

## CRSP PROGRAM OVERVIEW

### PURPOSE

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The Clinical Research Scholars Program (CRSP) is an intensive mentored research career development program. The objective of the CRSP is to support the development of successful clinical, translational and outcomes researchers among junior faculty affiliated with Seattle Children's. This goal is accomplished through a structured program of mentoring by dedicated CRSP Faculty, educational seminars, and financial support.

The CRSP supports career development in a wide range of research areas, including the mechanisms and treatment of diseases of children, as well as research related to areas such as patient safety and quality improvement.

The program is administered by Program Director Dr. Margaret Rosenfeld; Associate Program Director, Dr. Joseph Flynn; and the Center for Clinical and Translational Research (CCTR) Business Office. The program is being piloted for 2 years in the CCTR with the intention to ultimately become a Seattle Children's Research Institute-wide initiative.

### PROGRAM DETAILS

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#### Paths

The CRSP has two paths, standard and intensive. Both paths are two years in duration. They share a common program of educational seminars and mentoring, but have different expectations of the Scholar, requirements for protected time and financial support.

**Standard Path:** The standard path is designed for Scholars with limited protected time and background in clinical research. A primary objective of the program is to mentor the Scholar in the preparation of a successful application for intramural or pilot project grants.

The standard path requires a minimum of 20% protected research effort. The CCTR provides salary support for 10% effort for two years, not to exceed \$18,000 per year. The Scholar's division/department provides support for the balance of the protected time. In addition, the CCTR awards research support funds up to \$10,000 annually to each Scholar for career or project development. Examples of appropriate uses of the research support funds include tuition for courses, biostatistical or bioinformatics consultation regarding study design, administrative support for grant preparation or publications, and assistance with IRB application preparation.

Scholars are strongly encouraged to apply for pilot funding within their first six months in the program. Potential funding sources include CCTR and ITHS pilot project grants and the Academic Enrichment Fund (AEF).

At the completion of the program, Scholars are expected to have 1) submitted abstracts and at least one manuscript; 2) presented at local or national meetings; 3) have grant funding as a principal investigator on a pilot or internal award or as a co-investigator on an extramural award.

**Intensive Path:** The intensive path is designed for Scholars with substantial protected research time and background in clinical, translational or outcomes research. Applicants must enter the program with a well-defined research proposal.

The intensive pathway requires a minimum of 50% protected research effort. The CCTR will pay up to 25% of the Scholar's salary for two years, not to exceed \$25,000 per year. The Scholar's division/department must provide support for the balance of the protected effort. In addition, the CCTR awards up to \$20,000 annually to each Scholar for tuition and/or pilot funding for a research project.

At the completion of the program, Scholars are expected to have 1) submitted abstracts and manuscripts, 2) presented at national meetings, and 3) to have successfully applied for a K-series or equivalent career development award.

## **Mentoring**

Mentoring is a critical component of CRSP. A Scholarship Oversight Committee (SOC) is established for each Scholar, consisting of the primary and secondary mentors and an additional assigned CRSP faculty member. Each Scholar will meet with their primary and secondary mentor regularly. The primary mentor is identified by the Scholar, and the secondary mentor is assigned from the CRSP faculty. A division faculty member is invited if the primary and secondary mentors are outside of the Scholar's division.

The Scholar will have an SOC meeting within the first month of the award start date. The initial SOC meeting will evaluate the appropriateness of the project's scope, establish a timeline, review the drafted budget submitted in the Scholar's application, and make any adjustments to the project. The Scholar will continue to have SOC meetings semi-annually during the award period so that typically the scholar will complete five SOC meetings during the award period

The primary and secondary mentors are expected to assist the Scholar with development of objectives and a training plan (as applicable), grant writing, project development and implementation. They review all grant applications, presentations and publications. The SOC tracks the Scholar's progress. The Scholar submits a semi-annual progress report, reviewed by the SOC and shared with the division chief/department chair or designee. Clear written guidelines for mentors and Scholars are provided by the CRSP Directors.

## **Educational & Works-In Progress Seminars**

CRSP educational seminars occur every four to six weeks. These seminars address the "nuts and bolts" of clinical, translational and outcomes research at Seattle Children's. Topics include: working with the IRB to create a successful application, grant writing, budget management and oversight, introduction to Pediatric Clinical Research Center and CCTR core services, supervising and managing research staff.

In addition, interactive works-in-progress seminars allow Scholars to present their work to peers and the CRSP faculty for thoughtful critique. Each scholar presents twice annually.

All Scholars are required to attend CRSP seminars and works-in-progress. In addition, these educational offerings will be open and widely advertised to all interested faculty and fellows.

Scholars may also choose to participate in a variety of other research training and career development opportunities, including courses in their research field, the Institute of Translational Health Sciences (ITHS) Clinical Research Boot Camp, seminars and workshops offered by the ITHS education core, the

University of Washington School of Medicine (UWSOM) faculty development series, and the Seattle Children's Hospital Fellows' College.

<b>Comparison of Standard and Intensive Paths</b>		
<b>Details</b>	<b>Standard Path</b>	<b>Intensive Path</b>
<b>Eligibility</b>	<ul style="list-style-type: none"> <li>• Full (primary) CCTR membership</li> <li>• Junior faculty in <b>clinician-educator track*</b></li> <li>• Feasible research idea required</li> </ul>	<ul style="list-style-type: none"> <li>• Full (primary) CCTR membership</li> <li>• Junior faculty, generally in <b>physician-scientist track</b></li> <li>• Well-defined research proposal required</li> </ul>
<b>Required protected time and salary support</b>	Minimum 20% FTE (10% from CCTR, balance from division/department)	Minimum 50% FTE (25% from CCTR, balance from division/department)
<b>Research/career development financial support</b>	Up to \$10,000 annually	Up to \$20,000 annually
<b>Number of new scholars annually</b>	Up to 4	Up to 2
<b>Duration of participation</b>	2 years	2 years
<b>Common components</b>	<ul style="list-style-type: none"> <li>• Educational seminars</li> <li>• Works-in-progress seminars</li> <li>• Mentoring</li> </ul>	<ul style="list-style-type: none"> <li>• Educational seminars</li> <li>• Works-in-progress seminars</li> <li>• Mentoring</li> </ul>
<b>Expectations of scholar at program completion</b>	Investigator on pilot or internal award, or Co-PI on extramural award	K-series or equivalent independent career development award

*\*Faculty in clinician-clinician path may apply only if clear documentation by division chief of expectation and protected time for research*

## **AWARD TERMS AND CONDITIONS**

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1. CRSP awards are intended to support the direct costs of research only. Facilities & Administration costs, indirect costs, overhead, etc. are not allowable costs for CRSP awards.
2. Scholars must be CCTR members and planning to submit future grant applications through CCTR.
3. CRSP awards made for research to be conducted at Seattle Children's and should not be used to hire new research coordinators outside the existing CCTR staff core support. If clinical research staff core support is needed, the Center for Clinical Translational Research staff support core must be used.
4. The award's budget will be finalized within the first three months of the award start date. Funding amounts are subject to change based on finalized project adjustments.
5. It is expected that the research will be conducted within the timeline of and as outlined in the submitted proposal. Funds not expended by the end of the project date will be returned to the CCTR.
6. No-cost extensions require the approval of the CCTR Steering Committee. All requests for a no cost extension should be submitted to the Administrative Contact, as shown above, no less than thirty days prior to the project end date. Only one no-cost extension will be granted and the funds must be expended within 6 months of the no-cost extension approval.
7. The recipient must ensure that, before the research commences and during the full Award Period, all the necessary national and local ethical, legal and regulatory requirements to conduct the research are met, and all the necessary licenses and approvals have been obtained.
8. Where the Terms and Conditions of the Award have not been observed, CCTR reserves the right to withdraw the remainder of the Award.
9. Award recipients are required to submit semi-annual progress reports and abide by the program expectations listed in the award letter. At the conclusion of your project, a final progress report must be submitted to the Administrative Contact within 60 days of award end date.
10. Any publication or presentation of the results of research funded by a CRSP award should acknowledge the support from the Seattle Children's Center for Clinical and Translational Clinical Research Scholars Program.

## **CONTACT INFORMATION**

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