

# The Tuberous Sclerosis Alliance TSC Clinic Network

## TSC Clinic Guidelines

- Approved by TS Alliance Science and Medical Committee, TS Alliance Executive Committee, and Board of Directors on 02-25-2010
- Guidelines revised September 4, 2013 and approved by the TS Alliance Science and Medical Committee and Board of Directors on 10-04-2013
- Guidelines revised August 25, 2014 and approved by the TS Alliance Science and Medical Committee and Board of Directors on 10-24-2014
- Guidelines revised and approved by the TS Alliance Science and Medical Committee on 06-28-2017 and by the Executive Committee on 07-07-2017

### INTRODUCTION

The Tuberous Sclerosis Alliance (TS Alliance) recognizes clinical practices around the world that facilitate multidisciplinary, comprehensive coordination of care necessary for treating individuals with tuberous sclerosis complex (TSC). The TSC Clinic Guidelines describe the standards that a clinical practice should meet to be part of the TS Alliance TSC Clinic Network..

A TSC Clinic is expected to:

1. Submit a TSC Clinic Update Report annually to maintain or upgrade their designation in good standing.
2. Submit a TSC Clinic Change Request Form whenever there is a change in the Director, Co-Director, Administrative, or Nurse Coordinator position.
3. Participate in the “TSC Clinic Patient and Family Experience of Care Survey” Program.
4. Have their key healthcare providers complete one CME course related to TSC every two years

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The TSC Clinic Guidelines are divided into three sections:

- I. Definitions
- II. Clinical Care, Educational Resource, and Partnership
- III. Clinical Trials and Basic Science Research in TSC

A clinic is evaluated in four categories

- a. Clinical care
- b. Educational resource
- c. Partnership
- d. Clinical trials and basic science research in TSC

The Table below shows the distribution of the 11 core and 14 GOLD standards within the four categories by which a TSC Clinic is evaluated.

Category	Core standards	Gold standards
Clinical care	8	6
Educational resource	1	2
Partnership	2	3
TSC research	NA	3

A description of each standard is described in Sections II and III

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## I. DEFINITIONS

### 1. TSC Clinic

A TSC Clinic serves as the primary center for diagnosis, surveillance, and management of TSC in children and adults. The clinic model may range from a single to multi-specialty practice of board-certified healthcare providers with expertise in a specialty area related to TSC. The Clinic is expected to provide multidisciplinary care for children and adults with TSC through their clinic or referral network of specialists within their institution or partnering health systems. The healthcare providers may either be located at one institution or at multiple institutions, and they may meet on a given day or days every week/month, etc., or see individuals on an as needed basis.

### 2. TSC Clinic Director

The Clinic Director is expected to be a medical doctor, board-certified in their area of specialty or for non-U.S. physicians provide comparable documentation of meeting core competencies in their area of specialty.

### 3. TSC Clinic Co-Director

The Clinic Director may name a colleague (medical doctor, physician's assistant, or nurse practitioner) to serve as co-director. The co-director is expected to provide documentation of meeting core competencies in their area of specialty/profession. The Co-Director is expected to assist the director in administration of the clinic.

### 4. TSC Clinic Coordinator

The TSC Clinic Coordinator's role is to be the primary point of contact for the TSC Clinic to provide clinical information and assist the Clinic Director/Co-Director with coordination of care of the child or adult with TSC. A nurse is preferred in this role.

### 5. TSC Clinic Designation

The TS Alliance will recognize a clinical practice as a TSC Clinic if they meet the core standards as described in Section II and III.

### 6. Provisional TSC Clinic Designation

A clinical practice will receive provisional status if they meet seven core standards and will have one year to achieve full status.

**7. TSC Center of Excellence Designation**

A clinical practice that meets the 11 core standards and at least 9 of 14 Gold Standards\* will receive an additional recognition as a TSC Center of Excellence.

\* 4 of 6 clinical care gold standards,  
2 educational resource gold standards,  
2 of 3 partnership gold standards, and  
1 of 3 research in TSC gold standards.

**8. TSC Clinic Update Report**

The TSC Clinic will submit a TSC Clinic Update Report annually to maintain their designation as a TSC Clinic with or without recognition as a TSC Center of Excellence. The report will include an estimate of the total number of persons with TSC seen at the clinic since receiving clinic designation; confirming key clinic personnel and contact information; updating the list of specialists affiliated with the TSC Clinic; and date(s) of participation in TSC-related educational and community activities.

**9. TSC Clinic Patient and Family Experience of Care Survey Program**

The TSC Clinic will ask their TSC patients (or parents of TSC patients) to complete a short survey conducted by the TS Alliance. The survey will have no personal identifiers. The results will be compiled and shared with the TSC Clinic Committee and individual clinic who will have the opportunity to provide comments to the TS Alliance, if desired.

**10. TSC Clinic Standards**

a. Core Standard: This standard is expected to be met in order to receive TSC Clinic designation.

b. Gold Standard: This standard is not a requisite to receive TSC Clinic designation; however, it is a standard which the TS Alliance recommends all clinics achieve, where possible.

**II. CLINICAL CARE, EDUCATIONAL RESOURCE, AND PARTNERSHIP****1. Clinical Care Core Standards (8)**

1.1 The Director, who will be responsible for the administration of the TSC Clinic, should have an interest in providing comprehensive care for individuals with TSC. He/she is a medical doctor with medical board certification in their country of clinical practice in a specialty related to one or more aspect of TSC such as cardiology, dermatology, nephrology, neurology, etc. A Co-Director may be named to assist with oversight of the clinical management of the TSC Clinic. The co-director is a medical doctor, physician's assistant, or nurse practitioner with certification in their respective profession.

1.2 The Director and Co-Director (if applicable) will serve on the TS Alliance Professional Advisory Board (PAB), which provides clinical advice/recommendations to the TS Alliance as needed. Service on the Professional Advisory Board is for a renewable 3-year term.

1.3 The TSC Clinic is expected to provide multidisciplinary care and have the necessary board-certified healthcare providers with expertise in diagnosing TSC, as well as treating conditions that affect those with TSC including, but not restricted to genetics, epilepsy, skin lesions, brain tumors, kidney manifestations, lung manifestations, eye involvement and/or psychiatric/behavioral/cognitive issues. A TSC Clinic is expected to provide care in three core specialties – dermatology, nephrology (or urology), and neurology.

- If a children's only clinic, cardiology is recommended.
- Pulmonology is recommended if the clinic serves adult women.
- A TSC Clinic with designation of providing care to children, or up to young adult only is expected to have a transition plan for referral to adult care providers when age appropriate.

1.4 The TSC Clinic should perform a comprehensive initial evaluation on new patients and, on an as needed basis, provide recommendations for follow-up care.

1.5 All healthcare providers associated with the TSC Clinic are expected to be listed on the TSC Clinic Update Form with their email address for TS Alliance contact purposes only.

1.6 All healthcare providers associated with the TSC Clinic are expected to keep the Clinic Director or Clinic Coordinator updated about a child or adult with TSC who was referred to them. This may be accomplished by standard communication practice such as a note in the electronic health record.

1.7 The Clinic Director shall identify his/her core healthcare providers and should meet at least annually to review new treatments, research, and clinical trials for individuals with TSC. This meeting may be virtual or face-to-face.

1.8 The TSC Clinic staff should also include a Clinic Coordinator. Time commitment would be dependent on clinic and patient needs (i.e. the person may be employed part-time and/or shared with another department).

## 2. Clinical Care GOLD Standards (6)

2.1 In addition to providing care in the three core specialties: dermatology, nephrology (or urology), and neurology<sup>1</sup> a TSC Clinic providing care in six or more specialties will meet Gold Standard. The specialties include but are not limited to the following areas:

- Cardiology
- Dentistry
- Developmental medicine
- Endocrinology
- Epileptology
- Gastroenterology
- Genetics
- Genetic counseling
- Neuro-oncology/oncology
- Neuropsychology
- Neurosurgery
- Ophthalmology
- Psychology/psychiatry
- Social Worker
- Surgical oncology
- Urological surgery/interventional radiology

2.2 The TSC Clinic should provide care for individuals with TSC of all ages (birth to senior adults). Care includes comprehensive outpatient consultation, inpatient evaluation as needed and follow-up recommendations.

2.3 Upon invitation, a healthcare provider affiliated with the TSC clinic (in addition to the Director and if applicable the Co-Director) will agree to serve a three-year renewable term on the TS Alliance Professional Advisory Board (PAB).

2.4 The TSC Clinic administers the TAND Checklist annually or as needed.

2.5 The TSC Clinic utilizes telemedicine technology to provide consultation to children and/or adults with TSC.

2.6 One or more key healthcare providers complete at least one CME course related to TSC every two years,

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<sup>1</sup>Cardiology is recommended at a Children's Only clinic, and pulmonology is recommended the clinic serves adult women.

### 3. Educational Resource Core Standard (1)

3.1 The TSC Clinic should serve as an educational resource to educate the lay public, healthcare providers, educators and individuals with TSC and their families about TSC. The TSC Clinic should work closely with the TS Alliance to disseminate information to individuals with TSC and their families, and to promote awareness of TSC.

### 4. Educational Resource GOLD Standard (2)

4.1 The TSC Clinic should meet the Educational Resource Core Standard and should also hold at least one virtual or face-to-face TSC meeting annually to update the participating health care providers, local and/or regional health care providers and/or individuals with TSC and their families.

4.2 The TSC Clinic shares a TSC-related publication or other resource materials authored/co-authored by one of their healthcare providers with the TS Alliance and other TSC Clinics.

### 5. Partnership Core Standard (2)

5.1 The TSC Clinic should develop a partnership with the local TS Alliance volunteer branch (TSC Community Alliance), where such a group exists. This partnership should be mutual in that the TSC Clinic may utilize the volunteers from the Community Alliance to provide resource information<sup>2</sup> and support for individuals with TSC and their families, and TSC Clinic staff will refer the individuals and families to the Community Alliance.

5.2 When the TS Alliance extends an invitation to the Clinic Director or Co-director or other TSC Clinic healthcare provider, the group should collectively participate (i.e. as a speaker or attendee) in at least three (3) TS Alliance sponsored clinical or research events per year such as “Meet-the Expert” gatherings, town hall meetings, informational webcasts, research conference presentations, or educational teleconferences.

### 6. Partnership GOLD Standard (3)

6.1 The TSC Clinic should meet the Partnership Core Standard, and the Clinic Director or colleague (e.g. co-director, specialty healthcare provider, nurse coordinator) accepts an invitation to serve on a TS Alliance committee (such an ad hoc, clinic advisory, or other) when possible, and actively participate in their meetings

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<sup>2</sup> Materials provided by TS Alliance

(which are usually done by conference call on average 4 times/year but may be more frequently). A greater than 50% attendance is expected.

6.2 The TSC Clinic participates in the on-site TSC Clinic Ambassador Program, which is a TS Alliance initiative to partner an adult from the local community - usually a parent of a child with TSC or an individual with TSC. The Clinic Ambassador provides emotional support to newly diagnosed families; assists in helping families navigate through the specialists that are crucial to their child's care; provides information about local and regional resources, including Community Alliance events; and keeps them informed and updated of the services and the work that the TS Alliance is accomplishing.

6.3 The TSC Clinic Director and/or Co-Director attends the TSC Clinic Directors meeting.

### III. TSC RESEARCH (GOLD Standard)

1. One or more TSC Clinic healthcare provider conducts investigator-initiated TSC clinical trials.
2. One or more TSC Clinic healthcare provider participates in a TS Alliance or industry-sponsored TSC clinical trial.
3. One or more TSC Clinic healthcare provider conducts basic science research in TSC.