

Request for Applications for Two Funding Opportunities

INSTRUCTIONS

CTSI Mentored Translational Research Scholars Program (KL2) Sylvester Calabresi Clinical Oncology Research Career Development Program (K12)

The common goal of the *Sylvester Calabresi Clinical Oncology Research Career Development Program* and the *Miami CTSI Mentored Translational Research Scholars Program* is to identify outstanding investigators and prepare them to become the next generation of highly skilled independent researchers. These researchers will translate fundamental knowledge and new technologies from the laboratory to the clinic and to the community.

This year, with the goal to reduce application burden for potential Scholars and facilitate selection of the most competitive candidates at our institution, the two programs offer a **single common application process**, while retaining their specific eligibility criteria and review process.

Each program will recruit a diverse group of talented research Scholars for two-year terms and provide them with dedicated time for research, optimal mentorship, formal research education, and practical experience to support their research career development.

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Award Timeline

RFA	November 17, 2021 (W)
Q & A session	November 30, 2021 (T) 4:00 p.m. via Zoom [Register here]
Letter of intent (LOI) deadline	December 16, 2021 (TH) [Click here for LOI]
Invitation to apply	December 20, 2021 (M)
Full application deadline	February 9, 2022 (W)
Award notification	April 20, 2022 (W)
Program start date	June 1, 2022 (W)

Eligibility Criteria

All eligibility criteria are subject to verification by the CTSI and Sylvester program administrators.
All criteria must be met by the application due date (February 9, 2022).

You are eligible to apply to the Sylvester Calabresi Clinical Oncology Research Career Development Program (K12) if ALL the statements below apply:

- You are a permanent resident of the U.S. [\[Definition\]](#)
- You are a full-time Assistant Professor at UM.
- You are an MD/DO and board-certified or -eligible in one of the clinical oncology disciplines.
- You are a Sylvester member (you may apply concurrently for the K12 and SCCC membership).
- You completed your fellowship no more than 5 years before the program start date (June 2017 or later).
- You have never received a PHS-funded career development award (CDA, e.g., NIH K series). *If you are a current or past recipient of a CDA funded by a foundation, industry, or professional association, see note below.*
- You have never received or submitted any major research grant (such as R01) as PI or MPI from federal, industry, state, or foundation funding agency. *See below what constitutes a MAJOR grant.*
- Your proposed project is patient-oriented, clinical cancer research.
- This is your first application or your first resubmission to the Sylvester K12 award.

You are eligible to apply to the Mentored CTSI Career Development Award (KL2) if ALL the statements below apply:

- You are a permanent resident of the U.S. [\[Definition\]](#)
- You are a full-time Assistant Professor at UM.
- You have a doctoral degree. [\[definition\]](#)
- Your first appointment as Assistant Professor at any institution is no more than 6 years before the date of full application submission (February 2016 or later).
- You have never received a PHS-funded career development award (CDA; e.g., NIH K series). *If you are a current or past recipient of a CDA funded by a foundation, industry, or professional association, see note below.*
- You have never received or submitted any major research grant (such R01) as a PI or MPI from federal, industry, state, or foundation funding agency. *See below what constitutes a MAJOR grant.*
- Your proposed project is defined as translational research. [\(NCATS definition\)](#)
- Your proposed project is NOT a clinical trial beyond Phase IIA.
- Your proposed project has no foreign component.
- This is your first application or your first resubmission to the CTSI KL2 award.

You are NOT eligible for K12 and KL2 awards if ANY of the statements below apply:

- You are on a temporary visa.
- You are an adjunct professor, voluntary professor, lecturer, resident, clinical/post-doctoral fellow, or student.

- You are a current or past recipient of a PHS-funded mentored career development grant (e.g., NIH K series). *If you are a current or past recipient of a CDA funded by a foundation, industry, or professional association, see note below.*
- You are the Principal Investigator (PI) or Multiple PI (MPI) of any awarded or submitted major independent grant (R01, P01, or other equivalent research grant awards). *See below what constitutes a MAJOR grant.*

What constitutes a MAJOR grant vs. a NON-MAJOR grant?

MAJOR GRANTS: NIH research project grant or equivalent non-PHS (peer reviewed grants that are over \$100,000 direct costs per year, sub-projects of program project (P01) or center grants (P50).

NON-MAJOR GRANTS: NIH small grants (R03), exploratory Developmental (R21) or SBIR, STTR (R43, R44 grants) (Source: <https://grants.nih.gov/grants/guide/pa-files/par-15-304.html>)

Career development awards funded by a foundation, industry, or professional association

If you are a current or past recipient of a CDA funded by a foundation, industry, or professional association, please contact the program administrators as soon as possible to determine your eligibility (CTSI: Patricia Avissar, PAvissar@med.miami.edu; Sylvester: Vaughn Edelson, vte3@miami.edu).

Please provide:

- RFA for your award (must include details about award duration and funding)
- Rationale for why an additional CDA is necessary for your research and career development, and how the K12/KL2 will complement and expand on current/previous training

Program Support

Duration of Award

CTSI KL2 and Sylvester K12: 2 years (24 months): 6/1/2022 to 5/31/2024

Number of Awards

CTSI KL2: Up to two awards

Sylvester K12: Two awards

Protected Time

CTSI KL2 and Sylvester K12: 75% protected time for two years for career development in either clinical investigation or community-based research (**Sylvester K12**) or C/T research (**CTSI KL2**).

Funding

CTSI KL2: 75% salary support up to the NIH Salary Cap (\$120K)
\$2.5K for travel and training-related activities including registration fees
\$30K for research expenses

Sylvester K12: 75% salary support
\$30K for research expenses (including travel)

Expectations of Awardees

- **CTSI KL2 and Sylvester K12:** Scholars are encouraged to enroll in the Master of Science in Clinical and Translational Investigation program (MSCTI) administered through the Miami CTSI. This degree program was created to provide didactic, hands-on training in clinical and translational science research. Important note on tuition¹.

¹ **Tuition is not waived.** As a UM faculty member, you are eligible for the employee tuition remission benefit. Graduate tuition remission is subject to Federal Income and Social Security withholding taxes. You can find more information on the [UM HR website](#).

- **CTSI KL2 and Sylvester K12:** Scholars are expected to publish papers in high-impact journals and apply for peer-reviewed extramural funding by the end of their award period.
- **CTSI KL2 and Sylvester K12:** Scholars will voluntarily participate in various conferences, seminars, and symposia to develop a thorough scientific and medical knowledge base.
- **CTSI KL2 and Sylvester K12:** Scholars must acknowledge the Miami CTSI or Sylvester Comprehensive Cancer Center in any publication, presentation, abstract, chapter, poster, etc. resulting from research and protected time supported by KL2/K12 program, or other services provided by the programs.
- **CTSI KL2 and Sylvester K12:** Scholars will complete an Individual Enhancement Plan (KL2) or Individual Development Plan (K12) within 30 days of the program start date.
- **CTSI KL2 and Sylvester K12:** To ensure career development, Scholars will meet with their mentors on a regular and frequent basis and at regular intervals with program leadership.
- **CTSI KL2 and Sylvester K12:** During the funded period, Scholars will submit biannual progress reports and other reports/documentation as requested. Upon completion of the program, individuals will submit a final report and yearly updates on academic progress.
- **Sylvester K12:** Awardees are required to participate in the Design and Management of Cancer Clinical Trials course, including attendance at all lectures and completion of weekly homework assignments. Scholars will also attend the K12 Monthly Scholars Forum and annual Paul Calabresi Symposium.

Resubmissions

Only **one submission** and **one resubmission** are allowed per candidate.

With your resubmission, you will be asked to (1) upload the summary statement or the reviews of your first submission and (2) address the reviewers' comments.

Review of Proposals and Selection Criteria

All applications will be evaluated in a rigorous review by K12 and KL2 review committees. Applications will be scored using the [NIH 1-9 scoring scale](#) and according to the following criteria:

- **Candidate**
 - Compliance with all eligibility requirements
 - Evidence of commitment to a career in patient-oriented cancer research
 - Suitability of the applicant for an accelerated career in clinical and translational research
 - Scholarship, as assessed from biosketch, CV, and letters of reference
- **Career Development/Educational Plan**
 - Appropriateness and rigor of the educational plan
 - Likelihood that the career development plan will contribute significantly to the candidate's development and independence
 - Plan to pursue Master of Science in Clinical and Translational Investigation or other relevant degree (e.g., MPH, MS in Biostatistics)
- **Research Plan**
 - Novelty of the research proposal
 - Scientific merit of the research proposal
 - Feasibility of the research proposal and applicant's ability to execute the research plan
 - Likelihood that it will result in translational research
 - Likelihood that the project could lead to a future grant application or clinical trial
 - Use of University of Miami/Sylvester Comprehensive Cancer Center/CTSI shared resources
 - Addressing minority health & health disparities (e.g., plan to ensure minority participation)
- **Mentorship**
 - Appropriateness and commitment of mentoring team and collaborators
 - Qualifications of the mentors and evidence of mentoring success

- **Institutional/Departmental Support**
 - Commitment of the necessary resources and protected time from the primary department

Application Requirements

Applications are submitted online via REDCap form.

Applications that do not adhere to page limit and format guidelines will not be reviewed.

Uploaded documents:

- Page limits are indicated for all uploaded documents
- Format: Arial 11 pt. font, 0.5" margins, single-spaced

Letters of Intent (LOI)

Letters of Intent are required for both the CTSI KL2 and Sylvester K12 programs. The LOIs are used to (1) verify the eligibility of the applicants and their proposals, and (2) select the review committee members.

The LOI is a structured questionnaire, not a standard abstract. It is submitted [online](#) and includes:

- Applicant information
- Applicant eligibility (U.S. residency, academic rank, funding, etc.)
- Project eligibility
- Mentors and collaborators
- Project information: Purpose, Research Question, Data Sources, Significance, etc.
- Current biosketch

Full Application

Full applications are submitted online and by invitation only. The full application includes:

1. Project Title

If you use any acronyms, spell them out.

2. Scientific Abstract (LIMIT 250 words)

State purpose, hypothesis, aims, and clinical/translational significance of potential findings.

3. Personal Statement (LIMIT 1 page)

Arial 11 pt. font, 0.5" margins, single-spaced

Must include:

- Specific areas of health research interest
- Long-term career goals and short-term objectives
- Statement on how the KL2/K12 award will enhance your research career
- Statement on how your proposal addresses health disparities (CTSI)

4. Research project (LIMIT 4 pages)

Arial 11 pt. font, 0.5" margins, single-spaced

Describe the proposed clinical research project, including clinical need, hypothesis, aims, and clinical significance of potential findings.

The 4-page limit applies to all text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the narrative and could confer an unfair competitive advantage is not allowed and may result in administrative withdrawal of the application.

The Research Plan must include ALL the following sections:

- **Preliminary work:** Summarize the research completed toward this project or accomplishments relevant to this project.

- **Specific Aims:** State concisely the goals of the proposed research and summarize the expected outcomes, including the impact that the results of the proposed research will exert on the field involved.
- **Significance:** Describe the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- **Innovation:** Describe how the application challenges and seeks to shift current research or clinical practice paradigms.
- **Approach:** Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.
- **Analysis Plan:** Describe how the data will be collected, analyzed, and interpreted. Your application must include a statistical plan.
 - Cancer-focused researchers are encouraged to engage the Sylvester Biostatistics and Bioinformatics Shared Resource (BBSR). Services are subsidized for Sylvester members. More information on BBSR services and fees can be found on their [website](#).
 - **CTSI KL2** applicants are required to consult with the Biostatistics Collaboration and Consulting Core ([BCCC](#)) prior to submitting their application. The first consult is free of charge. Awarded scholars will receive free biostatistics service from the BCCC².
- **Other required information:**
 - **CTSI KL2:** Translational Nature of the Research: A brief description of the translational, clinical, or public health impact of your research. Clearly state how a disease or group of diseases will be better diagnosed, treated, or prevented, or how the successful completion of your research will improve human health.
 - **Sylvester K12:** A brief description of any plans to include minority/catchment area participation

5. Cited References (no page limit)

This section will contain ONLY the references cited in the research plan. Visuals, tables, and any other information are not allowed.

Adding anything other than references will result in administrative withdrawal of the application.

6. Career Development / Educational Plan (LIMIT 2 pages)

Prepare this document with your mentor(s).

Describe your individualized training program, including:

- Required curriculum elements (see K12 Curriculum document, or CTSI IEP).
- Graduate-level coursework, including coursework in pursuit of a Master of Science in Clinical and Translational Investigation, if applicable. *See note on tuition on page 3.*
- Include specific courses that you plan to take to enhance your research capabilities (e.g., biostatistics, epidemiology, etc.) or attendance at specific scientific conferences.
- Relevant short courses, such as informatics, scientific writing, and grantsmanship.
- A training overview table and project timeline with planned curriculum courses (*see examples in [Appendix A](#) and [Appendix B](#)*).

7. Mentoring Plan (LIMIT 2 pages)

Prepare this document with your mentor(s). Provide the following:

- Rationale for the selection of mentors, including mentor qualifications.
- Plan for monitoring candidate's career progression and path to independence.

² To schedule an initial consult with the BCCC, contact Ms. Maria Jimenez-Rodriguez, B.A., M.A.L.S. Biostatistics Collaboration and Consulting Core (BCCC) | Email: MJRodriguez@biostat.med.miami.edu

- Plans for mentored project(s) to be conducted, including how the applicant's approach will differ from that of the mentors and how the applicant's approach will complement that of the mentors.
- Description of all planned activities, including didactic courses that will be incorporated into the career development and mentored research experience. Please outline:
 - Format of Instruction (i.e., face-to-face lectures, coursework, and/or real-time discussion groups. A plan with only on-line instruction is not acceptable). Mentors are required to provide both formal and informal instruction to their mentees.
 - Subjects of instruction
 - Mentor and other faculty participation
 - Duration of instruction
 - Frequency of instruction

8. Budget and Budget Justification for Research

We strongly encourage you to work with your departmental administrator.

- Use the template provided on our website to prepare a detailed budget and justification.
- The budget will include the annual research expenses only, i.e., supplies needed for the conduct of the research project, clinical training, and education during the award period.
- **Sylvester K12:** Please note your salary in the budget justification, but do not include your percent effort cost in the budget.

Sylvester K12: \$30K per year for 2 years

CTSI KL2: \$30K + \$2.5K for travel per year for 2 years. NOTE: Travel to expert labs or scientific meetings during the award period (**U.S. travel only**)

For a list of allowed and not allowed expenditures, please see [Appendix C](#).

9. Biosketch AND Curriculum Vitae

Both are required. Use the [NIH format](#) (non-fellowship template) for the Biosketch and the [UM format](#) for the CV.

10. Regulatory Approvals

If the proposal is awarded, and if your research requires regulatory approval(s) **for the project to commence**, you will be asked to provide all approval documentation before receiving funding. Research will not start until all the appropriate regulatory approvals are in place:

- Institutional Review Board (IRB) for research involving human subjects
- Institutional Animal Care & Use Committee (IACUC) for research involving the use of animals
- Institutional Biosafety Committee (IBC) for research involving the use of recombinant DNA
- Embryonic Stem Cell Research Oversight Committee (ESCRO) for research involving the use of embryonic stem cells or somatic cell nuclear transfer
- **CTSI KL2:** in addition to the regulatory approvals, projects that involve the use of human subjects and/or live vertebrate animals must obtain [Prior Approval from NCATS](#).

11. Letters of Recommendation

CTSI KL2 and Sylvester K12:

- **REQUIRED:** Letter from the Chief/Chair: Must include assurance that the candidate will be hired into their department for the duration of the award AND will have 75% protected time for the two-year KL2/K12 term. Also describe plans for continued protected time after the program ends.

Sylvester K12: Chief/Chair must also include commitment to facilitating Scholar participation in

required K12 curriculum elements (e.g., Design & Management of Cancer Clinical Trials course).

- **REQUIRED:** Letter from the scientific/primary mentor: Include plans for career and leadership development of the Scholar and a specific statement of sufficient time and dedication to development of the awardee.
- **REQUIRED:** One additional letter of recommendation from another current mentor, a previous mentor, or another individual familiar with the applicant's potential.
- **OPTIONAL:** Up to two additional recommendations are permitted.

12. Demographics – Investigator Personal Data

The Miami CTSI KL2 and the Sylvester K12 awards are funded by the Department of Health and Human Services (DHHS), NCATS and NCI respectively.

As part of annual progress reporting to their sponsors, the two programs are asked to gather personal information from individuals who apply to grant awards, and those who receive support or services from them.

Submission of the requested information is **VOLUNTARY** and is not a precondition of award. If you do not wish to submit this information, check the "Do Not Wish to Provide Answer" boxes.

This information will remain **confidential** and will not be displayed in the reviewer evaluations.

Questions?

Patricia Avissar for CTSI: PAvissar@med.miami.edu

Vaughn Edelson for Sylvester: vte3@miami.edu

Appendices

Appendix A: Training Overview

Include a training overview table in the Career Development Plan portion of the application. Select the 2-4 most important elements of your training. For each element, specify objectives, mechanisms, and relationship to research project.

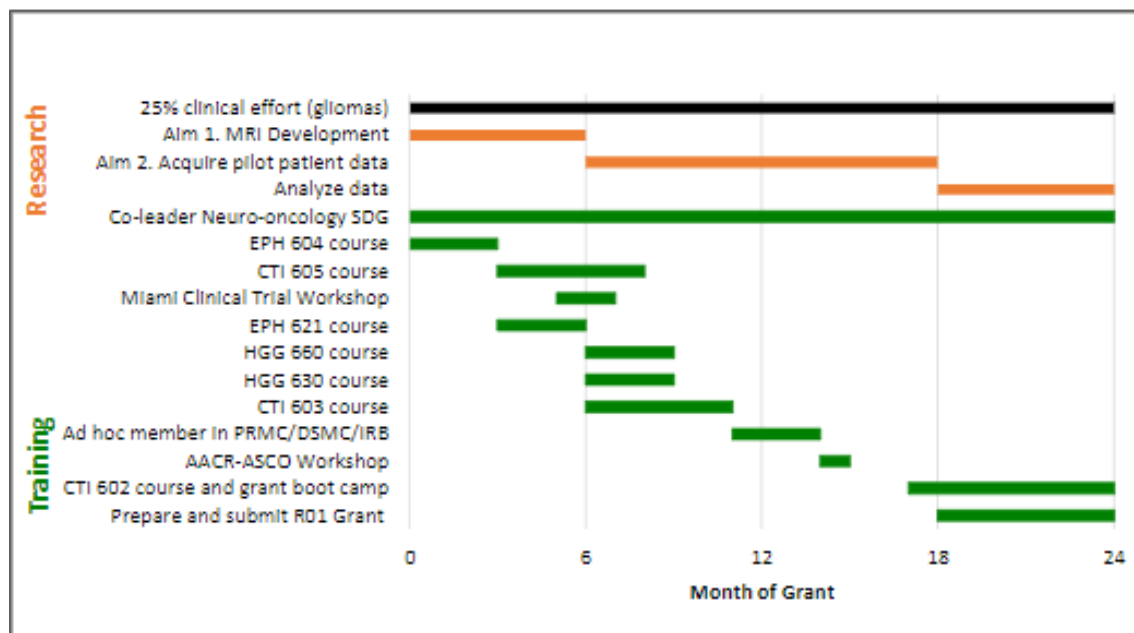
Sample training overview

Training Subject	Training Objectives	Training Mechanisms	Relationship to Research Project
1. Clinical trial design and function	<ul style="list-style-type: none"> Improve understanding of clinical trial design and implementation Properly execute pilot study in aim 2 Design larger and interventional clinical trials 	<ul style="list-style-type: none"> Trial workshops: Miami, AACR-ASCO Ad hoc member IRB/PRMC/DSMB EPH 604 course in clinical trials CTI 603 course in bioethics Conferences such as ASTRO, SNO, ECOG, Alliance, NRG 	<ul style="list-style-type: none"> Aim 2 implementation of pilot study Use of resultant research data to develop next grant and study
2. Broaden scientific knowledge	<ul style="list-style-type: none"> Discover correlates to imaging data such as bioinformatics and molecular findings Build collaborations with other groups for mutual benefit 	<ul style="list-style-type: none"> CTI 605 course in team science EPH 621 course in epidemiology HGG 630 course in variation and disease HGG 660 course in bioinformatics Collaborations in informatics and molecular biomarkers 	<ul style="list-style-type: none"> Rigorous analysis of imaging findings in Aim 2 Identify correlates to imaging for future grants and studies
3. Grant writing and professional development	<ul style="list-style-type: none"> Develop and produce a quality R01 application Presentation of this work and other trial concepts internally and at national meetings Transition to independence 	<ul style="list-style-type: none"> Monthly Scholars Forum Calabresi Annual Symposium UMPIRE junior faculty mentoring program CTI 602 course in grant writing Miami grant writing boot camp 	<ul style="list-style-type: none"> Future directions and application of findings of research in this grant Training for related research concepts in development

Appendix B: project timeline

Create a Gantt chart or other visual representation of your project timeline to include in the Career Development Plan portion of the application. [How to make a Gantt chart in Excel or PowerPoint](#)

Sample project timeline



Appendix C: list of allowed AND not allowed expenditures

Expenditures Allowed

- Research supplies and animal maintenance (including animal per diem charges)
- Per diem charges for patients if part of a clinical study not reimbursable by standard payment terms
- Technical assistance (e.g., lab technician, clinical coordinator, etc.). NOTE: Overload method of payment for technical assistance is not allowable.
- Stipends for graduate students and postdoctoral assistants if their role is to promote and sustain the project presented by the faculty member (please justify in budget justification)
- Domestic travel when necessary to carry out the proposed research program
- Publication costs, including reprints, study instruments, surveys, etc.
- Registration fees at scientific meetings where the results of the research supported by this award are being presented
- Costs of computer time
- Special fees (pathology, photography, etc.)
- **Sylvester K12:** Non-office equipment costing **less than \$5K**. Special justification is required for items exceeding this amount
- **CTSI KL2:** Non-office equipment costing **less than \$2.5K**. Special justification is required for items exceeding this amount

Expenditures NOT Allowed

- Indirect costs
- Foreign travel
- Secretarial/administrative personnel salary support
- Office equipment and supplies
- Computer/equipment maintenance fees
- Purchasing and binding of periodicals and books
- Dues and membership fees in scientific societies
- Honoraria and travel expenses for visiting lecturers
- Recruiting and relocation expenses
- Office and laboratory space
- Non-medical or personnel services to patients
- Construction or building maintenance