



The Role of the CF Community in CF Foundation-Funded, Investigator-Initiated Clinical Research

The term **community members** refers to people with cystic fibrosis and their families who collaborate with CF researchers through Community Voice, care centers, and other patient-centered collaboratives with a CF focus.

The term **investigators** refers to principal investigators¹ (or co-PIs, including multi-site) submitting research proposals on behalf of their academic institutions. Collaboration with community members is recommended but not required for CF Foundation-funded clinical research.

Development Stage of Research	Possible Roles of Community Members	Potential Collaboration Mechanisms
CF Foundation Program-Level Initiatives	Community members provide feedback to the CF Foundation on overarching research priorities, initiatives, and research programs.	<ul style="list-style-type: none"> • Surveys • Focus groups • Steering committees • Access to data repository of previous Community Partnership projects/surveys
Concept Developing/Grant Writing	Investigators may work as needed with Community Voice or other patient-centered collaboratives to gain feedback on research proposals or study question ideas.	<ul style="list-style-type: none"> • Surveys • Focus groups • Access to data repository of previous Community Partnership projects/surveys

¹ Eligibility requirements state that applicants must be independent investigators defined as individuals who are out of fellowship training and whose institution allows them to submit applications for research funding as principal investigators. (Source: CF Foundation’s Policy and Guidelines for programs supporting basic research grants and clinical research awards)



Grant Review	<p>Community members review research proposals to provide feedback on the project’s topic area using the following criteria:</p> <ul style="list-style-type: none"> ➤ Is the research question important to the CF community? ➤ Is the study design feasible for someone with CF, and how may the proposal be improved? 	<ul style="list-style-type: none"> • Standing committee (e.g., Clinical Research Committee Community Representative Reviewers) • Ad hoc committees/reviews
Protocol Development/Study Design	<p>Community members and investigators work together to develop the ideas and framework for a study design or protocol and to develop the protocol materials, including review of patient-facing materials and recruitment strategies. Community members are available to provide input throughout the protocol development process as needed by the investigators.</p>	<ul style="list-style-type: none"> • Surveys • Focus Groups • Patient partners (individuals who can collaborate with PIs throughout the project) • Design Days
Protocol Review	<p>Community members use a standard set of criteria to evaluate protocols and comment on interest, feasibility, and study burden. Feedback is collated with other reviewer comments and within categories of scientific merit, study design, and feasibility. Feedback is provided to investigators.</p>	<ul style="list-style-type: none"> • Standing committee (e.g., Protocol Review Committee) • Ad hoc committees/reviews
Data Safety Monitoring Board	<p>Community members participate as members of individual study data monitoring committees. This participation includes review of the protocol and proposed safety monitoring plan before the trials start and continues safety monitoring throughout the study’s duration.</p>	<ul style="list-style-type: none"> • Standing data monitoring committees
Communication/Study Execution	<p>Community members work with CF Foundation or investigators to develop communication plans/materials/media, including patient-facing materials related to a research project or initiative.</p>	<ul style="list-style-type: none"> • Surveys • Focus groups • Patient partners