The Tourette Association of America grant awards program wants to encourage applications for clinical treatment studies. However, how the proposal is written can make a significant difference in how the proposal is reviewed and ultimately its chances for funding. The TAA understands that all promising treatments have to start somewhere and may require several steps before the treatment is ready for a randomized controlled trial which can be competitive for federal funding.

Therefore proposals for pilot studies that will be most successful are those that start with a promising idea, delineate the steps for its development and explicitly states how TAA funding will be use to take a good treatment idea from concept to actuality. The aim of the proposal should not be a small randomized controlled trial as these trials are likely to be underpowered to answer the question about the efficacy of the treatment. Below is a list of the kinds of treatment studies that have the potential to advance a treatment idea to a federally funded randomized controlled trial and therefore have the best opportunity for TAA funding.

Considerations for writing treatment proposal for the TAA grant awards program.

1. The intervention should have "promise" of a treatment effect across the age span for tics or comorbid conditions in people with tics; "Promise" is defined as a plausible mechanism of action, basic science evidence or clinical experience in another disorder?
2. The pilot study develops and tests the protocol to be used in a larger trial.
3. The pilot study evaluates the feasibility of a multisite collaboration.
4. The pilot study gathers data on the expected adequacy of recruitment for the future trial (i.e., this may justify the use of placebo in a pilot trial – even if the trial is not large enough to detect a difference between drug and placebo).
5. The pilot study provides information on the pharmacokinetics of an effective or potentially effective medication.
6. The pilot study provides information on time to effect for the purpose of identifying clinical trial duration.
7. The pilot study is likely to inform investigators on the dosage for evaluating in a larger trial across the age span?
8. The intervention needs to be evaluated for safety and/or tolerability.
9. The pilot study may seek to identify the mechanism of action of an effective or potentially effective treatment.
10. The pilot study evaluates procedures for blinding that can be used effectively in a definitive trial.
11. The pilot study may provide information on potential biomarkers as study outcome measures or as correlates of outcome
12. The pilot study develops and follows ethical approaches in a study of new or unconventional treatments.
13. The pilot study is unlikely to produce ambiguous results (e.g., use of a crossover design with a compound that has uncertain onset and offset of action would produce ambiguous results).
14. The pilot study contributes to the development of the database necessary for a larger clinical trial.
15. The pilot study develops new outcome measures or evaluates existing outcome measures.
16. The pilot study evaluated new data analytic methods on existing or model data sets.