Dana Farber/Harvard Cancer Consortium Career Development Program in Clinical Oncology
K12CA087723
APPLICATION INSTRUCTIONS
Deadline: Friday May 1st, 2020

The DF/HCC K12 Internal Advisory Committee is currently seeking applicants for the K12 Paul Calabresi Award for Clinical Oncology, entitled "Dana Farber/Harvard Cancer Consortium Career Development Program in Clinical Oncology." Funding for the Scholar will be available, retroactive to April 1, 2020 for the first appointment period. Senior fellows and junior faculty, within three years of their first appointment, are eligible, provided they do not hold R01 or equivalent funding. The deadline for applications is Friday May 1st, 2020.

Eligibility:

1. All candidates must be U.S. citizens, naturalized citizens, or permanent residents. Individuals on temporary or student visas are not eligible.
2. Candidates must be able to spend a minimum of 75 percent effort conducting research and research career development including courses during the period of the award.
3. Eligible appointees must be physicians (MD or MD/PhD) who have completed subspecialty training in adult or pediatric hematology/oncology or radiation oncology. Junior faculty members (Instructor or Assistant Professor) must be within 3 years of their first faculty appointment.
4. Individuals who may have been or currently are a PI of an NIH R03 or R21 grant or a PHS or non-Federal award that duplicates the provisions of an R03 or R21 grant remain eligible for an NCI K12 appointment.
5. Individuals are NOT eligible:
    - Current or former PI on an NIH individual mentored career development career, e.g., K01, K07, K08, K23 award; an NCI Transition Career Award (K22); the Pathway to Independence (K99/R00) award; or non-PHS equivalents;
    - Current or former PI on NIH research grants (such as R01, Program Project (P01) or Cancer Center (P50) grants or subprojects of such grants); and
    - Current or former PI on peer-reviewed non-NIH research grants over $100,000 in direct costs per year intended for independent faculty investigators.

Selection Process:

The DF/HCC K12 Internal Advisory Committee will review all applications and make a final selection of the K12 awardee in May 2020. Candidates will be chosen for participation in this program based on the following:

1. A record of outstanding scholarship in biomedical research and in related post-graduate work.
2. Training in a clinical subspecialty of cancer medicine, including radiation oncology, medical or pediatric hematology/oncology, and excellence in the practice of his/her specialty.
3. Demonstrated commitment to, and proficiency in cancer research, as evidenced by an initial successful completion of high quality research project(s), and a preliminary record of high quality publication.
4. A proposal for a multi-year research program in translational research that, if successful, will include performance of a prospective clinical trial, and an independent career in clinical investigation
5. A plan for mentorship and formal training in laboratory ("wet" or "dry" lab) and clinical aspects of translational research. The training experience should be designed to enhance the candidate's research capabilities. Mentors will ordinarily include both laboratory and clinical faculty members; however, it will be required that at least one of the mentors have a broad background in clinical trials design and evaluation. The candidate will actively participate in a clinical subspecialty as a basic

component of the research plan. Formal training should include course work in clinical trial design, responsible conduct of research, biostatistics, and regulatory medicine, unless those courses have already been completed as part of the candidate's fellowship or post-graduate training. Additional courses relevant to the candidate's research interests, including hands-on training in laboratory methods and translational research, may be included in the candidate's research plan.

6. Special attention will be given to recruitment of candidates representing diverse background and under-represented groups, including minorities and women.

Application Format:

A formal application is required, which must include the following items in Ariel size 11 (figure legends at a minimum of 9), with 0.5" margins:

1. K12 Application Cover Page (use attached form)
2. NIH biosketch for applicant and mentors (one basic science and one clinical science)
3. A proposal for a multiyear research project in clinical or translational cancer research. This should be organized as follows (maximum length: 5 pages): Introduction, Specific Aims, Background and Rationale, Preliminary Findings, Experimental Plan, Timetable for completion of project and references. References are not included within the 5-page limit.
4. A plan for didactic coursework (maximum length: one page). The plan should timelines for completion of required and optional training (see K12 Scholar Program Requirements).
5. A plan for mentorship (maximum length: one page). Include role and expected contributions of basic and clinical science mentors towards the Scholar's career development and completion of the research project. Describe planned frequency of meetings with each mentor.
6. Attestation of support from both the institution and the proposed mentor(s), in letter format. A total of three letters of recommendation must accompany applications. This includes a letter from the candidate's Chief of Service, in which the institution's commitment to the long-term development of the candidate's career is stated. The Chief's letter must acknowledge that the Scholar will have at least 75% protected time for research and must indicate how this effort will be supported if budgeted funds from the K12 fall short of this threshold. If the candidate is not already in a faculty position, the institution should provide evidence of intent to support promotion of the candidate to faculty status in a clinical oncology department (Radiation Oncology, Medical Hematology/Oncology, or Pediatric Hematology/Oncology).
7. Note: Budget and Justification are not required at the time of application. These will be requested at the time of grant award.

Please do not include copies of IRB protocols or manuscripts referenced. All reference letters must signed and on letterhead. Assemble all documents into a single PDF named "Last Name, First Name.PDF" (EX: Laning, Kelsey.PDF) in the order outlined above and submit by email to Kelsey Laning at klaning@mgh.harvard.edu before 5pm on Friday May 1, 2020.

Bruce Chabner, MD
Timothy Graubert, MD
Program Directors

Dana Farber/Harvard Cancer Consortium Career Development Program in Clinical Oncology
K12CA087723
PROGRAM REQUIREMENTS

Background:
The overall mission of the DF/HCC K12 Program is to identify the most talented trainees in our academic community and prepare them for careers in translational oncology research through didactic and practical experience in clinical investigation that is closely linked to laboratory research (including "wet" and "dry" lab). This K12 Program is designed exclusively for physicians (MD or MD/PhD) who have completed subspecialty clinical training in adult or pediatric hematology/oncology, or radiation oncology. Each scholar must identify a Basic Science Mentor and a Clinical Science Mentor. Additional mentors from any DF/HCC institution, as well as the Broad and Koch Institutes, may be recruited to supply content-specific advice or assistance if their expertise is not well-represented in the core DF/HCC K12 faculty. Each mentoring committee will also include either Dr. Chabner or Dr. Graubert as representatives of Program leadership. Scholars are required to meet weekly with at least one Mentor and monthly with both. In practice, Scholars often interact daily with at least one Mentor.

Required Didactic Training:
All Scholars are required to complete the following training exercises. Typically, this training is completed in the first two years of funding.

1. Program in Clinical Effectiveness (https://www.hsph.harvard.edu/clinical-effectiveness/). The PCE is a fulltime program of lectures and small group activities taught over a 7-8 week period during the summer at HSPH. Classes are taught by HSPH faculty in biostatistics, epidemiology, research ethics, medical informatics, clinical trial design, and other topics. The curriculum is rigorous and requires, on average, 20 hours/week of homework. K12 scholars who have received similar training in the past as part of MA/MS or PhD coursework are exempted from this requirement. Students receive a certificate upon successful completion of the PCE. PCE graduates are eligible to proceed to the Master of Science in Epidemiology Program, which requires an additional year of coursework and thesis. This course satisfies, in part, the NIH-mandated training in Methods for Enhancing Reproducibility.

2. Cancer Translational Research. This is a semester-long course run by Harold Burstein that meets once per week, January through June. The course covers topics relevant to cancer researchers, including regulatory requirements and compliance, biomarkers in clinical research, biostatistics, grantsmanship, conflicts of interest, scientific misconduct, and protocol development. The format includes structured weekly seminars, small group tutorials and didactic sessions. Please contact Dr. Burnstein for details (hal_burstein@dfci.harvard.edu).

3. Responsible Conduct of Research. All awardees must complete the following during their tenure on the K12:
    a. The *University of Miami, Collaborative IRB Training Initiative (CITI),* which is an 8-hour online course on the conduct of research involving human subjects. This is supplemented by institution specific (MGH, BWH, BID) modules on *Responsible Conduct of Research.*

    b. Scholars also attend at least one 4-hour Partners Healthcare seminar on Responsible Conduct of Research, which is offered several times per year and cover topics including: research integrity and data management, mitigating conflicts of interest, and best practices for responsible authorship and publication.

    c. Scholars engaged in animal research are required to complete the IACUC-accredited training program at the institution where they will be performing their laboratory research.

    d. One year of service on the Institutional Review Board of the Dana Farber Cancer Institute, which serves all of DF/HCC, or on one of its four Scientific Review subcommittees. *Responsibilities*

include attendance at all meetings and a review of protocols in regular rotation with permanent committee members.

Additional Didactic Training:
The following are examples of additional local training activities available to Scholars.

1. Pipelines in Oncology. This is a monthly DF/HCC event featuring leaders from the pharmaceutical and biotechnology industry. A one-hour pipeline presentation, describing products and associated trials planned or in progress, is given by industry leaders, followed by 1:1 meetings with trainees and faculty members engaged in relevant pre-clinical and clinical cancer research (morning at MGH, afternoon at DFCI). The intent is to encourage the collaboration between industry and DF/HCC and to provide opportunities for DF/HCC participation or leadership in important new areas of drug development.

2. Molecular Tumor Board. These are well-attended monthly interdisciplinary meetings at MGH and DFCI designed to introduce new locally-developed genomic profiling assays, raise the level of understanding around the interpretation of genomic findings, and incubate ideas for new collaborations on targeted therapy and mechanisms of resistance. The 'Precision Medicine Tumor Board' at the DFCI has adopted a didactic format around specific themes (recent topics include: "Precision Medicine in Pancreatic Cancer", "Personalized Approaches to Immune Therapy"). At the MGH, the 'Molecular and Precision Medicine Tumor Board' begins with a 30 minute didactic presentation (recent topics include: "Actionable Intergenic Fusions in ER+ Breast Cancer", "Biomarkers of Response and Resistance to Immunotherapy in Melanoma"), followed by an hour of 'rapid fire' cases presented by faculty from the Center for Integrated Diagnostics.

3. Translational Oncology 101. This is a 12-hour course taught by MGH faculty comprised of monthly didactic presentations, followed by interactive "chalk-talk" discussions. The course objectives are to provide background insight into basic mechanisms underlying cancer development and approaches to developing and implementing novel therapies. Topics include: cancer genetics, cancer metabolism, immunotherapy, diagnostics, mouse models, and mechanisms of drug sensitivity and resistance.

4. Current Techniques in Molecular Genetics. This annual 12-hour course, offered by the MGH Center for the Study of Inflammatory Bowel Disease, is open to faculty and trainees from any DF/HCC institution. Scholars may benefit from this basic introduction to techniques in genome sequencing and gene editing, unless they have had prior training in these areas.

5. Design and Conduct of Clinical Trials. This is an intensive 13-session course, organized each fall by the MGH Division of Clinical Research, the Division of Infectious Disease, and the Department of Psychiatry. Sessions are included on clinical trial design, protocol development, informed consent, regulatory oversight, and clinical trial management. Participation is open to clinical fellows and junior faculty at all DF/HCC institutions.

6. Regulatory Cancer Medicine. Dr. Chabner designed and coordinated this course, consisting of six onehour case studies, with representatives from industry and the Food and Drug Administration. It covers specific topics in drug approval, regulatory oversight, and responsibilities of the sponsor and PI in clinical trial administration.

7. Focused Workshops. Additional short-term training opportunities are available for scholars at the Broad, MGH, and Longwood Area. Examples include: "Epigenetics: An Introduction and Applications" (1 day, 3 hours); "Introduction to Qualitative Research Design and Methodology" (4 day, 4 hours); "Introduction to Bioinformatics" (2 day, 3 hours); "Budgeting for Industry Sponsored Clinical Trials" (1 day, 2 hours); and many others held on an annual basis.

8. Disease Center Meetings. Each Scholar is required to affiliate with one of 17 DF/HCC research programs and to conduct clinical activities through that program, with their review and approval before submitting protocols to the SRC/IRB.

Additional Career Development Activities (Off site):

1. Methods in Clinical Research Workshop (http://vailworkshop.org/Pages/AboutWorkshop.aspx). Scholars are encouraged to apply for participation in the annual Vail workshop, sponsored by ASCO and AACR. Participation in Year 2 or later is preferred, so that Scholars can take advantage of the daily sessions critiquing their clinical protocols in development.

2. Translational Research in Hematology (http://www.hematology.org/Awards/Career/). Scholars with a focus in hematologic malignancies are encouraged to apply for participation in this year-long program, organized jointly by the American Society of Hematology (ASH) and European Hematology Association (EHA). Participation includes a week-long course on methods in translational research and mentored sessions on protocol development. Follow-up sessions are held at the annual meetings of ASH and EHA.

4. Molecular Biology in Clinical Oncology (http://www.aacr.org/Meetings). This intensive workshop, sponsored by AACR, focuses on the latest developments in molecular biology and is geared towards physician scientists bridging the gap between laboratory and clinical investigation in oncology. Scholars who are predominantly laboratory-based are encouraged to apply.

Annual Retreat:

To enhance cohesiveness of the Program and to encourage interactions between Scholars and Mentors, the Program will host an annual retreat. The retreat will consist of a full day of scientific presentations and discussions, held over a weekend each Fall. The location will alternate annually between facilities available at the MGH and the Longwood campus. All current Scholars, Mentors, Internal Advisory Committee members, and Program Leadership will be invited. All Scholars in years 3-5 of the program will be asked to give short talks on their projects (10 minutes + 5 minutes of discussion). Each year, one member of the External Advisory Committee will be invited to attend and give a lecture on some aspect of mentoring or career development, citing examples from their personal academic careers. A lunch for Scholars and Mentors will provide opportunities for informal networking. The Program Leadership and the External Advisory Committee member will have a separate working lunch to discuss progress, challenges, and program enhancements.

Individualized Career Development Plan:

Each Scholar will work with their mentors to develop a Career Development Plan (CDP) and will obtain approval from the K12 Program Director for proceeding with the plan in the first 6 months of funding. The CDP should be tailored to include the didactic and practical experiences that each Scholar needs to satisfy K12 Program requirements and to emerge as proficient investigators in clinical oncology research. The CDP is a living document that the Scholar should refine annually. An updated CDP must be included with each Scholar's annual progress report. A timeline of typical progression through the K12 program is, as follows:

Years 1 and 2

All Scholars are expected to complete the required didactic training in Year 1 of the Program. They must document completion in their Year 1 progress report, or indicate plans for completion in Year 2. In addition, they will choose to participate in additional on-site didactic training activities that are appropriate to their chosen field of investigation.

A hands-on research component is required for each Scholar. The initial research may be devoted to developing and refining competency in a field directly related to translational medicine. The Scholars will attend all laboratory and group meetings that are a part of the routine schedule for members of the research mentor's group. In addition to the specific focus of their own research project, the Scholars will be oriented to the core laboratories of the DF/HCC and the spectrum of specialized research services available for the support of clinical research at K12 member institutions. If the Scholar's focus is in outcomes research or epidemiology, the initial practical component may be targeted to developing competency in trial design and biostatistics, augmenting the training received in the mandatory PCE coursework.

During the first two years of training, Scholars will initiate the design of a clinical protocol that translates findings from the mentor's laboratory and includes substantial scientific correlates. The correlates may include an imaging or molecular biomarker used to enrich the study population for potential responders, pharmacodynamic markers to demonstrate target engagement, or assays that will interrogate potential mechanisms of response or resistance. Scholars will develop and refine these assays under the direct supervision of the Research Mentor, often with the assistance of other laboratory technical staff. Scholars will work with the Clinical Mentor on clinical trial protocol development, ensuring that the study will address an important question in the field, and that the appropriate patient population is available for accrual. The Clinical Mentor will assist the Scholar in development of the final protocol and consent documents and guide the Scholar through the submission process for regulatory approval and support from industry sponsors, as needed. Scholars will be expected to have submitted their research proposal to the DF/HCC clinical trials system for approval by the disease committee, SRC, and IRB by the end of their second year.

The Scholars will affiliate with one of the 17 disease-based or discipline-based research programs within the DF/HCC. They will attend all regular clinical research meeting for the research program that is aligned with their clinical protocol. All Scholars in Years 1-2 of training will attend the annual K12 retreat.

Years 3-5
The major focus in Years 3-5 is implementation of the Scholar's clinical research protocol. Depending on the phenotype of the Scholar and the nature of the clinical trial, the majority of effort may be on management of the translational trial (i.e., subject accrual, adjudication of responses and toxicity, reporting to regulatory agencies, submission of trial amendments) or on perfecting and completing the laboratory components of their trial. Scholars will continue to attend regular meetings with their laboratory research group and disease center. Scholars may elect to take advantage of additional on-site didactic training opportunities, or apply for participation in off-site programs. Scholars will work with their Clinical, Research, and Biostatistical Mentors to prepare publications and apply for additional funding.

All Scholars in Years 3-5 of training will attend and give an oral presentation at the annual K12 retreat.

Reporting Requirements:
The following materials must be received no later than December 31st after each year of funding.

1. Updated Career Development Plan
2. Current CV in HMS format
3. Scholar Progress Report
4. Scholar Evaluation of Mentor (Basic and Clinical)
5. Mentor Evaluation of Scholar (Basic and Clinical)

Grant Citations:
The K12 grant must be cited if any of the following applies to the peer-reviewed article or work:

1. The publication was completed during your protected time granted by the program
2. Training gained from the program supported the publication
3. Funds or salary support was used to publish the article
4. The publication resulted from work conducted while you were participating in the training program (Note: Manuscripts resulting from work conducted while in the training program, but not published until after the program appointment has ended, still require citation of the grant)

All citations must obtain a PMCID within twelve months of publication per PMCID policy NOT-OD-15-091.If you need assistance obtaining a PMCID, please contact the Program Administrator.

K12CA087723 APPLICATION COVER SHEET
Submission Deadline: Friday May 1st, 2020.

Application Checklist

- ❑ K12 Application Cover sheet
- ❑ NIH biosketches for Applicant and Mentors (Basic, Clinical)
- ❑ Proposal for a multiyear research project (five page maximum, excluding references)
- ❑ Didactic coursework (one page maximum)
- ❑ Plan for mentorship (one page maximum)
- ❑ Three letters of support (Institution, Basic Mentor, Clinical Mentor)

Project Title:

Candidate Name, Degree(s):

Academic Title:

Institution:

Institutional Address:

Phone Number:

Email Address:

	Mentor #1 - Basic	**Mentor #2 - Clinical**
Name, Degree(s):		
Academic Title:		
Institutional Address:		
Phone Number:		
Email Address:		
Admin Name:		
Admin Phone Number:		
Admin Email Address:		