**Clinical Research Scholars Program**

**PROGRAM OVERVIEW**

**PURPOSE**

The Clinical Research Scholars Program (CRSP) is a mentored research career development program for CCTR investigators. The program objective is to support junior faculty in the development of successful clinical, translational and outcomes research at Seattle Children’s. This goal is accomplished through a structured program of mentoring by dedicated CRSP Faculty, educational seminars, and financial support.

CRSP supports career development in a wide range of pediatric 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 proposal must involve human subjects research. *Note: Projects with international components will not be funded at this time. Specifically, research projects involving recruitment of participants, prospective collection of data or transfer of funds abroad are not eligible. Studies using existing data collected abroad are allowed as long as there is no transfer of funds abroad.*

CRSP 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. Amanda Hartman, PhD is the Project Manager and your CCTR GCA is your finance contact.

**PROGRAM DETAILS**

**Paths**

CRSP has two paths, standard and intensive. Both paths are two years in duration, contingent on successful Year 1 completion. They share a common program of educational seminars and mentoring, but have different expectations of the Scholar, requirements for protected time and financial support.

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| **Comparison of Standard and Intensive Paths** |
| **Details** | **Standard Path** | **Intensive Path** |
| **Eligibility** | * Full (primary) CCTR membership
* Junior faculty in **clinician-educator track**
 | * Full (primary) CCTR membership
* Junior faculty, generally in **physician-scientist track**
 |
| **Required protected time and salary support** | Minimum 30% FTE (10% from CCTR and the existing 20% protected time from division/department/SCH) and up to $25,769\*\* salary plus fringe per year, limited to the NIH salary cap  | Minimum 50% FTE (25% from CCTR and 25% match from division/department) and up to $64,424\*\* salary plus fringe per year, limited to the NIH salary cap |
| **Research/career development financial support** | Up to $10,000 annually(e.g. tuition, travel, IRB fees, biostatistics, research coordinator, etc.) | Up to $20,000 annually(e.g. tuition, travel, IRB fees, biostatistics, research coordinator, etc.) |
| **Duration of participation** | 2 years \*Year 2 is contingent on successful Year 1 completion | 2 years \*Year 2 is contingent on successful Year 1 completion |
| **Common components** | * Educational seminars
* Works-in-progress seminars
* Mentoring
 | * Educational seminars
* Works-in-progress seminars
* Mentoring
 |
| **Expectations of scholar at program completion** | Co-PI or PI on an extramural award | K-series, equivalent independent career development award, or extramural award |

\*\*Salaries may be subject to change based on updated 2022 NIH salary cap.

**Mentoring**

Mentoring is a critical component of CRSP. Scholars establish their primary mentors prior to applying to the program. Each Scholar has a Scholarship Oversight Committee (SOC) that convenes at least semi-annually. If the Scholar already has an SOC through the Division, the primary mentor will typically join the existing committee rather than convening a new committee.

Expectations include:

* Initial meeting with CRSP Program Director and Division Chief before start of award period to evaluate the appropriateness of the project’s scope, establish a timeline, review the drafted budget submitted in the Scholar’s application, make any adjustments to the project and discuss SOC membership.
* Regular meetings with primary mentor and with other mentors and advisory statistician as necessary
* Initial SOC meeting within first month of the award start date
* Semi-annual SOC meetings
* One of the CRSP Program Directors will attend each SOC meeting.

**Advisory Statistician**

* Provides scientific oversight and guidance for the statistical aspects of the study
* Assigned at the beginning of the award period
* Typically participates in SOC meetings
* If study team includes a statistician, that individual will assume the responsibilities of the advisory statistician

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

* Attendance is required for all scholars. First-year scholars are required to attend the CRSP ‘Boot Camp’ held each fall.
* CRSP Educational and Works-in-Progress seminars occur every four to six weeks
* Seminars address the “nuts and bolts” of clinical, translational and outcomes research
* Scholars must give an annual works-in-progress. These are meant to be interactive discussions rather than formal presentations
* Scholars must submit an abstract for CCTR’s annual Science Day (typically held in May)

**Progress Reports**

Semi-annual progress reports are required to be submitted by the Scholar prior to each Scholarship Oversight Committee (SOC) meeting and should include the following components:

* Attendance at required educational offerings
* Presentation at works-in-progress
* Participation in courses or other types of training
* Grants in preparation, submitted, and/or received
* IRB protocols in preparation, submitted, and/or approved
* Presentations at local and national meetings
* Manuscripts in preparation, submitted, and/or accepted for publication
* Promotion activities if applicable

**Application Review Process**

Applications will be evaluated by the CRSP Application Review Committee, comprised of members of the CRSP faculty. Prioritization will be based on:

* Likelihood of career development plan to promote applicant’s success in stated research area
* Likelihood of promoting the applicant’s academic status
* Feasibility within a justified budget and allotted time

All applicants will receive a summary of reviews from the review committee.

**CONTACT INFORMATION**

**Margaret Rosenfeld, MD, MPH** **Joseph Flynn****, MD, MS** **Amanda Hartman, PhD, PMP**

CRSP Co-Director CRSP Co- Director CCTR Project Manager

206-987-6547 206-987-2524 206-884-1716

**Jennifer Harry**

CCTR Business Manager

206-884-1318

**KEY DATES**

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| --- | --- |
| RFA Released  | January 14, 2022 |
| Letter of Intent Due | **March 25, 2022** |
| **Biostats Consultation Due** | **April 15, 2022** |
| **Budget Draft Due** | **April 15, 2022** |
| **Full Application Due** | **May 13, 2022** |
| Award Announcement  | By July 1, 2022 |
| Project Initiation Period | **July 1 – Sept 30, 2022** |
| IRB Approved & 1st Mentor Meeting Completed  | **Sept 30, 2022** |
| **Funding Begins**  | **October 1, 2022** |

**APPLICATION DETAILS**

Interested applicants will need to complete a two-part process by submitting a letter of intent and then a final application.

**Letter of Intent (Page 10 of this packet)**

The purpose of the letter of intent is to help CCTR plan for the anticipated number and type of CRSP applications and yield quality finalized CRSP applications that have been fully developed. Letters of intent are due one month prior to the final application deadline. **Final applications will not be accepted unless a letter of intent was submitted by the LOI deadline.** Letters of intent are non-binding (i.e., applicants may choose not to submit a full application.)

**Eligibility Criteria**

* Rank of acting instructor, acting assistant professor or assistant professor\*
* Primary member of the CCTR. Future grant applications must be submitted through CCTR
* Standard path: Seattle Children’s based clinician-educator or clinician-clinician track\*
* Intensive path: Seattle Children’s based junior faculty, generally in physician-scientist track
* Applicant’s Division Chief must guarantee:
	+ Standard: Minimum 30% FTE (10% from CCTR up to $25,769\* salary & fringe maximum set by NIH cap and your existing 20% protected academic time from division/department/SCH)
	+ Intensive: Minimum 50% FTE (25% from CCTR up to $64,424\* salary & fringe maximum set by the NIH cap and your existing 25% protected research time from division/department)

*\*Salaries subject to change based on 2022 NIH salary cap updates*

* A primary mentor must be identified, with willingness to mentor demonstrated in a letter of support.
* The applicant should propose career development in pediatric clinical, translational or outcomes research that includes human subjects research (Research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated).
* CRSP awards are intended to support the direct costs of research at Seattle Children’s. Indirect costs are not allowed. CRSP awards should not be used to fund work occurring at an external institution. This includes staff or employees outside of Seattle Children’s. Subcontracts will not be approved. If the required expertise to complete your project is not offered at Seattle Children’s, this must be discussed with Program Directors and pre-approved by CCTR Business Office before final application submission.
* Projects with International components will not be funded at this time. Specifically, research projects involving recruitment of participants, prospective collection of data, or transfer of funds abroad are not allowed. Studies using existing data collected abroad are allowed so long as there is no transfer of funds abroad.

*\*If not yet appointed as a faculty member, a letter from the division head/department chair should be supplied stating the date of appointment will commence at or before the time that CRSP funding begins.*

**APPLICATION INSTRUCTIONS**

For the funding cycles beyond 2020, note that there have been major updates to the Clinical Research Scholars Program structure, application, and the award terms and conditions. Please read these instructions thoroughly.

1. All required application materials can be downloaded from the [Apply to the CRSP](http://www.seattlechildrens.org/research/clinical-and-translational-research/funding/applying-to-crsp/) webpage.
2. To view an example of a successfully awarded CRSP application, contact the CRSP Program Manager.
3. All applicants must complete a Letter of Intent *prior to submission of their final application* (page 12 of this packet). The Letter of Intent must be submitted as one single PDF to the CRSP Inbox by **5:00pm on March 25, 2022.**
4. Your GCA will provide assistance with the development of your budget and guide you through the internal sign-off process upon receipt of your LOI. Your **draft** budget is due by **April 15, 2022** to prepare for the final submission deadline.
5. Full Application format specifications (Page 13 of this packet):
	1. Font: Arial 11pt regular
	2. Margins: Use at least one-half inch margins on all sides
	3. The application must be single-spaced
	4. Page limit: Follow guidelines for each section (*see Application Checklist*)
6. To assist with navigating the CCTR core services and resources available, applicants can find more information on the [Core Services and Facilities web page](http://www.seattlechildrens.org/research/clinical-and-translational-research/cores/).
7. To request a biostatistics study design consultation, applicants must contact the [Biostatistics, Epidemiology, and Analytics in Research (BEAR) Core](https://child.seattlechildrens.org/research/center_support_services/research_integration_hub/clinical_research_cores/biostatistics_epidemiology_and_analytics_in_research_bear/) **least 4 weeks in advance of the application deadline (no later than April 15, 2022)**.
8. Final application materials must be submitted as **one single** PDF to the CRSP Inbox by **5:00 pm on May 13, 2022.**

Unsuccessful applicants may resubmit their applications for review the following year unless the reviewers determine that the application does not meet the intent of the program. If the application is a resubmission of a previously unfunded CRSP application, please include a cover letter with a description of how the application has been modified in response to the previous review.

**AWARD TERMS AND CONDITIONS**

1. CRSP awards are intended to support the direct costs of research at Seattle Children’s. Indirect costs are not allowed. CRSP awards should not be used to fund work occurring at an external institution and subcontracts will not be approved.
2. As a CCTR member and CRSP scholar, all future grant applications must be submitted through CCTR.
3. CRSP funds will not be available until the funding period commences on October 1, 2020 (start of the award period). Expenses cannot be incurred prior to the effective date of the funding period.
4. CRSP funds should not be used to hire new staff. If research coordinator support is required, CRSP scholars are encouraged to use the [Research Coordinator Core (RCC](https://www.seattlechildrens.org/research/resources/rcc/)).
5. CRSP awards are not allowed to fund capital equipment purchases.
6. The project research plan and budget must be finalized within the three months between the award announcement and the start date through meetings with the Scholar’s mentors, statistical advisor and the CCTR Finance Manager. The IRB application should be approved during this period as well.
7. Before the start of the award period, the recipient and his/her Division Chief must meet with the CRSP Program Director or Associate Director to review the parameters of the protected time required of a CRSP award recipient.
8. Your research must be conducted within the timeline outlined in your submitted proposal. Funds not expended in your budget by the end of each award period will be returned to CCTR.
9. **No-cost extensions and fund carry overs from year to year are not allowed for this program.**
10. The recipient must ensure that, before the research commences and during the full award period, all the necessary national and local ethical, legal and human subjects and regulatory requirements are met to conduct the research, and any necessary licenses and approvals have been obtained.
11. Scholars must submit an abstract for CCTR’s annual Science Day.
12. You are required to inform the CRSP Program Director, CCTR Business Office, and Finance Manager receipt of extramural career development funding (direct salary support, project-related expenses) during your award period. Your CRSP award will be reviewed for budgetary overlap and may be subject to funding reduction.
13. Budget Revisions: If you propose to change a budget line item by 25% or more at any time during the award period, you must contact the Program and Finance Manager first to obtain approval by the CCTR Business Director. If you are proposing adding on or revising a core service, you must notify the related core manager of your proposed change and a new quote will be required.
14. Where the Terms and Conditions of the Award have not been observed, CCTR reserves the right to withdraw the remainder of the Award.
15. **You are required to submit a semi-annual progress report** and abide by the program expectations listed in the award letter. At the conclusion of your project, you are required to submit a **final progress report to the Administrative Contact within 60 days of award end date**.
16. Any publication or presentation of the results of research funded by a CRSP award should acknowledge the support from the *Seattle Children’s Research Institute - Center for Clinical and Translational Research, Clinical Research Scholars Program*.
17. Inform the CRSP Program Manager and your Finance Manager/GCA of upcoming family leave or changes to your family leave if applicable.

**FREQUENTLY ASKED QUESTIONS**

**General Questions**

1. **Does the Div/Dept Letter need to be submitted with the LOI?**

The Div/Dept letter does not need to be submitted with the LOI. You only need to submit the LOI form.

1. **Are fellows eligible for the CRSP award?**

Fellows are eligible contingent on having a faculty appointment that starts before the start date of the CRSP. If not yet appointed as a faculty member at time of application submission, then a letter from the division head/department chair should be supplied stating the date of appointment will commence at or before the time that CRSP funding begins (October 1, 2020). They can be appointed to acting Instructor, acting assistant professor or assistant professor.

1. **Will my full application be accepted if I have not submitted the Letter of Intent by the deadline?**

No, full applications require the submission of an LOI. The LOI is due one month prior to the full application deadline. Final applications will not be accepted unless a letter of intent was submitted. Letters of intent are non-binding (i.e., applicants may choose not to submit a full application). All applicants will be notified within 3 days post-deadline on if they should proceed onward with a full application submission.

1. **Do you have an example of a successful CRSP application?**

Yes, you may contact the CRSP Program Coordinator for a copy of a successful CRSP application.

1. **What happens after I submit my LOI? Will I automatically be eligible to submit a full application?**

Full applications require the submission of an LOI by the LOI deadline to be considered. Once you have submitted your LOI, the CRSP Program Coordinator and Program Director will review your LOI. If there are any concerns with your LOI, they will be addressed within 7 days of receipt or within 3 days post LOI deadline in preparation for your full application submission.

If you choose not to proceed with a full application, please notify the CRSP Program Manager, since the LOIs are non-binding but are used for planning purposes.

**Budget Questions**

1. **What are the FTE requirements for the Standard Path and Intensive Path?**

For the Standard path, 10% funding is from CCTR and the Div/Dept/SCH continues to cover your committed 20% protected academic effort. Together, standard path awardees are committing to 30% FTE for this project.

For the Intensive path, 25% is from CCTR and the Div/Dept matches 25% protected research effort. Together intensive path awardees are committing to 50% FTE for this project.

Both of these paths are subject to the Executive Level II salary cap of $199,300

1. **What are salary and fringe caps for the Standard Path and Intensive Path?**

The amount of funding for salary and fringe is estimated based off the current federal Executive Level II salary cap of $199,300 plus a fringe benefits rate of 24.7%. If your salary is less than $199,300 you may only charge the cost of your salary and fringe at 10% for the Standard Path and 25% for the Intensive Path.

1. **Are subcontracts/subawards from other institutions allowed?**

CRSP awards are intended to support the direct costs of research at Seattle Children’s. Indirect costs are not allowed. CRSP awards should not be used to fund work occurring at an external institution and subaward contracts will not be approved. In some cases, Seattle Children’s may not have the necessary expertise or provide the required service to complete a project. In this case, please contact the CCTR Center Business Manager for further guidance.

1. **I want to take a course or attend a seminar prior to the award project period. Can I get an advance in my budget to pay for these expenses?**

Advances are not allowed for this program. The program only funds activities that take place during the funding period. If your seminar or course occurs before the project start date, then you will have to find alternative sources to fund those activities. You cannot incur expenses prior to the start of the award

1. **Am I allowed to travel to present at a conference or meeting?**

It is allowable only if your travel is related to presenting and promoting your CRSP project. Travel must follow SCRI travel policies. Pre-travel authorization must first be obtained through Concur. Submit pre-travel authorization requests to Program and Finance Manager. It will then need approval by CCTR Business Director and SCRI President before incurring travel expense.

1. **I was awarded the CRSP and need to do a budget revision to my project. How do I do this? Who do I contact?**

If you propose to change a budget line item by 25% or more at any time during the award period, you must first contact the Program and Finance Manager/your GCA so that she can obtain approval by the CCTR Business Director. If you are proposing adding on or revising a core service, you must notify the related core manager of your proposed change.

**Mentor Questions**

1. **Is it a requirement that the primary mentor be faculty at SCH/UW? My mentor for the type of work that I would like to propose is located outside of the SCH/UW system or out of state?**

Generally, CRSP mentors are faculty at SCH/UW. There may be circumstances for which an outside mentor is appropriate. Your mentorship plan will be reviewed during the review of your application.

**Other Questions**

1. **Where should I send letters of recommendation? Do they need to be sent separately or directly from my source?**

You should have your letters of recommendation sent to the CRSP Program Coordinator (crsp@seattlechildrens.org) to be compiled for the final submission of your application packet. Letters can be address to Dr. Margaret Rosenfeld and Dr. Joseph Flynn or the CRSP Review Committee. These letters need to be received before the final application deadline.

1. **Are international projects funded?**

Projects with international components, such as recruitment of participants, prospective collection of data, or transfer of funds abroad will not be funded. Studies using existing data collected abroad are allowed so long as there is no transfer of funds abroad.

1. **I applied last year for CRSP and was not awarded. What is the process to reapply?**

Unsuccessful applicants are encouraged to resubmit their applications for review one additional time unless the reviewers determine that the application does not meet the intent of the program. If the application is a resubmission of a previously unfunded CRSP application, please include a cover letter describing how the application has been modified in response to the previous review.

1. **My CRSP project has led to a publication. How should I reference the CRSP’s financial support?**

Any publication or presentation of the results of research funded by a CRSP award should acknowledge the support from the *Seattle Children’s Research Institute - Center for Clinical and Translational Research, Clinical Research Scholars Program*.

1. **Would CRSP support awardees on their maternity/paternity/family leave?**

We are happy to accommodate our awardees’ maternity/paternity/family leave! If, as a CRSP awardee you are preparing for leave, we would pause your CRSP award for that duration.

Additionally, please discuss the duration of your leave with your GCA and the CCTR project manager prior to taking it.

Per our business office and NIH guidelines, standard leave is defined as 3 months. If the duration of your leave deviates from this time, please make sure to reflect this in your documentation and clearly discuss this timeline with your GCA. If your duration of leave exceeds 3 months, the center business office may need to re-process your award.

**Letter of Intent Template – Limit to 2 pages – Deadline March 25, 2022**

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| **CRSP LETTER OF INTENT**  |
| Applicant Information |
| **Name:** |       | Phone: |       |
| **Email:** |       | **Mailstop:** |       |
| **Academic Rank:** |       |
| **Department/Division:**  |  |
| **CCTR Member** | YES  |
| **Proposed CRSP Path** | [ ]  Standard [ ]  Intensive |
| **Is this an international project?** | [ ]  NO [ ]  YES – STOP HERE – International projects are not being funded at this time.\*See specific details in RFA. |
| **Have you completed a BEAR consultation?** | [ ]  YES, Project Number:       [ ]  NO |
| **Has your application been reviewed by the IRB?** | [ ]  YES, when? [ ]  NO |
|  |

|  |
| --- |
| Title of Project |
|       |
| Project Overview (2-3 paragraphs) |
| * Give an overview of the objective and activities involved.
* Highlight why your approach is significant. How will this project and program specifically benefit your career development?
 |
| [ ]  I acknowledge that no-cost extensions and fund carry overs are not allowed for this program. |
| *By signing and submitting this application, the applicant and the applicant’s institutions agree that they have read and understand the Research Scholar Program Terms and Conditions and that, if the project is funded, it will be conducted in accordance with those terms and conditions, as well as any applicable institutional policies and/or government regulations.* |
| **Applicant Signature:** *Electronic signature is acceptable* |  | Date:  |

**\*\*All applicants will be notified by Wednesday, April1st on whether your application would advance to a full submission by the final deadline of Friday, May 13th. We advise continuing to work on your full application unless you hear otherwise.**