

Parents of Galactosemic Children Research Grants Program Policies and Procedures 2010



Parents of Galactosemic Children, Inc.
P.O. Box 2401
Mandeville, LA 70470-2401

Email: research@galactosemia.org **Website:** http://www.galactosemia.org/grant_detail.asp

PGC Research Priorities

Parents of Galactosemic Children, Inc (PGC) funds a broad range of research to lead to improvements in the lives of people with galactosemia. This grants program provides support to practitioners conducting medical and scientific research involving the metabolic disorder Galactosemia. Research funded by this grant program shall include, but not be limited to, research about galactosemia involving nutrition, diet, speech, physical and occupational therapy, premature ovarian failure, and other research.

Eligible Projects

Projects eligible for the grants program can be designed as a research study, a clinical project, an educational project, or a collaborative meeting.

1. Research Project:

A research project is one that asks a research question that is answered through rigorous systematic methods. These projects may include but are not limited to research that investigates measurable outcomes in galactosemia care, epidemiology of galactosemia, and aspects of galactosemia care.

2. Clinical Project:

Clinical projects seek to improve galactosemia care through the development of tools that may augment the delivery of care. Examples of this may include but are not limited to development of clinical pathways and creating measurement tools (e.g., quality of life).

3. Educational Project:

Education is an essential aspect for the galactosemia community. Projects that provide relevant educational programs, develop educational materials, or develop innovative educational tools for patients and the community are examples of these types of projects.

4. Collaborative Meetings:

PGC recognizes the need for collaboration among professionals and therefore also encourages studies that demonstrate this important quality. The grants program will accept applications to fund collaborative meetings among professionals, which may lead to future research projects.

Funding

Funding varies from year to year based on fundraising efforts.

Review Process – Awarding of Grants

The timeline and procedure for acceptance, review for grants:

Proposal Announcement: Friday, July 23, 2010

Proposals due: By Thursday, September 30, 2010

Reviewed both by peer/outside review panel (if available) and PGC's Research Committee: ***By Friday, November 5, 2010***

Final Decision by PGC Board upon review and based on recommendation by PGC's Research Committee: ***By Friday, November 26, 2010***

Applicants will be notified by the PGC Board of the results of their proposal's evaluation by Friday, December 10, 2010

The PGC Research Committee has \$75,000 of funding available for this round of grants. Applicants may request any amount less than or equal to \$75,000. Because the PGC Research Committee is trying to provide startup funding for promising proposals, it will likely award multiple grants and it is suggested that proposals target one third or one-half of this amount, depending upon the scope of the research, clinical, or educational project. Research projects are expected to be completed within the time frame selected for the research as stated on the application.

Administration

- The Research Committee of PGC is responsible for the administration of the grant program. The Research Committee shall submit to the PGC Board a complete analysis of all applications and include its recommendation for rewards for the grant monies. All final decisions on the award of grant monies, however, shall rest with the PGC Board.
- Grantees are employees not of PGC but of their grantee institution and are subject to the policies and regulations of the grantee institution.
- PGC is a nonprofit organization and all grants are offered based on funds available within a specific year. Grant money may not be available each year, and amounts of grant money available may vary based upon funds available.

Review Process

Applications that are incomplete or are not filed according to the procedures herein specified shall be returned.

All grant and fellowship applications are subjected to a rigorous research committee review process. Applicants are critiqued on scientific merit and relevance to PGC research priorities.

Peer/Outside Review Panel

A variety of professionals (as many as possible) will be asked to serve in a pool of potential outside reviewers to be called upon, as needed, for as long as the professionals are willing to serve, and/or as long as research funds are available. For any given research proposal, reviewers will be selected by the Research Committee based on individual expertise for a specific research proposal. A minimum of two, but not more than three, professional reviewers will be asked to review any given proposal.

Outside reviewers will be required to agree to a “*PGC Guidelines for Reviewers*” that will address conflict of interest and confidentiality issues. Professionals who violate these guidelines will be permanently removed from the list of outside reviewers.

In order to further minimize conflict of interest issues, professionals who wish to submit a proposal in a given year will not be used as an outside reviewer during that same year. The research committee will temporarily remove applicants from the pool of potential reviewers.

In the event that there are an insufficient number of volunteers to fully constitute the Peer/Outside Review Panel, the members of the Research Committee will perform the portion of the review process intended for the Panel.

Review Process Activities:

Proposals will be sent to outside reviewers who will evaluate the proposals based on a scoring rubric developed by the Research Committee (see Attachment 1: *EXPERT REVIEW OF PGC RESEARCH PROPOSAL*). The scores from the outside reviewers will then be averaged and incorporated by the Research Committee as one component of their own evaluation of a research proposal as described on the internal scoring rubric. (See Attachment 2: *RESEARCH COMMITTEE REVIEW OF PGC RESEARCH PROPOSAL*). The Research Committee will then make recommendations to the PGC Board of Directors, which will make the final decision for funding approval.

Applications are reviewed and scored in the following areas:

Significance:

1. Does this study address an important problem facing the galactosemia community?
2. If the aims of the application are achieved, how will scientific knowledge of galactosemia be advanced?
3. What will be the effect of this study on the concepts or methods that drive this field?

Approach:

1. Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project?
2. Does the applicant acknowledge potential problem areas and consider alternative approaches?

Innovation:

1. Does the project employ novel concepts, approaches or methods?
2. Are the aims original and innovative?
3. Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator:

1. Is the principal investigator appropriately trained and well suited to carry out this work?
2. Is the work proposed appropriate to the experience of the Principal Investigator (PI) or fellow and other researchers?

Scientific or Institutional Environment:

1. Does the scientific or Institutional environment in which the work will be done contribute to the probability of success?
2. Do the proposed experiments take advantage of the scientific environment or employ useful collaborative arrangements?
3. Is there evidence of institutional support?

Change in Status

The grantee is responsible for contacting the Research Committee as soon as possible in case of any changes in status of the grantee institution, budget, or in the status of pending grants.

The grantee is expected to remain at their institution for the duration of the project. In the event that the grantee does leave the institution, he or she should notify the Research Committee immediately. The transfer of the project to another institution or investigator is in the sole discretion of PGC. Any budget increases after a grant or fellowship is awarded must be requested in writing. All reasons for the budget change must be explained in detail. PGC retains the sole discretion to reject or accept budget changes.

Additional Funding

Applicants must submit information on all current and pending funding sources that are related to their research application. It is permissible for an applicant's project to receive additional funding from another source. In the event of a change in the status of a pending application, all grantees are required to notify the PGC Research Committee (see above).

Termination of Support

PGC reserves the right to terminate support of a funded project at any time for any reason in its sole discretion.

Publications

Grantees are required to place an acknowledgment of PGC grant support on any publication resulting from PGC sponsored research. Publications resulting from research funded by PGC must accompany progress reports.

PGC reserves the rights to publish, reproduce, and distribute non-confidential material generated from all projects. All work including, but not limited to, videos, written reports, and other materials deriving from a fully funded project shall remain the property of PGC.

Availability of Research Results and Resources

Restricted availability of research results or resources upon which further studies are dependent can impede advancement of research and delivery of medical care.

Therefore, all results and resources developed while funded by a PGC grant must be made available for research as well as treatment purposes to qualified individuals within the medical, clinical and scientific medical community.

Human Subjects or Use of Animals in Research

The applicant's institution has the primary responsibility for protecting the rights and welfare of human subjects in any research activity supported by PGC.

PGC requires and expects that all researchers or institutions awarded funds from PGC comply with NIH requirements for animal and/or human testing. Noncompliance to these rules will result in the termination of support of a funded project.

Inventions and Patents

PGC understands that patents and licensing agreements may be sought on intellectual property resulting from research by the grant recipient supported in whole or in part by funds furnished by PGC. Accordingly, it adopts the following policy:

Intellectual property resulting from the support in whole or in part to the grant recipient of funds awarded by PGC shall be reported promptly in writing to PGC's Research Committee.

With respect to any such intellectual property, the institution or investigator shall have the right to file a patent application at the institution or researcher's own expense. In case the institution or investigator decides against filing a patent application PGC shall be notified in writing within 45 days. PGC shall then have the right to file a patent application on PGC's behalf.

PGC shall have free and unlimited use of any intellectual property that is developed from PGC funded research.

Scientific Misconduct and Fraud

The grantee institution is responsible for having and instituting a written policy or guidelines on conflict of interest and scientific misconduct and fraud. This policy must be supplied to PGC. It is the responsibility of the institution and the grantee to inform PGC of any institutional investigation involving the conduct of a researcher funded by PGC. In addition it is the responsibility of the institution and grantee to keep PGC informed of the progress and outcome of the investigation. Findings of fraud or misconduct are sufficient grounds to terminate support of the funded project.

Assurance of Compliance

PGC complies with all relevant state and federal equal opportunity and discrimination laws and regulations. All institutions awarded funds from PGC must comply with relevant state and federal equal opportunity and discrimination laws and regulations.

Inquiries

For applications, policies and procedures, and programmatic information, please contact the PGC Research Committee:

Christy Johnson
PGC Research Committee Chairperson
421 Gambit Circle
Wake Forest, NC 27587
Attention: Research Grants Program

Phone: Christy Johnson, PGC Research Committee Chairperson: (919) 562-4864 or (919) 357-7345

email: research@galactosemia.org

Application Forms

Applications are not sent to institutions for general distribution. Applications can either be downloaded from the PGC website www.galactosemia.org/pdf/PGC_Research_Proposal_Application.pdf or requested in writing from the PGC Research Committee at Research@galactosemia.org.

Application Procedure

One original **and** one electronic version of the application must be submitted. The *original signed* application along with all supporting documents should be sent by mail to:

Dan Lambert
PGC Research Committee Chairperson
1936 Cottonwood Drive
Aiken, SC 29803
Attention: Application for Research Grant

Ideally, the electronic version will be submitted by e-mail. Alternately, it may be submitted on a CD/DVD by postal service or other mail delivery service. The electronic version must be in *pdf* or *doc* format.

Send e-mail version to: research@galactosemia.org

Please note: The **original paper copy** of the application **must be postmarked** by the application deadline. The **electronic version** of the application **must be submitted** by the application deadline. (In cases where the electronic version is submitted by CD/DVD, please email research@galactosemia.org to alert PGC to expect a proposal). Applications not submitted/postmarked by the application deadline will be returned. **There will be no exceptions.**

It is the applicant's responsibility to verify that the PGC Research Committee received his/her application by the application deadline.

Application Format

Use standard size black type that can be photocopied. Font shall not be smaller than 10 point.

The application must be signed by the applicant, the department chair (or comparable), and the financial officer.

Application procedure

Applications must include the following items:

1.	Summary of proposed project not to exceed 500 words in layman terms
2.	CV of the Principal Investigator (not to exceed 5 pages)
3.	Proposed budget and justification for project (1-2 pages) Statement addressing willingness to accept partial funding in case PGC is unable to provide full funding
4.	Proposed timeline for project and a desired timeline for receipt of funds. (one page)
5.	Research proposal: (not to exceed 10 pages)(see details below) Specific aims Background information and significance Description of relevant preliminary work Study design and method Description of future studies that may come from this research Cited References
6.	Statement addressing institutional approval and signed by an appropriate administrator (Department Chair and Financial Officer), acknowledging appropriation of funding, including information related to indirect costs and instructions for disbursement of funds to institution

Research Proposal:

The research description should include sufficient information needed for evaluation of the project, independent of any other document. Be specific and informative, and avoid redundancies.

1. Specific aims for the project. Include a statement of your hypotheses.
2. Background and significance. Describe the background leading to the present application, evaluate existing knowledge, and identify gaps the project is intended to fill.
3. Preliminary studies by applicant, if any. (If none, state "none".) Relevant manuscripts and published papers by the applicant may be submitted but are not necessary. Two relevant publications is the maximum number that can be submitted with the application. All publications must be photocopied and shall not be stapled together.
4. Experimental design and methods. Describe the research design and the procedures to be used to accomplish the specific aims of the project. Indicate how the data will be collected, analyzed, and interpreted. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.
5. Future Studies: At least one-half page describing where future studies may be directed if all of the specific aims listed in section A are accomplished shall be included.
6. References must be cited.

Authorized Expenses

The following expenses are permitted under the institutional overhead when PGC deems them justified by the research. All expenses must be justified. Use additional pages if necessary.

1. Salary and fringe benefits for the grantee, not to exceed the percent effort on the project multiplied by the investigator's salary.
2. Equipment and supply expenses necessary to fulfill the project's specific aims.
3. Travel expenses:
 - a. Directly related to the implementation of the research;
 - b. Expressly and solely for the purpose of reporting the results of PGC-supported research at suitable scientific or medical meetings;
 - c. Limited to \$1,500 maximum per year.

4. Costs associated with publication of the research.
5. Costs associated with making the products of the research (i.e., cell lines, DNA, protein, and other biological substances) available to others for research.
6. Certain patient care costs. Funds requested for hospitalization and/or professional medical services for study subjects may be granted if justification is presented in the application to show that these charges are needed for the research proposed. It must be shown that the usual sources available for these costs are not adequate. All third-party payments received by the grantee institution for these services are to be offset from the funds awarded in the grant for this purpose.

Unauthorized Expenses

The following expenses are not permitted under PGC's research program:

1. Salaries, travel, and/or housing related to sabbatical leaves.
2. Purchase or rental of office equipment (i.e., typewriters, word processors, furniture, filing cabinets, and copy machines).
3. Expenses normally covered by the indirect cost of the grantee's institution.
4. Fees for tuition.
5. Membership dues, subscriptions, books, or journals.

Reporting

The PGC Research Committee requires semi-annual progress reports, financial reports and a final research report as directed below. The reports shall be sent to the Research Committee Chair at the email and/or mailing address supplied above.

Notification

After final approval by the PGC Board of Directors, all applicants will be notified of their status. All grantees are required to send a letter of acceptance, enter into an acceptable agreement outlining obligations and understandings, and submit semi-annual progress reports and financial reports from their institution stating the grant has been received and expended.

Financial Reports

Grantees must submit financial reports from their institution stating the grant has been received and describing the status of expenditure.

Final Research Report

A **final written report** consisting of a summary in lay language of the research accomplished must be provided within **90 days** of conclusion of the research project. This final report is in addition to any interim progress reports submitted.

Publications and Presentations

PGC must be acknowledged in any publications, including abstracts, which result from the funded research. A list of the resulting publications, and a copy of each publication must be provided when complete. In addition, PGC may ask the grantee to present the research at a PGC meeting, and summarize it for the PGC newsletter.

EXPERT REVIEW OF PGC RESEARCH PROPOSAL

PROPOSAL NAME: _____

APPLICANT: _____

PROPOSAL COMPONENT	POINTS EARNED	COMMENTS (Strengths & Weaknesses)
<p>A. Introduction to Proposal (Score between 1 & 10----10 best)</p> <ul style="list-style-type: none"> • Does the proposal provide adequate background information • Are the goals/purpose clearly stated • Is there an attached literature search • Is preliminary work described 		
<p>B. Does the proposal expand the knowledge of galactosemia within the stated areas of concern (Score between 1 & 20----20 best)</p> <ul style="list-style-type: none"> • Does this study address an important problem facing the galactosemia community • How innovative is this proposal? 		
<p>C. Design and Methods (Score between 1 & 25----25 best)</p> <ul style="list-style-type: none"> • Does the project have clear, realistic goals and objectives • Is the target population clearly defined • Are the proposed activities well thought out and able to meet the objectives • If applicable, is the recruitment strategy, potential risk and method for maintaining patient confidentiality described • Is there an appropriate plan for data analysis • If applicable, are the survey tools or questionnaires provided 		

PGC RESEARCH PROPOSAL REVIEW

<p>D. Institutional support/staffing (Score between 1 & 10----10 best)</p> <ul style="list-style-type: none"> • Does the PI have adequate background and/or an adequate mentor to complete the project • Is there adequate staffing • Is there institutional support 		
<p>E. Anticipated Problems (Score between 1 & 5----5 best)</p> <ul style="list-style-type: none"> • Does the applicant anticipate problems and strategies consider alternative tactics 		
<p>F. Budget (Score between 1 & 10----10 best)</p> <ul style="list-style-type: none"> • Is the budget realistic • Do the line items meet the criteria established by PGC 		
<p>G. Is there a plan described to share information learned/produced by this project (Score between 1 & 10----10 best)</p>		
<p>H. Timeline (Score between 1 & 10----10 best)</p> <ul style="list-style-type: none"> • Is the timeline realistic • Does the timeline meet the criteria established by PGC 		

Total Possible points: 100

Total Points: _____

Reviewer: _____

Date: _____

RESEARCH COMMITTEE REVIEW OF PGC RESEARCH PROPOSAL

PROPOSAL NAME: _____

APPLICANT: _____

PROPOSAL COMPONENT	POINTS EARNED	COMMENTS (Strengths & Weaknesses)
<p>A. Is the Application Complete? Are all of necessary items included with the application? (As requested in checklist in Research Proposal Application Document)</p>	<p align="center">Yes or No</p> <p align="center">If no, review is complete, application is rejected</p>	
<p>B. Significance to PGC Community Will this study have an impact (short term or long term) on the PGC community and on those families living with galactosemia? Does the research provide a real benefit to those living with galactosemia? What is the cost/benefit? Total Possible points: 50</p>		
<p>C. Results of outside review process: (Concerning: research design and methods, qualifications of the investigator, facilities, innovation, etc.) Total Possible points: 100</p>		
<p>D. Sharing Information with PGC Is there a plan described to share with the PGC community information learned/produced by this project? Total Possible points: 50</p>		

Possible Points: 200

Total Points: _____

Reviewer: _____

Date: _____