PARKINSON STUDY GROUP

POLICIES & PROCEDURES

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 Associate Executive Director
svsperling.psg@outlook.com

PSG TRIALS

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 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.

PARTICIPATION IN PSG TRIALS

For **clinical drug trials**, all PI's and sub–I's **MUST** be credentialed PSG members. If you are a provisionally approved PSG member you must provide the name of the PI at your institution that will be your "admin PI" while completing your first clinical trial with the PSG.

For **observational,** and **non-pharmacological cognitive or behavior clinical trials**, all primary investigators must be credentialed. The PI of the study will be charged with deciding if sub-I's must be credentialed as well. Their decision must be stated in the study protocol.

Those who are approved as **"study specific**" PI's for PSG trials may only work on the trial in which is specified in their credentialing application. Their status in the PSG database will be end-dated at the completion of the trial. Should these individuals wish to participate in additional PSG trials they must fully re-apply for credentialing with updated documentation.

If a PSG credentialed PI moves to a new institution which is not a current PSG site, they must inform the PSG Administrative Director and proceed with the application to credential their current site before submitting for participation in upcoming PSG trials.

Coordinators are not required to be credentialed. Their qualifications are taken into consideration during the credentialing of their institution or the primary investigator that they are working with.

COMMITTEES

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, or 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 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 to 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.

PSG PUBLICATION POLICIES

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.

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”.