**Tuberous Sclerosis Alliance**

**Board of Directors Meeting Minutes**

**June 7, 2017**

**Approved: October 13, 2017**

**In attendance:**

**Board Members:** Tim Dills (Chair), Rebecca Anhang Price, Martina Bebin, John Bissler, Cassandra Carroll, Sara Chieffo, Margaret Cox, Andrew Duffy (ex-officio), Bonnie Hogue Duffy, David Fitzmaurice, Tom Gwinn, Laura Lubbers, Jim Maginn, David Michaels, Darren Miles, Debora Moritz, Julie Scroggins

**Endowment Fund:** Doug Loftus

**Staff:** Kari Luther Rosbeck, Rich Gollub, Steve Roberds

**Chair’s Welcome and Report Tim Dills, Chair**

Tim Dills called the meeting to order at 8:02 pm and confirmed a quorum of voting officers.

Tim noted that committees should begin planning their goals for 2018 and have a draft completed by July 10 to enable the staff to utilize them during the staff retreat.

**Approval of Board Meeting Minutes from March 2, 2017 (Attachment B), Rebecca Anhang Price**

A motion was made to approve the March 2 Board meeting minutes as written *(Gwinn/Miles)*. *The minutes were approved as written without dissent.*

**Governance Committee Report, David Fitzmaurice**

Membership:

David Fitzmaurice presented proposed Bylaws amendments to grandfather in Lifetime Members from having to annually state their intent to be members and to extend membership terms from one to two years (Attachment C). As background, he noted that a membership committee composed of current and prior board members convened in a series of meetings. In the initial meeting, those in favor of membership indicated that if it were kept, efforts should be made to increase number of members. However, there were concerns that this may burden staff (who would be responsible for recruiting and maintaining members), and potentially make it more challenging to achieve a majority for voting for new board members. In a subsequent meeting, the committee determined that it would make more sense to maintain membership but not take active measures to grow membership rolls. To reduce the current burden of membership, Bylaws amendments are proposed to (1) to extend length of membership from one year to two years; and (2) indicate that lifetime members do not need to indicate their intent to become a member again (i.e., their lifetime membership suffices as “lifetime intent,” but may not be transferred). Tim Dills commended David’s leadership of the working group and their arrival at a win-win solution that allows the TS Alliance to move forward on its important mission.

The Resolution reads as follows:

**RESOLUTIONS**

**OF THE**

**BOARD OF DIRECTORS**

**OF**

**NATIONAL TUBEROUS SCLEROSIS ASSOCIATION, INC.**

**WHEREAS** this Board of Directors has deter­mined that it is in the best interests of this corporation to approve proposed amendments to the current Bylaws of this corporation, attached hereto as Exhibit A (the “Proposed Amendments”), in order to clarify membership terms, subject to approval of the members of this corporation;

**NOW, THEREFORE, IT IS RESOLVED** that the Proposed Amendments are hereby approved and adopted, substantially in the form attached hereto as Exhibit A, provided that such adoption is expressly contingent on and shall only become effective upon the approval of the members of this corporation;

**RESOLVED FURTHER** that the Secretary of this corporation is hereby directed to file a copy of the Proposed Amendments so approved with the minutes of this meeting;

**RESOLVED FURTHER** that the officers of this corporation are hereby authorized and directed to seek the approval of the members of this corporation as to the Proposed Amendments approved in the preceding resolutions;

**RESOLVED FURTHER** that, subject to obtaining the approval of the members, the Secretary of this corporation is hereby authorized and directed to certify the amendments approved by the preceding resolutions as part of the Bylaws of this corporation, and to file a copy of the amendments, so certified, in the minute book of this corporation;

**RESOLVED FURTHER** that the Secretary of this corporation is hereby directed to notify this corporation’s tax preparer and provide a copy of such certified amendments to him or her, to facilitate proper reporting of these changes to the Internal Revenue Service and Franchise Tax Board; and

**RESOLVED FURTHER** that the officers of this corporation are hereby authorized and directed to take all such further actions as they may deem necessary or appropriate in order to implement the foregoing resolutions and any actions heretofore taken by the officers to further the purposes of the foregoing resolutions prior to the date of this meeting are hereby ratified, approved, and confirmed.

**EXHIBIT A**

**Proposed Amendments**

Article III, Section 2.A., is hereby amended and restated to read as follows:

A. Membership File and List. The Corporation shall maintain a membership file, containing the name, address and other pertinent information on each member of the Corporation, including but not limited to a member’s designation as a Lifetime Member, if applicable. Termination of the membership of any member of the Corporation shall be recorded in the file, together with the date of termination of such membership. The membership file shall be maintained electronically at the Corporation’s principal office and shall be available for inspection by any member of the Board or member of the Corporation on a confidential and restricted basis, in all cases subject to the provisions, restrictions and limitations contained in Cal. Corp. Code §§ 6330 - 6338, during regular business hours and upon reasonable notice to the President and Secretary. Any request for inspection shall state the purpose for the inspection. The contents of a Membership Application or a membership file may not be disclosed by the Corporation to third parties without the applicant or member’s prior written consent, unless mandated by applicable law or as described in this Section.

Article III, Section 2.C., is hereby amended and restated to read as follows:

C. Establishment of Membership by a Membership Application, by Election to the Board, and by Appointment to a Committee, and Lifetime Members.

i. An individual may apply for membership by submitting an application for membership on a form designated by the Corporation (“*Membership* *Application*”). Membership shall commence upon receipt of the Membership Application and upon payment of any dues if so required by the Corporation. Membership shall begin on the date of commencement and shall terminate automatically on December 31 of the calendar year following the year in which membership commenced, unless the member elects to renew the membership in accordance with Section C.ii. below.

ii. From December 1 through December 31 of the year in which a member’s membership would otherwise terminate in accordance with Section C.i. above (the “Renewal Period”), such member, in order to maintain his or her membership with the Corporation, must confirm in writing as directed by the Corporation his or her intention to remain a member, in a form provided by or otherwise acceptable to the Corporation (a “*Membership Confirmation*”). If the member submits a Membership Confirmation within the Renewal Period, his or her membership shall extend an additional two years from the prior termination date and shall terminate automatically on the calendar year end when the additional two years have elapsed, unless the member elects to renew the membership again in accordance with this Section.

iii. Any person who is elected to the Board, is, by virtue of that election and for the period he or she is serving as a member of the Board, a member of the Corporation.

A motion was made to approve the resolution to amend the *(Bissler/Chieffo)*. *The motion passed without dissent.*

A motion was made to approve the 2018 renewing members Cassandra Carroll and Beth Dean *(Gwinn/Scroggins)*. *The motion was approved without dissent.*

David thanked the nominating committee for their effort in developing an incredible slate of nominees for next year’s board. A motion was made to approve 2018 new Board members *(Bissler/Cox)*. *The motion was approved without dissent.* The seven new nominees are:

1. David Coit
2. Peter Crino
3. Rob Grandia
4. Dana Holinka
5. Adolfo Orive
6. Chriss Russell
7. Tara Zimmerman

**CEO Report, Kari Rosbeck**

The Infantile Spasms Taskforce aims to develop solutions to challenges faced by caregivers around insurance and timely delivery of Sabril for infantile spasms. The ultimate goal is to improve communication and the delivery system so the burden of access is not placed on the families. Four action items are to:

1. Develop best practices sheet for physicians and nurse coordinators, based on one developed by Jessica Krefting at UAB.
2. Educate specialty pharmacies in coordination with Lundbeck (including Accredo, now part of ExpressScripts; CVS Caremark).
3. Educate the TSC community through webinars, information sheets, *Perspective* articles, social media.
4. Triage communication for families acutely in need.

Challenges ahead include that vigabatrin lost its exclusivity April 26, 2017, and that at least three companies developing new generics (PAR – already approved; TEVA, ACOVA, perhaps others). The TS Alliance will need to educate the community regarding one REMS system, which will be shared across all companies selling the drug, but we don’t know which distribution systems generic companies will use, and it’s not known if bridge supplies of vigabatrin will be possible (as it has been with SHARE). Martina Bebin will host a webinar next week (mid-June 2017) to talk about changes to the REMS system that took effect June 1. Kari has established a communication tree directly with the pharmacies to address issues as they arise.

Partnership with the LAM Foundation:

There is a strong, growing partnership among organizations with very different cultures: the TS Alliance focuses on life span support for families, while the LAM Foundation focuses on women patients. The two organizations hosted a regional conference in Houston, April 22 in which 79 individuals participated.

Patient-Focused Drug Development Meeting: The TS Alliance has recruited panelists for four panels, which will cover experience and treatment of epilepsy in infants with TSC, and of angiomyolipomas and LAM in young adults in TSC. The meeting will result in a “Voice of the Patient” report. The goal is to position TS Alliance as the “voice of the patient” for future drug development, build a stronger relationship with FDA, and boost venture philanthropy for drug development.

Preparation for the World TSC Conference is proceeding on schedule. The next steps are development and submission of Sponsorship Proposals and Exhibitor Prospectus.

Global Awareness Day was a huge success, and included events launching the TS Alliance of Mexico.

Development: Corporate support has been slower to come in than usual; while we have been making targets, each target has required more follow-up. An event was held in Boston on June 2 to share updates in research so that donors and corporate partners can see the value that we’re bringing to the community. *Perspective* magazine articles to come will describe the synergy between the organizations and the community. The TS Alliance is planning follow-up meetings with all Presidential Council members and looks forward to the Board fundraising training taking place on October 13.

There were 11 Step Forward walks through May, running 13% below budget. All told, to date, the TS Alliance is $97K below budget on walks for this year. To address this, we are adding three new unbudgeted walks and one virtual walk. There has been some redistribution of walks from spring to fall. Some communities that came in under budget on walks are planning other events to compensate. Shelley Meitzler, who recently joined the TS Alliance staff, is highly motivating to walk chairs and great at coaching, training and supporting walk chairs, as she has more than 10 years of her own walk chair experience.

Fundraising Trends: Year-to-year revenues for Comedy for a Cure are extremely variable, down from an annual consistent revenue of $250K in 2010 and before; we will continue to watch expenses and ratio closely.

April Cooper led the effort to get the Endurance campaign off the ground: the TS Alliance will have 7 bibs in NY marathon. Each runner committed to raise or give $5000.

**Science & Medical Report, Martin Bebin/Brendan Manning and Steve Roberds**

As background information, Steve Roberds reviewed the outcomes of the 2015 NIH- and TS Alliance Sponsored workshop, which identified the following priorities:

* Understanding biology underlying person-to-person variability of TSC
* Gaining a deeper knowledge of TSC-related signaling pathways and cellular consequences of TSC1/2 deficiency
* Improving TSC disease models and preclinical testing
* Developing clinical biomarkers for TSC
* Facilitating therapeutics and clinical trials research

The TS Alliance doesn’t have funds to take a new drug through the entire path, but we can incentivize researchers and private sector partners to develop drugs for TSC by:

* Giving research grants to promote hypothesis generation
* Promoting drug screening through the preclinical consortium
* Promoting Phase 1 and 2 trials through the clinical research consortium
* Supporting Phase 2 and 3 trials through the Biosample Repository and Natural History Database

The Clinical Research Consortium has been extremely successful and impactful. The EEG biomarker study led to the PREVeNT trial. The autism biomarker study is following 166 infants with TSC from age <10 months to 3 years of age. The Rare Disease Clinical Research Network study of determinants of ASD and ID in TSC has enrolled 66 individuals from 3 to 21 years of age.

Opportunities for clinical research: measuring outcomes

There are 200 samples in in the Biosample Repository, with lots of room to grow since the Natural History Database has >2000 participants. Funding would allow this to grow even faster.

Two types of scalability:

* Vertical: More samples, at more sites (requires investment)
* Horizontal: Get different set of outcomes (likely requires more extensive investment)

With $3-4 million, could not only grow vertically, but horizontally (e.g., by bringing someone onto the staff could push forward on assessing clinical effectiveness).

Martina Bebin briefly discussed the PREVeNT Trial. She shared that this is a pivotal trial and progress is being made due to the generosity of Bcureful in providing travel funds for participants. PREVeNT is also springboard for preventative trials utilizing other compounds in the future.

**Finance Report, Jim Maginn and Richard Gollub**

Jim Maginn and Rich Gollub provided a review of the financial reports from April 30, 2017. Highlights were that the Alliance was over on major donor contributions due to an unbudgeted $50K bequest from the estate of Robert McBride and two unexpected donations of $25K or more.

*Review of Balanced Scorecard*

Jim then summarized the balanced scorecard, noting that it was important to improve on the program spending ratios achieved in the first quarter. Preclinical spending started the year slower than originally budgeted. However, three new companies signed up for the preclinical consortium in May, so the Alliance expects to pick up program spending so that the relative portion going to admin/overhead will be within the desired ratio.

Pledges receivable are dominated by the Engles family gift. A future property expense for this year that will be depreciated over 5 years is mouse EEG equipment to be housed by PsychoGenics and paid for by TS Alliance (~$51K).

Liabilities were $431,796 as of April 30, 2017. Unrestricted net assets are low ($812,997) due to Engles and Bill Watts pledges, which are considered temporarily restricted net assets. Cash in unrestricted went down when the TS Alliance made an effort at end of 2016 with more favorable ratios and made additional research grants, some of which came out of unrestricted net assets.

Summary of statement of activities:

* Total revenue higher than budget by $294K due to major donor gifts exceeding budget by $132K and the first planned Endowment contribution of $104K being received earlier in the year than budgeted.
* Expenses lower than expected by $72K due to lower spending on the Preclinical Consortium, which should pick up in the coming quarters.
* Overall, there was a positive variance of $365K compared to budget for the overall change in net assets for the three months ending April 30, 2017.
* Special events revenue as of April 30, 2017 has been negatively impacted by $50K in budgeted walk sponsorships that did not come through; however, this is compensated substantially by:
  + Walks starting the year better than projected, with the new Tampa Bay walk raising $35,000 instead of the budgeted $7,500
  + DC Sound Bites event came in $10K higher than budgeted
  + And as previously mentioned, the large unbudgeted major donor gifts: $50K from Robert McBridge; two additional $25K donations that had not been anticipated, plus $20K unanticipated donation of Laura Wasserman

The TS Alliance will plan to hold off as late in the year as possible to make decision regarding taking the full budgeted Endowment contribution.

*Review of Projections from April 30, 2017*

Total revenue is anticipated to come in close to budget, with the current projection being $4,750K.

Occupancy costs are likely to be higher than budgeted by $6-7K, since the landlord has notified us that there was a substantial increase in the building’s 2016 operating expenses and our share of that increase is being passed through to tenants as additional rental expense this year.

Travel and board expenses are likely to be $16K higher than budgeted, primarily because costs of March on the Hill were higher than anticipated due to higher attendance.

Audit and lobbying fees are expected to be as budgeted; legal fees are likely to be higher in support of preparation of the Patient-Focused Drug Development meeting and legal consulting for FDA around advocating for the FDA to take into consideration patient perspective on an indication for epilepsy for Afinitor. Afinitor has this approval in other countries, but not in the US, where families would bear high costs for the drug if it were to be prescribed for epilepsy, since this would be an “off-label” use not be covered by insurance.

Projection for Preclinical Consortium contract expense is reduced by $25k compared to the budgeted amount of $830k.

Total expenses are anticipated to be $15K higher than budgeted, and total revenue $1K above budget, so the current projected change in net assets for 2017 is anticipated to be $13k below budget – at a negative ($595k) for the year.

**Endowment Fund Report, Doug Loftus (Attachment R-S)**

The main expense is $104K transfer to operating. First quarter returns were 3.4%.

The fund is acting in compliance with its investment policy. The change in net assets is $126K YTD April 30, 2017. The Endowment Fund is engaging with David Levitt’s law firm to research a question from auditors regarding whether the Endowment is a Type 2 supporting organization, which (requires overlap of functions and oversight with the operating organization). Auditors suggested that lawyers review whether bylaws indicate that the Endowment is a Type 2. Should a change in bylaws be required, it will likely make sense to make this change at the same time as the changes to the bylaws regarding membership.

The staff plans to put in an article in *Perspective* about the Eternal Flame Society (participation requires the individual to put the TS Alliance Endowment Fund in their will, indicating that the TS Alliance should be notified). There is consideration regarding adding a new named fund to the Endowment, which requires $25K commitment over five years.

**Government Relations Report, Debora Moritz**

Debora noted that President Trump signed FY2017 budget on 5/5/2017, so $6 million is appropriated for the TSCRP. 165 House members signed the Dear Colleague letter for FY2018; the letter is currently circulating in the Senate, sponsored by Isaacson and Murphy. The Committee will need to look for a new Republican House signer for 2019, as Ileana Ros-Lehtinen, the current signer, is not running for re-election.

The American Health Care Act passed the House on 5/4/2017. The Senate is rumored to be writing their own bill. TS Alliance may need to be in position to take strong opposition due to proposed changes to Medicaid, essential health benefits, and education delivery of services. Therapeutic Medical Access Act may also be legislation of interest or concern for advocacy.

**Other Business**

Tim Dills noted that the next Board meeting takes place in person on October 12-13, 2017 at Hotel Monaco, Baltimore, MD.

**Adjourn**

A motion was made to adjourn the meeting *(Bissler/Scroggins)*. *The motion passed without dissent.* The meeting adjourned at 9:37 pm.

Respectfully submitted,

Rebecca Anhang Price, Secretary