

ECD GLOBAL ALLIANCE ERDHEIM-CHESTER DISEASE

Medical Research Grant Application Guidelines

Thank you for your interest in medical research grants from the ECD Global Alliance (ECDGA). These guidelines provide a brief introduction to the goals and policies of ECDGA, and list the specific information required when submitting a proposal.

I. Statement of Research Grant Policy and Procedures

The ECD Global Alliance awards grants to applicants who seek to conduct research to find the cause, treatment, or cure for Erdheim-Chester Disease (ECD).

II. Application Guidelines

The following general guidelines apply to ECDGA research grants:

- a. Principal investigators must hold post-doctoral positions or beyond.
- b. Proposed projects must have specific relevance to ECD, and show promise for contributing to the scientific advancement in this field of study.

III. Funding Guidelines and Limitations

- a. Projects will ordinarily be funded for one year. Where appropriate, funding requests for follow on study is encouraged.
- b. Grant awards will be provided in amounts up to \$50,000 per year. Projects requiring a higher budget can be submitted and may be considered if the plan justifies a higher budget is required to make significant gains in a specific area of research.
- c. A first payment will be made representing $\frac{1}{2}$ of the grant amount. A second payment representing $\frac{1}{4}$ of the grant amount will be made within 30 days after receipt and approval of the interim project report as specified in Section VI below. A final payment representing the final $\frac{1}{4}$ of the grant amount will be made following receipt of the final project report as specified in Section VI below.
- d. ECDGA reserves the right to withhold payment at any time pending resolution of any discrepancies in the use of funds, and/or if the specific aims are not met, all as set forth in the grant proposal and any revisions required thereto by ECD prior to acceptance and approval.
- e. Awards may not be contributed to a unified or pooled fund that will be used to award grants or support other projects.
- f. Grants are awarded on the basis of the content of the proposal, as well as the specified Principal Investigator (PI) and sponsoring institution. If the PI terminates his/her affiliation with the institution identified in the grant award, and wishes to continue the project at another qualified sponsoring institution, the principal investigator must notify ECDGA in writing. ECDGA reserves the right to require resubmission of the grant with the appropriate changes in staff and/or venue, and ECDGA reserves the right to reject such a change.
- g. If the PI wishes to discontinue the project prior to completion, he/she must notify ECDGA in writing within sixty days of termination of work on the project. The original institution identified in the grant award shall have the opportunity to identify another PI within sixty days of notification. ECDGA reserves the right to require resubmission of the grant with the appropriate changes in staff and ECDGA

reserves the right to reject such a change. If the original institution does not wish to continue the project, the remaining funds from the grant award as of the date of termination of work on the project must be returned to ECDGA.

h. The following will not be funded:

- Overhead or indirect costs in excess of 1.5% of the total grant amount
- Salaries or stipends for students
- General institutional expenses
- General fundraising campaign expenses such as dinners and mass mailings
- Religious, political, or other research that does not fall within ECDGA's areas of interest, as described above
- Journal subscriptions, advertisements, tuition fees, professional society dues, meals, receptions, or parking fees

IV. Processing of Grant Applications

Grant applications will be accepted as requested following the submission and review of Letters of Intent (LOI). The ECDGA Grant Application Review (GAR) Committee will review each proposal and present its recommendations to the Board of Directors, whose decisions on awards are final. The Board of Directors will consider proposals at the regularly scheduled meeting following the receipt of the GAR Committee's recommendation.

Notification of accepted and denied proposals will be made within two weeks of the Board of Directors meeting. For approved awards, the grant period will begin within four months thereafter, at the discretion of the Principal Investigator.

V. Detailed Application Instructions

Submission of an incomplete application will result in a delay in review or non-consideration. Due to administrative resources, only proposals written in the English language will be considered.

a. Format:

- Maximum length is ten one-sided pages, single-spaced, using a standard 12-point font (The 10-page limit applies to Sections IIA-IIG, including any supporting figures, tables, etc., as described below.)
- Number each page consecutively
- Include Principal Investigator's name on each page as a header
- Abbreviate only after complete wording has been provided
- Use standard black type that can be photocopied
- Black and white diagrams and drawings are recommended

b. Content:

The proposal should describe the rationale and potential importance of the project, and should include the specific aims and research design and methodology. Summarize previous relevant work with progress to date. Include sufficient detail in a concise manner to facilitate evaluation of the proposed work. Reviewers will consider brevity and clarity of the proposal to be indicative of a focused approach to a research objective and the ability to achieve the specific aims of the project.

The application should include the following items:

I. Principal Investigator Information Page

- A. **Name of organization:** Provide the name of the affiliated organization
- B. **Title of project:** Choose a title that is descriptive and specific, not general
- C. **Principal Investigator:** Provide name and relevant title(s)
- D. **Contact information:** Provide mailing address, telephone number, fax number, and e-mail address
- E. **Specific amount requested:** Indicate the total dollar amount in US Dollars requested from ECDGA for the one year project.

II. Project Description

- A. **Abstract:** Provide a project summary that addresses the following: What problem does the project address? Why is the work important to those affected by ECD? How will the project be accomplished? Signify up to eight key words in bold lettering.
- B. **Hypotheses & objectives:** List the project's primary, and any secondary, objective(s) and describe concisely the specific goals of the research, including any hypotheses to be tested. One page is recommended.
- C. **Background and significance:** Briefly outline the background of the proposed project. Include a critical evaluation of previous research and existing knowledge, and specifically identify the gaps that the project is intended to fill. State explicitly the importance of the proposed research. Two to three pages are recommended.
- D. **Preliminary studies:** For new applications, a report of the Principal Investigator's preliminary studies is recommended.
- E. **Research design and methods:** Describe the research design and methodology that will be used to accomplish the project's specific aims. Include the means by which data will be collected, analyzed, and interpreted. Describe facilities, laboratory space, and major equipment that are pertinent to the project. Describe any new methodology and its advantage over existing techniques. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the project's aims. Provide a tentative sequence or timetable for the project. Describe any procedures, materials, or situations that may be hazardous to personnel and the planned precautions to be exercised.

- F. **Human subjects:** Regulations require that all affiliated institutions establish and maintain appropriate policies and procedures for the protection of human subjects. If applicable, briefly describe the population of subjects involved in the project, key inclusion criteria, the process for informed consent, and the means by which protection will be ensured. Provide proof of current or pending project approval by an Institutional Review Board or similar oversight committee.
- G. **Animal studies:** All proposals must conform to regulations for the safe and humane treatment of animals. If applicable, briefly describe the animals to be studied, and measures to minimize pain and discomfort. Provide proof of current or pending project approval by the institution's Animal Use and Protection Committee or similar oversight group.
- H. **Budget:** Provide a detailed budget for the project. All amounts must be in U.S. dollars.
- I. **Budget justification:** In narrative form, provide justification for the following budget items: salary and benefits for the principal investigator and other project personnel; travel, printing/publications, consultant costs, patient care costs; and equipment and supplies.
- J. **Project personnel:** Provide the name, title, and role of any individual who will be involved in the project, including the Principal Investigator. Indicate the percent effort that each person is expected to devote to the project. Provide the curriculum vitae (CV) of all project personnel and any collaborator(s). The CVs are not included in the ten-page limit for the proposal, and the CV of the collaborator(s) may be abbreviated to include relevant work and publications.
- K. **Funding history:** If applicable, indicate the amount and granting organization for any other sources of funding for the proposed project. For the Principal Investigator, provide a list of current funding support as well as awards received in the past five years.
- L. **Letters of reference:** For Principal Investigators who are at the assistant professor level or below, provide two sealed, confidential letters of reference.
- M. **Institutional support:** Provide a letter of institutional endorsement of the project, signed by an appropriate official and the institution's business manager or fiscal officer. Provide contact information for each.

Applications approved for funding will be required to submit the following prior to initial payment:

1. Copy of *patients Informed Consent* approved by Institution.
 2. Copy of *Institutional Review Board (Ethics Committee) approval*.
- If this is a multi-site study, Informed consent document and IRB approval is required from each study site.

c. Submission

Submit the original of the completed application in a PDF file(s) on a CD (in PC, not in MAC, format) or by email to support@erdheim-chester.org. Please include all documents, including institutional letters, publications, etc. in PDF format if possible. Sealed letters should be sent in paper form in a sealed envelope. Physical materials should be mailed to:

ECD Global Alliance
Attn: Kathy Brewer
P.O. Box 775
DeRidder, LA 70634 USA

Please do not submit applications via fax. Applications sent via email should be followed by a separate email requesting confirmation that the material was received.

Application materials and further information on research can be obtained from the Global Alliance at the above address or via the website www.erdheim-chester.org or by contacting the organization at:

ECD Global Alliance
Phone: 1-337-515-6987
Email: support@erdheim-chester.org

d. Acknowledgement of Receipt

ECDGA will acknowledge receipt of proposals within fourteen days. Applications will be reviewed for completeness within thirty days of receipt, and then will be forwarded to the Grant Application Review (GAR) Committee. Applicants submitting incomplete proposals will be notified and applications will be held on file pending receipt of all required documents.

VI. Responsibility of Recipient

The recipient of any grant award from ECDGA must use the funds for the specific purpose for which they were originally intended in the grant application. ECDGA requires a project progress report along with a detailed accounting of all funds expended to be submitted at a 6 month interim period and within 60 days of the 12 month final period. At the discretion of ECDGA a more frequent reporting may be requested with thirty days notice. Any funds not used in the manner specified above must be returned to ECDGA, and any budget change that is greater than 10% of the total budget amount must be submitted in writing for approval by the ECDGA GAR Committee, such approval not to be unreasonably denied. Principal Investigators may apply for an extension of time to use remaining funds at the end of the grant period.

Finally, the grant recipient and institution are expected to agree in writing to the terms of the ECD Global Alliance Grant Agreement.

Erdheim-Chester Disease Global Alliance

Full Proposal Research Grant Application 2014

Principal Investigator Information Page

Face Sheet: Applicant Information:

Please type or print clearly

Name of Applicant

Email

Mailing Address

Telephone

City, State, Country

Fax

Institution Name

Proposal Information:

Please type or print clearly

Title of Proposal: _____

Amount Requested: _____

Will research involve human subjects? Yes [] No [] If yes, has Investigational Review Board approved the research? Yes [] No [] Approval Date: _____ Pending [] date expected: _____

Applicant Signature

Deadline: July 10, 2015. Send pdf files of this page and complete project description on CD in PC format (NOT MAC), to ECD Global Alliance, P.O. Box 775, DeRidder, LA 70634 USA, Attn: Kathy Brewer, or by email to support@erdheim-chester.org.

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Grant Agreement Form

1. In accepting a Grant from the ECD Global Alliance, Inc. (ECDGA), the Principal Investigator (“PI”) and the grantee institution (“Institution”) assume an obligation to expend grant funds for the research purposes set forth in the application, and to affirm that there is no duplicate funding for these purposes. The PI and Institution will promptly notify ECDGA of activation or funding of any application for support to which ECDGA support is alternative.
2. Grant Period: The initial date of the grant period is the earliest that funds may be obligated or expended. Termination date of the award will be the date indicated in the original notification letter or the date provided by an authorized extension. Termination date of the award is the latest that funds may be expended except to liquidate authorized obligations.
3. The Institution is obligated to administer the grant in accordance with the regulations and the policies governing the grant programs of ECDGA or, where not specified, consistent with the policies and practices of the Institution.
4. The fiscal officer of the Institution will provide an Expenditures Report co-signed by the PI within 60 days after termination of the award. The fiscal officer of the Institution will agree to make available to representatives of ECDGA, following due notice, accounting records of disbursements made from ECDGA’s grant funds. Any funds not used in the manner specified in the grant proposal must be returned to ECDGA. Any budget change that is greater than 10% of the total budget amount must be submitted in writing for approval by the ECDGA GAR Committee, such approval not to be unreasonably denied.
5. At the 6 month interim period of the award, the PI shall submit an interim Progress Report of his/her technical accomplishments and a financial report with a detailed accounting of all funds expended. More frequent reports may be required at the discretion of ECDGA with thirty days notice.
6. Within 60 days of the termination date of the award, the PI shall submit a final report of the research results, a financial report per item 4 above, and a list of articles published or accepted for publication..
7. A first payment representing $\frac{1}{2}$ the grant amount will be made on the initial date of the grant period. A second payment representing $\frac{1}{4}$ of the grant amount will be made within 30 days after receipt and approval of the interim project report and financial statement as specified in item 5 above. The final $\frac{1}{4}$ payment for each grant year will be made following receipt and approval of the final receipt and approval of all required reports as identified in item 6 above. This sum will revert to ECDGA in the event the reports are not received and approved within 60 days following the report due date.
8. Results of research will be made freely available to the public through appropriate scientific channels and all publications will bear the statement: "THIS WORK WAS SUPPORTED BY A GRANT FROM

THE ECD GLOBAL ALLIANCE". The PI and Institution will provide the ECDGA advance notice of any publicity regarding the award or the research.

9. If the research results are to be published, the PI shall provide ECDGA with advance written notice, no later than one week before publication, a PDF of the article and any press releases related thereto. ECDGA shall not disclose such information to the public until the article is published and embargo released, if required. ECDGA has discretion to permit shorter notice if circumstances warrant.
10. Permission for a change in PI or Institution must be authorized by ECDGA in advance or the grant will terminate on the date the PI leaves or ceases to work at the Institution at which the grant was awarded.
11. ECDGA endorses the principles of the Association of American Medical Colleges (AAMC) report, "The Maintenance of High Ethical Standards in the Conduct of Research."
12. ECDGA does not fund scientific research that involves the use of human fetal tissue. With respect to human and animal experimentation, the Executive Officer of the sponsoring institution and the principal investigator affirm: that the investigations which might involve human subjects have been endorsed by a committee on clinical investigation, or other clearly designated appropriate body, of the sponsoring institution; and that any research involving human subjects will conform ethically with the guidelines prescribed by the National Institutes of Health (NIH) including the provision of suitable explanation to human subjects or their guardians concerning the experimental design and all significant hazards, so that they may be in a position to provide appropriate informed consent prior to the investigations; and that research involving animals will conform with the current "Guide for the Care and Use of Laboratory Animals," NIH publication, DHHS/USPHS, and with federal laws and regulations, and has been approved by the Institutional Animal Care and Use Committee; and that wherever applicable, the research protocol will be reviewed and approved by the institution's biohazards committee, as well as conforming to NIH guidelines.
13. The nature of this arrangement is a funding agreement, and no employment or agency relationship is created.
14. The ECD Global Alliance is not responsible for any claim, judgment, award, damages, settlement, negligence or malpractice arising from the research or investigation related to this award. The institution acknowledges responsibility for the conduct of research or investigations related to this award, and releases the ECD Global Alliance from all claims or liability that may arise from the conduct of research or investigations related to this award resulting from any act or omission on the part of the institution, its employees, agents, or representatives.
15. ECDGA reserves the right to modify the terms or conditions of this contract with six months written notice to the Principal Investigator and the sponsoring institution.

SIGNATURES

Signature of Principal Investigator Print Name Date

Address

City, State, Zip Code Country

Telephone Number FAX Number

E-Mail Address

Award Period From, To Date:

Signature of Fiscal Officer preparing Expenditures Report Print Name Date

Title

Address

City, State, Zip Code Country

Telephone Number FAX Number

E-Mail Address for Fiscal Officer

Signature of Witness #1 Print Name Date

Signature of Witness #2 Print Name Date

Signature of Notary Public Print Name Date

Review Criteria for Grant Proposals

OVERALL IMPACT

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence in ECD knowledge, in consideration of the following seven scored review criteria.

SCORED CRITERIA

1. Significance

Does the project address an important problem or a critical barrier to understanding ECD, including the etiology, pathophysiology, diagnosis or treatment? 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?

2. Investigator

Is the PI well suited to the project? If an investigator is new to ECD research, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced the field? If the project is collaborative, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

3. 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 ECD research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

4. 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?

5. 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?

6. Collaboration

Will the study promote meaningful collaboration among scientists? Among institutions?

7. Appropriateness

Is it likely that this project will meet its intended objective? Is achieving the patient population target likely? Is the study design well thought out and adequate? Are the estimated time and budget reasonable given the scope of the research and its potential significance?

All of the criteria, weighted as appropriate for each application, will be considered when assigning the overall score. An application does not need to be strong in all categories to be judged likely to have a major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out work that, by its nature, is not innovative but is essential to move a field forward.

ECD-GA 2014 Scoring Values

The following guidance will be used by reviewers to determine individual review criterion and overall impact/priority scores:

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	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	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
<p>Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed</p>			
<p>Minor Weakness: An easily addressable weakness that does not substantially lessen impact Moderate Weakness: A weakness that lessens impact Major Weakness: A weakness that severely limits impact</p>			

ECD Global Alliance Interim Grant Report

NARRATIVE REPORT – To be completed by the Primary Investigator. Please include answers to these questions, preferably in 2-3 pages total. ****Terms may be abbreviated, provided that the complete term is used initially. (Interim Report)**

RESEARCHER'S NAME	
EMAIL ADDRESS	
INSTITUTION	
PROJECT TITLE	

1. WHAT WERE THE ORIGINAL OBJECTIVES OF THIS STUDY?
2. WHICH OBJECTIVES HAVE BEEN ACCOMPLISHED?
3. PLEASE SUMMARIZE THESE ACCOMPLISHMENTS.
4. WHICH OBJECTIVES HAVE NOT BEEN MET?
5. DESCRIBE ANY PROBLEMS IN MEETING THESE OBJECTIVES.
6. ANY BUDGETARY QUESTIONS?
7. FUTURE PLANS FOR THIS PROJECT.
8. PUBLICATIONS OR SCIENTIFIC PRESENTATIONS RESULTING FROM THIS PROJECT.
9. Individuals and organizations who have helped the ECD Global Alliance sponsor research projects may ask for updates on studies currently underway. PLEASE PROVIDE A STATEMENT WRITTEN FOR THE GENERAL PUBLIC SUMMARIZING THE HIGHLIGHTS OF THIS REPORT. *These comments should be suitable for publication on the ECD Global Alliance website or in the organization's newsletter.*