

**SPORE in Myeloid Malignancies
Career Enhancement Program (CEP)
2020 Application Instructions**

A. Deadlines

Application due: May 1, 2020 (by 5:00 pm)
Earliest possible start: Saturday, August 1, 2020

B. Purpose

The goal is recruit and support new independent investigators in the field of translational myeloid malignancy research. A potential human endpoint is required for each project, which is defined by the NIH as one of the following:

1. Early phase clinical trials of new investigational drugs and biologics, experimental procedures, medical devices, or combinations thereof, or
2. Early phase clinical trials of new combinations or new uses of the FDA-approved agents and devices, or
3. Discovery and development of biomarkers, only when measurements are made in human specimens, or directly in human subjects, or
4. IND-directed toxicology studies conducted following a pre-IND meeting with the FDA in which the plan proposed by the investigators is acceptable to the FDA, or
5. Population, behavioral, or psychosocial studies, when these studies address mechanistic aspects of the biology of the disease, or
6. Clinical studies that lead to laboratory studies, which address new clinical hypotheses.

C. Eligibility

Early career faculty (Instructor or Assistant Professor) without R01 or equivalent grant or senior post-doctoral fellows (PhD, MD, or MD-PhD) who have a written commitment from their department chair confirming plan for promotion to faculty position within one year will be eligible. Current or previous K awards are allowed.

D. Amount

Up to two awards of up to \$50,000 (direct cost) will be made for the funding period from August 1, 2020 through July 31, 2021. The grantee is expected to completely utilize the full amount by end of the funding period. All unspent funds at the end of the grant period will be returned.

E. Submission Guidelines

The completed application must be received by the deadline: **5:00 pm on May 1, 2020**. Late or incomplete applications will not be accepted. Combine all sections noted below into one PDF document and submit by email to Dr. Dora Levin JD_Levin@DFCI.HARVARD.EDU. Required application templates are attached to the end of this document.

Complete applications must include the following:

- 1) **Face Page:** Form include below
- 2) **Budget & Justification:** Use continuation page as needed. (See allowable expenditures below)
- 3) **NIH Biosketch:** Please use NIH guidelines; biosketches are required for all key personnel. Must include PMID numbers on publications.
- 4) **NIH Other Support:** Please use NIH guidelines.
- 5) **Career Development Plan** (1-page maximum): Concisely describe how the applicant plans to establish an independent research program, including: 1) plan for didactic training; 2) plan to obtain extramural funding; 3) clinical duties.
- 6) **Research Plan** (5-page maximum, not including citations; All tables and figures are included in the 5-page limit). Provide citations in *Blood* format. *The following headings should be used:*
 - a. **Specific Aims:** State concisely the hypothesis to be tested and the specific aim(s) that will be achieved during the grant period. Completion of the aims should be feasible during the two-year period of the grant.
 - b. **Significance to Myeloid Malignancy Research:** State the relevance of the proposed project to planning, conducting, and facilitating the discovery and development of anti-myeloid malignancy interventions and novel therapeutics. Indicate how the project meets a human endpoint, as defined by the NIH.
 - c. **Background and Preliminary Investigations:** Discuss the pertinent research findings that have been described in the scientific literature and how this proposal will add to these results. Also, discuss any preliminary data you have that is relevant to this proposal.
 - d. **Experimental Design and Methods:** Concisely present the experimental design and the methods to be used to accomplish the specific aims. Also, indicate how the results will be interpreted and how they will lead to future investigations. Well-known methods and standard procedures may be described very briefly or referenced, but novel experimental approaches should be outlined in detail.
 - e. **Potential for Progression to Full Scale Translational Studies:** Discuss plans to move this pilot project into a larger and explicitly translational or clinical research study.
- 7) **Appendix**
 - a. References
 - b. Mentor letters. Each applicant will be required to identify at least one clinical and one basic research mentor at any DF/HCC institution to provide mentoring concerning research design, manuscript preparation, and grant writing.
 - c. Copies of IRB and IACUC approvals, if applicable.
 - d. If applicant is a post-doctoral fellow, a letter of support is required from his/her Department Chair indicating intended promotion to Instructor or Assistant Professor within one year.
 - e. If the project requires a sponsor, consultant or collaborator, this individual should write a letter of support for the application, including an explanation of how any overlap in effort will be reconciled if the project is funded.

Expenditures Allowed:

- Salary and fringe benefits up to a maximum of 50% effort per year for the PI
- Research materials, laboratory supplies, salary/fringe support for technicians, fees for core services
- Tuition reimbursement for coursework taken at DF/HCC institutions
- Travel to one national meeting per year

Expenditures NOT Allowed:

- Secretarial/administrative personnel salary support
- Office equipment and supplies
- Major Equipment
- Computer/equipment maintenance fees
- Indirect institutional costs

F. Terms of the Award

- Up to fifty thousand (50,000) dollars will be provided in the funding period (August 1, 2020 through July 31, 2021). It is expected that the grantee will completely utilize the full amount by the end of the funding period. All unspent funds at the end of the grant period will be returned.
- IRB & IACUC approvals are not required at the time of submission. However, all awards must have appropriate institutional regulatory approvals before funds will be allocated.
- CEP awardees are required to submit an interim progress report, due April 1, 2021, and are expected to present their findings once per year at a SPORE steering committee meeting.
- CEP awardees are expected to apply for extramural funding to continue their research prior to the end of the funding period. The SPORE Biostatistics Core and CEP committee members are available to assist with grant submission.
- Recipients are expected to acknowledge the SPORE in Myeloid Malignancies (P50CA206963) in any publications/presentations that result from the funded work and must be submitted by the investigator to PubMed Central.

G. Review Process

All applications will be reviewed by members of the CEP Review Committee with the statistical review conducted by personnel in the Biostatistics Core (if needed) and scored for merit according to the following criteria:

- Candidate
 - Quality of the candidate's academic and clinical record.
 - Commitment and potential to develop as an independent and productive translational researcher focused on myeloid malignancies.
- Research Plan
 - The degree of relevance of the research plan to developing an independent research program focused on translational myeloid malignancy research.
 - Usefulness of the research plan as a vehicle for enhancing existing research skills as described in the career enhancement plan.
 - Scientific and technical merit of the research question, design and methodology judged in the context of the candidate's previous training and experience.
- Career Enhancement Plan
 - Likelihood that the proposed plan for additional training and concurrent clinical responsibilities is conducive to the applicant's development as an independent investigator.

If you have questions, please contact Dr. Dora Levin JD_Levin@DFCI.HARVARD.EDU.

SPORE in Myeloid Malignancies Career Enhancement Program (CEP)
2020 Request for Applications (RFA) Cover Page

| | | | |
|--|-----------|--|--|
| Title of Project (no more than 81 characters): | | | |
| Project Start Date: | | Project End Date: | |
| Principal Investigator(PI) | | | |
| Name: (Last, First, Middle) | | Degree(s): | |
| Title: | | Mailing Address: | |
| Applicant Organization: | | | |
| Department: | Division: | E-mail Address: | Phone Number: |
| Grant Administrator Contact Name: | | Grant Administrator Phone Number: | |
| | | Grant Administrator E-mail Address: | |
| | | | |
| Clinical Mentor: | | | |
| Basic Science Mentor: | | | |
| HUMAN SUBJECTS RESEARCH | | IRB APPROVAL | PENDING |
| <input type="checkbox"/> No <input type="checkbox"/> Yes | | <input type="checkbox"/> No <input type="checkbox"/> Yes | <input type="checkbox"/> No <input type="checkbox"/> Yes |
| Clinical Trial | | DATE ANTICIPATED | |
| <input type="checkbox"/> No <input type="checkbox"/> Yes | | | |
| VERTEBRATE ANIMALS <input type="checkbox"/> No <input type="checkbox"/> Yes | | IACUC APPROVAL <input type="checkbox"/> No <input type="checkbox"/> Yes PENDING <input type="checkbox"/> No <input type="checkbox"/> Yes | |
| | | Approval Date: Date Anticipated: | |

Eligibility Requirements:

- Early career faculty as of August 1st of the funding year (Instructor or Assistant Professor without RO1 or equivalent grant)
- Trainee within one year of promotion to faculty (Chief letter required)

List Co-Investigators/Collaborators expected to participate in the project.

| Name | Prime Institution | Department/Division |
|------|-------------------|---------------------|
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| SIGNATURE OF PRINCIPAL INVESTIGATOR (electronic signature is acceptable) | DATE |
|---|------|

Program Director/Principal Investigator (Last, First, Middle):

**DETAILED BUDGET FOR INITIAL BUDGET PERIOD
DIRECT COSTS ONLY**

FROM

THROUGH

List PERSONNEL (*Applicant organization only*)
Use Cal, Acad, to Enter Months Devoted to Project
Enter Dollar Amounts Requested (*omit cents*) for Salary Requested and Fringe Benefits

| NAME | ROLE ON PROJECT | Cal. Mnths | Acad. Mnths | INST.BASE SALARY | SALARY REQUESTED | FRINGE BENEFITS | TOTAL |
|------|-----------------|------------|-------------|------------------|------------------|-----------------|-------|
| | PD/PI | | | | | | |
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SUBTOTALS →

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CONSULTANT COSTS

SUPPLIES (*Itemize by category*)

TRAVEL

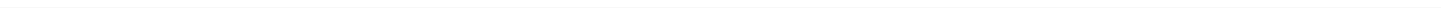
OTHER EXPENSES (*Itemize by category*)

TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD

\$

Program Director/Principal Investigator (Last, First, Middle):

BUDGET JUSTIFICATION



BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

| INSTITUTION AND LOCATION | DEGREE (if applicable) | Completion Date MM/YYYY | FIELD OF STUDY |
|--------------------------|---------------------------|----------------------------|----------------|
| | | | |

Program Director/Principal Investigator (Last, First, Middle):

OTHER SUPPORT (NIH format)



Program Director/Principal Investigator (Last, First, Middle):

CAREER DEVELOPMENT PLAN (1 page maximum)



Program Director/Principal Investigator (Last, First, Middle):

RESEARCH PLAN (5 pages maximum)

