

Galactosemia Foundation Research Grants Program Policies and Procedures



Galactosemia
Foundation
Linked for Life.

Galactosemia Foundation
P.O. Box 1512
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Email: research@galactosemia.org **Website:** <http://www.galactosemia.org/research-grant-program/>

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Galactosemia Foundation Research Priorities

Galactosemia Foundation, Inc. (GF) funds a broad range of research to lead to improvements in the lives of people with galactosemia. This grant 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 grant 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 novel treatments for galactosemia.

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. Note: copies of any educational/outreach materials developed under a Galactosemia Foundation-funded grant shall be given to the research committee upon completion of project for the purpose of advancing education in our community.

4. Collaborative Meetings:

The Galactosemia Foundation recognizes the need for collaboration among professionals and therefore also encourages studies that demonstrate this important quality. The grant 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:** *Biennial announcement via the Galactosemia Foundation Website and emails to known researchers, clinicians, and related list-serves*
- **Proposals due:** *Biennially on January 31 in odd numbered years*
- **Reviewed** by peer/outside review panel (if available) and Galactosemia Foundation Research Team and Research Team recommendations sent to Galactosemia Foundation Board within 60 days of proposal due date
- **Final Decision** by mutual decision of the Galactosemia Foundation Board and Research Team within 30 days of the Research Team's recommendation.
- **Applicants will be notified by the Galactosemia Foundation Research Team of the results of their proposal's evaluation.**

The Galactosemia Foundation Research Team will publicize a maximum amount of funding to be made available during each round of grants. Applicants may request any amount less than or equal to that maximum. Because the Galactosemia Foundation has an interest in providing startup funding for promising proposals, it will likely award multiple grants. It is suggested that proposals target one third or one-half of the publicized 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 proposed on the application, but not to exceed 12 months, unless a no-cost extension is approved in advance by the research team.

Administration

- The Galactosemia Foundation Research Team is responsible for the administration of the grant program. The Research Team shall submit to the Galactosemia Foundation Board a complete analysis (summary, budget and links to all information) of all applications and include its recommendation for rewards for the grant monies.
- The Galactosemia Foundation Board and Research Team will openly communicate via e-mail, throughout the grant process. Proper and timely responses will be a priority to expedite decisions.

- The Galactosemia Foundation Board will approve or disapprove the Research Team's recommendations. If the Research Team's recommendations are disapproved, further collaboration between the Board and Research Team via conference calls will be required to obtain mutual agreement.
- Letters of rejection or approval will be sent by the Galactosemia Foundation Research Team after mutual agreement on the proposed funding has been reached between the Board and the Research Team.
- Grantees are not employees of the Galactosemia Foundation but of their grantee institution and are subject to the policies and regulations of the grantee institution.
- The Galactosemia Foundation is a nonprofit organization and all grants are offered based on funds available within a specific two-year grant cycle. The 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 Team review process. Applicants are critiqued on scientific merit and relevance to the Galactosemia community.

Expert Peer/Outside Review Panel

A variety of professionals (as many as possible) will be asked to serve in a pool of potential outside peer 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 Team based to the extent possible on individual expertise for a specific research proposal. A minimum of two, but not more than three, external peer reviewers will be asked to review any given proposal.

Peer reviewers will be required to agree to a "Galactosemia Foundation *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 Team 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 Team 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 Team (see Attachment 1: *EXPERT PEER REVIEW OF GF RESEARCH PROPOSAL*). The scores from the outside reviewers will then be averaged and incorporated by the Research Team as one component of their own evaluation of a research proposal as described on the internal scoring rubric. (See Attachment 2: *RESEARCH TEAM REVIEW OF GF RESEARCH PROPOSAL*). The Research Team will then make recommendations to the Galactosemia Foundation Board of Directors, who will approve or disapprove those recommendations. If recommendations are NOT approved, the Board and the Research Team will communicate via conference calls until a mutual agreement is found.

Applications are reviewed and scored in the following areas:

EXPERT PEER REVIEW

Introduction

- Is there adequate background information?
- Are the goals/purpose clearly stated?
- Is there an attached literature search?
- Is preliminary work described?

Significance

- Does the proposal address an important problem facing the galactosemia community?
- Does the project employ novel concepts, approaches or methods?
- Are the aims original and innovative?

Design and Methods

- Does the project have clear, realistic goals and objectives?
- Is the target population clearly defined?
- Are proposed activities well thought-out and able to meet the objectives?
- If applicable, are the recruitment strategy, potential risk and method for maintaining patient confidentiality described?
- Is there an appropriate plan for data analysis?
- If applicable, are survey tools or questionnaires provided?

Institution

- Does the PI have adequate background and/or mentor to complete the project?
- Is there adequate staffing?
- Is there institutional support?
- Do the proposed experiments take advantage of the scientific environment and/or employ useful collaborative arrangements?

Anticipated Problems

- Does the applicant anticipate problems and strategies consider alternative tactics?

Budget

- Is the budget realistic?
- Do the line items meet the criteria established by the Galactosemia Foundation?

Information sharing

- Is there a plan to share information learned/produced by this project?

Timeline

- Is the timeline realistic?
- Does the timeline meet the criteria established by the Galactosemia Foundation?

RESEARCH TEAM REVIEW

Completeness of the Application:

- Are all of necessary items listed in the Application Format checklist (below) included with the application? (If not, review is stopped and application is rejected).

Significance to the Galactosemia Community:

- Will this study have an impact (short term or long term) on the Galactosemia 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?

Information Sharing:

- Does the proposal describe how information learned/produced by this project will be shared with the Galactosemia Foundation and community?

Change in Status

The grantee is responsible for contacting the Galactosemia Foundation Research Team 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 Team immediately. The transfer of the project to another institution or investigator is in the sole discretion of the Galactosemia Foundation. 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. The Galactosemia Foundation 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 Galactosemia Foundation Research Team (see above).

Termination of Support

The Galactosemia Foundation 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 Galactosemia Foundation grant support on any publication resulting from Galactosemia Foundation sponsored research. Publications resulting from research funded by the Galactosemia Foundation must accompany progress reports.

The Galactosemia Foundation 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 solely Galactosemia Foundation funded project shall remain the property of the Galactosemia Foundation. The Galactosemia Foundation will be provided one electronic transcript of any publication that may be shared with Galactosemia Foundation members upon request, in keeping with copyright laws and limitations.

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 Galactosemia Foundation 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 the Galactosemia Foundation.

The Galactosemia Foundation requires and expects that all researchers or institutions awarded funds from the Galactosemia Foundation 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

The Galactosemia Foundation 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 the Galactosemia Foundation. 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 the Galactosemia Foundation shall be reported promptly in writing to the Galactosemia Foundation's Research Team (a nondisclosure agreement between the Galactosemia Foundation and the grant recipient is required to protect the grant recipient's intellectual property).

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, the Galactosemia Foundation shall be notified in writing within 45 days (disclosures to the Foundation will be held in confidence – the Galactosemia Foundation Research Team members must sign a nondisclosure agreement as part of their participation in these types of reviews). The Galactosemia Foundation shall then have the right to file a patent application on the Galactosemia Foundation's behalf.

The Galactosemia Foundation shall have free and unlimited use of any intellectual property that is developed from Galactosemia Foundation 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 the Galactosemia Foundation. It is the responsibility of the institution and the

grantee to inform the Galactosemia Foundation of any institutional investigation involving the conduct of a researcher funded by the Galactosemia Foundation. In addition, it is the responsibility of the institution and grantee to keep the Galactosemia Foundation 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

The Galactosemia Foundation complies with all relevant state and federal equal opportunity and discrimination laws and regulations. All institutions awarded funds from the Galactosemia Foundation 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 Galactosemia Foundation Research Team:

email: research@galactosemia.org

Application Forms

Applications are not sent to institutions for general distribution. Applications can either be downloaded from the Galactosemia Foundation website <http://www.galactosemia.org/s/GF-Research-Grant-Application.pdf> or requested in writing from the Galactosemia Foundation Research Team at research@galactosemia.org

Application Procedure

One electronic version of the application must be submitted. The electronic version must be in *pdf* format or a Microsoft Word document.

Send electronic version to: research@galactosemia.org

Please note: The **electronic version** of the application **must be submitted** by midnight US Eastern Standard Time on the application deadline. Applications not submitted by the application deadline will be returned. **There will be no exceptions.**

It is the applicant's responsibility to verify that the Galactosemia Foundation Research Team received his/her application by the application deadline.

Application Format

Applications must be submitted in English. 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.

Applications must include the following items:

1.	Summary of proposed project in layman terms (not to exceed 500 words)
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 GF is unable to provide full funding
4.	Proposed timeline for project, not to exceed 12 months, and a desired timeline for receipt of funds (1 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.	Information Sharing plan (presenting outcomes to GF community) Minimum: Mid-term and Final summary in lay terms (suitable for use in GF newsletter and on GF website) Additional: Description of further outreach/education approaches (e.g., publication, conference presentation, web outreach, etc.)
7.	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 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 scanned and submitted electronically.
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 1 are accomplished shall be included.
6. References must be cited.

Authorized Expenses

The following expenses are permitted under the institutional overhead when the Galactosemia Foundation deems them justified by the research. Many institutions charge a lower overhead rate when working on grants funded by nonprofit organizations. The use of the lower overhead rate is requested. All expenses must be justified. Use additional pages if necessary.

- Salary and fringe benefits for the grantee, not to exceed the percent effort on the project multiplied by the investigator's salary.
- Equipment and supply expenses necessary to fulfill the project's specific aims.
- Travel expenses¹:
 - Directly related to the implementation of the research;

¹ Funding to cover researchers' travel expenses to attend the Galactosemia Foundation biannual meeting should not be included in the grant application, but may be available from the Galactosemia Foundation General Fund.

- Expressly and solely for the purpose of reporting the results of Galactosemia Foundation-supported research at suitable scientific or medical meetings;
 - Limited to \$1,500 maximum per year, except for collaborative meetings where travel might be a significant portion of the expenses.
- Costs associated with publication of the research.
 - Costs associated with making the products of the research (i.e., cell lines, DNA, protein, and other biological substances) available to others for research.
 - 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 the Galactosemia Foundation's research program:

- Salaries, travel, and/or housing related to sabbatical leaves.
- Purchase or rental of office equipment.
- Expenses normally covered by the indirect cost of the grantee's institution.
- Fees for tuition.
- Membership dues, subscriptions, books, or journals.

Notification and Acceptance

After final approval by the Galactosemia Foundation Board of Directors, all applicants will be notified of their status. All grantees are required to send a letter of acceptance and enter into a mutually acceptable agreement outlining obligations and understandings for the duration of the grant period.

Reporting

Grantees must submit semi-annual progress reports and financial reports from their institution and a final research report to the Galactosemia Foundation Research Team

at the email address supplied above.

Financial Report

Financial reports should outline the extent to which the grant has been expended and describe any unanticipated delay or acceleration in expenditures.

Midterm Progress Report

Within 6 months of receiving Galactosemia Foundation research funds, the grantee shall submit to the Galactosemia Foundation Research Team via email a midterm written report which summarizes the progress achieved on the project. The report should include, but is not limited to, a brief description of goals met, any delays or acceleration in activity, and work yet to be completed. The narrative shall be written in lay language suitable for use in the Galactosemia Foundation newsletter and/or on the Galactosemia Foundation website.

Final Report

Within 90 days of the completion of the grant project, the grantee shall submit to the Galactosemia Foundation Research Team via email a final written report which summarizes the outcomes of the project. The report should include, but is not limited to, presentation and interpretation of results, description of any likely impacts on the Galactosemia community, implications for future research or activities, and any limitations of the grant project and results. This final report shall be submitted in addition to the midterm and any other interim progress reports. The narrative shall be written in lay language suitable for use in the Galactosemia Foundation newsletter and/or on the Galactosemia Foundation website.

Publications and Presentations

The Galactosemia Foundation 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, the Galactosemia Foundation may invite the grantee to present the research at a Galactosemia Foundation meeting.

Attachment 1: *EXPERT PEER REVIEW OF GF 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. Significance (Score between 1 & 20---20 best)</p> <ul style="list-style-type: none"> • Does this study address an important problem facing the galactosemia community? • Does the project employ novel concepts, approaches or methods? • Are the aims original and innovative? 		
<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 survey tools or questionnaires provided? 		

EXPERT PEER REVIEW OF GF RESEARCH PROPOSAL

<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? • Do the proposed experiments take advantage of the scientific environment or employ useful collaborative arrangements? 		
<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 GF? 		
<p>G. Information sharing (Score between 1 & 10---10 best)</p> <ul style="list-style-type: none"> • Is there a plan to share information learned/produced by this project? 		
<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 GF? 		

Total Points (out of 100 possible): _____

Reviewer: _____

Date: _____

Attachment 2: RESEARCH TEAM REVIEW OF GF RESEARCH PROPOSAL

PROPOSAL NAME: _____

APPLICANT: _____

PROPOSAL COMPONENT	POINTS EARNED	COMMENTS (Strengths & Weaknesses)
<p>A. Is the Application Complete? (score YES/NO) Are all of necessary items included with the application? (As presented in GF Research Grants Program Policies and Procedures document)</p>	<p>If NO, review is halted, application is rejected</p>	
<p>B. Significance to GF Community (Score between 1 & 50----50 best)</p> <ul style="list-style-type: none"> • Will this study have an impact (short term or long term) on the GF 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? 		
<p>C. Sharing Information with GF (Score between 1 & 50----50 best)</p> <ul style="list-style-type: none"> • Does the proposal describe how project progress and outcomes will be shared with the GF community? • Is there a plan to share information with other clinicians/researchers/other stakeholders? 		
<p>SUBTOTAL (Total possible points = 100)</p>		
<p>D. Averaged score of Expert Peer Review(s) (Total Possible points = 100)</p>		

Total Points: (Maximum possible = 200) _____

Reviewer: _____

Date: _____