ARTICLE XI – CONFLICT-OF-INTEREST GUIDELINES

ETHICAL AND CONFLICT-OF-INTEREST GUIDELINES
FOR MEMBERS OF THE PARKINSON STUDY GROUP (PSG)
(AS PROPOSED BY THE PSG EXECUTIVE COMMITTEE AND ADOPTED BY THE MEMBERS OF THE PARKINSON STUDY GROUP ON MAY 14, 2015)

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.

Updated 2/10/16
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.

Updated 2/10/16