

Tuberous Sclerosis Alliance and Tuberous Sclerosis Complex Clinics

Scope of Relationship Policy

ROLE OF THE TSC CLINIC

A Tuberous Sclerosis Complex (TSC) Clinic or Center of Excellence serves as the primary center for diagnosis, surveillance, and management of TSC in children and 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 Clinic or Center of Excellence also is a 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 and endorsement 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.

1. The TS Alliance strongly encourages TSC Clinic and Center of Excellence healthcare providers to:
 - a. Follow the current diagnostic criteria and recommendations for screening and follow-up¹ care of individuals with TSC.
 - b. Stay abreast of the latest treatments for the various aspects of TSC.
 - c. Publish research results in peer-reviewed medical journals and publications and provide the TS Alliance with a reprint.
 - d. Participate in TSC clinical and/or research conferences, training opportunities, and educational activities sponsored or endorsed by the TS Alliance.

¹ Appendix A: 2012 Diagnostic Criteria Table
Appendix B; Northrup, H., et al., Tuberous sclerosis complex diagnostic criteria update: recommendations of the 2012 international tuberous sclerosis complex consensus conference (2013) *Pediatric Neurology*
Krueger, D.A., et al., Tuberous sclerosis complex surveillance and management: recommendations of the 2012 international tuberous sclerosis complex consensus conference (2013) *Pediatric Neurology*

- e. Partner with the local TS Community Alliance and/or Community Support Group to promote awareness of TSC and associated issues by participating in TS Alliance-sponsored events, such as local public relations events, medical conferences, “meet-the-expert” gatherings, and parent support group meetings.
 - f. Partner with the local TS Community Alliance to provide educational materials for patients, their families, lay persons, medical and allied health care professionals.
2. Other provisions for maintaining a relationship in good-standing with TS Alliance:
- a. The TSC Clinic or TSC Center of Excellence Director/Co-Director will maintain a professional conduct in accordance with their institutional policy
 - i. If the TS Alliance becomes aware of any serious type of professional misconduct, which is under inquiry by the institution, the Director or Co-Director (if applicable) will be asked to name a colleague to temporarily assume his/her role during the inquiry period.
 - ii. During the inquiry period, the TSC Clinic or TSC Center of Excellence designation will be placed on provisional status.
 - b. The Director/Co-Director of the TSC Clinic or TSC Center of Excellence will maintain designation by:
 - i. Completion of the *TSC Clinic Designation Application and Renewal Form* or the *TSC Clinic Status Update Form*, when applicable.
 - ii. Annual completion of the *Standard of Care Metrics for TSC Centers of Excellence and TSC Clinics*.
 - iii. Facilitate completion of the annual *Patient and Family Experience of Care Survey* by TSC patients seen at their clinic or center of excellence.
 - iv. Notifying the TSC Clinic Liaison at jnakagawa@tsalliance.org or 240-638-4654 or 301-562-9890 if there are changes in clinic leadership, collaborating specialists, or coordinator during the interval period or whenever issues develop at the clinic which jeopardize the clinic’s ability to maintain recognition requirements or have the potential to impact the reputation of the TS Alliance.
 - c. The TSC Clinic or Center of Excellence will not solicit the Community Alliance leadership team to raise funds on behalf of their clinic.

- d. TSC Center of Excellence Directors will serve as a resource for a new or established TSC Clinics by providing advice (if asked) about how they navigated through their institution to start their own clinic (i.e. What did or did not work).

ROLE OF THE TS ALLIANCE

The TS Alliance recognizes that the coordinated care that individuals receive at a recognized TSC Clinic or TSC Center of Excellence plays a vital part in serving the organization's mission. As such, the TS Alliance will provide the following:

1. Marketing

- a. The TS Alliance will provide notice to area constituents about the TSC Clinic or Center of Excellence in a variety of ways. The scope of marketing is limited to three areas:
 - Targeted mailings to TS Alliance constituents;
 - Articles about the TSC Clinic or Center of Excellence in the TS Alliance quarterly magazine, *Perspective*; and
 - Information about the TSC Clinic or Center of Excellence on the TS Alliance Web site (<http://www.tsalliance.org>)
- b. The TS Alliance will partner with the TSC Clinic or Center of Excellence to distribute information about the clinic so that the TSC Clinic or Center of Excellence may serve as a source for consultations and referrals for individuals with TSC and their healthcare providers.

2. Business Resources

- a. Upon request, the TS Alliance will provide a sample TSC Clinic business plan, budget template, and job description for the nurse coordinator position.
- b. The TS Alliance believes that communication with other clinics and specialists who specialize in the care of individuals with TSC is important. Upon request, the TS Alliance will provide a list of other TSC Clinic Directors and their contact information. In addition, upon request, the TS Alliance will assist in the establishment and maintenance of regional and national referral networks and provider communication between TSC Clinics and TSC Centers of Excellence.
- c. In addition, the TS Alliance will initiate contact between the TSC Clinic or Center of Excellence and the chair of the local TS Alliance volunteer branch ("Community Alliance"), if one exists in that area.

- d. Finally, TS Alliance print materials will be provided to the TSC Clinic or Center of Excellence. These materials include but are not limited to informational brochures and the TS Alliance magazine, *Perspective*.
3. Ongoing Education, Research Opportunities & Support
- a. Education
- i. Up-to-date information on the diagnosis, care and treatment of TSC will be provided by the TS Alliance through its Web site, *Perspective* magazine, and other electronic and print materials.
 - ii. Information about continuing medical education opportunities will be posted on the TS Alliance website and by email when available.
- b. Research Opportunities & Support
- i. Funding opportunities are available through the TS Alliance Grants Program at www.tsalliance.org/researchers/grants-and-funding/
 - ii. TSC Clinics and Centers of Excellence in good standing are eligible to participate in two TS Alliance supported research projects contingent on availability of funds
 - (a) TSC Natural History Database Project
In 2006, the TS Alliance launched the TSC Natural History Database, a web-based central research repository for detailed information about individuals with TSC. The TS Alliance conducts this project through the TS Alliance network of TSC Clinics.
 - (b) TSC Biosample Repository Project
In 2015, the TS Alliance established a TSC Biosample Repository to serve as a national resource providing a centralized, standardized source of high quality, well-documented human biospecimens for TSC research.

Original Scope of Relationship approved by clinic committee 1/22/2002
 Modified 10/27/2003 when clinic committee approved the "fund raising policy"
 Modified and approved by clinic & executive committee, March 2006
 Modified 04/05/2010, approved by science & medical committee, 4/12/2010
 Approved by Executive Committee, May 7, 2010
 Approved by Board of Directors, June 16, 2010
 Modified August 2013 and approved by science and medical committee and Board of Directors, October 4, 2013
 Modified August 2015 and approved by science and medical committee and Board of Directors, October 24, 2015
 Modified 05/26/2017 and approved by science and medical committee June 28, 2017 and by Executive Committee, July 7, 2017.
 Modified 10/1/2020 and approved by science and medical committee 12/3/2020 and by Board of Directors, December 14, 2020.

:TS Alliance & TSC Clinic Scope of Relationship 2.0, Board approved 12/14/2020