

# INSTRUCTIONS

## Mentored Research Career Development Program Award in Clinical and Translational Science (K12)

The goal of the *Mentored Research Career Development Program Award in Clinical and Translational Science (K12) 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.

The 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.

### Table of Contents

Table of Contents .....	1
Award Timeline .....	1
Eligibility Criteria .....	2
Program Support .....	3
Expectations of Awardees .....	3
Resubmissions .....	3
Review of Proposals and Selection Criteria .....	3
Application Requirements .....	4
Letters of Intent (LOI) (One LOI per person) .....	4
Full Application (One application per person and by invitation only) .....	4
1. Project Title .....	4
2. Scientific Abstract (LIMIT 250 words) .....	5
3. Personal Statement (LIMIT 1 page) .....	5
4.1 Research project (LIMIT 4 pages) .....	5
<b>4.2 Health Disparities and Community Engagement</b> .....	5
5. Cited References (no page limit) .....	6
6. Career Development / Educational Plan (LIMIT 2 pages) .....	6
7. Mentoring Plan (LIMIT 2 pages) .....	6
8. Budget and Budget Justification for Research .....	6
9. Biosketch AND Curriculum Vitae - Both are required. ....	6
10. Regulatory Approvals .....	6
11. Letters of Recommendation .....	7
12. Demographics – Investigator Personal Data .....	7
Appendices .....	7
A. Appendix A: Training Overview Example .....	7
B. Appendix B: Project Timeline .....	8
C. Appendix C: list of allowed AND not allowed expenditures .....	8

### Award Timeline

Request for Applications (RFA)	May 1, 2023
Q&A information session for K12 applicants	May 8, 2023, at 5 PM (Zoom invite to follow)
<b>Letters of Intent due</b>	May 24, 2023 (W)
Invitation to submit Full Application	May 31, 2023 (W)
<b>Full Application (by invitation only) due</b>	July 12, 2023 (W)
Notification of awards	August 28, 2023
Beginning of the award period	<b>September 1<sup>st</sup>, 2023</b> (contingent on the CTSI K12 award)

## Eligibility Criteria

All eligibility criteria are subject to verification by the CTSI K12 program administrator.

**All criteria must be met by the application due date (July 12, 2023).**

**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 have a doctoral degree. [\[Definition\]](#)
- You have a full-time faculty appointment at UM, JHS or the VA. JHS or VA investigators are eligible if their primary mentor is a UM faculty.
- You meet the [NIH Early-Stage Investigator \(ESI\) criteria](#): ESI is a Program Director/Principal Investigator who has completed their terminal research degree or end of post-graduate clinical training, whichever is later, within the past 10 years and who has not previously competed successfully as a PD/PI for a substantial NIH independent research award.
- You have never received funding as a Principal Investigator (PI) on any federal individual-mentored career development award (e.g., K07, K08, K22, K23).  
*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 science (refer to [NCATS website](#))
- Your proposed project is NOT a clinical trial beyond Phase IIB.
- Your proposed project has no foreign component.
- This is your first application or your first resubmission to the CTSI K12/KL2 award.

**You are NOT eligible for K12 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 federally-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 K12 Administrator: Patricia Avissar, [PAvissar@med.miami.edu](mailto:PAvissar@med.miami.edu)). You will be asked to provide:

- RFA (link) 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 will complement and expand on current/previous training

## Program Support

**Duration of Award:** 2 years (24 months): 9/1/2023 to 8/31/2025.

**Number of Awards:** Up to four (4) awards.

### Protected Time

**75% protected time** for two years for career development in CTS research.

**50% protected time** for surgical disciplines.

### Funding

- 75% salary support up to the NCATS Scholar Salary Cap (\$120K)
- \$20K annually for research expenses

## Expectations of Awardees

- Scholars are strongly 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. 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](#).
- Scholars are expected to publish papers in high-impact journals and apply for peer-reviewed extramural funding by the end of their award period.
- Scholars are expected to participate in various conferences, seminars, and symposia to develop a thorough scientific and medical knowledge base.
- Scholars must acknowledge the Miami CTSI in any publication, presentation, abstract, chapter, poster, etc. resulting from research and protected time supported by K12 program, or other services provided by the program.
- Scholars will complete an Individual Development Plan (K12) within 30 days of the award start.
- To ensure career development, Scholars will meet with their mentors on a regular and frequent basis and at regular intervals with program leadership (as described in their IDP).
- During the funded period, Scholars will submit progress reports and other reports and documentation as requested. Upon completion of the program, individuals will submit a final report and yearly updates on academic progress.

## Resubmissions

Only **one submission** and **one resubmission in subsequent cycles** 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 review committee. 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/Innovation of the research proposal
  - Scientific merit of the research proposal
  - Clinical translational science relevance
  - 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 and/or clinical trial
  - Use of University of Miami/Sylvester Comprehensive Cancer Center/CTSI shared resources
  - Addresses minority health, health disparities, health equity, underserved populations (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) (One LOI per person)

LOIs are required and used to (1) verify the eligibility of the applicants and their proposals, and (2) select the review committee members.

LOIs are a structured questionnaire, not a standard abstract. They are 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 and UM-format CV

### Full Application (One application per person and by invitation only)

Applicants are required to complete **3 mandatory consultations requirements** by June 28, 2023:

- Biostatistics consultation  
*To schedule an initial consult with the Biostatistics Collaboration and Consulting Core, contact Ms. Maria Jimenez-Rodriguez, B.A., M.A.L.S.; [MJRodriguez@biostat.med.miami.edu](mailto:MJRodriguez@biostat.med.miami.edu)*
- Community consultation
- Budget/administrative consultation  
*To schedule an appointment for community and budget/administrative consultations, contact Ms. [Patricia Avissar](#).*

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 K12 award will enhance your research career
- Statement on how your proposal addresses health disparities (CTSI)

**4.1 Research project (LIMIT 4 pages)**

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

Describe the proposed clinical translational science 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.  
CTSI K12 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 biostatics service from the BCCC.
- **Translational Science Impact:** A description (2-3 paragraphs) of the translational science impact of your research. Utilize [NCATS resources](#) on Translational Science to inform this section.
- The proposed research **must** address minority health, health equity, health disparities, and/or underserved populations. For the LOI submission, applicants are required to describe how their project will address these issues and impact the health of our community.

**4.2 Health Disparities and Community Engagement**

- 4.2.1 Health Disparities** - Provide a lay language abstract summarizing the project and describing how it will improve the health of the community and address health disparities. LIMIT 500 WORDS.
- 4.2.2 DEIA-** Summarize how your proposal will advance Diversity, Equity, Inclusion, and Accessibility (DEIA). LIMIT 300 WORDS.
- 4.2.3 Stakeholder Engagement** - Summarize how relevant stakeholders will be engaged in your project. LIMIT 300 WORDS.
- 4.2.4 Dissemination** - Describe your plans for dissemination beyond scientific presentations and publications. LIMIT 300 WORDS

## 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). Make sure to include:

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

- 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.
- The support will include yearly (1) 75% salary support up to the NCATS Scholar Salary Cap (\$120K); (2) \$20,000 for research expenses. 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
- 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

- **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 K12 term. Also describe plans for continued protected time after the program ends.
- **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 K12 awards are funded by National Center for Advancing Translational Sciences of the National Institutes of Health.

Demographic information is requested for all applicants to internal awards and others receiving support through the Miami CTSI.

Submission of the requested information is required and is not a precondition of award. Applicant responses to this section will remain confidential and will not be displayed to the reviewers.

#### Questions?

Patricia Avissar– CTSI K12 Administrator: [PAvissar@med.miami.edu](mailto:PAvissar@med.miami.edu)

### Appendices

#### A. Appendix A: Training Overview Example

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.

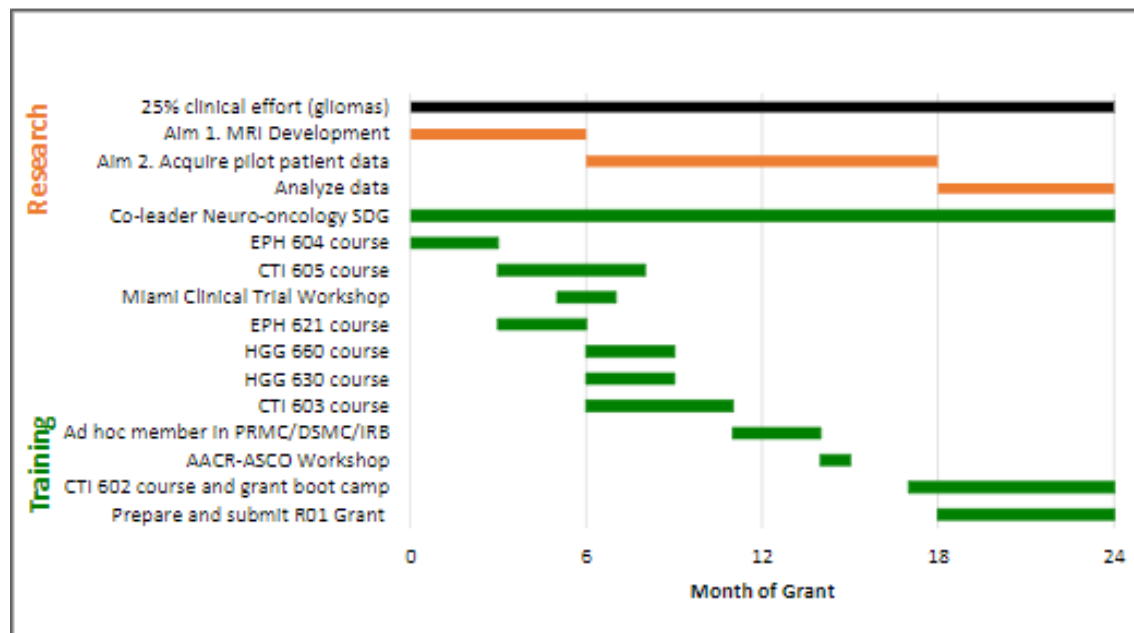
#### Sample training overview

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

**B. 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**



**C. 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.)
- 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 clerical 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