GRANTS TO PROMOTE COLLABORATIVE AND TRANSLATIONAL RESEARCH (GCAT)

OFFICE OF THE DEAN OF THE SCHOOL OF MEDICINE 2024

Purposes:

- Develop insights and approaches to clinically relevant issues that have the potential to make a difference in the lives of patients
- Promote collaborations between clinical and basic scientists within the School of Medicine
- Develop grant preparation skills and generate preliminary data for subsequent extramural peerreviewed proposals

Phase I:

- Goal: To gather the preliminary data needed to compete for a Foundation, R03 or R21 grant (or equivalent)
- Indicators of success:
 - Publication of one or more peer-reviewed manuscripts
 - Submission of one or more applications for a Foundation, R03 or R21 grant (or equivalent)

Description:

Maximum award: \$75,000
Term of award: 24 months
Number of awards for 2024: Up to 4

New Applications:

Letters of Intent must be submitted no later than
Deadline for submission:

Anticipated date of award announcement:

Monday, August 7, 2023 - 5:00 PM
Monday, September 18, 2023 - 5:00 PM
December 2023

Resubmission Applications 2023: By invitation only.

Letters of Intent and Application Process: Intent to submit a GCAT application must be indicated by completing the **Letter of Intent form**, *including the signatures of both PIs*, and submitting it to Research Affairs via email rapreaward@llu.edu or fax to (909-558-0199) by the due date. Questions should be directed to the Pre-Award team https://researchaffairs.llu.edu/pre-post-award/contacts. An electronic record LLeRA (InfoEd) record will be created into which the application will be loaded by the PIs. Any signature approvals must be electronically signed and are required by the application deadline.

Eligibility:

- The project must be co-directed by two faculty members, both of whom meet the requirements of the <u>PI Eligibility</u> policy. Both must have primary appointments within the LLU School of Medicine, and the two Principle Investigators must have their primary appointments in two different departments. Additional individuals can provide letters of support as co-investigators, but no more than two Principle Investigators may be named on an application.
- One member must be a clinician, with a primary appointment in one of the clinical departments
 of LLU, and the other must be a full-time basic scientist with a primary or secondary appointment
 in one of the basic science departments (Department of Basic Science or the Department of
 Pathology and Human Anatomy).
- At least one co-PI must have received less than \$100,000 in direct support for their research activities during the 12 months preceding the deadline for applications. There are no financial restrictions on the funding that has been available to the other co-PI.
- Publication of a minimum of one peer-reviewed manuscript during the past year [to be included
 in the biosketch(es)] is required for eligibility. This publication can be authored by either member
 of the team.

- Individuals who have received prior awards through the GCAT mechanism may reapply for GCAT support provided that for each prior GCAT award one or both of the PIs have met the indicators of success noted above, where both the manuscript submission and the grant application must have occurred after receiving the prior GCAT award. This requirement applies regardless of whether the proposed partnership is the same as previously or represents a new team. Additional details are noted in the section below.
- Teams that submitted applications that were not funded in a previous round may be invited to resubmit a revised application. The application should be preceded by an "Introduction to the Revised Application", of up to one page, that describes the changes made to the proposal.
- Only studies conducted at facilities within the School of Medicine will be considered, though supplies, services or reagents from other facilities are allowed.
- While an individual or a team may submit more than one application per cycle, no more than one
 award will be made to any investigator. For example, if a clinician submits two applications, each
 of which represents a partnership with a different basic scientist, only one would be eligible for
 an award. Individuals can serve as the PI on only one active GCAT award at a time.

Eligibility for previous GCAT recipients (one page per previous awardee): If one or both of the applicants is a previous GCAT recipient, provide the following for each previous GCAT award.

- Peer-reviewed and published papers:
 - Citations for one or more articles that were published or accepted subsequent to the previous GCAT award and that acknowledge GCAT funding support from LLU.
 - PDF of or hyperlink to the article(s).
- Extramural grant applications:
 - LLeRA number
 - Principal Investigator
 - o Title
 - Sponsor name
 - Date of submission
 - Amount
 - o Current status (i.e., funded, pending, scored, not discussed, etc.)

Application Format: Text must be 11 point or larger with six lines per inch and margins of at least one-half inch. Headers and footers should not be used. The sections identified below may not exceed their indicated page limits, and appendices are not allowed. The following headings are expected.

Title Page (one page): Include the title of the project, names of both principle investigators, their contact information (including (as applicable) institutional e-mail, phone numbers, WhatsApp ID, Skype ID, Zoom ID, ORCID ID, name of department and/or center and any collaborating institution(s)), a list of all key personnel involved in the project, and total dollars requested.

Abstract and Key Words (up to 30 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.

Biographical Sketches (up to five pages per investigator): Provide biosketches of the principal investigators and other key personnel using current NIH guidelines (see the Biographical Sketch Format Page and Biographical Sketch Sample at http://grants.nih.gov/grants/forms/biosketch.htm).

Budget (template generated in LLeRA): Design a complete budget for up to 24 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; however, effort should be reported for each PI. A minimum of 10% effort from each PI is required. GCAT awards do not provide for purchases of major equipment (\$10,000 or more), travel expenses, or indirect costs. If neither PI

has previously had grantwriting training, additional funds of up to \$5,000 which do not count against the \$75,000 total may be requested for this training for one or both investigators. With this exception, the total budget may not exceed \$75,000. Consult with a Pre Award team member (ext. 55160).

Budget Justification (one page): Indicate the purpose of supplies, support personnel and other costs. Indicate how the total budget will be split between the two investigators.

Research Plan:

- **A.** Introduction to Revised Application (one page, required only for revised applications): Summarize the substantial additions, deletions and changes to your application. In addition, concisely address each of the concerns raised by the previous reviews.
- **B.** Specific Aims (one page): "State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed." (*Text taken from NIH instructions*)
- **C.** Research Strategy (limited to 6 pages): Six pages in total are allowed for the subsections of Significance, Innovation, and Approach. Suggested allocations of this space for those three subsections are noted below.
 - a. **Significance** (suggested length of ½ page): "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 capacity, 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." (Text taken from NIH instructions)
 - b. **Innovation** (suggested length of ½ page): "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 interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions." (Text taken from NIH instructions)
 - c. Approach (suggested length of 5 pages): "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. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised." (Text taken from NIH instructions) While not required, preliminary studies or data may be incorporated within the Approach section.
- **D. References:** Include references that demonstrate the need for this research, establish feasibility for hypotheses and procedures, and provide support for the approach. Include titles and authors.

Leadership and Financial Oversight Plan (one page): Both Pls must make major contributions to the project. Indicate the individual research assignments of the Pls. State how the Pls will coordinate their activities, resolve problems, and allocate responsibilities for management and reporting. Specifically indicate how the research funds are to be allocated. For example, a team may wish to divide up the funds into two accounts covering different types of expenses, with one Pl responsible for each account, or they may wish to consolidate funds into one account with one Pl serving as the point of contact for all financial matters.

Grantwriting training (one page): If one or both PIs have received formal grantwriting training or successfully obtained extramural funding in the past, describe briefly the training program, including dates, format (in person, online, individual coaching, group sessions, etc.). If neither PI has received such training or obtained funding in the past, indicate one or more possible courses or programs, including the provider, approximate dates, approximate cost, etc. Note that up to \$5,000, which does not count against the \$75,000 total, can be requested for such training.

Future Directions (one page): Briefly describe the future directions to be taken with this project, assuming that this initial phase is successful. For example, describe grants or industry funding to be applied for and how the preliminary data obtained in this first phase will enhance those applications. Also, if this pilot data will allow design of a larger study, describe briefly the anticipated study design for this larger study.

Letter of Support (Department) (up to two pages): Provide a letter of support from the Chair of the Department in which the clinical scientist resides. This letter must include the following elements:

- A commitment to transfer an amount equal to half the total support (\$37,500 of the total award
 of \$75,000) into an account dedicated to the research described in the accompanying
 application, should the application be funded. This deposit will need to be made within one
 month of the opening of this account.
- A description of the time the clinical scientist will be able to dedicate to this project, free of clinical responsibilities.

Letters of Support (Others): Letters of support from key personnel and consultants are encouraged.

Phase II:

- **Goal:** To leverage and extend results from Phase I to develop and submit a competitive application for R01 (or equivalent) funding
- Indicators of success:
 - Publication of one or more peer-reviewed manuscripts
 - Submission of one or more applications for a R01 grant (or equivalent)

Description:

Maximum award: \$100,000 plus other support (see below)
 Term of award: 24 months or as requested

Number of awards for 2024:

New Applications:

Letters of Intent must be submitted no later than
Deadline for submission:

Anticipated date of award announcement:

Monday, August 7, 2023 - 5:00 PM
Monday, September 18, 2023 - 5:00 PM
December 2023

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Letters of Intent and Application Process: Intent to submit a GCAT application must be indicated by completing the Letter of Intent form, including the signatures of both Pls, and submitting it to Research Affairs via email rapreaward@llu.edu or fax to (909-558-0199) by the due date. Questions should be directed to the Pre-Award team https://researchaffairs.llu.edu/pre-post-award/contacts. An electronic record LLeRA (InfoEd) record will be created into which the application will be loaded by the Pls. Any signature approvals must be electronically signed and are required by the application deadline.

Eligibility:

- Teams that have received Phase I GCAT funding and met the following milestones will be eligible to apply for Phase II GCAT funding.
 - One or both members of the team must have applied for external funding (R21, R01 or equivalent) and received feedback.
 - One or both PIs must have completed grant writing training.
 - A "grant coach" will have been identified. This grant coach will help to guide the project towards the receipt of external funding.
- As in Phase I, the project must be co-directed by two faculty members, both of whom meet the
 requirements of the <u>PI Eligibility</u> policy. Both must have primary appointments within the LLU
 School of Medicine, and the two Principle Investigators must have their primary appointments in
 two different departments. Additional individuals can provide letters of support as coinvestigators, but no more than two Principle Investigators may be named on an application.
- As in Phase I, one member must be a clinician, with a primary appointment in one of the clinical departments of LLU, and the other must be a full-time basic scientist with a primary or secondary appointment in one of the basic science departments (Department of Basic Science or the Department of Pathology and Human Anatomy).
- If it is necessary to replace one or more members of the team that initially received the Phase I award, this change must be justified in the application.
- Teams that submitted applications that were not funded in a previous round may be invited to resubmit a revised application. The application should be preceded by an "Introduction to the Revised Application", of up to one page, that describes the changes made to the proposal.
- Only studies conducted at facilities within the School of Medicine will be considered, though supplies, services or reagents from other facilities are allowed.
- Individuals can serve as the PI on only one active GCAT award at a time. This includes both
 Phase I and Phase II awards; an individual with a Phase II award is ineligible to also apply for a
 Phase I.

Grant Coach: The purpose of a grant coach is to guide the investigators toward obtaining extramural funding. Expectations include providing advice in shaping the Specific Aims, identifying the most appropriate institutes for funding and study sections for review, and mentoring the team toward success. The Grant Coach may or may not be listed as a coinvestigator on the application.

Application Format: Text must be 11 point or larger with six lines per inch and margins of at least one-half inch. Headers and footers should not be used. The sections identified below may not exceed their indicated page limits, and appendices are not allowed. The following headings are expected.

Title Page (one page): Include the title of the project, names of both principle investigators, their contact information (including (as applicable) institutional e-mail, phone numbers, WhatsApp ID, Skype ID, Zoom ID, ORCID ID, name of department and/or center and any collaborating institution(s)), a list of all key personnel involved in the project, and total dollars requested.

Abstract and Key Words (up to 30 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.

Biographical Sketches (up to five pages per investigator): Provide biosketches of the principal investigators and other key personnel using current NIH guidelines (see the Biographical Sketch Format Page and Biographical Sketch Sample at http://grants.nih.gov/grants/forms/biosketch.htm).

Budget (template generated in LLeRA): Design a complete budget for up to 24 months of support. Identify amounts for each PI, expenditures for non-faculty salaries, supplies, and miscellaneous costs. Funds covering up to 0.2 FTE for the clinical faculty member may be requested which do not count against the \$100,000 total; no funds are to be applied toward salary support of the non-clinical

faculty member. Effort should be reported for each PI, with a minimum of 10% effort from each PI required. GCAT awards do not provide for purchases of major equipment (\$10,000 or more), travel expenses, or indirect costs. In addition to the \$100,000 and 0.2 FTE for the clinical partner, up to \$20,000 of in-kind support from SM-supported core facilities (ie, sequencing, confocal microscopy, mass spec analysis, etc.) may be requested, with the expectation that appropriate amounts of support for these core facilities will be requested in subsequent external applications. Quotes from the core facility(ies) should be included as an attachment to the budget justification. Consult with a Pre Award team member (ext. 55160).

Budget Justification (one page): Indicate the purpose of supplies, support personnel and other costs. Indicate how the total budget will be split between the two investigators.

Research Plan:

- A. Response to Previous Reviews (one page): Provide the reviews from any proposal submissions to external funding agencies (these reviews do not count against the 1 page limit). Within the 1-page document, summarize the reviewer's concerns, your response to those concerns, and clearly indicate how the data obtained from the current GCAT Phase II application, should it be funded, is anticipated to convincingly address the reviewer's concerns.
- **B. Specific Aims** (one page): "State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed." (*Text taken from NIH instructions*)
- **C.** Research Strategy (limited to 12 pages): Twelve pages in total are allowed for the subsections of Significance, Innovation, and Approach. Suggested allocations of this space for those three subsections are noted below.
 - a. Significance (suggested length of 1-2 pages): "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 capacity, 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." (Text taken from NIH instructions)
 - b. **Innovation** (suggested length of 1 page): "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 interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions." (Text taken from NIH instructions)
 - a. **Approach** (suggested length of 9-10 pages): "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. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised." (Text taken from NIH instructions) Preliminary studies or data may be incorporated within the Approach section.
- **D. References:** Include references that demonstrate the need for this research, establish feasibility for hypotheses and procedures, and provide support for the approach. Include titles and authors.

Leadership and Financial Oversight Plan (one page): Both Pls must make major contributions to the project. Indicate the individual research assignments of the Pls. State how the Pls will

coordinate their activities, resolve problems, and allocate responsibilities for management and reporting. Specifically indicate how the research funds are to be allocated. For example, a team may wish to divide up the funds into two accounts covering different types of expenses, with one PI responsible for each account, or they may wish to consolidate funds into one account with one PI serving as the point of contact for all financial matters.

Mentorship Plan (one page): Describe the qualifications of the proposed Grant Coach. Include their history of obtaining external funds over the past 5 years, as well as a summary of their service on external review panels (such as NIH study sections). Also include a summary of this individual's previous mentees and their success. Describe the proposed frequency and nature of the interactions between the grant coach and the PIs, to include plans for the coach to participate in (or mentor through) the grant writing process, and whether or not this person is anticipated to participate as a co-investigator.

Future Directions (one page): Briefly describe the future directions to be taken with this project, assuming that this initial phase is successful. For example, describe grants or industry funding to be applied for and how the preliminary data obtained in this first phase will enhance those applications. Also, if this pilot data will allow design of a larger study, describe briefly the anticipated study design for this larger study.

Letter of Support (Grant Coach): The Grant Coach must provide their Biosketch along with a letter of support, committing to guiding the PIs toward developing into independent investigators with external funding equivalent to an R01.

Letter of Support (Department) (up to two pages): Provide a letter of support from the Chair of the Department in which the clinical scientist resides. This letter must include the a description of the time the clinical scientist will be able to dedicate to this project, free of clinical responsibilities, taking into account the protected time requested in this application.

Letters of Support (Others): Letters of support from key personnel and consultants are encouraged.

Criteria for Evaluation: Awards will be based on primarily on scientific merit, including significance, innovation, approach, and investigator. The strength of the basic/clinical collaboration, the PI leadership plan, and the adequacy of the budget, with justification, will also be considered. Inclusion of preliminary data supporting the proposed study is highly recommended. In the absence of preliminary data, strong literature support for the planned study 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. Applications are expected to appropriately address issues of <u>rigor and reproducibility</u> (see <u>Researcher's Alert</u> for more information). Proposals will be reviewed by a panel of investigators, selected to include those with a record of extramural funding and a preference for those who have served on federal grant review panels. To the extent possible, applications will be kept confidential, but the abstracts of funded projects may be published.

Compliance: When the proposal involves human embryonic stem cells, ionizing radiation, laboratory animals, human subjects, or other elements that require approval by an oversight committee, integrate the descriptions into the Research Strategy section. If the proposal is awarded, separate applications must be made to the appropriate committee **before** the work can begin, e.g., Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), and/or the Stem Cell Research Oversight Committee (SCRO).

Final Report: Extensions of the project period may be requested and if granted, will follow NIH guidelines. Within 60 days of the end of the project period, a final report is due. It should include accomplishments,

significant results, manuscripts prepared for publication, and plans for extramural grant applications. Send reports to basicscienceadmin@llu.edu.

Contacts:

For General Information, Technical and Application Guidance: https://researchaffairs.llu.edu/pre-post-award/contacts

For eligibility questions, contact the office of the Associate Dean for Basic Science and Translational Research: basicsciencesadmin@llu.edu