

Tuberous Sclerosis Alliance and Tuberous Sclerosis Complex Clinics *TSC Clinic Structure and Expertise Requirements for Recognition/Designation*

Purpose of the TS Alliance Recognition/Designation Program

A TSC Clinic or Center of Excellence serves as the primary center for diagnosis, surveillance, and management of TSC in children and/or adults. The TSC Clinic or Center of Excellence provides coordinated, multidisciplinary care for children and/or adults with TSC—either directly through board-certified healthcare providers in specialty areas related to TSC or through utilization of a defined referral network of specialists within their institution or partnering health systems. The TSC Clinic or Center of Excellence also is leader in advocacy, education, and/or research locally, regionally, and nationally for improving TSC patient care and outcomes.

The TS Alliance advocates and supports the establishment of TSC Clinics and TSC Centers of Excellence to realize these goals. Recognition by the TS Alliance provides assurance to affected individuals and families, regulatory authorities, medical providers, and payers that the care provided to TSC patients meets appropriate quality standards for best possible outcomes in this complex and frequently difficult rare genetic disorder.

Definition of TSC Clinics and TSC Centers of Excellence

- a. **TSC Clinic:** A TSC Clinic may focus care on pediatric patients, adult patients, or both. This designation indicates all essential services are available for diagnosis and management of major aspects of TSC, but more complex patients with rare or advanced manifestations of the disorder resulting in significant disability, medical complications, or in need of advanced specialty services will likely need referral to an affiliated TSC Center of Excellence for appropriate care. A TSC Clinic may receive a designation status as Provisional or Established. Provisional status is typically re-evaluated every year. Established status is typically re-evaluated every 3 years.
- b. **TSC Center of Excellence:** A TSC Center of Excellence also provides care to pediatric, adult, or patients of all ages with TSC. However, TSC Centers of Excellence who do not provide care for patients of all ages are required to have well-established procedures for coordinating and transitioning care with specialists for patients outside of the patient age range their TSC Center serves. In addition, designation as a TSC Center of Excellence indicates not only all essential services for diagnosis and management of major aspects of TSC are provided, but additional multispecialty services are available with advanced experience and expertise in providing necessary care for complex TSC patients with advanced disease, medical complications, in need of advanced treatment options, or access to new and emerging interventions. TSC Centers of Excellence serve as resource and referral center for

TSC Clinics regionally and nationally. A TSC Center of Excellence may only receive a designation status of Established, which is typically re-evaluated every 3 years.

Requirements for Designation as a TSC Clinic or TSC Center of Excellence

- a. **Clinical Standards:** Many manifestations of TSC can be life-changing and even life-threatening and appropriate surveillance and management is necessary to limit morbidity and mortality in this disease. Appropriate management is also crucial for optimal quality of life of affected individuals and requires coordination of care among medical specialties and from childhood to adulthood on a regular basis. In 2013, recommendations using the best available scientific evidence for the optimal clinical management of patients with TSC were published (Krueger, Northrup, *et al. Pediatric Neurology* 49:255-265). These are the basis for evaluating the quality of clinical care each TSC Clinic and TSC Center of Excellence clinical care is expected to provide.
 - i. TSC Clinics and Centers of Excellence are expected to meet minimum requirements* for all *TSC Standards of Medical Care*.

- b. **Patient Experience:** Nearly as important as the clinical standards of care is how a TSC Clinic or TSC Center of Excellence interacts with TSC patients to address their needs and concerns. Coordination of care amongst medical specialists and the patients' ability to communicate with healthcare providers and their office and support staff are expected. The TS Alliance collects patient feedback annually in the form of a patient questionnaire in anonymous fashion from patients seen in TSC Clinics and Centers of Excellence.
 - i. TSC Clinics and Centers of Excellence are expected to achieve the minimum requirement* for completed surveys from patients (or caregivers) seen by the clinic within the past year

- c. **Clinic Structure and Expertise:** TSC is a multisystem rare disease with significant disease morbidity and mortality. Furthermore, disease symptoms vary regarding timing, severity, progression, and secondary complications. For optimal patient outcomes and quality of life, comprehensive, coordinated, up-to-date multi-disciplinary specialty care is essential. TSC Clinic and TSC Centers of Excellence must demonstrate advanced expertise in TSC clinical care, care coordination among specialties, continuing education, engagement with TSC patient and medical/scientific communities, and institutional investment (clinician time, space, support personnel, etc.).
 - i. TSC Clinics:
 1. Provide TSC patient care to children, adults, or all-ages.

2. Provide all essential services for diagnosis and management of major aspects of TSC are provided (Neurology, Nephrology, Genetics, Psychiatry/Psychology and/or Developmental Pediatrics, Cardiology, Ophthalmology, and Dermatology). Adult clinics must also provide Pulmonology specialty care.
 3. Refer TSC patients with rare manifestations or advanced manifestations of TSC resulting in significant disability, medical complications, or in need of advanced specialty care to a TSC Center of Excellence.
 4. Schedule a minimum of one clinic per month specifically for TSC patient care.
 5. Coordinate multi-disciplinary care among specialties.
 6. Have a dedicated TSC Clinic Coordinator as point of contact for TSC patients, specialists, and TS Alliance.
 7. Able to prescribe and manage all therapies specifically approved by the FDA for the treatment of TSC.
 8. Director is board-certified and in good standing in their TSC-related medical specialty.
 9. Director must demonstrate activity in the areas of TSC advocacy, education, and/or research, including profession engagement with the TS Alliance (nationally, regionally, or locally) and with the TSC medical and scientific community.
 10. Director is expected to participate (in person or virtually) in the TS Alliance annual director's meeting.
- ii. TSC Centers of Excellence:
1. Provide TSC patient care to children, adults, or all-ages. TSC Centers of Excellence who do not provide care for patients of all ages are required to have well-established procedures for coordinating and transitioning care with specialists for patients outside of the patient age range or medical services their TSC Center provides or manages.
 2. Provide all essential services for diagnosis and management of major aspects of TSC are provided

(Neurology, Nephrology, Genetics, Psychiatry/Psychology and/or Developmental Pediatrics, Cardiology, Ophthalmology, and Dermatology. Adult clinics must also provide Pulmonology specialty care.

3. Additional multispecialty services are available with advanced experience and expertise in TSC for complex TSC patients with advanced disease, medical complications, or in need of advanced treatment options or access to new and emerging interventions and clinical trials.
4. Serve as a resource center and referral destination to TSC Clinics regionally and nationally for TSC patients with rare manifestations or advanced manifestations of TSC resulting in significant disability, medical complications, or in need of advanced specialty care and treatment options.
5. Schedule multiple clinics per month specifically for TSC patient care.
6. Coordinate multi-disciplinary care among specialties, preferably within the same clinic or coordinated between specialties to be on the same or adjacent clinic days whenever possible.
7. Have a dedicated TSC Clinic Coordinator as point of contact for TSC patients, specialists, and TS Alliance.
8. Able to prescribe and manage all therapies specifically approved by the FDA for the treatment of TSC.
9. Director is board-certified and in good standing in their TSC-related medical specialty.
10. Director must have a minimum of 5 years of TSC Clinic experience.
11. Director must demonstrate activity in the areas of TSC advocacy, education, and/or research, including profession engagement with the TS Alliance (nationally, regionally, or locally) and with the TSC medical and scientific community.

12. Director is expected to participate (in person or virtually) in the TS Alliance annual director's meeting.

Recognition/Designation as a TSC Clinic or TSC Center of Excellence

- a. Designation as a **TSC Clinic** may be granted with status of being *provisional* or *established*.
- i. A TSC Clinic with *Provisional Status* designation is a temporary designation and cannot be renewed without evidence of progress towards status recognition as an TSC Clinic with *Established Status* designation. *Provisional status* will require annual renewal. Typically, *Provisional Status* will apply to first-time applications for recognition or clinics for which prior recognition status as an *Established* TSC Clinic has lapsed without being renewed or maintained. *Provisional status* would also apply to TSC Clinics with previous *Established status* with new leadership or in process of addressing areas of concern or deficiency.
 - ii. *Established status* as a TSC Clinic requires for the TSC Clinic Director to have a minimum of 1 year of prior TSC Clinic experience.
 - iii. *Established status* as a TSC Clinic requires renewal every 3 years with status updates submitted annually between renewals.
- b. Designation as a **TSC Center of Excellence** may only be granted with status of being *Established*. There is no provisional status for TSC Centers of Excellence.
- i. TSC Centers of Excellence require for the TSC Center of Excellence Director to have a minimum of 5 years prior TSC clinical experience working in a recognized TSC Clinic or TSC Center of Excellence. The TSC clinical experience does not have to occur at the same institution from which the application for TSC Center of Excellence originates.
 - ii. Established TSC Centers of Excellence unable to meet the experience requirements for the named Director or with additional areas of concern or deficiency identified by the TS Alliance will revert to designation as a TSC Clinic. Such clinics are encouraged to re-apply for designation as a TSC Center of Excellence as soon as eligibility requirements are met and/or identified areas of concern have been resolved.
 - iii. Established status as a TSC Center of Excellence requires renewal every 3 years with status updates submitted annually between renewals.

****NOTE:*** *Minimum requirements for TSC Standards of Medical Care and Patient/Caregiver Surveys are established by the TS Alliance TSC Clinic Committee, a sub-committee of the Science and Medical Committee of the TS Alliance Board of Directors.*

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