***Request for Applications***

***Paul Calabresi Award for Clinical Oncology Research (PCACOR) Scholars University of Colorado Cancer Center (UCCC) K12 Award***

**Deadline:** July 1, 2022

**Earliest Start Date:** September 1, 2022

**Program Plan and Goals**

The **purpose** of this PCACOR is to prepare highly qualified cancer clinical researchers called Paul Calabresi Clinical Oncology Research Scholars (Scholars) who can independently design, manage and complete cancer clinical trials. Scholars learn to communicate and coordinate with multidisciplinary teams of clinical and basic/behavioral research scientists to test rational hypotheses and manage all phases of cancer clinical trials using state-of-the-art laboratory analyses to personalize cancer treatment. This K12 is led by Madeleine Kane, MD, PhD, Professor of Medicine, Division of Medical Oncology, and Virginia Borges, MD, Professor of Medicine, Division of Medical Oncology.

The **specific objectives** are to:

1) Provide a flexible Individual Development Program for oncology medical doctors and PhD clinicians (nurses, pharmacists, clinical psychologists, epidemiologists, oral surgeons) who have completed their clinical training and basic research scientists who have completed their postdoctoral training and are committed to a translational clinical cancer research career in an academic setting

2) Foster interdisciplinary training, communication and interaction through multiple and multidisciplinary mentoring of Scholars;

3) Create an opportunity for ongoing mentorship to support these junior faculty as they achieve independence

**Eligible Scholars** are clinical oncologists (M.D., D.O., Ph.D. R.N., Pharm. D. or equivalent) who have completed their clinical training, and Ph.D.’s in a scientific discipline who are pursuing translational human-oriented cancer research and who have completed at least two years of postdoctoral training. The level of faculty appointment is determined by UCD-AMC Human Resources policy. Strategies for recruitment of candidates for this PCACOR program (leading into its 18th year of funding) focus on junior faculty in oncology disciplines who have already received appointments at UCD-AMC. Expansion of the program pool to include senior fellows in clinical disciplines as well as basic scientists has permitted expansion of recruitment efforts, but awards are made when Scholars begin their junior faculty status.

Scholars will be recruited from all areas of Oncology (e.g., medical, surgical, pediatric, radiation, gynecologic, epidemiology, as well as other basic and clinical disciplines pursuing translational cancer research). NIH requires that candidates must be U.S. citizens, nationals or permanent resident aliens. The recruitment pool will target junior faculty who are early (within the first five years) in an academic career focused on Clinical Oncology Research. Women and underrepresented minorities are encouraged to apply.

**What the PCACOR K12 award provides:**

- At least two years of mentored support; additional years depending on productivity, need, and available funds, with a maximum of 4 years

- Up to $100,000 salary plus fringe benefits per annum

- $30,000 per annum research and educational costs

- Structured mentoring and defined training program with a primary mentor in the Scholar’s discipline and two or more additional mentors

- Scheduled formal evaluation of progress and feedback from Advisory Committee

**Applications are solicited** once a year or when positions become available as a result of Scholar(s) completion of PCACOR experience. Applicants can apply up to 6 months prior to completion of their clinical training or postdoc. Scholar start date is flexible depending on the timing of the Scholar selection process and the request of the Scholar.

**Application requirements** include completion of clinical training in a residency or clinical fellowship or completion of at least two years of postdoctoral training for basic science candidates. The **application will consist of**: 1) the application face page; 2) curriculum vitae including training history, awards, bibliography, presentations, clinical trials; 3) a detailed personal statement (maximum two pages) demonstrating a commitment to a career in clinical oncology research, personal strengths that will insure success, a discussion of the steps needed to successfully pursue this career, examples of projects and/or the applicant's area of interest, a statement of why the individual should be chosen for the program; 4) previous Research Experience checklist; 5) three letters of reference sent directly to the Paige Diller (paige.diller@cuanschutz.edu), including a letter of commitment from the applicant’s Chair or Division Head. This commitment includes guarantee to grantee of 75% protected time (50% for surgeons) as specified in PAR 18-292.

**Criteria for selection** include: 1) excellence of training and board eligibility; 2) appropriateness of training for a human-oriented oncology research career; 3) evidence of scholarship; 4) clarity of career direction and goals; 5) supportiveness of references; 6) commitment to human-oriented oncology research career; 7) potential for clinical research in oncology success based on research/scholarship activities during training, letters of reference, personal statement, interview. Each application is reviewed in detail by at least three members of the Advisory Committee, and each candidate will be presented and discussed by the Advisory Committee as a whole. Review assignments are made by the Program Leaders. After full Advisory Committee discussion, NIH-style priority scores are assigned by secret ballot, and the scores averaged and ranked. Any Advisory Committee member with a conflict of interest leaves the room during the entire review and discussion of the applicant and does not vote. Applicants are notified in writing of the outcome of the review. Candidates who are not selected as PCACOR Scholars are encouraged to meet with the Program Leader and/or other Advisory Committee members to review their application to discuss how future applications can be strengthened.

**Description of the Program**

Each Individual Development Plan will be defined to address the background, individual interests, needs and career goals for each Scholar. This PCACOR K12 training program will partner with the CCTSI Clinical Science Graduate Program which offers a variety of courses relevant to PCACOR Scholars, and both Masters and Ph.D.’s in Clinical Science. This program provides an integral part of the educational opportunities supported by the CCTSI.

A variety of **required Core Experiences** are part of each Scholar's program as outlined in Table 1 which shows the expected year of training and length of time to be spent on each of the core requirements. Similar experiences are planned for both clinical and basic Scholars, but the time spent and emphasis varies since each Scholar generates an Individual Development Plan similar to that recommended by the National Postdoctoral Association.

**Table 1: *Required Core Activities for Clinician and Basic Scientist Scholars Indicating Expected Time of Completion***

|  |  |  |
| --- | --- | --- |
| **Basic Scholar** | **Required Core Activities** | **Clinical Scholar** |
| Yr 01 | 1. Literature review in area of interest | Yr 01 |
| All | 1. Responsible conduct of research | All |
| All | 1. Clinical experience in discipline | All |
| All | 1. Clinical trials participation | All |
| All | 1. Basic research experience | 24+ months |
| Yr 01-02 | 1. COMIRB membership, training and participation | Yr 01 – 02 |
| Yr 01-02 | 1. UCCC PRMC | Yr 01 – 02 |
| Yr 01 – 02 | 1. Required core courses | Yr 01 – 02 |
| Yr 01 | 1. Presentation of written plan | Yr 01 |
| Yr 01/all | 1. Elective courses | Yr 01 / all |
| Yr 01/all | 1. Research project and presentation of results | Yr 01 / all |
| Yr 02-04 | 1. Clinical cancer trial | Yr 01 / all |
| Yr 02-04 | 1. NIH style grant submission | End of yr 02 or 03 |
| All | 1. O-K Club (Scholars Conference) | All |
| Throughout | 1. Training of students/residents/fellows | Throughout |
| > 2 y | 1. Independence | > 2 y |

Examples of **required and elective Core coursework** for all Scholars are listed below. The didactic course requirements are met by UCD-AMC CCTSI Clinical Science Program (CSP) and the Graduate School. Drs. Kane and Borges work collaboratively with the CCTSI to integrate in a seamless manner for career development of the PCACOR Scholars. Required coursework includes Responsible Conduct of Research, Applied Biostatistics and Clinical Research Methods as a minimum. A formal process for granting substitution for any CSP required course by means of a more advanced course has already been established by the CSP program. Additional courses offered by the Graduate School or other Schools and Colleges at UCD-AMC may be relevant and utilized by some Scholars, especially the basic scientists, if deemed to be desirable and approved by the Advisory Committee.

**Examples of Coursework (or equivalent)**

|  |  |  |
| --- | --- | --- |
| **Course Number** | **Title** | **Credit Hours** |
|  |  |  |
| CLSC 7200 | Clinical Outcomes Assessment | 3 |
| CLSC 7151 | Lectures in Ethics and Regulation in Human Subject Review | 1 |
| (This course will provide an overview of the field of ethics in clinical research. It is designed for investigators who will be conducting research involving human subjects. Participants will learn the historical background, current regulations, and IRB requirements related to human subjects protection issues. Hands-on experiences will be provided to participants to learn how to develop approaches to address conducting ethical human subjects’ research in an optimal manner. In addition, participants will learn the essentials of responsible conduct of research.) | | |
| BIOS 6646 | Survival Analysis | 2 |
| This course covers the analysis of time-to-event data with applications to biology, medicine, and public health. Nonparametric methods for group comparisons and semi-parametric regression models will be emphasized. Parametric methods and distribution theory for survival analysis will also be included.) | | |
| BIOS 6648 | Design of Clinical Trials and Experiments | 2 |
| (This is an introduction to the design and conduct of human intervention trials. Specific topics include: specifying the research question, study endpoints, study populations, study treatments, sample size evaluation, and choice of control groups. Common trial designs and issues in trial) | | |
| BIOS 6649 | Statistical Methods for Clinical Trials | 1 |
| (This course is a companion to BIOS 6648 that focuses on statistical issues in the design and analysis of clinical trials including sample size calculations, trials with repeated measurements, and the statistical aspects of trial monitoring (group sequential designs)). | | |
| CLSC 6260 | Conducting Clinical Trials for Investigators | 2 |
| (This course is designed for investigators involved in the operations of conducting clinical trials. The course will cover good clinical practices and regulations that surround setting up and running clinical trials. Clinical studies and popular press articles highlighting what can go wrong in clinical trials will be reviewed and discussed.) | | |
| CLSC 7101 | Grant Writing I | 1 |
| (This course prepares students to write research grant submissions. Topics covered include writing the various sections of grants: background, specific aims, hypotheses, methods, analysis, potential problem, and the summary. A fully prepared grant submission is required at the end of the course.) | | |
| CLSC 7102 | Grant Writing II | 1 |
| (This course builds on CLSC 7101 and further prepares students for subsequent grant submissions. Strategies for preparation (including hypothesis generation, experimental design, statistical considerations, and potential problems) will be discussed. At the end of the course, a KO8, R23, or equivalent national grant application will be completed for submission. A fully prepared grant submission is required at the end of the course.) | | |

**Examples of Courses for Oncology or Technical Electives**

|  |  |  |
| --- | --- | --- |
| **Course Number** | **Title** | **Credit Hours** |
| EPID 6622 | Cancer Prevention and Control | 2 |
| (Course provides overview of preventable cancers, epidemiology and contributing factors. Phases of cancer control research and appropriate methodologies are discussed. Basic principles of intervention development are reviewed. Psychosocial issues related to cancer are discussed. Students research topics related to course.) | | |
| MED 6626 | Molecular Biology of Cancer | 2 |
|  | | |
| PHSC 7530 | Cancer; Experimental and Medical Aspects | 2 |
| (This is an interactive seminar course on recent topics in cancer biology. Topics include biochemical/morphological description of tumors and tumor behavior, such as metastasis and angiogenesis, and tumor development. This course also covers aspects of carcinogenesis: mechanisms, modulation, testing/epidemiology, chemotherapy.) | | |
| PHSC 7561 | Pharmacology of Anticancer Agents | 2 |
| (This is a course that will examine the principles behind the pharmacological treatment of cancer. Focus will be on the agents currently used in the clinic as well as developing therapies. Mechanistic aspects and therapeutic strategies will be emphasized.) | | |
| MOLB 7617 | Topics in Molecular and Cellular Biology | 2 |
| MOLB 7661 | Molecular Biology Seminar | 1 |
| NURS 6743 | Issues in Terminal Illness and Palliative Care | 2 – 3 |
| NURS 6753 | Current Concepts in Caring for the Cancer Patient and Family | 2 – 3 |
| NURS 6767 | Detection and Education for Cancer Prevention | 3 |
| NURS 6783 | Psychosocial and Cultural Implications in Cancer | 2 |
| NURS 6823 | Management of Chronic Pain | 3 |
| NURS 7320 | Qualitative Research Designs and Methods | Variable |
| NURS 7420 | Quantitative Research Methods | Variable |
| PHCL 7606 | Receptors and Cell Signaling | 4 |
| PHSC 7325 | Pharmaceutical Development: Evaluating External Environment | 2 |
| PHSC 7360 | Signal Transduction | 2 |
| PRMD 6626 | Research methods in Community Health | 3 |
| PRMD 6629 | Clinical Epidemiology Studies | 2 |

**Other Core Didactic Experiences**

**Lectures/Seminars**: Division/Departmental weekly conferences (various times); Multidisciplinary Tumor Boards (weekly); Disease-specific conferences (e.g., lung, breast, head/neck, melanoma, etc.) (weekly or biweekly at various times); Techniques in Molecular Biology (presented July and August at UCD-AMC); Clinical Trials Seminar Series; Health Services Research Seminar Series; UCCC Grand Rounds (weekly) (Appendix 2)

**Journal Clubs** (various times)

**Workshops**: AACR/ASCO Clinical Trials Design (strongly encouraged); NIH Grant Writing Workshop; Informatics; FDA Regulations

**National Meetings** (examples, depending upon discipline): ASCO; AACR; GOG; Society of Surgical Oncology; ONS; RTOG; SWOG; ASCB; ASBMB

**PCACOR Scholars Conference** (OK Club, See below)

**CCTSI K Club** (Nuts and Bolts of Academic Success in Translational Research)

**Essential Communication Skills** are taught and developed through coursework, Scholar participation in the Seminar series, and assistance with preparation of research results for presentation at national meetings and in peer-reviewed publications. The ability to write clear, effective manuscripts and grant applications is critical to a successful academic career. Since participation in scientific meetings and symposia is a critical aspect of PCACOR, travel funds may be used by Scholars. Mentors help the Scholars to select the annual meetings to be attended. Scholars with difficulties writing will be asked to take writing classes offered in the Graduate School or at the Writing Center at the downtown UCD campus. Writing skills are also be cultivated through coursework and practical experience while preparing grant proposals for appropriate funding agencies (NCI, other NIH, ACS, DOD, various cancer foundations). In addition, as Scholars advance, preparation of proposals for review by the CCTSI K to R program, in which draft NIH R-type proposals are formally reviewed by a group of experienced investigators chaired by Margaret Wierman, MD, Professor of Medicine, Division of Endocrinology, is very important. Mentors and the Advisory Committee serve as preliminary reviewers for both manuscript and grant application submissions.

All Scholars are offered the two-hour practical class: “Promotion 101” as taught by SOM Dean’s office in the fall each year, which teaches junior faculty the requirements for promotion.

The CCTSI Colorado Mentor (CO-Mentor) Program is encouraged for the mentee-mentor pairs in which they receive curriculum-based training in how to benefit from and participate in mentorship. The CO-Mentor Program provides essential instruction to faculty members who have mentored others for years, but have not had formal training. Evidence-based strategies are used to teach mentor/mentee pairs the skills they need to get the most out of their mentoring relationships.

**Required Core Clinical Research Experience**

A Core Clinical Experience is required for the clinical Scholars which will consist of 1-2 half day clinics weekly; for surgical oncologists, 1-2 half days of operating room experience related to the Scholar’s program focus will also be required under the supervision of the clinical mentor(s) in the discipline. For R.N., Ph,D,’s, this clinical experience may occur as part of pain management clinics, patient education, cancer prevention screening and/or patient/family support groups. A relevant clinical experience at least one-half day per week for at least six months or monthly throughout PCACOR participation is required for the basic scientist Scholars. During the first phase of clinical cancer research, the Scholars participate in existing clinical trials by enrolling eligible human subjects, treating them and monitoring effects of treatment. The Scholars participate in the Combined Institutional Review Board (COMIRB) as a full member. The Scholar attends the monthly meetings of the UCCC Protocol Review and Monitoring Committee and becomes a member. This committee reviews all cancer protocols involving human subjects for soundness of approach, scientific merit and feasibility.

Another Core requirement is the definition by both clinical and basic Scholars of at least one translational clinical trial. Such clinical studies will be required to have a scientific component as well as a treatment component. A Scholar will be encouraged to develop more than one study. Collaboration between clinician and basic scientist Scholars is facilitated as appropriate to their areas of research interest, and clinical trials developed jointly by a clinician and basic scientist scholar will be strongly encouraged.

**Required Core Basic Research Experience.**

A Core Basic Research Project with potential translational/clinical application will also be required if a clinician Scholar has not spent at least two years doing laboratory research. This project may involve behavioral, epidemiologic, molecular, cellular, genetic or topics from other scientific disciplines as appropriate. Collaboration between clinical and basic scientist Scholars will be encouraged to the extent that research interests complement each other. During the latter years of the Scholar’s Individual Development Program, another Core requirement is that each Scholar write a translational cancer research proposal for submission to NIH or similar agency. Each Scholar supervises and teaches students, residents or trainees as part of their clinical and/or laboratory activities, as well give formal presentations in their developing area of expertise.

**Scholars Conference (OK Club for Oncology K12)**

PCACOR Scholars meet monthly for 60-90 minutes as the ‘OK Club’ to promote collegial interactions, sharing of experiences, presentation of research in progress, brainstorming approaches to human-oriented research, acquisition of familiarity in working in a collaborative setting and pursue Responsible Conduct of Research. The Program Leader and members of the Advisory Committee attend this meeting in rotation, and both Advisory Committee members and Mentors as well as other interested participants attend schedule permitting. The format of these meetings varies to include Scholar research-in-progress presentations, research proposal strategy discussions, tutorials such as psychosocial topics in cancer or biostatistics applications, new basic science information of translational relevance, informal Scholar sharing of experiences, Scholar feedback on effectiveness of various aspects of the program, an occasional outside speaker invited for the PCACOR, especially former Scholars, and Responsible Conduct of Research case discussions.

**Certification, Degree or Other Form of Recognition from this Program.**

Scholars have the opportunity to pursue a formal advanced degree as part of their training program. A Masters or Ph.D. in Clinical Science is available through the CCTSI CSP. An alternative is the Master's of Public Health from the new College of Public Health. These can be integrated into an individual Scholar's career goals if desired. The Scholar would apply separately to the Graduate School. Minimum requirement for a PCACOR Scholar is to obtain a certificate of completion awarded by the UCCC.

***Sample Milestones for Training Program of a Paul Calabresi Scholar (first two years)***

Year 1

1 month: Complete the selection of the mentor committee

1-3 months:

Define components of the individual training program

Develop a proposed time table

3-6 months:

Define a research project and submit a brief research proposal

1-12 months:

PRMC Participation

Prepare Literature Review

Basic research experience for clinician (at least 6 months)

Clinical research experience for basic scientist and clinician Scholars

Scholar symposium Presentation

Abstract submission/Presentation

Seed grant application

Core didactic coursework (Ethics, Trial Design, Biostatistics)

Year 2

1 month: Refine proposed time table with AC and Mentor Committee input

1-12 months:

Core didactic coursework (Statistics, Grant Writing, electives)

Basic research experience for clinician, continued, if appropriate

Clinical research experience

COMIRB participation

Design and initiate a clinical oncology study with translational component

Abstract submission/Presentation

Manuscript Submission

Symposium Presentation

Grant Submission

***Application:***

1) Face page (below)

2) Detailed Curriculum vitae (not Biosketch) including training history, awards, bibliography, presentations, clinical trials, teaching experience

3) A detailed personal statement (maximum two pages) demonstrating a commitment to a career in clinical oncology research, personal strengths that will insure success, a discussion of the steps needed to successfully pursue this career, examples of projects and/or the applicant's area of interest, a statement of why the individual should be chosen for the program

4) Previous Research Experience checklist (see below)

5) Three letters of reference sent directly to Paige Diller (paige.diller@cuanschutz.edu), **including a letter of commitment from the applicant’s Chair or Division Head**

***FACE PAGE***

***Application for Paul Calabresi Award for Clinical Oncology Research Scholars***

***(UCCC K12 Award)***

***2022***

**Date:**

**Applicant Name and Degree(s):**

**Applicant Title (Check one):**

**Assistant Professor:**

**Instructor:**

**Fellow:**

**Clinical:**

**Basic:**

**Years of Fellowship Completed:**

**Board Eligible (if applicable): YES NO N/A**

**Applicant Department/Division:**

**Mentor (if known):**

**Area of Research Interest:**

**Brief Summary of Career Research Goals (1/2 page maximum):**

**Check List for Previous Research Experience**

1. Have you participated in research? Yes: No:

In what setting?

2. Have you evidence of any scholarly activity during previous training? (Talk presentations, clinical case reports, teaching awards, etc.) Yes: No:

3. What type of research and for how long has it been pursued?

Laboratory:

Clinical Treatment Protocol:

Epidemiologic:

Behavioral:

Cancer prevention/Control Protocol:

Other :

4. Have you published any papers? Yes: No:

Examples if not on CV:

5. Have you presented any abstracts? Yes: No:

Examples if not on CV:

6. Have you received any grants? Yes: No:

Examples if not on CV:

7. Do you have any advanced degrees in addition to M.D., D.O. or Ph.D.?

Yes: No:

Which:

Thesis Project (if applicable):

8. What relevant coursework have you completed during your clinical training (Biostatistics, Ethical Conduct of Research, Research Methods, Clinical research, etc.)?

**Instructions for electronic submission:**

Completed applications should be combined into a single PDF and submitted via smartsheets: <https://app.smartsheet.com/b/form/73884a7ba4194185bdac8fe17fa92591>.

**Deadline: Friday, July 1, 2022 - 5:00pm (NO EXCEPTIONS)**

**Earliest Start Date: September 1, 2022**

For more information:

Contact Virginia Borges, MD, Virginia.Borges@cusanchutz.edu) or Paige Diller ([Paige.Diller@cuanschutz.edu](mailto:Paige.Diller@cuanschutz.edu)) with any questions.