



Galactosemia Foundation Research Grants Program Policies and Procedures

Stage 2

The Galactosemia Foundation
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Email: research@galactosemia.org **Website:** <http://www.galactosemia.org/research-grant-program/>
Revision 2024

Galactosemia Foundation Research Priorities

The Galactosemia Foundation provides funding for scientific and medical research related to the identification, treatment, and therapies primarily related to classical galactosemia. The goal of this research initiative is to improve the lives of people with galactosemia. All proposals will be given equal consideration in the review process, however, for this 2024-2026 round of funding, the foundation is especially interested in receiving projects related to premature ovarian insufficiency/failure (POI/POF), motor/neurological deficits (i.e.: tremors, seizures, etc.), cognition, bone health, advancements in diet related issues (i.e.: quality of life, diet liberalization and enzyme activity). See the RFA for further details of areas of interest.

Stage 2 of the review process is **by invitation only based on outcomes from Stage 1** of the application process. Please see procedures for Stage 1 if you are submitting a proposal for consideration. Only proposals promoted into Stage 2 will be considered for the Stage 2 process. If you do not submit an application for Stage 1, you will not be considered for Stage 2.

Please note, by submitting an application into Stage 2 you are agreeing to the policies and procedures provided. You will be required to sign a financial agreement should you be awarded the grant.

For this grant round, indirect costs or institutional overhead will not be allowed. Only direct costs will be allowed for this award. All monies awarded should be for direct costs.

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 Team 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.

The foundation will accept projects that answer an outstanding question or address an unmet need of our community. We are particularly interested in advancing the identification and treatment of complications related to classic galactosemia and the variability of outcomes which may include but, not limited to treatments or cures as well as advancing our knowledge of the sequela of classic galactosemia through the

lifespan.

Funding

Funding varies from year to year based on fundraising efforts and available funds.

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. Please see the RFA for more details. Stage 1 applications are due September 30 in the even-numbered year (*i.e.*: 2024)
- **Stage 2 Proposals due: Biennially on January 13 in odd numbered years (i.e.: 2025)**
- **Review Process** Stage 2 applications will be reviewed by the Research Team and external expert peer reviewers. All peer reviewers will be required to agree to a non-disclosure agreement and further be evaluated for conflict of interests. Additionally, professionals who submit a proposal during this funding cycle will not be used as a reviewer for other proposals during this same cycle. The external expert reviewers will review each proposal individually using the criteria listed below in addition to a standard 9-point scoring scale typically used. The peer reviewer will not take funding priorities into consideration. PIs will receive feedback from the peer reviewers. Research Team recommendations are presented to Galactosemia Foundation Board.
- **Final Decision** by mutual decision of the Galactosemia Foundation Board and Research Team within 45 days of the Research Team's recommendation. Award of grants is at the discretion of the Galactosemia Foundation.
- **Applicants will be notified by the Galactosemia Foundation Research Team of the results of their proposal's evaluation.**

The Galactosemia Foundation Research Grant is made possible by available funding which is reliant on fundraising efforts of our community and generous donations. The Research Team may publicize a maximum amount of funding to be made available during each round of grants however, we reserve the right to not disclose total available funding. Because the Galactosemia Foundation has an interest in providing startup funding for promising proposals, its goal is to award multiple grants as funding is made available. Historically, proposals have been with \$10,000 to \$50,000 in total approved costs 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. No-cost extensions may be approved if written requests are given in advance to the research team. Proposals intended to go beyond 1 year will not be considered.

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, peer reviews, 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, and/or video conference 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 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 declined.

All grant applications are subjected to a rigorous Research Team review process. Applicants are critiqued on scientific merit and relevance to the Galactosemia Foundation priorities.

Stage 2 Expert Peer Review Panel

Stage 2 applications will be reviewed by the Research Team and external expert peer reviewers. All peer reviewers will be required to agree to a non-disclosure agreement and further be evaluated for conflict of interests. Additionally, professionals who submit a proposal during this funding cycle will not be used as a reviewer for other proposals during this same cycle. The external expert reviewers will review each proposal individually using the criteria listed below and will not take funding priorities into consideration.

Stage 2 Peer Review Criteria:

Introduction

Does the proposal provide adequate background information? Are the goals/purpose of the research clearly stated? Is there an attached literature review? Is any related preliminary work clearly described?

Significance

Does the study 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 the proposed activities well thought out and able to meet the

objectives? If applicable, is the recruitment strategy, potential risk, and methods for maintaining patient confidentiality described? Is there an appropriate plan for data analysis? If applicable, are survey tools or questionnaires provided?

Institutional Support and Staffing

Does the Principal Investigator (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?

Anticipated Problems

Does the applicant anticipate problems and provide strategies to consider alternative tactics?

Budget

Is the budget realistic? Do the line items meet the criteria established by funding guidelines?

Information sharing

Is there a plan to share information obtained by this project?

Timeline

Is the timeline realistic? 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.

Applications are not sent to institutions for general distribution. The application format is found within this document under "Application Procedure for Stage 2". The complete Stage 2 document and application format can be either be downloaded from the Galactosemia Foundation website or requested in writing from the Galactosemia Foundation Research Team at research@galactosemia.org

Application Procedure for Stage 2

One electronic version of the application must be submitted. The electronic version must be a PDF 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 Time on the application deadline. Applications not submitted by the application deadline will not be considered. There will be no exceptions. It is the applicant's responsibility to verify that the Galactosemia Foundation Research Team received their application by the application deadline. **There will be no exceptions.**

Deadline for Stage 2 applications for this grant round is January 13, 2025, Midnight US ET.

Stage 2 Application Instructions

Applications must be submitted in English. Use standard size type that can be photocopied. Font shall not

be smaller than 11-point.

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

Applications must include the following items:

1.	Proposal Title (must match Stage 1 title)
2.	Names and complete contact information for Principal Investigator, Co-Investigators, Department Chair (or comparable), and the Grants/Contracts Officer.
3.	Lay Abstract: Summary of proposed project in layman terms (not to exceed 500 words)
4.	Technical Abstract: Summary of proposed project in technical terms (not to exceed 500 words)
5.	CV of the Principal Investigator and Co-Investigators (not to exceed 5 pages each, NIH bio sketch format preferred) All current and pending funding sources that are related to this research application must be included and marked as related to this application.
6.	Proposed detailed budget and justification for project (1-2 pages) Statement addressing willingness to accept partial funding in case GF is unable to provide full funding
7.	Proposed timeline for project, not to exceed 12 months, and a desired timeline for receipt of funds (1 page)
8.	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 (reference do not count toward the page limit)
9.	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.)
10.	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 Section: (maximum 10 pages not including references)

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. Each of the following sections must be included.

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. Describe how the proposed research addresses a problem facing the galactosemia community and the potential impact of this research to the community.
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. Publication reprints do not count toward the page limit.
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.
6. References must be cited and do not could toward the page limit

Additional Funding

Applicants must submit information on all current and pending funding sources that are related to their research application. This information must be included in the 5-page CV and marked as related to this 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 below).

Budget: Authorized Expenses

For this round, institutional overhead will not be allowed. All monies awarded will be direct costs. The following expenses may be considered when the Galactosemia Foundation deems them justified by the research. 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
 - Expressly and solely for the purpose of reporting the results of Galactosemia Foundation-supported

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.

- 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. Fringe benefits for the grantee beyond the percent on the project multiplied by the investigator's salary.
- Purchase or rental of office equipment including laptops or desktops.
- Equipment and supply expenses in excess of what is deemed necessary to fulfill the project's specific aims.
- Expenses normally covered by the indirect cost/institutional overhead of the grantee's institution.
- Fees for tuition.
- Membership dues, subscriptions, books, or journals.
- 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.

Grant Policies

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. All grantees will be required to sign a financial agreement and agree to the policies and procedures.

Reporting

Grantees must submit a semi-annual/midterm progress report and financial reports from their institution as well as a final research report to the Galactosemia Foundation Research Team at the email address supplied above.

Financial Report

Financial reports must outline the extent to which the grant funding 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. Publications resulting from research funded by the Galactosemia Foundation must accompany 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.

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. Publications resulting from research funded by the Galactosemia Foundation must accompany progress reports. 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. Participation in the Galactosemia Foundation Biennial Conference is required.

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.

Information Sharing

The Galactosemia Foundation encourages the grantees to participate in the biennial conference held in July of the even year. For example, July 2026. This is typically a presentation to our Galactosemia community to share the findings of the investigator's funded project. Details would be made available closer to the conference date. The President of the Galactosemia Foundation will contact recipients to discuss their participation in the biennial conference and related expenses. Grant money is not intended for the use of travel or lodging related to the Galactosemia Foundation Conference and money allocated for such expenses will be considered unauthorized expenses. 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. A description of further outreach/education approaches such as publications, conference presentations, web outreach opportunities, etc. should be outlined in the application. It is an objective of the research team to disseminate information to our community regarding funded projects.

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 PI is expected to remain at their institution for the duration of the project. If the PI does leave the institution, they 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.

Transaction of Funds

The transaction of funds is the responsibility of the Galactosemia Foundation Treasurer. The Research Team would like to be notified of any issues with the transaction of funds as this may impact or delay projects. The recipients of the Stage 2 grant will receive half of the awarded amount initially at the start of the project and receive the remaining half of the awarded amount after a mid-year report has been submitted to the team and approved. Financial agreements will be managed by the Galactosemia Foundation Treasurer. By submitting an application for this grant, you are accepting the terms and conditions of the financial agreement.

Termination of Support

The Galactosemia Foundation reserves the right to terminate support of a funded project at any time for any reason at its sole discretion. The Galactosemia Foundation reserves the right to terminate or suspend the agreement in the event the funded project does not meet the terms of the agreement. This may result in a delay or discontinuation of funds from the Galactosemia Foundation to the awardee. The funding will only be available for 1 year and projects are expected to be completed within the year. Additional funds will not be awarded. Extensions will only be considered on a case-by-case basis due to extraordinary circumstances if the awardee notifies the research team and Galactosemia Foundation Board in writing with a detailed explanation. If the grantee is not able to fulfill their obligation, complete the awarded project, ceases the awarded project or unable to conduct the research as awarded and initially agreed upon, the

grantee will be obligated to return any monies exchanged thus far within 60 days of termination.

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