



PSG RATIONALE, REVIEW CRITERIA, SCORING SYSTEM AND PROCEDURE FOR RATING AND SELECTION OF RESEARCH PROPOSALS

Background:

The Parkinson Study Group (PSG) represents 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.

As part of this mission the Scientific Review Committee (SRC) reviews all research proposals coming to the PSG. This includes proposals requesting funding from the PSG when funding is available, proposals seeking access to existing datasets, videos, cerebrospinal fluid, blood, urine, or DNA, and proposals for new PSG studies. It is expected that at least one member of the investigative team be a PSG member.

Following receipt of a proposal, the Chair or Co-chair of the PSG Executive Committee (EC) will review the proposal to determine if it is sufficiently developed for review by the SRC. 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 SRC for assignment of primary and secondary reviewers.

All proposals are then sent to the SRC members for their review. The Committee Chair and Co-chair assign a minimum of two reviewers for each proposal. The reviewers will prepare written critiques modeled on NIH methods (see below for details). During the telephone conference or email meeting, the reviewers will present their reviews and scores and there will be opportunity for discussion by the entire committee. All Committee members will then score the proposal. The Committee will also consider whether the proposal may be appropriate for consultation with the Mentoring Committee or one of the six established PSG working groups.

In the case of proposals that duplicate or significantly overlap with work that is ongoing, the SRC may table the review and suggest that the proposers explore possibilities for collaboration with the ongoing project. If collaboration is not possible, the SRC will determine whether a second project is appropriate to the research question. In the case of significant overlap with completed projects, the SRC will determine whether a second investigation is appropriate.

For those proposals seeking PSG funding, the reviewer will assign two priority scores, one for funding and one for approval as a PSG study. This will allow meritorious applications to move forward even if they do not receive PSG funds, provided that applicants can identify funds from another source. Proposals requesting funding support from the PSG will be scored numerically, based on the NIH system. Proposals not requesting funds, but seeking approval as a PSG study, will receive a categorical score: (i) approved, no revision needed; (ii) approved pending minor revisions (answerable in a letter of response), (iii) not approved, major revisions needed (proposal should be revised and resubmitted), (iv) not recommended as a PSG study. Written comments and suggestions will be provided to the applicants.

Approved PSG studies, whether supported by PSG funds or not, will incur certain obligations:

- (1) Investigators must report the outcome of requests for funds from non-PSG sources. If funding has not been secured within one year, the investigator must request continuing approval to seek funds in the form of a brief memo. If the application has changed in response to peer review, these changes should be described in the same memo.
- (2) Investigators must submit manuscripts for review by the publications committee, and acknowledge the PSG in the manuscript.
- (3) Studies using PSG data will return an analytic data set to the PSG after study completion. This data set will become part of the PSG data repository and will be available for future hypothesis testing. Specific data sharing agreements will be established as appropriate for each project. The data sharing plan must be in place before work on the project begins.
- (4) For studies requiring approval by a human subjects committee, evidence of approval must be provided to the PSG before work on the project begins.

Scoring System and Procedure:

The PSG scoring system uses the new NIH 9 point scoring system. Priority scores reflect the strengths and weaknesses of a proposal, with the lowest scores indicating the highest level of merit. Reviewers should use the full range of the rating scale using whole numbers. Effort should be made to spread the scores to better discriminate among applications.

Applications will receive impact/priority scores from all eligible reviewers (e.g., without conflicts of interest). Individual reviewer scores will be averaged and the result multiplied by 10 to determine the final impact/priority score (range of 10 to 90).

Impact	Score	Descriptor	Additional Guidance on Strengths and Weaknesses
High Impact	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Moderate Impact	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low Impact	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses
Non-numeric score options: NR = Not Recommended for Further Consideration; DF = Deferred, AB = Abstention; CF = Conflict, NP = Not Present, ND = Not Discussed			

Reviewers should consider not only the relative number of strengths and weaknesses noted, but also the importance of these strengths and weaknesses to the criteria or to the overall impact when determining a score. For example, a major strength may outweigh many minor and correctable weaknesses.

Core Review Criteria:

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on Parkinson's disease, in consideration of the following five core review criteria, and additional review criteria (as applicable).

Significance:

Does the project address an important problem or a critical barrier to progress in Parkinson's disease? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s):

Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation:

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to Parkinson's disease or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach:

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment:

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria:

Have other necessary considerations been addressed? (Yes/No responses ok; Indicate N/A, Not Applicable, when question does not apply):

- 1. Do the investigators assure unrestricted access to the study database?**
- 2. Do the investigators 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?**
- 4. Is there appropriate provision for study coordination?**
- 5. Is there appropriate data management and biostatistical support?**
- 6. Are there unresolved human subjects concerns?**
- 7. Does this proposal pose any conflict-of-interest or potential conflict-of interest?
If so, please state:**
- 8. Do the investigators agree to provide to the PSG any new data obtained and a copy of their analysis?**

Additional Review Considerations:

Budget and Period Support

The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget. Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Resubmission Applications

When reviewing a Resubmission, the committee will evaluate the proposal as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project. The PSG will allow up to 2 resubmissions and will consider more than 2 only under exceptional circumstances.

Summary:

All proposals will be reviewed by the PSG SRC, which will respond to proposals within thirty (30) days of their scheduled meeting. Upon completion of the SRC review, the Chair of the SRC will forward comments to the Chair of the EC, who will prepare the reviews for further distribution to the EC and proposing investigator.

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.

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 SRC (and reasons therefore). A copy of the communication will be provided to the Chair of the PSG EC and the PSG Administrative Manager for recordkeeping.