collaborative awards from NIH and any required funds should be budgeted for this additional site accordingly. Applicants must include a letter from their IRB/OHRPP confirming they are either serving as sIRB or will cede to the ASCENT/CU sIRB.
11. **Studies with an NIH-defined clinical trial will be required to comply with the requirements specified in NOT-AG-24-081: NIA Clinical Research Enrollment Policy.**

Peer Review of Applications

The ASCENT Scientific Review Committee (SRC) will review the proposals. The SRC is composed of scientists with expertise in palliative care, patient-oriented research, health services research, communication, epidemiology, research design and biostatistics. In addition, the SRC includes lay-reviewers with personal lived experiences of serious illness.

Review Criteria

Applications will be reviewed using the current NIH scoring system. Lay-reviewers will evaluate the proposal's lay summary and relevance to the lived experience of serious illness.

Specific considerations that contribute to overall score include the following:

- **Factor 1: Importance of the Research**
    - Significance, Innovation
    - Alignment with request for applications and ASCENT priorities
    - Potential of the research to progress to a large extramurally funded award
- **Factor 2: Rigor and Feasibility**
    - Approach

    - Inclusion of sex as a biological variable
- **Factor 3: Expertise and Resources**
    - Investigators, Environment
    - Use of the ASCENT Cores

Note: All projects proposed for funding after the ASCENT scientific review process will require approval by NIH prior to initiation.

Resubmission

Applications that are not funded may be revised and resubmitted for the next ASCENT funding cycle. However, only one resubmission is allowed. Resubmitted applications will be reviewed in the same detail and will compete on an equal basis with all other new applications. Resubmitted applications will include all the above elements plus a 1-page introduction to the revised application that summarizes substantial additions, deletions, and changes to the application and responds to the issues and criticism raised in the prior review.

Contact

Please email ASCENTadmin@cuanschutz.edu with any questions.