



1351 Mt. Hope Avenue, Suite 223
Rochester, New York, 14620
(585) 275-1642

Procedures for Submission and Review of New Study Proposals

Background and Rationale:

The Parkinson Study Group (founded in 1986) is an international 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 other experimental therapeutic research for Parkinson's Disease (PD). The goal of the PSG is to advance knowledge about the cause, pathogenesis and clinical impact of PD, and to systematically examine promising therapeutic interventions.

The PSG was founded on the basis of collaborative academic research and the premise that our whole is greater than the sum of our individual investigators and their institutions. The benchmark principles of the PSG are:

1. free and unfettered access to data and publication
2. strict conflict-of-interest policies and full disclosure of actual and potential conflicts
3. democratic governance
4. open scientific meetings

The identification of new research initiatives, the creation of innovative and unique research projects and the nurturing of new investigators and coordinators are cornerstones of the PSG's collaborative efforts and are essential to our goal of advancing knowledge.

This document establishes the procedures for new study proposals to be evaluated, reviewed, and considered for approval as formal PSG projects, bearing the support of the PSG, its participating sites, staff and Coordination and Biostatistics Centers.

The PSG has limited funding available to support the development of new projects. In addition, PSG credentialed Coordination and Biostatistics Centers function as independent fiscal entities from the PSG, without designated funding to support the effort required for development of new initiatives. Hence, in addition to scientific content, investigators must consider the financial aspects of proposals. The Executive Committee of the PSG will work with interested PSG investigators and coordinators to advise regarding potential sources of support (grants/foundations/donations etc) to fund project development efforts, but it is ultimately the responsibility of the proposing investigator to secure funding to cover planning costs.

Principles Concerning the Review of new Research Proposals:

The PSG will make all reasonable efforts to support the submission of promising and scientifically rigorous research proposals from investigators. Efforts will be made by the PSG Executive and Scientific Review Committees to review and respond to proposals in a prompt and timely fashion and to avoid unnecessary delays; however, thorough scientific review should not be sacrificed purely for speed.

Presubmission Information and Requirements:

Prior to the submission of a new proposal, the proposing investigator should discuss the idea(s) broadly with other experts in the field, and should have vetted the concept with experts and other colleagues to ensure that the scientific rationale is sound and there is genuine uncertainty (equipoise) about the scientific question to be addressed.

The proposing investigators should review prior PSG studies to see if their question has already been addressed and explain why their project should go forward if it appears similar to another. A list of PSG research studies can be found on the PSG web site.

As part of the initial submission to the PSG, the proposing investigator should identify or generate preliminary data (or note the lack thereof).

If the proposing investigator will require the resources of consultants, additional personnel or a PSG-credentialed Coordination Center or Biostatistics Center during the development of the proposal, the investigator will need to identify funding to cover those costs. Such costs may include salary support for faculty and staff working on the project, supplies and other expenses directly related to project development. When available, limited PSG funds may be used for this, but support must be specifically requested, and in most cases will be subject to scientific review (at the level of the Executive Committee or Scientific Review Committee, as appropriate).

Format for Proposals and Process for Review:

All proposals should be submitted in the format specified below, and sent to Roseanna Battista, PSG Administrative Manager, at the University of Rochester Clinical Trials Coordination Center.

All proposals must include the planned timeline for the project, including timeline for submission of grant proposals, initiation of the project, and enrollment of first subject (if applicable). The proposing investigators must include a plan to share their data (measurements) with the PSG so these data can be merged with the central PSG database, and to provide the PSG with a copy of the analysis.

All proposals should be submitted at least thirty (30) days prior to a scheduled Scientific Review Committee meeting. Investigators may contact Roseanna Battista for a calendar of upcoming meetings, and for assistance with the application process, if needed.

Following receipt of a proposal, the Chair or Co-chair of the PSG EC will review the proposal to determine if it is sufficiently developed for review by the Scientific Review Committee. If not, s/he will contact the proposing investigator to discuss alternatives, including revising the proposal, working with the PSG Mentoring Committee, seeking additional co-investigators (e.g. a PSG working group) or withdrawing the proposal. If the proposal is suitable for review it will be given to the Chair of the Scientific Review Committee for assignment of primary and secondary reviewers.

At any time during the above reviews, either the SRC or the EC may request that the proposing investigator provide clarifications or additional information. In all cases where additional information is requested, an adequate opportunity will be given to provide this information in advance of the meeting (e.g. 10 days notice).

Response to Principal Investigator:

Following the SRC meeting, the PSG EC will communicate with the proposing investigator in writing, informing him or her of the decision with regard to the proposal. The written communication shall be sent within thirty (30) days of the SRC meeting where the proposal was discussed. The communication will include information regarding approval, denial, or other status of the project as determined by the PSG EC and SRC (and a short description of the reasons therefore). A copy of the communication will be provided to the Chair of the PSG EC and the PSG Administrative Manager for recordkeeping.

Format for Submissions:

In keeping with the PSG's academic interests, all proposals shall include the following information:

1. Cover letter stating intent and clearly stating if submission is a revision of a proposal previously submitted. If it is a resubmission, include a brief introductory section addressing the response to the reviewers' comments. Indicate actual changes in the revised application using some convention, such as bold, italic or highlighting text, unless the changes are so extensive that this is not practical. In the later case, please indicate this clearly in the introduction to the revised application.
2. Completed application face page (Attachment 1); unnumbered.
3. *Abbreviated* NIH format proposal (maximum=5 pages) to include the specific aims of the study, background, preliminary studies, research design and methods, plus references, and a protocol synopsis and schedule of activities, if applicable (Attachment 2); using Times Roman font, 12 point, 1" margins and pages numbered.
4. Where collaboration with a PSG credentialed Biostatistics Center is requested, the resources requested should be identified.
5. Where collaboration with a PSG credentialed Coordination Center is requested, the resources requested should be identified.
6. Individuals submitting proposals should identify the potential source of funding for the project.

7. Proposing investigators should attach a summary list of their proposed leadership for the study, including Steering Committee members, and Biostatistics and Coordination Center collaborators, if applicable.
8. Biosketches for the PI and co-PIs should be included with the application.
9. Checklist, should be last page of application (Attachment 3).

Additional Responsibilities upon Approval of Project:

Once a project has been approved as a PSG project, the proposing investigator will assume the role of principal investigator (PI). The protocol for the project will then need to be fully developed and the Steering Committee members will have to be approved by the PSG Executive Committee. Attachment 4 is an example of a protocol template. The PI and Steering Committee for this project will agree (in writing) to conduct the study in accordance with established PSG policies and procedures, including:

1. Conducting regular Steering Committee meetings and ensuring appropriate documentation of such meetings via meeting minutes;
2. Regularly reporting on the development/conduct of the study to the PSG Executive Committee;
3. Maintaining scientific and fiscal responsibility and oversight for the project;
4. Adherence to the PSG Publication Policy (Article XII, version dated 10/13/1990);
5. Data sharing plan to provide to provide any new data, and the analysis of the data, to the PSG.



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**Application Face Page for PSG Scientific Proposals and Studies
 Attachment 1**

1. Project Title	
2. Principal Investigator(s): (Name and Institution)	
3. Co-Investigator(s): (Name and Institution)	
4. Is this a resubmission? (yes/no)	
5. If PSG data-mining project, has this question been addressed in PSG populations before? (yes/no)	
6. If yes, explain how/why your proposal is different from what was previously done	
7. Note if abbreviated NIH application is attached (yes/no)	
8. Note if protocol synopsis is attached (yes/no)	
9. If grant application is anticipated, please list name of granting organization or entity	
10. List proposed grant submission due date	
11. Is collaboration with a PSG credentialed Biostatistics Center requested? (Required if a clinical trial) If yes, please indicate resources needed.	
12. If yes to question #11 above, are funds available to support a Biostatistics Center's efforts (including during grant application process)?	

Application Face Page (Continued)

13. Is collaboration with a PSG credentialed Coordination Center requested? (Required if a clinical trial) If yes, please indicate resources needed (i.e. data requested for access).	
14. If yes to question #13 above, are funds available to support a Coordination Center's efforts (including during grant application process)?	
15. Estimated project budget	
16. Source of Funding. Note if funding is requested or received	
17. Identify any participating "for profit" company/partnership	
18. Identify any participating "not for profit" company/ partnership, including lead institution for project	
Include any additional background or other information that may help in the review process.	
For studies not intended as observational: An abbreviated NIH format proposal (max=5 pages) to include the specific aims of the study, background, preliminary studies, research design and methods, plus references, and a protocol synopsis and schedule of activities, is required.	

[ACRONYM] PROTOCOL SYNOPSIS (SAMPLE)
(Prepared by the [SG NAME] with the support of [SPONSOR])
Attachment 2

Protocol Number	Provide the protocol number identifier.
Protocol Title	Provide the title from the protocol.
Acronym/Title	Provide the acronym and title upon which the acronym is based
Clinical Phase	Specify Phase I, Phase II, Phase III, or Phase IV.
Investigators	Specify Parkinson Study Group (PSG), Huntington Study Group (HSG), or other Investigator(s).
Study Centers	Specify the number of study sites.
Study Period	Specify the length of the study.
Study Objective	Provide a brief description of the study objective from the protocol.
Study Population	Provide a brief description of the study population.
Study Design	Provide a brief summation of the design of the study using information regarding number of sites, blinding, dosage escalation, length of study, treatment course, patient groups, etc.
Number of Subjects	Provide number of subjects required for the study.
Main Eligibility/ Exclusion Criteria	Specify the subject diagnosis and all Main Inclusion/ Exclusion Criteria
Route and Dosage Form	Specify the route (oral, IV, etc.) and dosage form (tablets, caplets, placebo, etc.).
Dosage	Specify dosage (i.e., 150 mg QD).
Duration of Treatment	Specify the length of treatment course.
Primary Outcome Measure(s)	Provide a brief description of any Primary Outcome(s) to be studied.
Secondary Outcome Measure	Provide a brief description of any Secondary Outcome(s) to be studied.
Sample Size Considerations	Briefly describe any Sample Size issues or considerations.

SCHEDULE OF ACTIVITIES (SAMPLE)
Attachment 2 (continued)

	Screening	Baseline	Maintenance Phase				Post-Drug Evaluation
	Visit SC Week-2 (-14d)	Visit BL Week 0 (Day 0)	Visit 1 (10d±3d)	Visit 2 (10d±3d)	Visit 3 (10d±3d)	Visit 4 (10d±3d)	Visit 5 (10d±3d)
Written Informed Consent							
Subject Entry Number							
Eligibility Criteria							
Med/Neuro History							
Physical Exam							
Hoehn & Yahr Scale							
UPDRS II-IV							
CGI							
MMSE							
Beck Depression Inventory							
Vital Signs							
ECG-12 LEAD							
Standard Clinical Labs*							
Pregnancy Test							
Adverse Experience Information							
Concomitant Drug Therapy							
Instruct and Supply Home Diary Card							
Review Home Diary Card							
Dispense Study Drug							
Check Drug Compliance							

*Specific analyses may be listed here at the bottom of the page.

CHECKLIST

Attachment 3

Type of Application:

- NEW application
- RESUBMISSION of application submitted (date previously submitted)_____

Does your submission include the following?

- Cover letter
- Face Page (Attachment 1)
- Narrative not extending 5 pages (not including references) and including: specific aims of the study, background, preliminary studies, research design and methods, plus references, and a protocol synopsis and schedule of activities, if applicable (Attachment 2);
- Budget
- Budget justification
- Biosketches for PI and co-PIs on project

Please answer the following questions:

1. Do you assure unrestricted access to the study database (if applicable)?
2. Do you assure unrestricted right to publish all results?
3. Is a study steering committee in place, with appropriate expertise? If not, is there an adequate plan for identifying a steering committee? (if applicable)
4. Is there appropriate provision for study coordination?
5. Is there appropriate data management and biostatistical support?
6. Are there human subjects concerns in your proposal?
7. Does your proposal pose any conflict-of-interest or potential conflict-of-interest? If so, please state:
8. Will you agree to provide to the PSG any new data obtained and a copy of your analysis?

THIS SHOULD BE YOUR LAST PAGE, NUMBERED

EXAMPLE OF PROTOCOL TEMPLATE
Attachment 4

This document is separate and posted on the PSG website in the PSG Toolkit. This document is 37 pages. Please refer to that for further information.