

2025 GRANT APPLICATION GUIDELINES

Application deadline: October 31, 2025 at 11:59 pm (ET)

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Grant Application Instructions

ABOUT EMILY'S ENTOURAGE:

Emily's Entourage (EE) is an innovative 501(c)3 that accelerates research for new treatments and a cure for individuals with cystic fibrosis (CF)—a fatal genetic disease primarily affecting the lungs and digestive system—that do not benefit from currently available CFTR modulator therapies. Since 2011, EE has awarded millions of dollars in research grants, securing over \$52.3 million in follow-on funding; launched a clinical-stage CF gene therapy company; developed a patient database and clinical trial matchmaking program to accelerate clinical trial recruitment; and led worldwide efforts to drive high-impact research and drug development. The organization has been featured in national media, including *The New York Times*, STAT, CNN, *People*, and more.

KEY OBJECTIVES:

Mutations in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene cause cystic fibrosis (CF). Since 2012, incredible progress has been made with the development and approvals of CFTR-modulator therapies to benefit approximately 90% of individuals with CF. The final 10% of the CF community that does not benefit from currently available CFTR modulators due to genetically ineligible mutations are left without effective treatments. In addition, there is also a significant portion of the CF community that despite having mutations that are genetically eligible for CFTR modulators are unable to benefit due to side effects from or a suboptimal response to CFTR modulators.

EE has spearheaded efforts to prioritize and drive research for all individuals with CF who do not benefit from current CFTR modulators. EE's ongoing commitment to accelerate research and drug development is designed to provide a sustained and robust pipeline of novel therapeutics for people with CF for whom there are no mutation-targeted therapeutic options currently available.

EE has identified critical high-need areas with the potential to speed therapeutic development for those that do not benefit from CFTR modulators and remove barriers and limitations that are holding back the advancement of such therapies. EE's grant program aims to provide essential



seed funding to researchers pursuing innovative strategies in key research areas to advance CF treatment. The following research areas are currently supported by the program:

1. Delivery of Nucleotide-Based Therapies

Nucleotide-based therapies offer transformative potential for CFTR correction. Recent breakthroughs in inhalation-optimized encapsulation techniques, respirable carrier particles, and chemically modified nanoparticles have created unprecedented opportunities for genetic therapy delivery. Novel formulations for systemic and inhalation delivery will be considered within the scope of this RFP.

This RFP seeks innovative approaches including but not limited to:

- Gene editing platforms (CRISPR, base editing, prime editing) formulated for inhaled and systemic delivery with enhanced lung deposition and cellular uptake
- Novel encapsulation technologies including lipid nanoparticles, polymeric carriers, and hybrid delivery systems optimized for nebulization
- Immune-evasive formulation strategies incorporating immune-suppressive excipients, stealth coatings, and targeted delivery to specific lung cell populations
- Next-generation viral vectors (AAV, lentiviral, adenoviral) with reduced immunogenic profiles and enhanced lung tropism

2. Novel Inhaled Formulations for Staphylococcus aureus and CF Pathogens

Multidrug-resistant bacterial pathogens significantly impact outcomes in people with CF, driving urgent need for innovative inhaled antimicrobial formulations and delivery systems. Priority targets include MRSA, nontuberculous mycobacteria (NTM), and other high-burden CF pathogens.

This RFP seeks novel formulation approaches including but not limited to:

- FDA approved antimicrobials formulated specifically for pulmonary delivery
- Advanced liposomal and lipid-based formulations of existing antibiotics for enhanced lung penetration and sustained release
- Sustained-release formulations enabling extended antimicrobial activity with reduced dosing frequency
- Combination inhaled therapies integrating antimicrobial-adjuvant combinations



- Novel inhaled antifungal formulations addressing fungal co-infections and emerging resistance patterns
- 3. Understanding Immunogenicity in CF Nucleotide-Based Therapies—Nucleotide-based therapies for CF encounter significant obstacles from immune recognition and safety issues that can substantially reduce treatment effectiveness. The distinctive CF lung microenvironment amplifies these challenges, highlighting the critical need for insights to advance research on safe, effective, and repeatable gene therapy delivery systems. Our goal is to support research that overcomes current barriers to successful gene therapy administration, enabling patients to receive multiple treatments safely and effectively over time.

This RFP seeks to fund studies including but not limited to:

- Understanding of pre-existing immunity and treatment-induced immune reactions.
- Immunosuppressive approaches to reduce immune system activation
- Novel strategies to bypass immune recognition

GRANT PROGRAM OVERVIEW:

Investigators are expected to have a good track record of peer reviewed publications and extramural funding. Awards are set at \$100,000 per annum (direct costs) and, typically, funding will last for a total of two years. Awards are associated with additional indirect costs set at 10% such that total payments per annum will be \$110,000. Funding will be allocated at 6 month intervals with payments of \$50,000 released by EE, subject to sufficient progress being accomplished. Acceptance of funding requires submission of PROGRESS REPORTS that will be used to assess research progression. Continued financial support is contingent upon satisfactory completion of proposed research objectives delineated in the 'MILESTONES' section of GRANT APPLICATIONS. The first PROGRESS REPORT will be requested after 5 months of funding, and thereafter at 6 month intervals. Acceptance of funding will require execution of the EMILY'S ENTOURAGE GRANT CONTRACT by an authorized representative of the grantee institution.

APPLICANT ELIGIBILITY CRITERIA:

Applicants must have:

- Faculty appointment at an academic institution
- PhD, MD, or DO

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- There are no restrictions on citizenship or geography
- No funding from other sources for the project for which they are applying to EE
- Track record of publication and funding
- Multiple PIs are encouraged to collaborate and apply

EVALUATION CRITERIA:

Competitive proposals will demonstrate:

- Potential to have a major scientific impact in the field of CF
- Innovation
- Objectives that will enable therapeutic advances
- Feasibility (for instance in the form of preliminary data, or research conducted in the Principal Investigator's laboratory)
- Milestones that are clearly and logically delineated

REVIEW PROCESS:

- Applications will be reviewed internally and by external reviewers prior to consideration by members of the EE Scientific and Leadership Team
- Following preliminary review, additional information may be requested from applicants

KEY DATES:

- 2025 global call for proposals opens on September 22, 2025 and closes on October 31, 2025 at 11:59 pm (ET).
- Applicants will be notified by December 2025 if they are selected to move to the next round of reviews.
- Applicants will be invited to respond to reviewer comments.
- Funding decision will be made by February 1, 2026 with project start dates by March 1, 2026.

APPLICATION INSTRUCTIONS:

Provision of the following components is required to complete the GRANT APPLICATION process. All components should be compiled and submitted as a single <u>pdf</u>. In addition, the IMPACT STATEMENT and LAY ABSTRACT (described below) should be provided as a single <u>.docx</u> document. Finalized grant packages should be returned on or before the closing date to Chandra Ghose PhD, CSO, Emily's Entourage (<u>research@emilysentourage.org</u>).



SPECIFIC AIMS: (Page limit: one page)

Please provide a project title and include an overview of the proposed research project with proposed objectives, and rationale for the studies described. Also include explicit details of each SPECIFIC AIM that will be addressed to achieve the proposed project goals.

RESEARCH PLAN: (Page limit: 2 pages)

The RESEARCH PLAN should detail information related to the project including:

- SIGNIFICANCE describe the relevant background for the current research plan
- *INNOVATION* discuss how the proposed research challenges or advances current knowledge, or introduces novel concepts, approaches or technology
- APPROACH detail methodologies to address the proposed research objectives

It is strongly recommended that the *APPROACH* section includes any pertinent preliminary data Any cited literature in the GRANT APPLICATION should be included in additional pages using a numbered format.

In terms of institutional compliance, the *RESEARCH PLAN* should explicitly state, as appropriate, that the proposed research requires use of animals and / or human subjects. As necessary, an IACUC approval letter or note if approval is pending, and / or an IRB approval letter or note if approval is pending, should be included in an *APPENDIX*. Otherwise, please note in the *RESEARCH PLAN* that IACUC and / or IRB approval are not required.

MILESTONES: (Page limit: 1 page)

Provide a schematic representation and written description of the proposed project progression based on 6 month intervals. As stated above, continued financial support is contingent on submission of PROGRESS REPORTS and satisfactory completion of proposed research objectives specifically detailed in the MILESTONES section. In the event that MILESTONES are not robust, quantifiable and described in sufficient detail, EE may request resubmission of a revised MILESTONES section prior to making a funding decision. EE reserves the right to terminate funding if there is a lack of adequate scientific progress during any funded time period. The described MILESTONES will play a key role in the assessment of project progression.



BUDGET: (Page limit: 1 page)

Please submit a budget and justification using this Excel spreadsheet (save as a pdf for submission) for each of the two years of funding. Indirect costs are set at 10%, which will be included in addition to the \$100,000 annual award (total award \$110,000 per year). The budget justification should explicitly state that overlapping funds do not support the proposed studies. PLEASE DOWNLOAD THE SPREADSHEET

IMPACT STATEMENT: (Page limit: half page)

Describe how the proposed research will lead to new or improved therapeutic approaches for people with CF that do not benefit from existing CFTR modulators or address an unmet need in the CF therapeutic landscape, particularly for the population without highly effective modulator therapies.

LAY ABSTRACT: (Page limit: half page provided on the same page as the IMPACT STATEMENT)

Summarize the research project in a manner that the layperson could appreciate. As described in the **EMILY'S ENTOURAGE GRANT CONTRACT**, information provided in the LAY ABSTRACT will be used and potentially published via formats such as the EE website or social media accounts, at the discretion of EE.

NIH BIOSKETCH(ES):

Please provide an NIH format Biosketch for Principal Investigator(s) associated with the application. In the RESEARCH SUPPORT section, please include all current and pending grant applications, and include an explicit statement that current funding does not directly overlap with funding for the proposed research to be supported by EE.

APPENDIX:

A brief appendix is allowed for information pertinent to the GRANT APPLICATION, including accepted but not yet published manuscripts, additional supplementary experimental results, and similar information. In addition, IACUC and / or IRB approval, and all other pertinent material, should be included in the APPENDIX. The following may be added to the Appendix -

RESOURCE SHARING:

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In the event that a resource is generated that could enable development of novel CF therapies for individuals with CF that do not benefit from CFTR modulators (for instance, cell lines, murine models, etc.), information should be forwarded to research@emilysentourage.org for inclusion on the EE resource webpage: https://www.emilysentourage.org/research-resources/

COLLABORATORS AND/OR CONSULTANTS:

Include any appropriate letter from all individuals confirming their involvement in the proposed project.

FORMATTING INSTRUCTIONS:

- All pages of the application should include a header with the name of the Principal Investigator at the top right hand corner, and a footer with a page number in the center of the page
- Application formatting should follow NIH guidelines using 11pt Arial font with a minimum of 0.5" margins
- Any tables or figures should be embedded in the body of the Application and not included in the APPENDIX