BYLAWS OF THE

PARKINSON STUDY GROUP

As proposed by the PSG Executive Committee

and adopted by the members of the

Parkinson Study Group on May 14, 2015

Address inquiries to:

PSG Executive Committee

c/o PSG Administrative Manager

roseanna.battista@chet.rochester.edu
ARTICLE I – NAME AND OBJECTIVES

This organization shall be known as the Parkinson Study Group (PSG), representing a nonprofit organization of scientific investigators from academic and research centers that 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, which was originally founded in 1986 as an independent, nonprofit consortium of scientific investigators who conduct research at the institutions with which the investigators are affiliated, is now organized as a nonprofit corporation under the laws of Massachusetts with the same purpose as the original organization. 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 is no administrative or overhead charges.
ARTICLE V – MEMBERSHIP

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, based upon a review of a self-report form completed by members before voting. 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

The PSG shall be governed 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 X,

4. Formulating and maintaining standards for the PSG regarding the conduct of trials, publication policies, and conflict-of-interest guidelines (Article XI),

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 XIII.

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

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 – STANDING PSG COMMITTEES**

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 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 XIV.

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 XI – CONFLICT-OF-INTEREST GUIDELINES

ETHICAL AND CONFLICT-OF-INTEREST GUIDELINES
FOR MEMBERS OF THE PARKINSON STUDY GROUP (PSG)

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 XII – 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 XIII – 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 XIV – AMENDMENTS

Amendments to the 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 XV – 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 XIV.

Upon termination or dissolution of the Parkinson Study Group, any assets lawfully available for distribution shall be distributed to one (1) or more qualifying organizations described in Section 501(c)(3) of the Internal Revenue Code of 1986 (or described in any corresponding provision of any successor statute). These organization(s) shall have a charitable purpose which, at least generally, includes a purpose similar to the terminating or dissolving corporation.

The organization to receive the assets of the Parkinson Study Group hereunder shall be selected by the discretion of a majority of the managing body of the Parkinson Study Group and if its members cannot so agree, then the recipient organization shall be selected pursuant to a verified petition in equity filed in a court of proper jurisdiction against the Parkinson Study Group by one (1) or more of its managing body which verified petition shall contain such statements as reasonably indicate the applicability of this section. The court upon a finding that this section is applicable shall select the qualifying organization or organizations to receive the assets to be distributed.