

Lampe-Kunkel

Memorial Award for Research on Natural Products Grant Program

Sponsored and administered by the American Academy of Clinical Toxicology (AACT)

Application Instructions

These instructions should be followed carefully. Only after all the requested information has been received, will an application be considered complete and eligible for evaluation by the AACT Grant Review Panel.

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**APPLICATIONS THAT DO NOT STRICTLY COMPLY WITH THE
APPLICATION INSTRUCTIONS WILL BE
RETURNED WITHOUT REVIEW**

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I. GRANT PROGRAM DESCRIPTION

To memorialize the contributions of Drs. Lampe and Kunkel in the field of clinical toxicology of natural products, the AACT is offering a research grant program that supports clinical toxicology research in natural products.

The goal of this grant program is to provide competitive funding for original research, utilizing standard experimental design to investigate some aspect of toxicity due to naturally occurring phenomenon (i.e., plants, mushrooms, algae, insects, snakes). The intended research should advance the mission of the AACT to unite “scientists and clinicians in the advancement of research, education, prevention and treatment of diseases caused by chemicals, drugs and toxins.” The project may be part of a larger project but must have a specific hypothesis, aims and obtainable results that are separate and distinct.

II. ELIGIBILITY

- The research must focus on clinical toxicology research.
- The principal investigator must be a member of the American Academy of Clinical Toxicology in good standing.
- Multidisciplinary research teams are encouraged.
- If applicable, the proposed research must be submitted to an institutional review board (IRB) or to an institutional animal care and use committee (IUCAC) for approval. Evidence of these approvals must be provided to the AACT upon acceptance of the grant award. Grant funds will not be disbursed until evidence of these approvals or evidence of exemption from IRB review has been received.
- The research must comply with the [NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research](#) that was amended in October, 2001.
- The research must comply with the [NIH Policy and Guidelines On the Inclusion of Children As Participants in Research Involving Human Subjects](#).
- The research must comply with the [NIH Guide for the Care and Use of Laboratory Animals](#).
- The study timeline should not exceed 24 months from project initiation.

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III. FUNDING INFORMATION

One grant, offered every other year, of up to \$3,000 is available to fund one study. An additional award of a maximum of \$750 will be provided for travel to the NACCT to present the results of the project. Grants are awarded to provide funding for specific projects that address clinical toxicology research and are not intended for long-term support of research programs. All of the awarded funds will be disbursed at study initiation.

Funds may not be applied to:

- Ongoing general operating expenses or existing deficits
- Salary support for study personnel
- Purchase of permanent equipment, facilities, or software, or other capital costs
- Endowment contributions
- Stipends or loans
- Facilities and administrative (institutional indirect) costs

Funding is generally available for:

- Consumable supplies and services
- Travel to the NACCT meeting to present the results of the proposed project
- Subject expenses/reimbursement
- Laboratory analysis, statistical analysis and similar activities

Grants will be awarded to individuals and the funds will be disbursed directly to the sponsoring institution for administration.

IV. GRANT RECIPIENT RESPONSIBILITIES

- The grant period will begin upon grant award by the AACT and will expire no later than 24 months after the initial disbursement.
- Following initial disbursement of funds, the grantees must submit semi-annual Research Reports to the AACT that address:

Progress toward completion of activities included on the study timeline for the quarter in question;

Any protocol modifications and documentation of IRB/IUCAC review and approval of such modifications; and

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A summary of all adverse events associated with execution of the study during the quarter in question and documentation of IRB/IUCAC review of such adverse events.

- Within 60 days of study completion, the grantees must submit a Final Research Report to the AACT. This report must include:

A summary of the study results including statistical analysis if applicable;

Preliminary conclusions;

A summary of all adverse events associated with execution of the study and documentation of IRB or IUCAC review of such adverse events;

A summary of all protocol modifications and documentation of IRB or IUCAC review and approval of such modifications; and

Specific plans for presentation and publication of the study findings.

- Along with the Final Research Report, the grantees must submit a Final Financial Report. This report must include a complete and full accounting of the expenditure of AACT funds related to the execution of the study.
- Any unused funds must be returned to the AACT by the grantees.
- If, for any reason, the grantee does not complete the project, the investigator must inform the AACT in writing within 30 days of study termination. Within 60 days of study termination, the grantees are required to complete the Final Research Report and Final Financial Report and return any unused funds to the AACT as described above.
- The grantees may request a grant extension. Only one extension will be granted for any study. The project must be completed and all other requirements of the grant fulfilled by the end of the extension period.
- The AACT requires that the findings of the funded study be submitted for presentation at a national or international scientific meeting. The North American Congress of Clinical Toxicology retains the right of first refusal for presentation of all findings that emanate from this AACT-sponsored research.
- The AACT encourages investigators to submit the findings of the study to a peer-reviewed journal for publication. *Clinical Toxicology* retains the right of first refusal for publication of all findings that emanate from this AACT-sponsored research.

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- A reprint of all articles that emanate from this study should be submitted to the AACT.
- All presentations, publications, and other communications regarding this study must include the following acknowledgement: "This study was funded (or partially funded) by a research grant from the American Academy of Clinical Toxicology." This must be stated in the body (i.e., in the author identification page) of all manuscripts submitted for publication.
- By accepting this award, the grantee will undertake all reasonable efforts to complete the study and take responsibility for fulfilling the terms described within the award letter.

V. APPLICATION PROCESS/SELECTION CRITERIA

Grant application reviewers will use the following criteria in evaluating applications:

Objectives - 20 points maximum

Do the study objectives appropriately address research related to the specific grant program focus and the mission and vision of the AACT? Are the objectives original and innovative?

Rationale - 10 points maximum

Does the proposal clearly explain why this study should be undertaken? Does it reflect an adequate review of the literature? Does the study challenge existing paradigms or propose new methods or techniques? If the study is not innovative but is essential to move the field forward, the applicant should mention and discuss this aspect in the proposal.

Significance - 10 points maximum

Does this study address an important problem? Will the outcome(s) of the study make a positive contribution to the clinical toxicology evidence base? Can the proposed study methods be replicated and generalized?

Study Methods - 40 points maximum

Does the proposal describe with sufficient clarity and detail the study methods to be used? Are the described methods logical and appropriate for the stated objectives? Do the procedures to be followed include, where applicable, information on sampling techniques, controls, data to be gathered, subjects and/or facilities to be used, and statistical and other analyses to be made? Are there plans for recruitment and retention of study subjects?

Scope and Timeline - 5 points maximum

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Is the proposed timeline realistic? Is it probable that the study can be completed in the proposed time period (maximum 2 years)? Can the study be completed according to the methods described? Is the study feasible?

Personnel and Facilities - 15 points maximum

Are the professional competencies and experiences of the investigators appropriate to execute the work required? Is there evidence of a commitment to collaboration between the research team? Are the facilities appropriate and adequate for the proposed project? Is there evidence of institutional support?

VI. INSTRUCTIONS FOR SUBMISSION

The application and any appended pages should be sent as an email attachment to the AACT office, either as a Word document (.doc) or as a PDF file. In addition, the signature page (Page 4) should be sent by FAX to the AACT office.

If additional space is needed for any item(s), append additional page(s) and reference with item numbers. Letters of support should be appended in this fashion. The application must be collated in the order in which the items appear in the grant application:

1. Completed application form (5 pages)
2. Any attached pages required to complete Items 1-8
3. Project plan (Item 9 (a) parts 1-10)

Biosketches for all investigators (Item 9 (b))

VII. ITEMIZED INSTRUCTIONS FOR GRANT APPLICATION

1. Self-explanatory.
2. Funds may be requested for a maximum period of two years.
3. Total amount requested may not exceed \$3,750 for a two-year period.
4. (a,b) The Principal Investigator must be an AACT member in good standing.
Consider this entry carefully, as no changes will be accepted once a grant has been awarded.
(c,d) Institution and the department or division in which the Principal Investigator is currently employed.
(e-i) Self-explanatory.

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5. All other professionals engaged in the study must be named here with their official title, institution, e-mail address and the number of hours per week they will devote to the project.
6. (a) The sponsoring institution is that location at which the research will be conducted. Grant checks will be made payable to the institution name listed.
(b) Self-explanatory. (c-f) Grant officer at sponsoring institution to whom checks will be mailed.
7. (a) All consumable supplies must be itemized as to description, number, cost per unit, and total cost. If exact costs are not known, estimates must be provided. Provide a detailed justification for each budget item. The budget justification should correspond directly to the project plan.
(b) Travel to present project findings at the NACCT meeting in the second year is acceptable up to \$750. In the travel budget justification, provide a detailed justification for each budget item. Estimated costs for meeting registration fees, airfare, lodging, meals, and ground transportation must be provided.
(d) All other expenses not already specified must be itemized and justified in relation to the project. Requests for permanent equipment, facility construction or renovation, or software are not eligible for funding. Provide a detailed justification for each budget item. The budget justification should correspond directly to the project plan. Facilities and administrative costs rates are not allowed. TOTAL budget should be the same as Item 3.
8. This "certification" must be signed by the Principal Investigator and the financial officer.
9. (a) Each of the ten headings must appear in the stipulated order. The abstract should summarize the proposal and is limited to one page. In developing the proposal, the applicant should provide sufficient detail in the methods section including a power analysis, if applicable, and plans for data management and analysis. A detailed description of the subject recruitment process, including the informed consent process, should be provided. The application must address the ability to recruit a sufficient number of subjects to successfully complete the study. Describe the qualifications of the each researcher according to the eligibility requirements described above. The narrative of the project plan may not exceed five (5) pages (using 11 point font or larger, 8.5 by 11 inch paper, 1 inch margins, single spacing and single sided pages); an additional page is allowed for the Abstract. Applicants should strictly comply with font size, paper size, spacing and page limit requirements. Letters of recommendation should be appended to the

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application. Applications that do not strictly comply with the application instructions will be returned without review.

(b) Curricula vitae (biosketches) should be limited to 4 pages and should be submitted in the format provided in the U.S. Department of Health and Human Services PHS 398 form.

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