

ANNOUNCEMENT OF PROPOSAL DEVELOPMENT GRANTS

GRANTS FOR RESEARCH BY INTER-DISCIPLINARY PARTNERSHIPS (GRIP) FROM THE CENTER FOR HEALTH RESEARCH

Limited Competition RFA: Microbiome and Cancer in AHS-2: A Pilot Study

Purpose:

The anticipated pilot project seeks to achieve measurement and analysis of the gastrointestinal tract microbiome among participants of the Adventist Health Study-2. Feasibility of sample collection and response rates will be evaluated among a few hundred participants. Correlations between dietary patterns and the relative abundance of microbial species and strains will be examined. It is expected that a funded pilot project will produce publishable results and provide preliminary data to support NIH grant applications for microbiome research in the larger AHS-2 cohort.

Description:

- Total award: \$15,000
- Term of award: up to 18 months (typically 12 months for the Pilot project, and 6 months for grant proposal preparation)
- Number of award(s) in this cycle: One
- Deadline for submission: October 31, 2014 @ 12:00 noon
- Anticipated date of award announcement: December 1, 2014

PI/co-I Eligibility:

- The project must include at least two LLU-SPH faculty members (in PI/co-PI/co-I roles) from at least two different disciplines within the LLU SPH.
- Meets the PI/co-PI's eligibility requirements for the extramural grant proposal that will be submitted during the GRIP award.

Criteria for Evaluation:

Awards will be based on scientific merit, including significance, innovation, originality of approach and technical merit in the context federal grant proposals (i.e. NIH, CDC, and EPA). The quality of inter-disciplinary collaboration, the PI leadership plan, and adequacy of the budget and justification will also be considered.

Since the purpose of the GRIP award is to gather preliminary data for an extramural proposal, preliminary data is not needed for the GRIP application. In the absence of preliminary data, strong literature support and a conceptual framework for the study aims is required. The focus will be on funding high impact, paradigm shifting, innovative projects. Consequently, the application must clearly describe the potential impact of the project on the field and highlight its innovative elements. Proposals will be reviewed by a review panel selected by the SPH Research Affairs committee. Materials submitted as part of an application will be kept confidential.

Application Format: The application is paperless submission. Use the NIH R03 grant format and the

application must be submitted to CHR through LLeRA (InfoED). Contact Wesley James (wjames@llu.edu) for LLeRA login and technical support on the submission.

1. Title Page (one page): Include the title of the project, names of both principal investigators, their contact information (including institutional e-mail, phone numbers, name of department or center) and total dollars requested.

2. Abstract & Key Words (thirty lines of text): The abstract should briefly state the significance and goals of the proposed study and summarize the work to be accomplished. It should be suitable for assigning the application to appropriate reviewers. Four to six key words are required to identify the general area of research and the principle elements of the study.

3. Biographical Sketches (four pages per investigator): Provide biosketches of the principal investigators and other significant personnel in the format provided below (see p. 6).

4. Budget (template generated in LLeRA): Design a complete budget for up to 18 months of support. Identify amounts for each PI, expenditures for non-faculty salaries, supplies, and miscellaneous costs. Only non-faculty salaries and wages are permitted. GRIP awards do not provide for equipment purchases (\$1,500 or more) or indirect costs. The total budget may not exceed \$15,000. Consult with Wesley James, ext. 15732. **No carryover of funds will be permitted beyond 18 months from the date of award activation.**

5. Budget Justification: Indicate the purpose of supplies, support personnel and other costs.

6. Research Plan (follow the NIH R03 format): Provide information for the five subsections described below:

a. Specific Aims (one page): Summarize the overarching problem that is under investigation. Next, state the hypothesis or objective(s) and list the specific aims of the EXTRAMURAL GRANT PROPOSAL you are developing. Lastly, list the aims of the PILOT RESEARCH to be funded by GRIP.

b. Leadership Plan (one page): The PI/co-PI/co-I must make significant contributions to the project. If multiple PIs are proposed, indicate the individual research assignments of the PIs. State how the PIs will coordinate their activities, resolve problems, and allocate responsibilities for management and reporting.

c. Research Strategy (6 pages)

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 concepts, methods, technologies, treatments, services, or preventative interventions that drive this **field will be changed** if the proposed aims are achieved.

Innovation

- Explain how the application **challenges** and seeks to **shift** current research or clinical practice paradigms.
- Describe any **novel** theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any **advantage over existing** methodologies, instrumentation or intervention(s).
- Explain any **refinements, improvements, or new applications** of theoretical concepts, approaches or methodologies, instrumentation or interventions.

Approach

*For the anticipated Extramural Proposal: Briefly (1 page), describe the **overall strategy, methodology, and analyses** to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any **resource sharing** plans as appropriate.*

For any GRIP funded Activities (i.e. pilot study, papers to be written, external collaboration): Describe (1-1.5 pages) your methods or activity plan and how the results will provide preliminary data or supportive material for the external proposal. What alternate path could you take if the results are not supportive?

The approach section should also discuss **potential problems, alternative strategies, and benchmarks for success in the aims of your research.**

d. Timeline (one page). Describe in detail your plans for 1) 12 months of a pilot research project followed 2) Assessment of whether findings support an extramural grant application. 3) Extramural Grant preparation plan with suggestions of reviewers to critique the draft of your proposal.

	Pilot Research Project												Extramural Grant Preparation					
Months →	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Progress Report																		
Final Report & Assessment																		
CHR Proposal Review																		

Figure 1: Timeline for GRIP, ■ (progress report due)

e. References

Animal Studies or Human Subjects: When laboratory animals or human subjects are involved, integrate those descriptions into the Research Design and Methods section. If the proposal is awarded, separate applications for the use of animals or for the involvement of human subjects must be submitted and approved by the Institutional Animal Care and Use Committee (IACUC) or by the Institutional Review Board (IRB), respectively, before work may begin.

Progress and Final Reports: A progress report is due six months after award account activation. It will include a summary of results and observations, an assessment of the rate of progress, whether the study is on track for completion by the end of the project period and anticipated changes in the research plan with their justification. A final report is due 13 months after award account activation. It will include a description of the findings of your study, listing of reports submitted for publication/published, and an assessment of whether the findings support the preparation of the extramural grant application (with suggestions for reviewers). If you pursue a grant submission, CHR will work with you to find reviewers (internally, or external with honoraria) for your proposal.

No extensions of the project period are permitted. **Within 30 days of the end of the project period (18 months), a draft of the extramural proposal based on the GRIP award is due.**

Intent to Apply and Application Process: Applications are submitted electronically through the LLeRA Proposal Development module, a part of the institutional research management software. Intent to submit an application must be indicated by sending an email message to Wesley James (wjames@llu.edu) with the names of the two PIs, a tentative title, and a proposed start date (between December 1, 2014 and January 5, 2015). All queries must be submitted by e-mail to Wesley James by 5 p.m. on Wednesday, October 8, 2014. An electronic project record will be created for eligible applicants into which the application may be loaded. A printed, fully executed institutional transmittal form (available at <http://www.llu.edu/assets/research-affairs/docs/llu-transmittal-form.pdf>) is required by the application deadline (October 31, 2014, 12 noon.)

Contacts:

If you are interested in being part of the GRIP grant writing team for this RFA, please contact the current team members (copy both):

- Gary Fraser, MD, PhD, MPH, gfraser@llu.edu
- Michael Orlich, MD, morlich@llu.edu

For questions on completing the science portion of the application:

- Pramil Singh, DrPH, psingh@llu.edu

For budget and technical guidance on electronic submission of the GRIP:

- Wesley James, wjames@llu.edu, ext. 15732

What we will fund with GRIP awards:

- 1) **Twelve-month pilot project that collects highly innovative preliminary data to support the aim(s) of the extramural proposal that is prepared during the next 6 months (figure 1).** A direct link between the pilot project and the preliminary data section of the extramural proposal must be made clear in the application.
- 2) **Twelve months of secondary analysis and publication of reports from existing federally funded databases at SPH to support the aim(s) of the extramural proposal that is prepared during the next 6 months (figure 1).** Your budget could include a) student stipends for writing a draft of a manuscript, completing an extensive literature review, statistical programming, and b) publication costs.
- 3) **Twelve months of secondary analysis and publication of reports from other IRB-approved databases or data sources at SPH to support the aim(s) of the extramural proposal that is prepared during the next 6 months (figure 1).** Your budget could include: a) student stipends for writing a draft of a manuscript, completing an extensive literature review, statistical programming, b) publication costs.
- 4) **Secondary analysis and publication of reports from other approved data sources to support the aim(s) of the extramural proposal that is prepared during the next 6 months (figure 1).** Your budget could include a) student stipends for writing a draft of a manuscript, completing an extensive literature review, statistical programming, b) publication costs, c) database licensing fees.
- 5) **Costs associated with partnering with another institution on the extramural grant to be developed.** Your budget could include a) Travel/consultation for external experts to work with GRIP awardees at LLU, b) Travel for GRIP awardees to work with external experts at their institution.
- 6) **Honoraria for experts to serve as reviewers of your extramural proposal that is developed under the GRIP award.** CHR may add a supplement to your GRIP award to help you with this cost during or immediately after the term of your award.
- 7) **Travel to meet directly with the funding agency to plan your extramural proposal.**

What we will **not** fund with GRIP resources:

- 1) Conference travel.
- 2) Pilot projects for external research proposals in which LLU SPH is not the primary.
- 3) Pilot projects that do not list at least two LLU-SPH primary faculties as PI or co-I of the GRIP award.
- 4) GRIP award for PI's who are not primary faculty of LLU SPH.
- 5) GRIP award for PI's who are not eligible to serve as a PI on an external research grant originating from the LLU-SPH.
- 6) Travel costs in excess of \$3000.
- 7) PI's from previous GRIP awards who did not meet deadlines.
- 8) Concurrent GRIP awards.
- 9) Purchase of furniture or computer hardware without very detailed justification.
- 10) Investigator salary

Biographical Sketch Format – excerpts from the NIH Application Guide SF424 (R&R)
<http://grants.nih.gov/grants/funding/424/index.htm>)

Use the sample format on the Biographical Sketch Format Page (see above link) to prepare this section for grant applications. Include biographical sketches of all Key Personnel and other significant Contributors. The Biographical Sketch may not exceed four pages per person. This 4-page limit includes the table at the top of the first page. See the sample of a completed Biographical Sketch.

If the individual is registered in the eRA Commons, include the Commons User Name for the PIs and all other Senior/Key Persons. For information on the eRA Commons, see <https://commons.era.nih.gov/commons/index.jsp>.

Complete the educational block at the top of the format page beginning with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training, separately referencing residency training when applicable. For each entry provide the name and location of the institution; the degree received (if applicable); the month and year the degree was received, and the field of study. For residency entries, the field of study section should reflect the area of residency.

Following the educational block, complete sections A, B, C, and D as described below.

- A. **Personal Statement.** Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PI, co-investigator, mentor) in the project that is the subject of the application.
- B. **Positions and Honors.** List, in chronological order, previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.
- C. **Peer-reviewed publications or manuscripts in press (in chronological order).** Limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. When citing articles that fall under the Public Access Policy, provide the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not acceptable as appendix material).
- D. **Research Support.** List both selected ongoing and completed (during the last three years) research projects (federal or non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the Senior or Key Person identified on the Biographical Sketch. Do not include number of person months or direct costs.

The “Research Support” section of the biographical sketch should highlight your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers to assess each individual’s qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, “Other Support” information is required for all applications that have already received extramural grant awards.