The Society of Infectious Diseases Pharmacists

2017 Call for Grant Applications to Fund: SIDP/Nabriva Therapeutics

Community-Acquired Bacterial Pneumonia Award

INSTRUCTIONS FOR COMPLETING THE APPLICATION FOR A SIDP RESEARCH AWARD

The Society of Infectious Diseases Pharmacists (SIDP) is a dynamic association of health professionals dedicated to promoting the appropriate use of antimicrobials. SIDP is committed to excellence in infectious diseases education, pharmacotherapy, and research. One of the missions of SIDP is to promote research endeavors.

Purpose: Community-acquired bacterial pneumonia (CABP) is a common and serious infectious syndrome associated with millions of emergency room visits and hospitalizations each year. Nabriva in collaboration with SIDP is soliciting research proposals from SIDP members for research projects with a focus on CABP. Pharmacists practicing in infectious diseases (ID) and/or medical microbiology who are SIDP members are eligible for this award. The candidate must be a US citizen, or permanent resident of the US, and hold a PharmD degree. Applications should consist of research projects seeking to address an *unmet need in the area of the management of CABP in adults*. Preference will be given to projects focusing on the PK/PD, epidemiology, or health economics and outcomes research (HEOR) of CABP in adults. Measures of interest can be clinical, quality, economic or humanistic.

Funding: Funding limited to $30,000 for a one (1) year non-renewable grant is available.

Deadlines: Applications must be submitted **no later than 5 pm EST on Friday, June 30, 2017**.

Applicant Criteria: The Principal Investigator (PI) must be an Active or Associate Member of SIDP, and be employed by a non-profit institution. Furthermore, the Principal Investigator must NOT currently be receiving funding from NIH or other peer reviewed federal funding. SIDP members who have received a SIDP Research Award as PI in the past two years, and members of the SIDP Research Awards Committee, or Board of Directors are ineligible for these awards.

If a Research Awards Committee member chooses, to apply as PI, co-PI, mentor, or consultant; he/she will be excused from Committee participation for the remainder of that year. It is the responsibility of the Committee Member to notify the Committee Chair of their intent to participate in a SIDP Research Application, and they will be excused from further Committee activities and Committee-related communications. **Failure to comply with these requirements will result in rejection of the proposal.**

Format requirements: One inch margins on all four sides; the font cannot be less than 11 point; single spacing is allowed; and text format must be paragraph style from margin to margin (column format as used in journals is not allowed). Figures and tables, if needed, should be included in the body of the text. In support of their application, applicants can include no more than 2 **key** original papers that are relevant to their proposal and that they have authored, as appendices. Investigators must adhere to the noted page limitations. Brevity and clarity of proposal will be favorably considered. Grant applications must be completed using Public Health Service Form 398 (PHS 398) as required for NIH grant submissions. Use of the PHS 398 forms, which are available from the research offices of most institutions or at http://grants.nih.gov/grants/funding/phs398/phs398.html, is required. (Forms obtained from other sources should have PHS 398 (Rev. 3/2016) on the lower left corner). An abbreviated application based on the required forms specified in the table below is required for the **SIDP/Nabriva Therapeutics Award**:

PHS 398 Forms:	SIDP
Form Page 1: Face Page	Required
Form Page 2: Performance Sites and Key Personnel ONLY (you may omit the project summary)	Required
Form Page 3: Research Grant Table of Contents	Omit
Form Page 4: Detailed Budget for Initial Budget Period	Required
Budget Justification	Required
Biographical Sketch Format Page (up to 4 pages)	Required (Include "Research Support")
Resources Format Page	Required
Checklist Form Page	Omit
Continuation Page	As needed
Targeted/Planned Enrollment Format Page	Omit
Inclusion Enrollment Report Format Page	Omit
Mailing Address and RFA Labels	Omit
Other Support Format Page: Example	Omit
Personnel Report Format Page	Omit
Research Plan	Use continuation page

A link to instructions for completing PHS 398 forms is provided on the web site listed above. All applicants are advised to carefully read the instructions. Please note the new instructions for the Research Plan.

The IRB Process and Requirements for Human or Animal Research: All human subjects or animal research shall be submitted to an oversight committee for review and must be approved prior to awarding funds. The PI must include at a minimum, a letter or other documentation of IRB or IACUC submission before the deadline for submission of the award application. After notification of the award, the PI should provide documentation of IRB or IACUC approval when applicable. The SIDP will work with the PI to ensure timely initiation of the research. In some instances, approval to begin non-human subject or non-animal research related parts of a project may be considered along with an adjusted initial payment. Disbursement of funds related to any human subjects or animal research component will be withheld until documentation of IRB or IACUC **approval** is provided to SIDP.

SIDP Research Grant Applications must adhere to the following format:

I. Completed PHS 398 face page (Page 1)

II. Completed PHS 398 key personnel and study site location (Page 2 and 3). Please provide information on where the study will take place and list the key personnel and his or her role on the project. It is not necessary to list technical personnel in this section. For this abbreviated format, you may omit the project summary as this will be covered under your Research Plan.

III. Detailed budget for initial budget period (Page 4). **Specify the funding that is needed to complete the first six months of the research**. The SIDP award is limited to one year, thus all costs should be listed on this page. The following provisos should be noted when planning your budget:
   - Capital Equipment Requisition (e.g., infusion pumps, pipettes, statistical software, etc.): Funding for capital equipment should be provided by the investigators' employers. If this is not possible, SIDP will permit funding requests for these expenses provided the total amount is less than 20% of the total award and adequate justification is provided on Page 5 below.
   - Travel and Publication Expenses: cannot exceed 10% of the total award
   - Institutional Overhead: not permitted unless adequate justification, including a letter from Dean or Institutional Chairman indicating that these fees cannot be waived, and that total fees for both overhead and IRB (below) are less than 10% of the total award.

- Institutional Review Board (IRB) fees: not permitted unless adequate justification, including a letter from IRB Chairman, indicating these fees cannot be waived and that total fees for both overhead (above) and IRB are less than 10% of the total award.
- No support is provided for salary of the PI, Co-Investigator, or consultants. Salary may be included for technical personnel. Salary support for graduate students and fellows will be permitted if adequate justification is provided (e.g., graduate students or fellows are paid exclusively out of research grants).

IV. Budget for entire proposed project period (Page 5). Include subtotals and total direct budget from Page 4. The section titled "Additional years of support requested" should be left blank. You must complete the budget justification at the bottom and attach one continuation page if needed. The Awards Committee will review the justification statements carefully to ensure that requested funds are truly needed to complete the proposed project. Justification of the above provisos should be carefully considered. Use of one continuation page is suggested to ensure that the budget is adequately defended. The continuation page should include a header (same as PHS 398 forms), title (Budget for Entire Proposed Project Period) and subtitle (Justification – Page 2 of 2). The continuation page should be labeled as Page 6.

Please specify schedule of payments necessary to ensure that resources are available to efficiently complete the project.

Example:

First Payment 10/1/2017 (Request maximum 50%)

Second Payment 3/31/2018 (Request maximum 25%; 75% of total budget requested by this milestone))

- Specify benchmarks needed as prerequisites to requesting second payment
- Research Committee will review and recommend payment to BOD.

Final Payment 9/30/2018 (Final 25% of award)

- Provided upon receipt and acceptance of final report

V. Biographical Sketch (PHS 398 Form). Examples are provided with the forms. The first page should include name, position, and education/training at the top. Sections A and B should follow and be completed within the first page and one additional page. Section C (Research Support) should follow. Complete a biographical sketch for all personnel listed on page 2 and assemble in the order listed. The length of **each** biographical sketch should not exceed 4 pages. Limit the number of publications to 15. Sequentially number each page in the grant application.

VI. Resources Format Page. Provide information on facilities and equipment available to the research team. Any equipment required to complete the project should be listed here or included in the budget with justification. Limit to 1 page.

VII. Research Plan. (Sections A-C **NOT** to exceed 7 pages)

A. Title of Project
B. Specific Aims (Limit to 1 page)
C. Research Strategy
    1. **Significance**: explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses; explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields; describe how the field will change if the proposed aims are achieved.
    2. **Innovation**: explain how the application challenges and seeks to shift current research or clinical practice paradigms.
    3. **Approach**: describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project

4. Type of experimental design
5. Preliminary studies (if applicable)
6. Study population, sample selection, and sample size (if applicable)
7. Human Subjects or animal use committee: state whether human subjects or animal use committee will be involved. **See D below**.
8. Methods for data collection
9. Data analysis plan
10. Potential problems, alternative strategies, and benchmarks for success

D. Statement about IRB or IACUC submission including the name of the review Committee.
E. Literature cited (not included in page limit).
F. Project timetable for completion (not included in page limit). Provide specific dates by which each step of the project will be completed.
G. SIDP Proposal submission form

Review of Applications

Applications will be judged according to the scientific merit and feasibility of the research proposal; the strength and experience of the candidate; and the quality of the research environment. If none of the applications are deemed suitable for the Grant, then none will be awarded for the year of 2017.

Announcement of Winner

The recipient of the Grant will be announced at the SIDP Annual Meeting 2017. Recognition of the sponsor will also be given during the award proceedings. The results of the research project must be presented (poster/oral) at the SIDP Annual Meeting within 12 months of completion of the project. Travel expenses for the recipient's travel to the conference will be the responsibility of the recipient. The successful applicant will be notified by the end of September 2017.

Terms and Conditions

1. The term of the award is one (1) year, beginning October 1, 2017 and may not be deferred.
2. A written MID-YEAR report shall be submitted to the Chair of Research Awards Committee and the Board by April 30, 2018.
3. A written FINAL report shall be submitted to the BOTH Chair of Research Awards Committee and the SIDP President at the end of the one (1) year research project (as described below).

Submission of RFP

Proposals should be converted to a single PDF file adhering to the format described above. The PDF file should be electronically submitted to both Stephanie Bulak (sbulak@eami.com) and the Chair of the Research Committee, Vanthida Huang (vhuang@midwestern.edu). **Proposals must be submitted online no later than 5 PM EST on Friday, June 30, 2017.**

SUBMISSION OF MID-YEAR REPORT

Submission of a MID-YEAR report must coincide with either the six-month anniversary of the award (date as stated), six months following the IRB approval date, or six months from start-up funds

disbursement, **whichever is latest**. This mid-year report shall be submitted to **BOTH** the President of SIDP and the Chairperson of the Research Grants Committee. The following content should be covered in the mid-year progress report and submitted as a word document. Use additional pages as needed.

1. A summary of project accomplishments during the reporting period. These should relate to the project's goals, objectives, and time frame, and should not exceed four single-spaced typed pages.
2. A detailed explanation of any changes in focus or major changes in protocol. Provide justification for all changes.
3. A detailed explanation of specific problems encountered. Include a description of current efforts to resolve the problems.
4. An explanation of budget changes, both in the reporting period or anticipated changes in the next period.
5. A list and copies of all publications, including reprints, abstracts, manuscripts and presentations resulting from work accomplished during the reporting period.
6. Outline of work to be accomplished in the next reporting period.
7. Other relevant information.
8. The final report submitted could be shared with the external grant sponsor.

SUBMISSION OF FINAL WRITTEN REPORT

Submission of a FINAL report shall be submitted to BOTH the President of SIDP and the Chairperson of the Research Awards Committee. The following content should be covered in the report and submitted as a word document. Use additional pages as needed.

1. A summary of project accomplishments during the reporting period. These should relate to the project's goals, objectives, and time frame, and should not exceed four single-spaced typed pages.
2. A detailed explanation of any changes in focus or major changes in protocol. Provide justification for all changes.
3. A detailed explanation of specific problems encountered. Include a description of current efforts to resolve the problems.
4. A list and copies of all publications, including reprints, abstracts, manuscripts and presentations resulting from work accomplished during the reporting period.
5. Other relevant information.
6. The final report submitted could be shared with the external grant sponsor.

PRESENTATION AT ANNUAL SIDP MEETING

A poster presentation is required at the SIDP Annual Meetings following the research award grant date (2018 or 2019). A request to delay the presentation must be received by the Chair of the Research Awards Committee and the SIDP Board of Directors prior to the second annual SIDP meeting.

SIDP RESEARCH AWARD APPLICATION
INSTITUTIONAL/INVESTIGATOR APPROVAL FORM

In making this application, I hereby indicate that receipt of this award will not duplicate financial support available from other sources, and agree to perform the research project in accord with the attached proposal. I agree to file a mid-year/interim progress report which will coincide with either the six-month anniversary of the award (date as stated), six months following the IRB approval date, or six months from start-up funds disbursement, **whichever is latest**. This report will be filed with the President of SIDP and the Chairperson of the Research Awards Committee. My obligations to SIDP are to complete the research project, submit an interim report, and present the research findings at one of the two subsequent Annual SIDP meetings following the research award grant date. In the event that changes in personnel, research conditions, or facilities occur that may retard or prevent completion of the research project in the specified time, I agree to immediately notify the President of SIDP. If the project cannot be completed, I agree to return all unused funds to SIDP. I also agree to acknowledge support of the SIDP in any presentations and publications that arise from these efforts.

Disbursement of all grant funds (from SIDP) must be completed within 2 years of initial granting of the award. The final date for application of the remaining funds is the two-year anniversary from the date in which the grant was awarded. After that date, **unclaimed** grant funds from the award will be returned to SIDP general funds. Any money disbursed to the grantee within the period belongs to the institution representing the Principal Investigator, provided that obligations to SIDP are fulfilled. SIDP does not expect return of unused funds except as stated above, and any remaining funds are available to the grantee for any purpose allowed by the Institution.

SIDP is a not-for-profit professional organization. The SIDP Research Awards stipulate that a maximum of 10% of the total award may be allocated to indirect costs + IRB fees for the funding request. The funding request may **NOT** include salary support for principal investigators, co-investigators, or consultants.

Study Investigators

Key Personnel	Printed Name	Signature	Date
Principal Investigator			
Co-Investigator(s)			

Institutional Representatives

	Printed Name	Signature	Date
Department Chair/Supervisor*			
Institutional Official*			

*Write in position/title. Institutional official must be authorized by the institution to sign proposals and contracts (e.g. Director of Sponsored Programs).