The Cystic Fibrosis Foundation (CFF) Center Committee will consider an application for accreditation of a CF center or independent program if it meets all criteria for care, teaching and research as outlined below, and fulfills a geographic and consumer need.

### CARE and INFRASTRUCTURE

A CFF-accredited Center is typically comprised of a pediatric and adult care program as described below. A center may also include one or more CFF-accredited Affiliate Programs (Affiliate Program Accreditation Criteria provided separately). In special circumstances, a Center may provide care primarily for either a pediatric or adult population.

**The following requirements must be met by the Center and each of its component programs to establish and maintain CFF accreditation.**

A CFF Center must provide age appropriate care, both inpatient and outpatient, in age appropriate facilities for pediatric and adult patients. If the size of the adult patient population at a CFF Center meets the criteria for establishing an adult program as outlined in this document, the Center is required to develop a sustainable adult care program and submit an application for accreditation of the Adult Program.

For Centers treating only pediatric CF patients, a formal pediatric to adult CF care transition plan must be in place with a partnering CFF-accredited Center or Program within the local region to provide adult CF care.

### CLINICAL CARE GUIDELINES FOR CF

All CFF-accredited centers and programs are expected to adhere to the Cystic Fibrosis Foundation’s Clinical Practice Guidelines for CF (available on the [CFF Web site](https://www.cff.org)).

### MULTI-DISCIPLINARY CARE TEAM & OTHER SPECIALISTS

The following required care team members must regularly attend outpatient clinics and team conferences and be available for inpatient consultation or coordination of care with inpatient staff.

1. Program Director (physician as described in this document)
2. Associate Program Director (physician as described in this document)
3. Clinic Coordinator* (team member other than physician)
4. Social Worker*
5. Respiratory Therapist*
6. Nurse
7. Dietitian/Nutritionist* (Registered Dietitian)

*“101 Document” regarding the skills, role and responsibilities on this recommended Role is available to CFF-accredited Centers and Programs on PortCF in the Resources section under “Mentoring Program”.

<table>
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<tr>
<th>Guidelines for CFF Center Personnel Time Allotments</th>
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<tr>
<td>1. Physician: 1 Full Time Equivalent (FTE) per 100 – 150 patients. Please note there is a minimum requirement of 2 M.D.’s per center.</td>
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<tr>
<td>2. Registered Nurse: 1 FTE per 100 – 200 patients.</td>
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<td>3. Social Worker: 1 FTE per 100 – 200 patients.</td>
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<td>4. Dietitian: 1 FTE per 100 – 200 patients.</td>
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<tr>
<td>5. Respiratory Therapist: 1 FTE per 100 – 200 patients.</td>
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The full time equivalents (FTE) outlined below represent the minimum staffing levels necessary to maintain an effective outpatient multidisciplinary team. These guidelines are used to review and accredit care centers by the Cystic Fibrosis Foundation.
Centers with accredited pediatric and adult care programs must have separate, defined care teams in place for both the pediatric and adult programs meeting the above requirements. Care team members, other than physicians (except when board certified in Internal Medicine AND Pediatrics), may be shared between pediatric and adult programs where appropriate.

In addition to the above required team members, the team members listed below are also recommended.

- Administrative Assistant
- Pharmacist
- Physical Therapist
- Psychologist

The following consultative personnel must be available for pediatric and/or adult patients (if not included on core care team):

1. Allergist/Immunologist
2. Anesthesiologist
3. Cardiologist
4. Endocrinologist
5. Gastroenterologist
6. Geneticist/Genetic Counselor
7. Infectious Disease Specialist
8. Internist
9. Neonatologist
10. Obstetrician/Gynecologist
11. Psychiatrist and/or Psychologist
12. Pulmonologist
13. Radiologists including interventionist
   a. General
   b. Otorhinolaryngologist
   c. Thoracic
   d. Urologist

**FACILITIES AND SERVICES**
CFF-accredited Care Centers must utilize facilities with the following characteristics and services.

1. Hospital for inpatient care must be JCAHO approved
   a. Age-appropriate setting
   b. Defined age-appropriate service, i.e., Pediatrics, Adolescent Medicine, Internal Medicine and/or Family Medicine
   c. House officers (if affiliated with a teaching institution) or hospitalists
   d. Intensive care unit
   e. Respiratory Care Department
   f. Nutrition or Dietary Department
   g. Social Work Department

2. Age appropriate outpatient clinic area

3. Laboratories performing:
   a. Sweat test by quantitative pilocarpine iontophoresis as stated in the CLSI guidelines**
   b. Pulmonary function tests, including ability to measure lung volumes
   c. Daily, round the clock availability of:
      i. microbiology
      ii. blood chemistries
      iii. hematology tests
      iv. arterial blood gases
      v. Medical imaging

4. Respiratory therapy available 24 hours per day, 7 days per week.

**If the Center does not have sufficient patient volume to maintain an approved sweat testing lab, patients can be referred to a sweat lab at a CFF accredited Center in the immediate geographic area. The sweat testing lab must meet CFF accreditation standards in order for the referring CF Center to maintain accreditation.
**OTHER REQUIREMENTS**

1. A Center must regularly care for a minimum of 50 CF patients.
2. A Center with > 40 CF patients over 21 years old must establish and seek accreditation for an Adult Program (see below). A formal plan must be in place for the transfer of patients from pediatric to adult care with regular meetings of the Pediatric and Adult Program care teams.
3. For Centers treating only pediatric CF patients, a formal pediatric to adult care transfer plan must be in place with a partnering CFF-accredited Center or Program within the local region. *(Sample plan available on PortCF)*
4. Written or electronic patient records are to include, but not limited to:
   a. Documentation of definitive CF diagnosis (i.e., sweat test and genotype)
   b. Outpatient clinic visit records
   c. Discharge summaries
   d. Growth chart (Pediatrics)
   e. Laboratory data
   f. Pulmonary function test reports
   g. Radiology reports
5. The CFF strongly recommends that all sweat test results be reviewed by the Pediatric Program Director. Referral plans must be in place for procedures or unique services such as transplantation.
6. All outpatient clinic reports and discharge summaries should be sent to referring physician as appropriate.
7. Minimum of 1/2-day clinic every week is required.
8. 24-hour coverage by a center physician must be available.
9. Care team meetings are to occur on a regular basis.
10. Ongoing accreditation requires annual submission of the CFF Center Grant Application, entry of patient registry data, and the *Periodic Status Report Form* when required for requisite site visits to occur every 3-5 years by the dates specified by CFF. Centers must also adhere to the CFF *Terms and Conditions Governing CF Center Accreditation and CF Center Grants Awarded by the Cystic Fibrosis Foundation*.

**ADDITIONAL CRITERIA FOR ADULT CARE**

Active transition of patients to adult care should occur between the ages of 18-21 years. At least 90% of adult patients at the center past their 21st birthday must be transitioned to the adult program.

- All Centers must provide CF care for adults in accordance with one of the five acceptable models below.
- Centers with 20 patients, 18 years old or greater, as confirmed by the CF Foundation Patient Registry, who are cared for in the Adult CF Program **may** apply for accreditation if they meet the criteria established for Models II, III or IV.
- Centers with > 40 patients past their 21st birthday **must** have an accredited Adult Program that meets the criteria described in Models II, III or IV below.

**Model I.** Model I is acceptable for use by centers with less than 40 CF patients past their 21st birthday; however, this model does not meet the criteria for accreditation as an Adult Program.

- All adult patients have an adult care specialist as a primary care provider.
- CF-specific care is provided by the local CFF-accredited Center team.
- Adult patients are evaluated in adult-specific clinics for routine CF Center visits.
- Programs with ≥ 20 adult CF patients are strongly encouraged to identify an adult care provider to attend the adult clinic, with the understanding that this individual will begin to develop expertise to become the Adult Program Director as the adult population grows.
- An age-appropriate setting is required for inpatient care.
Model II.

a. The Adult Program is organized within the framework of a CFF-accredited center which cares primarily for children with CF.
b. There must be an Adult Program Director and Adult Program Associate Director who with other Adult Program physicians provide CF inpatient and outpatient care to all patients in the Adult Program.
c. The Adult Program Director and Associate Program Director must be primary-board certified in a specialty dedicated to providing care to adult patients and who provide care in both outpatient and inpatient settings. Subspecialty training in Pulmonary Medicine is strongly encouraged.
d. CF Center team and coordinator have adult CF experience and routinely interface with the adult Program physicians. Outpatient care is provided in either adult clinic areas or pediatric clinics during designated times for adults.
f. Adult Program Director or partner sees patients for sick visits.
g. The Adult Program Director, Associate Director or partners, fellows or coordinator respond to patient calls.
h. Adult care specialists and subspecialists provide the majority of inpatient and outpatient care.
i. Patient-care facilities are oriented to and appropriate for adult care. Inpatient care is provided in an adult hospital or in an adult unit with in-house physicians, nurse-practitioners and/or adult care house staff who predominantly treat adult patients with medical problems.

Model III. Same as #2 above except:

a. There is a separate coordinator for the Adult Program.

Model IV. Same as #2 above except:

a. A separate adult team and coordinator provide team care.
b. Outpatient care is provided in the adult outpatient department.

Model V. In certain cases, the CF Foundation will consider a pediatric to adult care transition affiliation between a pediatric Center without an Adult Program and a CFF-accredited Adult Program at another accredited Center. These relationships will be considered on a case by case basis by the CFF Center Committee when they do not pose a logistical burden to CF patients and no other practical option is available.
Ongoing education of CF care providers is critical to the continued development of their expertise in the care of people with CF. At a minimum, all CFF-accredited Centers and Programs must conduct or participate in educational activities such as:

1. Allied health personnel teaching and training in CF care as it relates to their discipline.
2. CF-related support groups and community/lay group activities.
3. CF-related presentations at area hospitals, medical meetings and national conferences.
4. Non peer-reviewed, CF-related articles and book chapters, and development of special educational materials, e.g., films, booklets, video tapes, etc.
5. Committee activities for extramural organizations, i.e., CFF, ATS, AAP, ACCP.

Centers and Programs situated within or affiliated with an academic institution must also implement the following:

1. Pediatric and adult specialty house officers must be involved in the care of CF patients in your program. This must include a formal teaching program.
2. Integration of CF into the core curriculum of your medical school and opportunities for medical students to be involved in CF patient care.
3. Well-defined program for involvement of clinical fellows in CF care and the CF program.

CFF-accredited Centers and Programs must have accomplished 3 of the following 9 activities (per Center) within the past three years and be involved in some IRB-approved research involving CF patients.

1. Extramurally-funded CF-related research project by core center staff.
2. Peer-reviewed and funded CF-related projects by other members of the institution who have a working relationship with the center.
3. Two CF-related articles by core center staff published in peer-reviewed journals.
4. Two CF-related articles by other investigators with acknowledged participation or facilitation by core center staff.
5. Active participation in a CFF-sanctioned multicenter study (counts as two activities).
6. Participation in Phase IV studies conducted under an IND filed with the FDA.
7. Participation in investigator-initiated, IRB-approved clinical studies.
8. Quality improvement work that is published or submitted for presentation at NACFC.

In Centers and Programs where resources and infrastructure do not exist for developing or participating in a research program, a formal plan for referring patients and families to other Centers conducting CF research must be submitted to the CF Foundation.
CENTER and PROGRAM DIRECTOR
QUALIFICATIONS and RESPONSIBILITIES

CENTER DIRECTOR
The Center Director is responsible for providing oversight of the operation of the center, which includes the coordination of care and administrative requirements of the component Pediatric, Adult, and Affiliate Programs within the center. The Pediatric or the Adult Program Director may serve as the Center Director, and must meet the qualifications outlined below. In Centers without component programs, the Center Director qualifications and responsibilities are synonymous with the applicable Program Director qualifications.

PEDIATRIC AND ADULT PROGRAM DIRECTORS
I. Qualifications
   a. The Pediatric Program Director must be board certified in Pediatrics, Family Medicine or a relevant Pediatric Subspecialty.
   b. The Adult Program Director must be board certified in Internal Medicine, Family Medicine or a relevant Medicine Subspecialty.
   c. All Program Directors should have at least 3 years post-residency clinical experience in the care of cystic fibrosis patients. This training is best achieved through a subspecialty fellowship program in Pulmonary Medicine or Gastroenterology where cystic fibrosis patients are regularly followed, i.e., an accredited cystic fibrosis center.
   d. Board certification in Pulmonary Medicine or Gastroenterology is recommended. However, other subspecialties or board certified pediatricians, internists, or family practitioners also may serve as Directors if their clinical training included extensive contact with cystic fibrosis patients.

II. Care/Administrative Responsibilities
The Program Director is responsible for providing oversight of the operation of their specific programs and working in a collaborative manner with the other component programs within the Center. The Director provides quality assurance for all aspects of patient care and the operation of the CF program.
   a. Ensures that CFF requirements relating to sweat testing, microbiology, clinical practice guidelines, continuous quality improvement and all other accreditation criteria are met and maintained.
   b. It is incumbent upon the Director to ensure that requirements regarding grant application submissions for continued accreditation and funding, and patient registry data entry are met annually.
   c. Assures that the institution is providing adequate facilities and ancillary support to the CF program.
   d. Assures that CF personnel (physician and non-physician) are of the highest quality and maintain expertise in cystic fibrosis care.
   e. Assures that personnel time allotted to the care of CF patients is appropriate for the CF patient population.

III. Teaching Responsibilities
   a. Center personnel
   b. House staff (as applicable)
   c. Medical students (as applicable)
   d. Fellows (as applicable)
   e. Allied health professionals
   f. Community
   g. Lay groups
   h. Presentations at regional, national or international meetings
IV. Research Responsibilities (as applicable)
   1. Facilitate collaboration between investigators within the institution and between institutions.
   2. Seek out funding for research by core center staff.
   3. Mentor or facilitate access for research fellows to become involved in CF-related research areas.
   4. Provide education throughout the institution or affiliated medical school to researchers in the most recent advances in CF research, as well as clinical correlations.

Absent an internal research program, works with other CFF-accredited Centers and Programs to provide research participation opportunities to patients and families.

V. NACFC Attendance
Directors must attend the CFF North American CF Conference a minimum of every other year.

PEDIOATRIC AND ADULT PROGRAM ASSOCIATE DIRECTOR
I. The Associate Director should have the same or comparable training as the Program Director so that he/she is fully capable of assuming directorship in the program director’s absence. Therefore, he/she must be board certified (Pediatrics, Internal Medicine, Family Medicine or Subspecialty) with at least 1 year post residency-training and/or clinical experience in the care of cystic fibrosis patients. Subspecialty board certification/eligibility is recommended.

II. This person must be involved on a day-to-day basis with inpatient and outpatient care and be knowledgeable about the administrative aspects of the center program.

III. It is strongly recommended that Associate Directors attend NACFC a minimum of every other year.