DF/HCC K12CA087723 SCHOLAR 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 (Scholars and Mentors must work at the same DF/HCC institution). 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. Scholars are required to meet at least monthly with each Mentor and at least annually with the Program Director.

Required Didactic Training:

All Scholars are required to complete the following training exercises. Typically, this training is completed in the first year 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 6-7 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. Students receive a certificate upon successful completion of the PCE and credits represent ~1/3 of those required for a Master's degree. 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. K12 scholars who have received similar training in the past as part of MA/MS or PhD coursework are exempted from this requirement.

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, design of clinical trials, biomarkers in clinical research, concepts in biostatistics, conflicts of interest, ethics in clinical research and publishing, and career development. The format includes structured weekly seminars and readings. Please contact Dr. Burstein 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. All Scholars engaged in human subject research must complete the MassGeneral Brigham (MGB) required training (available through Healthstream), including the Clinical Research Bootcamp (2-2.5 hours) and the Good Clinical Practices (1.5 hours) modules.

    b. Scholars must also complete at least 4 hours of additional training annually on Responsible Conduct of Research. Courses are offered live and through Healthstream on a variety of 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.

Additional Didactic Training:
Scholars may choose to participate in additional didactic activities tailored to their individual career plans. The Individualized Career Development Plan (see below) should indicate completed training and plans for future years. Examples of these activities include:

1. **Grant Review and Support Program** (GRASP). A multi-year program that guides junior investigators who have already obtained a career development award (e.g., K12) to understand the rules of engagement and the grant writing process, gain new skills, and to ultimately write competitive grant applications to achieve research independence. GRASP begins with a 3-day orientation workshop that provides participants with advice in grant writing, diversifying their funding portfolio, as well as training in using the resources of the Elements of Grant Writing. Participants will then receive ongoing grant preparation support and guidance from the GRASP team throughout the duration of their career development grant. Information at: https://catalyst.harvard.edu/services/grasp/.

2. **Molecular Tumor Board**s. These are well-attended monthly interdisciplinary meetings at MGH and DFCI designed to introduce 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. **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.

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. **Catalyst Workshops**. The Harvard Catalyst offers a wide variety of training courses relevant to K12 Scholars, including a series of workshops on *Successful Grant Writing Strategies* (https://catalyst.harvard.edu/services/grantwritingstrategies/) and targeted workshops on obtaining funding from NIH, Industry, and Philanthropy. Catalyst also offers a variety of professional development workshops, including *Effectively Communicating Research* (https://catalyst.harvard.edu/services/ecr/) which is a two-day intensive course designed to provide fellows and junior faculty with the skills necessary to express their science clearly to diverse audiences; to prepare abstracts, manuscripts, and posters, and to speak effectively.

Additional Career Development Activities (Off site):
Many Scholars choose to participate in some of the following outside workshops which generally require competitive application.

1. **Methods in Clinical Research Workshop** (http://vailworkshop.org/). 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** (https://www.hematology.org/awards/career-enhancement-and-training/translational-research-training-in-hematology). Scholars with a focus in hematology 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.

3. **Molecular Biology in Clinical Oncology** (https://www.aacr.org/meeting/molecular-biology-in-clinical-oncology-workshop-2023/). 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 wet laboratory-based are encouraged to apply.

Annual Retreat:
To enhance cohesiveness of the Program and to encourage interactions between Scholars and Mentors, the Program hosts an annual retreat. The retreat consists of a half day of scientific presentations and discussions, held each Fall. All current Scholars, Mentors, Internal Advisory Committee members, and Program Leadership are invited. Scholars in year 1 give a poster presentation. Scholars in later years of the program give 10-minute oral presentations on their projects. Each year, one member of the External Advisory Committee (leaders of K12 Programs at peer institutions) is invited to attend and give a lecture on mentoring and career development, citing examples from their personal academic careers.

Scholar Exchange:
Each year, the DF/HCC K12 Program sends 1 Scholar for a full-day visit at another funded K12 site. Generally, Scholars are invited to participate in the exchange during the 2nd or 3rd year of K12 support. During the exchange, the Scholar gives a seminar on their K12 project and meet 1:1 with faculty at the host site.

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 to proceed 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:

Year 1
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 year 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 first 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 will present a poster at the annual K12 retreat.

Years 2-3
The major focus in Years 2-3 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 2-3 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 June 1st after each year of funding.

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

Grant Citation:
The K12 grant (K12CA087723) must be cited in all peer-reviewed articles if any of the following conditions apply:

- Training gained from the program supported the publication
- Funds or salary support was used to publish the article

- 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 NIH policy. If you need assistance obtaining a PMCID, please contact the Program Administrator.