P30 Precision Medicine Center for Cystic Fibrosis

Pilot and Feasibility Program Application Instructions

The P30 Precision Medicine Center for Cystic Fibrosis Pilot and Feasibility Program supports innovative research addressing cystic fibrosis and its non-pulmonary, NIDDK-relevant complications. The program particularly encourages applications from new investigators and established investigators who are applying their expertise to cystic fibrosis for the first time. Investigators do not need to have an established CF research program to submit an idea.

Pilot awards provide up to $75,000 in direct costs for one year, with the possibility of competitive renewal for a second year.

Stage 1: Letter of Intent

Purpose

The Letter of Intent allows the P30 leadership team to:

- Determine whether the proposed project aligns with the mission of the Center and the NIDDK.
- Identify the P30 research cores, clinical resources, investigators, or mentors that could strengthen the project.
- Assess whether the proposed work is appropriate and sufficiently developed for a full pilot application.
- Connect investigators who are new to CF research with relevant scientific and clinical expertise.

Format

The LOI must not exceed one page, excluding investigator information and references.

- Arial, Helvetica, or Calibri, 11-point font or larger
- Single spacing
- Margins of 0.5 inch or larger
- PDF format
- Descriptive file name: LastName_PMCCF_LOI_2027.pdf

Investigator Information

Provide the following at the top of the page:

- Project title
- Principal investigator name, degree, title, department, and institution
- Email address and telephone number
- Career stage
- Current CF or CF-related funding, if applicable
- PMCCF collaborator or proposed CF mentor, if already identified

Required LOI Content

1. Research Question and Significance

- The clinical or biological problem being addressed.
- The central research question.
- Why the problem is important to CF or an NIDDK-relevant complication of CF.
- The gap in knowledge or capability that the project will address.

2. Central Hypothesis and Specific Aims

- State the central hypothesis or overall objective and list the proposed specific aims. For a one-year pilot project, one or two focused aims are recommended.
- The aims should be feasible within one year, generate interpretable preliminary data, and support a future independent grant application, manuscript, clinical study, or larger collaborative project.

3. Approach and Innovation

- The experimental strategy or study design.
- Key models, samples, datasets, technologies, or patient populations.
- What is new or distinctive about the proposed work.
- The expected outcome and how the results will advance the field.

4. P30 Resources and Anticipated Needs

- P30 research cores
- Specialized models or tissues
- Clinical samples or phenotyping
- Vector or gene-transfer expertise
- Pathology services
- Biostatistics or data-science support
- CF clinical or disease-area expertise
- Regulatory, technical, or logistical assistance

5. Future Direction

- In one or two sentences, explain how successful completion of the pilot project will position the investigator for subsequent extramural funding or a larger research program.

Applicants do not need to have finalized resource arrangements at the LOI stage. The Center will help selected investigators identify appropriate resources and determine feasibility, timelines, and costs.

LOI Review Considerations

- Alignment with the PMCCF and NIDDK missions
- Importance of the research problem
- Innovation and potential impact
- Feasibility within one year
- Potential to use or benefit from P30 resources

- Potential to generate preliminary data for future funding
- Opportunity to bring new investigators, expertise, or approaches into CF research

Submission
Submit the one-page LOI through the PMCCF Pilot Program submission portal by December 1, 2026. Selected investigators will be invited to complete the mentorship and consultation phase before submitting a full application by February 1, 2027.

Submission portal: https://pmccf.medicine.uiowa.edu/form/pmccf-pilot-program-submissions

Stages 2-5: Mentorship, Core Consultation, and Proposal Development
Investigators invited to submit a full application will participate in a structured, collaborative proposal-development phase. The purpose is to strengthen scientific alignment, identify appropriate Center resources, and ensure that the proposed work is feasible within the project period and budget. Participation is expected but does not guarantee funding.

Step 1: Initial Consultation with P30 Leadership
- Review alignment with the Center and NIDDK missions.
- Identify relevant CF investigators and clinical expertise.
- Determine whether a CF mentor or additional collaborator is needed.
- Identify appropriate research cores and other Center resources.
- Clarify project scope, feasibility, and expected outcomes.

Step 2: Core Consultation
- Experimental design and required samples, models, data, or reagents.
- Core capabilities, technical limitations, sample size, and throughput.
- Core charges, personnel availability, and budget requirements.

Step 3: CF Mentorship (for those new to CF)
- Understand relevant CF biology and clinical context through connection to a CF researcher
- Connect with the broader CF research community.
- Develop a strategy for subsequent funding and career development.

Step 4: Proposal Refinement
- Demonstrate alignment with the Center mission.
- Integrate P30 resources appropriately.
- Respond to recommendations from P30 leadership, core directors, and mentors.
- Define a credible path from pilot findings to future funding or broader impact.

The mentor serves in an advisory role. The applicant remains responsible for the scientific direction and preparation of the application.

Stage 6: Full Pilot Application

Only applicants invited following LOI review may submit a full application.

1. Cover Page (NIH Cover page - form available)

Project title; principal investigator; department and institution; contact information; project period; total funds requested; CF mentor or collaborator, if applicable; and P30 cores/resources to be used.

2. Project Summary/Abstract - Maximum 30 lines (NIH format)

Concise overview of the problem, hypothesis, aims, approach, expected outcomes, and relevance to CF and the NIDDK mission.

3. Specific Aims - Maximum 1 page (NIH Format)

Overall objective, central hypothesis, one or two focused aims, expected outcomes, and how the results will position the project for future funding or development.

4. Research Strategy - Maximum 5 pages (NIH Format)

- Significance: importance, knowledge gap, and effect on CF biology, clinical care, or an NIDDK-relevant complication.
- Innovation: new concept, method, model, technology, collaboration, or application.
- Approach: rationale, design, methods and analysis, expected outcomes, potential problems, alternatives, milestones, and success criteria for each aim.
- Clearly identify the P30 cores, clinical resources, models, tissues, datasets, or expertise supporting the project.

5. Milestones and Timeline - Maximum 1 page

One-year timeline; key milestones for each aim; measurable success criteria; decision points and alternatives; and end-of-award deliverables.

6. Future Funding and Sustainability Plan - Maximum 1/2 page

Anticipated next funding mechanism, expected preliminary data or proof of concept, approximate submission timeline, and development into a sustainable CF-related research direction.

7. Mentorship and Collaboration Plan - Maximum 1 page, when applicable

Mentor expertise and role; meeting frequency and format; contributions to rigor and CF relevance; and support for an independent or collaborative CF research program. Include a brief mentor letter.

8. P30 Core Utilization Plan - Maximum 1 page

For each core/resource: requested service, division of work, samples or experiments, timeline, estimated cost, and technical prerequisites. Include brief confirmation from the relevant core director.

9. Budget and Budget Justification (NIH Style)

Provide a detailed one-year budget and justification. The request may not exceed $75,000 in direct costs. Allowable expenses may include personnel, supplies, P30 core charges,

specialized services, data analysis, participant-related research costs, and other costs required to complete the aims.

10. NIH Biosketches

Provide current NIH-format biosketches for the principal investigator, key personnel, mentor when applicable, and major collaborators.

11. Other Support

Provide current and pending support for the principal investigator and key personnel. Distinguish the pilot from funded or pending work and address scientific or budgetary overlap.

12. References Cited

References are not included in the Research Strategy page limit.

13. Regulatory Status

Indicate whether the project involves human participants, human specimens or identifiable data, vertebrate animals, recombinant or synthetic nucleic acids, or biohazardous materials. State the status of IRB, IACUC, biosafety, or other required approvals.

Full-Application Review Criteria

1. Significance: Importance of the problem and potential effect on CF or an NIDDK-relevant complication.

2. Investigators: Suitability of the project team, collaborators, mentors, and core relationships.

3. Innovation: Novelty of the concept, approach, technology, model, or application.

4. Approach: Scientific rigor, feasibility, analysis, milestones, risks, and alternative strategies.

5. Environment and Center integration: Appropriate and meaningful use of P30 expertise and resources.

6. Pilot potential: Likelihood of generating actionable preliminary data.

7. Future funding potential: Strength of the plan for an independent grant, publication, clinical study, or larger collaborative program.

8. Overall impact: Likelihood of sustained influence on CF research or patient-relevant outcomes.

Applications will be reviewed through the P30 process, including input from the Executive Committee and, when appropriate, the External Advisory Board.

Timeline Summary

Stage	Target date
Letter of Intent due	December 1, 2026
Invitation to submit full application	December 2026

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P30 leadership consultation	December 2026
Core and mentor meetings	December 2026-January 2027
Proposal refinement and internal review	January 2027
Full application due	February 1, 2027
Scientific and programmatic review	Spring 2027
Regulatory and administrative preparation	Spring-Summer 2027
Anticipated project start	August 1, 2027

Program Contact

Amy L. Ryan, PhD
Director, Precision Medicine Center for Cystic Fibrosis
Email: amy-l-ryan@uiowa.edu