

**CONSTITUTION AND BYLAWS OF THE
DYSTONIA STUDY GROUP**

**Ratified by the DSG membership
May 9, 2001**

ARTICLE I - NAME AND OBJECTIVES

This organization shall be known as the Dystonia Study Group (DSG) representing a consortium of investigators committed to the cooperative planning, implementation, analysis, and reporting of controlled clinical studies and of other research and education for dystonia and related disorders. To this end, the DSG aims to advance knowledge about the cause(s), pathogenesis, and clinical impact of dystonia and related disorders, and to develop and implement scientific strategies to examine promising therapeutic interventions.

The DSG is committed to the principles of open and full scientific communication and collaboration, peer review, full disclosure of potential conflicts-of-interest, and democratic governance of its organization and activities. The DSG is also interested in providing scientific and medical information to professionals and the public regarding dystonia and related disorders.

ARTICLE II - ORGANIZATION

The DSG, founded in 1996, is organized as an independent, nonprofit consortium of investigators who conduct research at the institutions with which the investigators are affiliated. The views of the DSG do not necessarily represent the views of the institutions with which the investigators are affiliated or the agencies or companies that support the research and educational activities of the DSG.

ARTICLE III - INCOME AND EXPENSES

Any income or property of the DSG shall be applied solely towards the promotion of the objectives of the DSG as set forth in Article I, and no portion shall be paid or transferred to any officer, member or employee of the DSG, except for reasonable and proper remuneration, including repayment of out-of-pocket expenses, in return for any service actually rendered to the DSG. Accurate accounting shall be kept of the money received and expended by the DSG and a summary will be presented to the DSG membership at least once annually. This will be done by the Chair of the DSG.

ARTICLE IV - DSG HEADQUARTERS

The office of the DSG shall be located at the institution of the Chair of the Executive Committee where all income and expenses of the DSG shall be recorded and transacted in a discrete, designated account for which there is no administrative or overhead charges. A Secretary-Treasurer will oversee the accounting, with oversight by the Vice-chair of the Executive Committee.

ARTICLE V - MEMBERSHIP

Voting members will include investigators and steering committee members who are participating in an active DSG study or have participated in a DSG study within 3

years of the meeting date, the members of the DSG Executive Committee, and DSG members actively playing a role in other DSG affairs-educational symposia, meeting planners, etc. The eligibility of study investigators as voting members shall be determined by the steering committee of each active DSG study. The eligibility of steering committee members, as well as other DSG members actively involved in the DSG, as voting members shall be determined by the Executive Committee.

Each Voting Member will have one vote. Each member of an active steering committee and of the Executive Committee, including ex officio members, will be accorded one vote. Votes are not transferable to other persons and cannot be cast as a proxy in instances when the presence of the voting member is required.

Associate Members shall include: 1) DSG investigators who are not actively participating in a DSG study but who have been investigators in the past, but not in the past 3 years, 2) consultants who are actively serving on standing, advisory, organizing or monitoring committees, and 3) professional staff, including coordinators, at active DSG study sites. Associate members do not have voting rights.

ARTICLE VI - OFFICERS

The DSG shall be governed primarily by a nine-member Executive Committee consisting of a Chair, Vice-chair, Secretary-Treasurer, and six investigator members who are elected by the voting members. The Chair and Vice-chair must be from different institutions.

The Chair, Vice-chair, and Secretary-Treasurer, are to be elected by the voting members to serve a term of 4 years, and may be elected one time to succeed themselves for a second term. The Vice-chair will be eligible to be elected to chair at the conclusion of his/her 4-year term(s). Investigator members of the Executive Committee shall be elected by the voting members to serve staggered terms of 3 consecutive years and are not to succeed themselves. Therefore, two investigator members are to be elected to the Executive Committee each year.

The Chair of the Executive Committee shall appoint ex officio members of the Executive Committee to act as Standing Committee chairs. Ex officio members of the Executive Committee will not be able to vote on Executive Committee matters.

ARTICLE VII - EXECUTIVE COMMITTEE

The responsibilities of the DSG Executive Committee include, but are not limited to:

1. Developing and supporting the scientific projects of the DSG including, but not limited to, review and approval of research protocols, principal investigators, co-principal investigators and steering committees for these research projects

2. Formulating and maintaining standards for the DSG regarding the conduct of studies, publication policies (Article XII), and conflict-of-interest guidelines (Article XIII),
3. Overseeing the program and activities of the DSG including its annual meetings, symposia, and other administrative and scientific activities
4. Formulating and maintaining current and accurate listings of voting and associate members and of other qualified investigators who request participation in DSG studies and programs,
5. Proposing and overseeing the assessment and collections of dues, fees or surcharges for the DSG as specified in Article XVI.

The Executive Committee shall meet at least twice each calendar year and report through the Chair of the Executive Committee to the membership at the annual DSG meeting.

ARTICLE VIII - BUSINESS MEETINGS OF THE DSG

The DSG shall hold a business meeting of its membership at least yearly at the time of its annual meeting. At least 20 voting members shall constitute a quorum for the transaction of business of the DSG.

ARTICLE IX - NOMINATIONS AND ELECTIONS

Elections for the Chair, Vice-chair, and Secretary-Treasurer of the Executive Committee shall take place every 4 years by mail ballot, with the majority of total votes received from voting members required for election. The Chair and Vice-chair must represent different institutions. Each year, the voting members shall elect, by mail ballot, two investigator members of the Executive Committee to serve a term of 3 years.

Within 6 months prior to each election, a slate of officers and members of the Executive Committee shall be recommended for election from among voting members by a Nominating Committee appointed by the Chair of the Executive Committee. The slate of candidates will be mailed by the Nominating Committee to all voting members of the DSG who shall have the opportunity to nominate other candidates from the voting membership by mailing their preference to the Chair of the Nominating Committee. The Chair of the Nominating Committee shall close the nominations 4 weeks after sending out the selections of the Nominating Committee. Voting members need to receive nominations from at least 4 voting members in order to be declared an official candidate.

The Secretary-Treasurer of the DSG will then mail the election ballot to all voting members of the DSG. The ballot will contain the slate presented by the Nominating Committee plus all official candidates nominated by mail. In order to be counted, votes,

which shall be by secret ballot, must be received by the Secretary-Treasurer within 30 days after mailing out the official ballot.

The Secretary-Treasurer will oversee the election, ensuring that voting members are accorded their rightful votes, and will declare the winners of the election. If no one has received the majority of the votes cast for an office, the two candidates with the greatest number of votes will face each other in a second election to take place immediately; this election will be supervised similarly to the first.

The first election of Chair, Vice-chair, Secretary-Treasurer, and other Executive Committee members will take place by anonymous written ballot during the business meeting immediately following the meeting at which these Bylaws are first adopted. A voting member of the DSG may not be on the ballot for more than one position. The Chair will then have the authority to appoint the 6 at-large members of the Executive Committee. Given the staggered terms, 2 of these appointees shall serve a 2-year term, 2 will serve a 3-year term, and 2 will serve a 4-year term.

ARTICLE X - DSG STUDIES

Any voting or associate member of the DSG may make application to the Executive Committee for authorization of a DSG study by submitting a sufficiently detailed summary or outline of the proposed protocol. In its decision as to whether or not to authorize a study, the Executive Committee shall comment on the aims, objectives, scientific and clinical adequacy of the protocol, qualifications and capabilities of the investigators, mechanism for funding, and sponsorship for the proposed study.

For each authorized DSG study, a Principal Investigator (PI) and Co-Principal Investigator (Co-PI) will be appointed by the Chair and approved by the Executive Committee. The PI and Co-PI, who may be members of the Executive Committee, should represent different institutions.

The PI and Co-PI for each authorized DSG study shall appoint a steering committee consisting of three or four investigators. The steering committee will include a chief biostatistician for the study. All members of the steering committee, including the chief biostatistician, must be approved by the DSG Executive Committee. . Every effort should be made by the Chair, Executive Committee, PI, Co-PI and the steering committee to solicit participation from a wide selection of DSG sites. In practice DSG studies should not be limited to a few institutions or investigators.

All DSG steering committees will ensure that study policies governing confidentiality, human subject, clinical practice, conflict-of-interest and publication are consistent with policies contained in the DSG Constitution and Bylaws.

The PI for each DSG study will be responsible for formulating the protocol, overseeing the implementation, supervising the analysis and reporting for of the study. The PI will also be responsible for securing adequate sponsorship and support for the

study. Funding for the study will be directed primarily through an account at the affiliated institution of the PI, under the rules and regulations of that institution and of the sponsor. The PI, through his or her institution, will be responsible for subcontractual arrangements with the participating investigators and their institutions. The Co-PI will assist the PI in carrying out these responsibilities and assume the responsibilities of the PI in the event that the PI is absent or incapacitated.

Each steering committee will be responsible for the selection of site investigators for that study, and for assisting the PI and Co-PI in the implementation, analysis and reporting of the study results. Participating site investigators for the study will be selected from the current DSG listing of voting and associate members and of other qualified investigators who request participation in DSG studies.

Each steering committee will also be responsible for removing from active study participation any steering committee member, investigator, or coordinator, who does not fulfill his/her obligations to the study or who does not maintain the standards of the DSG with respect to confidentiality, conflict-of-interest, disclosure or publications policies.

ARTICLE XI - STANDING DSG COMMITTEES

The Chair of the Executive Committee will appoint chairs and members of the following standing committees: 1) Nominating, 2) Standards, 3) Publications, 4) Membership.

The Nominating Committee will be responsible for nominations and elections as set forth in Article IX. The Nominating Committee will consist of a chair and three other members to be appointed by the Chair of the Executive Committee for a one-year term (between annual DSG meetings). Members of the Nominating Committee are ineligible for nomination as an officer of the DSG during their term of service.

The Standards Committee will be responsible for professional standards including the annual review of conflict-of-interest guidelines of the DSG, as set forth in Article XIII, and for making recommendations, if any, to the Executive Committee for additions or revisions of these policies. The committee will also assist the Executive Committee in the oversight and adjudication, as necessary, of problems or conflicts arising in the maintenance of professional standards and the implementation of these guidelines. The Standards Committee will consist of a chair and three other members to be appointed by the chair of the Executive Committee for a term of four years and will rotate off one-half of its members every two years.

The Publications Committee will be responsible for an annual review of DSG publication policies and for making recommendations, if any, to the Executive Committee for additions or reviews to these policies. The committee will also assist the Executive Committee, as necessary, in the adjudication of problems or conflicts arising out of implementation of the DSG publication policy. The Publications Committee will consist of a chair and three other members to be appointed by the Chair of the Executive

Committee, to serve a term of four years and will rotate off one-half of its members every two years.

The Membership Committee will be responsible for recommending to the Executive Committee investigators to be recruited for studies. The Membership committee shall strive to see that all DSG sites are able to participate in the studies sponsored by the DSG.

The Chair of the Executive Committee shall appoint the chairs and members of the standing committee, subject to the approval of the Executive Committee. The chairs and members of the Standing Committee may be voting or associate members of the DSG.

Chairs and members of the standing committees may not be re-appointed for successive terms to the particular committees they are serving, but they may be appointed to other standing committees or re-appointed to previously served committees if the terms are not successive. For standing committees with terms of more than one year, appointments will be staggered to help ensure continuity and turnover of committee membership. Standing committees should not have more than one member from the same affiliated institution.

Other standing committees of the DSG may be established upon recommendation of the Executive Committee and approval of the DSG membership as outlined in Article XVIII.

ARTICLE XII - DSG PUBLICATIONS POLICIES

Publication of research data by members of the Dystonia Study Group (DSG) is encouraged. The reasons for a publication policy are both to encourage publications and to avoid potential conflicts about publication priorities and details before they arise. The authorship and acknowledgements of various types of articles should be formulated according to the following guidelines:

All articles utilizing data on patients recruited as part of a study must acknowledge support from the study sponsor(s), unless advised by the sponsor that an acknowledgement is not necessary.

Peer-reviewed articles on the major objectives and general demographic descriptions of the study populations should have as authors the first author for the Dystonia Study Group. All participants should be listed in the appendix with participating centers listed in descending order of the number of subjects enrolled. The order for each institution should be PI then co-investigators for that site, then any secondary authors and statisticians. Either the Dystonia Study Group (with membership listed in a footnote), or the members of the DSG in the following order: The primary author, the primary biostatistician, DSG investigators in order of the number of their patients enrolled in the study, DSG members without responsibility for subjects, and the Principal Investigator

and Co-Principal Investigator if not the primary authors. All authors should contribute to the writing of the article. DSG site coordinators should be cited in the acknowledgments in the order of their investigators.

Authorship on reports of ancillary studies should be decided by those who proposed the ancillary study to the steering committee.

Authorship on publications that come out of working groups must be decided before the steering committee allows the biostatistician to release the data, and should include all those who have intellectual input into the work, including biostatisticians, coordinators and consultants. The DSG should be last author on these papers.

Authorship on invited reviews and chapters should be decided by the invitee. The steering committee will need to approve the release of any data that is not already in press in a peer review journal to such authors.

For the consistency of data reporting, study raw data should not be released for individuals or working groups to analyze without an approved analysis plan. An individual's or working group's request for data from the steering committee should eventually consist of a hypothesis, together with a description of the items from the database to be analyzed, and the method of analysis to be done in order to test the hypothesis. Data analysis can be performed by a DSG biostatistician or a biostatistician working with the primary authors.

Individuals are encouraged to attach themselves to working groups. An individual can be a working group of one, but the steering committee will only release data sets to an individual if his/her hypothesis does not fit under the jurisdiction of an existing working group. Within a working group these can be subgroups interested in different aspects of a problem. Two subgroups cannot have the same set of data analyzed. They will have to combine into a single larger group. Individuals can belong to more than one working group or subgroup.

ARTICLE XIII - CONFLICT-OF-INTEREST GUIDELINES

Members of the DSG should maintain the highest personal and professional standards in conducting clinical studies and research. Real and perceived conflict-of-interest must be avoided.

To these ends, we agree that:

1. DSG members shall not in any way or manner benefit financially from the information obtained as a result of their participation in and knowledge of DSG studies. In particular, DSG members agree not to own or trade in the equity of a company whose drugs or products are being investigated by the DSG ("involved company"). DSG members further agree not to inform or influence relatives, friends or others in financial transactions regarding the "involved company".

2. DSG members have an obligation to act in the public interest and should be willing to educate the scientific and lay communities. DSG members agree that such practices are permitted provided there is no disclosure of confidential information or any potential for jeopardizing the successful outcome of any clinical study that is in progress.
3. DSG members agree not to serve as paid consultants to an "involved company" in relation to the study drug during the period of an active clinical study (this does not include open-label extensions to studies). Scientific consultation to the "involved company" on issues not related to drugs currently undergoing clinical study by the DSG is permitted. Such consulting services must be disclosed to the Executive Committee on an annual basis.
4. Certain activities with "involved companies" are not considered to be a conflict-of-interest. These activities include: (a) serving as an educator, e.g. giving a lecture or speaking in a panel discussion at a forum sponsored by an "involved company"; (b) participating in research activities unrelated to the study drug or product, and supported by the "involved company". Honoraria for speaking in an educational program may be kept by the DSG member.
5. These CONFLICT-OF INTEREST GUIDELINES will apply from the time of recruitment of subjects into a study until the later of one month following public disclosure of the results of the study, or one month after the final data analysis of the study has been completed. This will be binding for all members including those who might leave the study, for any reason, prior to its completion.
6. In these GUIDELINES a DSG member is defined as an investigator, coordinator, data processor, statistician, consultant, or any other person involved with or privy to information regarding DSG studies.
7. Members of the DSG should insist on full and meaningful disclosure of financial support for educational events to which they are invited to participate. Members of the DSG should fully disclose their research support, consultation fees, honoraria, and any significant financial interest with manufacturers(s) of commercial products related to the topic of their presentation for education events in which they participate.
8. A DSG member may be paid as a consultant to develop a research protocol that will be sponsored by a company so long as the study has not yet begun and there are no other conflicts-of-interest as noted above.

ARTICLE XIV - ANNUAL DSG MEETING

The Executive Committee will organize an annual meeting of the DSG to conduct its business and provide an opportunity for scientific review and meetings of DSG steering committees, standing committees, investigators, and coordinators.

ARTICLE XVI - DUES, FEES AND SURCHARGES

The Executive Committee may propose annual dues for DSG members and fees or surcharges for participation in DSG studies in order to support DSG activities, including but not limited to the planning and implementation of DSG studies, scientific and educational symposia, and its annual meeting. Proposals of the Executive Committee for dues, fees or surcharges will require approval by a majority of votes received from DSG members who respond.

ARTICLE XVII - DATE OF ACTIVATION OF CONSTITUTION AND INTERIM OFFICERS

When approved by at least two-thirds of the votes cast by voting members who are present, these Constitution and Bylaws will become active and adopted at the time of the business meeting of the DSG, on May 3, 2000. Upon adoption of this Constitution, the first election of the Chair, Vice-chair, and Secretary-Treasurer shall take place immediately thereafter by anonymous balloting under the procedures set forth by the DSG Nominating Committee. The elected and appointed members of the DSG Executive Committee shall begin their terms of service at the time of the business meeting on May 3, 2000.

ARTICLE XVIII - AMENDMENTS

Amendments to the constitution and Bylaws may be proposed by any voting member, must be made in writing, must be signed by 4 other voting members, and must be submitted to the DSG Secretary-Treasurer at least 2 months prior to a meeting of the DSG Executive Committee, at which time the proposed amendment will be considered and voted upon. If the proposed amendment is approved by a majority of the Executive Committee, it will be circulated to all voting DSG members for a mail ballot. Affirmation by at least two-thirds of votes received by the Secretary-Treasurer, within 2 months after the proposed amendment was circulated, and shall be required for the amendment to be adopted.

At the request of the proposer, amendments not approved by the Executive Committee may be placed on the agenda at least two months prior to an annual DSG meeting where the proposal may be enacted by an affirmative vote by least three-quarters of votes cast by voting members at the meeting.

ARTICLE XVIII - DISSOLUTION OF THE DSG

The dissolution of the DSG shall be decided by an affirmative vote by written ballot of three-fourths of votes of voting members of the DSG who respond. The procedure on dissolution shall follow that outlined for proposing amendments in Article XVII.