## Protocols for Trials of the ALS Treatment "Natural Science Therapy for ALS"

Principal investigator (PI): Steve Spiegel Investigation Website: Beat-ALS.org

These trials are designed to test *Natural Science Therapy for ALS* — a free, complementary naturopathic treatment designed to reverse the progression of ALS symptoms.

Goal of the study: Test Natural Science Therapy for ALS.

Who is eligible to participate: Trials are open to all ALS sufferers although the program targets those who respect science and logic, and remain capable of rational cognition. Participation is completely voluntary without penalty for early withdrawal.

**Protections against risks to participants:** Since the program is not a food or drug, or invasive, it is FDA approved by definition. The greatest risk or "harmful side-effect" is social criticism for testing an unconventional form of therapy. The PI generally supports "healthy scientific skepticism" and seeks to mitigate logical concerns with transparency and the "skepticism" link that addresses this issue.

**Procedure Details:** Natural Science Therapy for ALS explains methods for duplicating documented Reversals with additional materials provided by the PI. Trials participants are expected to familiarize themselves with the therapy program and other training materials provided by the PI, and thereafter have regular coaching sessions with him. Meetings and communication schedules to be determined by mutual consent.

**Trial duration:** Trials are projected to last at least through two quarterly ALS primary health care visits (typically more than three months) to facilitate standard successive clinical data collections and documentation regarding ALS symptom progressions (or regressions).

**Trial design and information gathered:** These trials are designed to duplicate the common element of therapies related to documented ALS Reversals; results will be based on reports from quarterly ALS physician visits (traditional ALS outcome measures). The trials are historically controlled (without placebos). Participants are encouraged to join Dr. Bedlack's research through ALSuntangled.com and registries PatientsLikeMe.com and the ALS Registry through the NIH. Trials will be considered successful if participants' clinically documented ALS symptoms begin reversing.