

# **CONSTITUTION AND BYLAWS OF THE PARKINSON STUDY GROUP**

As proposed by the PSG Governance Committee  
and as modified and adopted by the members of the  
Parkinson Study Group on February 26, 1994,  
and amended on February 15, 1995; May 4, 1996; October 17, 1998;  
May 19, 2000; May 19, 2001; December 31, 2005;  
October 20, 2006; April 19, 2010; and September 3, 2011

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## **ARTICLE I – NAME AND OBJECTIVES**

This organization shall be known as the Parkinson Study Group (PSG), representing a consortium of scientific investigators from academic and research centers who are committed to the cooperative planning, implementation, analysis and reporting of controlled clinical trials and of other research for Parkinson’s disease and related disorders. To this end, the PSG aims to advance knowledge about the cause(s), pathogenesis and clinical impact of Parkinson’s disease and related disorders and to develop and implement scientific strategies to examine promising therapeutic interventions.

The PSG is committed to the principles of open and full scientific communication, peer review, full disclosure of potential conflicts of interest, and democratic governance of its organization and activities. The PSG is also interested in providing scientific and medical information to professionals and the public regarding experimental therapeutics. Accordingly, the PSG helps organize symposia and other scientific forums such as the annual symposium on “Etiology, Pathogenesis, and Treatment of Parkinson’s Disease.”

## **ARTICLE II – ORGANIZATION**

The PSG, founded in 1986, is organized as an independent, nonprofit consortium of scientific investigators who conduct research at the institutions with which the investigators are affiliated. The views of the PSG do not necessarily represent the views of the institutions with which the investigators are affiliated.

## **ARTICLE III – INCOME AND EXPENSES**

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

## **ARTICLE IV – PSG HEADQUARTERS**

The office of the PSG shall be located at the institution of the chair of the Executive Committee, or at such other institution as directed by the chair, where all income and expenses of the PSG shall be recorded and transacted in a discrete, designated account for which there are no administrative or overhead charges.

**ARTICLE V – MEMBERSHIP**  
(AS AMENDED OCTOBER 20, 2006)

Voting Members will include those who either 1) have participated for one year or more (investigators, coordinators, and steering committee members) in an active PSG trial, 2) have attended at least two of the three most recent PSG annual or training meetings preceding each review of membership, or 3) have actively served for one year or more as members of the PSG Executive Committee, other PSG standing committees, or working groups. Voting members continue to be eligible to vote for one year following completion of one of the foregoing criteria. Mitigating circumstances of individuals who do not meet these criteria may be reviewed by the Executive Committee (or their designee) on a case-by-case basis. The eligibility of voting members shall be determined annually in advance of voting, based upon a review of a self-report form completed by members along with their annual conflict of interest form. A notice will be sent to those members who are no longer eligible to vote. Each member who is considered eligible as a voting member shall have 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) PSG investigators and coordinators who are not eligible to vote in the PSG but who have been in the past 3 years, 2) consultants who are actively serving on standing, advisory, organizing or monitoring committees, 3) professional staff members of the Coordination and Biostatistics Centers who are supporting an active PSG trial and 4) professional staff at participating sites who are supporting an active PSG trial. Associate members do not have voting rights.

**ARTICLE VI – OFFICERS**  
(AS AMENDED ON MAY 19, 2000, OCTOBER 20, 2006, AND APRIL 19, 2010)

The PSG shall be governed primarily by a ten-member Executive Committee consisting of a chair, co-chair, three investigator members and one coordinator member who are elected by the voting members, and the directors of a PSG credentialed Biostatistics Center and PSG credentialed Coordination Center, as selected by the chair of the Executive Committee, and the chairs of the PSG Scientific Review and Mentoring Committees who are appointed by the chair of the Executive Committee.

The chair and co-chair, as a team, are to be elected by the voting members to serve a term of 6 years, and may be elected to succeed themselves. Each investigator member of the Executive Committee shall be elected by the voting members to serve staggered terms of three consecutive years, not to succeed themselves. One investigator member is to be elected to the Executive Committee each year. The coordinator member shall be elected by the voting membership for a two-year term, not to be succeeded. The appointed directors of the Biostatistics and Coordination Centers shall each serve a term of 3 consecutive years, and if re-appointed by the chair, may succeed themselves for additional 3-year terms.

The chair of the Executive Committee may appoint *ex officio* members of the Executive Committee to serve a term of 3 consecutive years, and if re-appointed by the chair, may succeed themselves for additional 3-year terms. *Ex officio* members of the Executive Committee will not have voting rights for Executive Committee business.

## **ARTICLE VII – EXECUTIVE COMMITTEE**

The PSG Executive Committee shall be responsible for:

1. developing and supporting the scientific projects of the PSG including but not limited to the review and approval of research protocols, principal investigators, co-principal investigators and steering committees for these research projects,
2. reviewing and approving the appointments of the directors of the Coordination and Biostatistics Centers and for overseeing the high-quality performance of these centers,
3. reviewing and approving the appointments of appropriate personnel and the chair and members of the standing PSG committees as described under Article XI.
4. formulating and maintaining standards for the PSG regarding the conduct of trials, publication policies (Article XII), and conflict-of-interest guidelines (Article XIII),
5. overseeing the program and activities of the PSG including its annual meetings, symposia, and other administrative and scientific activities,
6. formulating and maintaining current and accurate listings of voting and associate members and of other qualified investigators who request participation in PSG trials and programs,
7. proposing and overseeing the assessment and collection of dues, fees or surcharges for the PSG 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 PSG meeting.

## **ARTICLE VIII – BUSINESS MEETINGS OF THE PSG**

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

**ARTICLE IX – NOMINATIONS AND ELECTIONS**  
(AS AMENDED ON MAY 19, 2000)

Elections for the chair and co-chair of the Executive Committee shall take place every 6 years by electronic ballot, with the majority of total votes received from voting members required for election. The chair and co-chair should represent different institutions but shall be considered for nomination and election as a team. Each year, the voting members shall elect by electronic ballot one investigator member of the Executive Committee to serve a term of 3 years. Every other year, the voting members shall elect by electronic ballot one coordinator member of the Executive Committee to serve a term of 2 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 emailed by the Nominating Committee to all voting members of the PSG who shall have the opportunity to nominate other candidates from the voting membership by emailing their preference to the chair of the Nominating Committee. The chair of the Nominating Committee shall close the nominations two months after sending out the selection of the Nominating Committee. Voting members need to receive nominations from at least 7 voting members in order to be declared an official candidate.

The Administrative Manager of the PSG will then email the election ballot to all voting members of the PSG. The ballot will contain the slate presented by the Nominating Committee plus all official candidates nominated. Votes, which shall be by secret ballot, must be received within 30 days after receiving the official ballot in order to be counted.

The Chair of the Nominating Committee 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.

In the event of the death, resignation or vacancy of an officer or member of the Executive Committee, the following provisions shall apply. In the event of the death, resignation or vacancy of the chair, the co-chair shall succeed the chair for the balance of his or her elected term. In the event of the death, resignation or vacancy of the co-chair (including his/her succession to chair as described above), the chair shall appoint a replacement from the current members of the Executive Committee. Such replacement shall be approved by majority vote of the voting members of the Executive Committee and shall be voted upon by the voting membership of the PSG. In the event of the death, resignation or vacancy of an elected Executive Committee member, the position shall remain vacant until the next regularly scheduled election, at which time the voting membership of the PSG shall elect a replacement to complete the remaining term of the departing member.

**ARTICLE X – PSG TRIALS**  
(AS AMENDED OCTOBER 20, 2006 AND APRIL 19, 2010)

Any voting or associate member of the PSG may make application to the Executive Committee for authorization of a PSG trial by submitting a proposal in accordance with the submission guidelines set forth in the document entitled “Procedures for Review of New Study Proposals,” which is posted on the PSG web site. All proposals will be reviewed by the Scientific Review Committee, and then a decision will be made by the Executive Committee, based on the recommendation of the Scientific Review Committee. In its decision as to whether or not to authorize a trial, the Executive Committee shall address the aims, objectives, scientific and clinical adequacy of the protocol, qualifications and capabilities of the investigators, mechanism for funding, and sponsorship for the proposed trial.

For each authorized PSG trial, 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 and be appointed as a team.

The PI and Co-PI for each authorized PSG trial shall appoint a steering committee consisting of three or four investigators who preferably are not directly involved in the evaluation of subjects for that trial and not participating as investigators in competing, commercially sponsored trials. The steering committee will include a chief biostatistician for the trial, to be appointed by the director of the selected Biostatistics Center, and a coordinating director for the trial, to be appointed by the director of the selected Coordination Center. The director of the Biostatistics Center and the director of the Coordination Center may serve respectively as the chief biostatistician and coordinating director for the trial. All members of the steering committee, including the chief biostatistician and coordinating director must be approved by the PSG Executive Committee. Subject to approval by the Executive Committee, the PI may also appoint a head study coordinator and other appropriate PSG personnel to serve as *ex officio* members of the steering committee.

All PSG steering committees will make use of the services of a PSG credentialed Coordination Center and PSG credentialed Biostatistics Center under the supervision of their respective directors. All PSG steering committees will also ensure that trial policies governing confidentiality, human subjects, clinical practice, conflict-of-interest and publication are consistent with policies contained in the PSG Constitution and Bylaws.

The PI for each PSG trial will be responsible for formulating the protocol, overseeing the implementation, and supervising the analysis and reporting for the trial. The PI will also be responsible for securing adequate sponsorship and support for the trial. Funding for the trial 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 PI will also be responsible

for subcontractual arrangements with the selected Coordination Center and the selected Biostatistics Center of the PSG. 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.

As appropriate, the PI will also appoint working groups and study committees to assist in the planning and implementation of the trial. These committees may include an independent (safety) monitoring committee and working groups to oversee secondary analyses and their publication.

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 trial results. Participating site investigators for the trial will be selected from the current PSG listing of voting and associate members and of other qualified investigators who request participation in PSG trials.

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

#### **ARTICLE XI – STANDING PSG COMMITTEES**

(AS AMENDED ON OCTOBER 17, 1998, MAY 19, 2001, OCTOBER 20, 2006, AND SEPTEMBER 3, 2011)

The chair of the Executive Committee will appoint chairs and members of the following standing committees: 1) Nominating, 2) Standards, 3) Publications, 4) Symposia, 5) Scientific Review, 6) Credentials, 7) Study Budget, and 8) Mentoring Committee.

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 approximately four other members to be appointed by the chair of the Executive Committee for a one-year term (between annual PSG meetings). Members of the Nominating Committee are ineligible for nomination as an officer of the PSG 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 PSG, 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 committee will establish mechanisms of due diligence and due process in considering and

making recommendations to the Executive Committee for disciplining or expelling a voting or associate member of the PSG. At the request of the Executive Committee, the Standards Committee may be asked to investigate and recommend action upon charges or allegations of scientific or professional misconduct or concerns raised regarding conflict-of-interest, relevant to participation in PSG studies, committees or in leadership roles (members of the Executive Committee and Chairs and Co-chairs of PSG Standing Committees and of Working Groups). PSG members, and especially members of the Executive Committee, are strongly encouraged to discuss any relevant information with and seek advice from the Standards Committee before they engage in any activity that may potentially present a conflict of interest. Any member of the PSG may bring to the attention of the Standards Committee potential conflict of interest and disclosure issues pertinent to PSG activities by writing a “request for review” to the Standards Committee Chair. The Standards Committee will treat such requests as Confidential, and will be obliged to maintain the inquirer's anonymity outside the Standards Committee to the extent feasible.

The procedures for investigating allegations or concerns and consequent recommendations for disciplinary action or conflict of interest management will be at the sole discretion of the PSG. Such procedures and recommendations will be consistent with those taken by academic institutions, employing organizations, Federal or State granting or regulatory agencies, and/or professional organizations. If a conflict of interest or disclosure issue pertains to one or more members of the Executive Committee, the investigation and recommendation will be the responsibility of the remaining uninvolved members of the Executive Committee and the Standards Committee. This ad hoc review committee will be responsible for final adjudication of the matter, unless it is determined by the ad hoc committee that due to the nature of the conflict it would be best for the Chair of the Standards Committee to appoint a panel of persons external to these committees, or even to the PSG, to adjudicate the matter. The procedures for investigation will be communicated in advance to the involved and affected parties. The Standards Committee will consist of a chair and approximately three other PSG 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 PSG publication policies and for making recommendations, if any, to the Executive Committee for additions or revisions 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 PSG publication policy. The Publications Committee will consist of a chair and approximately 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 Symposia Committee will be responsible for the annual PSG scientific symposia. The Symposia Committee will be responsible for the organization and peer-review requirements for the annual symposium on “Etiology, Pathogenesis and Treatment of Parkinson’s Disease” and for recommending other scientific forums that

may advance knowledge about the cause(s), pathogenesis and clinical impact of Parkinson's disease. The Symposia Committee will consist of a chair and approximately three other members, each to serve a term of four years and will rotate off one-half of its members every two years.

The Scientific Review Committee will review all PSG research proposals including retrospective data mining projects and prospective studies, whether observational or interventional. A primary and one or more secondary reviewers will be assigned and the Committee will review and score each proposal. The Committee will also facilitate contacts with the Mentoring Committee as appropriate. Requests for use of PSG repositories (DNA, CSF, blood, urine, video) will also be reviewed by the Scientific Review Committee. The Scientific Review Committee will consist of a chair and approximately ten to fifteen members to serve terms of three years and will rotate off one third of its members every year.

The Credentials Committee will be responsible for reviewing applications received from individuals interested in joining the PSG and evaluating the merits of submitted applications. The Committee shall develop and implement a uniform set of standards which shall be used in evaluating applicants; including, but not limited to: the applicant's education and training; academic experience, movement disorder experience; letters of reference; past clinical trial experience; clinical experience and number of patients currently followed and other factors as determined by the Committee. The Credentials Committee will consist of the co-chair of the Executive Committee, who shall act as chair of the Credentials Committee during his/her six year term, and approximately nine members who shall serve terms of three years, with one third of the members rotating off every year.

The Study Budget Committee will be responsible for developing site and "per subject fee" costs for study budget proposal purposes. The Committee will be responsible for providing uniform site and "per-subject-fee" budgetary input for all PSG projects. Costs shall be representative of the needs of the majority of PSG sites. The Committee will also be the focal point for considering changing and newly emergent issues related to site compensatory issues and shall make recommendations on site budgetary issues to the PSG Executive Committee. The Study Budget Committee will consist of a chair and approximately five members, half of whom shall be PSG investigators and half of whom shall be PSG coordinator members. Each committee member shall serve a term of three (3) years, with one third of the members rotating off each year. The Committee may elect to include a number of additional ad-hoc (temporary) members as needed when conducting its work.

The Mentoring Committee will have three main roles. The first is to be responsible for soliciting, reviewing, and selecting candidates to receive the Parkinson's Disease Foundation sponsored mentored clinical research fellowship awards. Secondly, the Committee would serve as a resource for individuals who need assistance in formulating and developing protocols to the point where they are ready for review by the Scientific Review Committee. The Mentoring Committee may provide direct mentorship

or refer to appropriate individuals within the PSG for provision of that mentorship. The third role will be to develop and organize innovative programs to promote interest in Parkinson's disease research, facilitate the development of mentorship relationships, and increase awareness of resources within the PSG that can provide opportunities for initiating research efforts. The Mentoring Committee will consist of a chair and approximately eight members, to serve a term of three years, with one third of the members rotating off every year.

The chair of the Executive Committee shall appoint the chairs and members of the standing committees, subject to the approval of the Executive Committee. The chairs and members of the standing committee may be voting or associate members of the PSG or otherwise qualified persons who are not members of the PSG. Upon completion of one year of active service on the standing committee, the committee member shall become a voting member of the PSG, as provided in Article V.

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 of service, 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 PSG may be established upon recommendation of the Executive Committee and approval by the PSG membership as outlined in Article XVII.

Working Groups may be established from time to time by the Executive Committee, who shall appoint chairs and co-chairs to serve 3 year terms.

## **ARTICLE XII – PSG PUBLICATION POLICIES** (AS APPROVED BY THE PSG, OCTOBER 13, 1990)

Publication of our research data by members of the Parkinson Study Group (PSG) is encouraged. There are several reasons for the PSG to prepare and submit publications. They are an important measure of the success of our studies. They are good for the morale of the PSG (investigators, coordinators, consultants). It is likely to be more personally satisfying and professionally rewarding to individual members of the PSG to be an important author on (a) smaller paper(s) than to be one of 70 authors on the primary analysis paper.

The reason for a publication policy is 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:

1. 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.

2. Peer-reviewed articles on the major objectives and general demographic descriptions of the study populations should have as authors either the Parkinson Study Group with membership listed in a footnote, or the members of the PSG in the following order: the primary author, the primary biostatistician, PSG investigators in order of the number of their patients enrolled in the study, PSG site coordinators in order of their investigators, PSG members without responsibility for subjects, and the Principal Investigator and Co-Principal Investigator if not the primary authors.

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

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

5. 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.

6. For the consistency of data reporting, study raw data should not be released for individuals or working groups to analyze. An individual's or a 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.

7. 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 there 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**

### **ETHICAL AND CONFLICT-OF-INTEREST GUIDELINES FOR MEMBERS OF THE PARKINSON STUDY GROUP (PSG) (AS APPROVED BY THE PSG ON APRIL 29, 1990, AND AMENDED ON FEBRUARY 27, 1993, MAY 4, 1996, DECEMBER 31, 2005 AND SEPTEMBER 3, 2011)**

Members of the PSG should maintain the highest personal and professional standards in conducting clinical trials and research. Real and perceived conflict-of-interest must be avoided. The term "conflict of interest" is defined as any financial (e.g. compensation in addition to regular salary support) or other interest that conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization. Additionally, officers of the PSG (members of the Executive Committee and Chairs and Co-chairs of PSG standing committees and working groups) must conform to a higher standard in that they represent the PSG. All officers must avoid or manage activities outside of their direct involvement with the PSG that conflict with the mission, goals, interests or reputation of the PSG.

To these ends, we agree that:

1. PSG members shall not in any way or manner benefit financially as a result of their participation in and knowledge of PSG studies. In particular, PSG members agree not to own (in part or in whole) or trade in the equity of a company or entity whose drugs or products are being investigated by the PSG ("involved entity"). "Involved entities" are defined as companies, organizations, or other entities that may benefit from the performance or outcome of a PSG-sponsored study, including entities whose drugs, biologics, devices, products or intellectual property are being investigated by the PSG in which that member is participating in the study. Further, PSG members or their immediate family members (including spouse and dependent children) shall not in any way or manner benefit financially from the information obtained as a result of their participation or knowledge of PSG studies. For members of the PSG leadership (which includes members of the Executive Committee and Chairs and Co-chairs of PSG Standing Committees and Working Groups), these conflict of interest requirements are applicable to all PSG studies and activities. PSG members further agree not to inform or influence relatives, friends or others in financial transactions regarding the "involved entity". PSG members agree not to accept compensation arrangements in which the value of the compensation could be affected by the outcome of the PSG studies in which they are participating. In addition, members participating in a PSG clinical trial agree not to hold a financial interest in the study drug or related drugs or products including, but not limited to, a patent, trademark, copyright or licensing arrangement.

2. PSG members have an obligation to act in the public interest and should be willing to educate the scientific and lay communities. PSG 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 trial which is in progress.

3. PSG members agree not to serve as paid consultants to an “involved entity” or to any individual or entity acting on behalf of the involved entity in relation to the study drug or related drugs or products of the entity during the period of the clinical trial, except as an activity or consultation under the auspices of the PSG. No personal compensation shall accrue to the PSG member for these activities. All educational, consulting and other payments from “involved entities” relating to the study drug or related drugs must be directed to a public charity, a scientific society, the member’s department university or hospital (an academic account administered by the PSG member is acceptable) or to the PSG. Such activities and payments must be disclosed to the Executive Committee at the time of their initial occurrence and via annual Conflict of Interest reports.

4. Certain activities with “involved entities” are permitted, however payments received by the PSG member must be disclosed to the Executive Committee via annual Conflict of Interest reports. These include serving as an educator in CME accredited programs sponsored by an “involved entity” or participating in consulting or research activities supported by the “involved entity” which are unrelated to the drug or product under evaluation by the PSG.

5. For the Principal Investigator, Co-Principal Investigator, Steering Committee members, Coordination and Biostatistics Center staff, the Executive Committee and members of the study Writing (Publication) Committee (if any), these ETHICAL AND CONFLICT-OF-INTEREST GUIDELINES will apply from the time of recruitment of subjects into a study until the latter of one month following publication of a manuscript reporting the primary endpoint of the study, or when the Steering Committee for the study determines that no such publication will occur. For site investigators, site coordinators and site support staff, these ETHICAL AND CONFLICT OF INTEREST GUIDELINES will apply until one month after the first public report of the primary results of the study, including in abstract form. This will be binding for all PSG members including those who might leave the study, for any reason, prior to its completion. For PSG Officers (Executive Committee members and chairs and co-chairs of Standing Committees and Workings Groups) these Guidelines apply for the duration of their terms as PSG Officers.

6. In these GUIDELINES, a PSG member is defined as an investigator, coordinator, data processor, statistician, consultant, or any other person involved with and privy to information regarding PSG studies.

## DISCLOSURES

1. Members of the PSG should insist on full and meaningful disclosure of financial support for educational events to which they are invited to participate.
2. Members of the PSG should fully disclose their research support and any significant financial interest with manufacturer(s) of commercial products related to the topic of their presentation for education events in which they participate.
3. If members of the Executive Committee and other PSG members consult with involved entities and potentially involved entities on behalf of the PSG, to the extent allowed by existing confidentiality agreements, the purpose of these meetings, the amount and destination of fees paid and outcome of the meetings will be disclosed to the Standards Committee. In addition, Chairs and Co-chairs of PSG Standing Committees, including the Executive Committee and Working Groups, must disclose the nature of consulting activities occurring outside of their role as a representative of the PSG if the consulting activity is with an involved entity. Such disclosure will be made to the Standards Committee to the extent allowed by existing confidentiality agreements.
4. There are two types of disclosure forms, one that is study-specific, and another form that is for disclosures required of members in leadership roles as defined above (members of the Executive Committee and Chairs and Co-chairs of PSG Standing Committees and Working Groups). Disclosure forms must be completed on an annual basis or whenever there is a change in the status of the PSG member regarding potential conflict of interest. Failure to fully disclose conflict or perceived conflict of interest constitutes an ethical violation, and may lead to dismissal from the PSG. All disclosures will be reviewed by the legal counsel to the PSG and those deemed to be in violation or potential violation will be reviewed by all the members of the Standards Committee and recommendations on the management of these conflicts will be forwarded by the Chair of the Standards Committee to the Chair of the Executive Committee.

## **ARTICLE XIV – ANNUAL PSG MEETING**

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

## **ARTICLE XV – SCIENTIFIC SYMPOSIA**

The PSG through its Symposia Committee shall help sponsor and organize scientific and educational programs such as the annual “Symposium on Etiology, Pathogenesis and Treatment of Parkinson’s Disease”.

## **ARTICLE XVI – DUES, FEES AND SURCHARGES**

The Executive Committee may propose annual dues for PSG members and fees or surcharges for participation in PSG trials in order to support PSG activities, including but not limited to the planning and implementation of PSG trials, 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 PSG members who respond.

## **ARTICLE XVII – AMENDMENTS**

Amendments to the Constitution and Bylaws may be proposed by any voting member, must be made in writing, must be signed by 6 other voting members, and must be submitted to the PSG Administrative Manager at least 2 months prior to a meeting of the PSG 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 via ballot to all voting PSG members. Affirmation by at least two-thirds of votes received within 1 month after the proposed amendment was circulated, 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 PSG meeting where the proposal may be enacted by an affirmative vote by at least three-quarters of votes cast by voting members at the meeting.

## **ARTICLE XVIII – DISSOLUTION OF THE PSG**

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