



Application Requirements and Guidelines for the Francis S. Collins Scholars Program in Neurofibromatosis Clinical and Translational Research Sponsored by the Neurofibromatosis Therapeutic Acceleration Program (NTAP) of Johns Hopkins University

The Francis S. Collins Scholars Program in Neurofibromatosis Clinical and Translational Research is designed to build a community of exceptional clinician scientists who will lead Neurofibromatosis Type 1 (NF1) research and clinical care. “Collins Scholars” receive essential support and resources that enable them to focus their efforts on improving treatment options and outcomes for people with NF1.

All applications, review processes, and post-award management are done through ProposalCentral. Please follow the ProposalCentral directions for each section (1-13). Please complete each as thoroughly as possible. Visit the following link to begin applying: <https://proposalcentral.com/GrantOpportunities.asp?GMID=229>

The deadline for this application is **December 9, 2022 by 11:59p.m. EST**. Additional details addressing frequently asked questions are presented in Addendum 1. Please read these instructions carefully before preparing and submitting your application and contact Rhonda Jackson, rjacks13@jhu.edu, if you have any questions. For general inquiries about NTAP, please email info@n-tap.org. For technical support in ProposalCentral, please email pcsupport@altum.com or call 1-800-875-2562.

A checklist of all items required for a complete application is included for your convenience in Addendum 2. The fully completed application and ALL supporting materials (including letters of support and signature pages) must be received by December 9, 2022 by 11:59p.m. EST. Applicants will be notified of award status by January 13, 2023. The FCSs tenure starts July 1, 2023.

ELIGIBILITY REQUIREMENTS

1. Hold a health-professional degree that permits patient care with a commitment to including patient care in your career plan.
2. Commit a minimum of 75% and up to 100% of professional effort to the program for a minimum of two years and a maximum of three years.
3. Be in the last stages of post-doctoral training or a junior faculty member within seven years of the first faculty appointment.
4. Have a commitment to patient focused research in the field of Neurofibromatosis type 1 (NF1). A redirection in focus from non-NF1 research to NF1-focused research is welcomed, but must be highlighted by the candidate and mentors.
5. Demonstrate prior research commitment and accomplishments.
6. Have a mentorship team that includes research, clinical, and career mentorship (these roles can be filled by up to four people) with expressed commitment to the candidate's training, expertise in the research skill set required for the work proposed in the application, and in the clinical management of NF1.
7. Have the appropriate access to resources to complete the clinical and research work proposed in the application.
8. Agree to meet all of the requirements of the Francis S. Collins Scholars (FCS) Program in Neurofibromatosis Clinical and Translational Research, including participation in all required Collins Scholars meetings and activities, and reporting.
9. Applications are encouraged from people around the world from all disciplines of medicine, and science (including bioinformatics, data mining, and artificial intelligence), as long as all of the above criteria are met.

APPLICATION COMPONENTS

Forms to be completed on ProposalCentral:

Title Page

Applicant Demographics

Letters of Support

Budget Period Detail

Budget Summary:

The personnel cost for the applicant's salary support (the percent support to include salary within the NIH salary cap and using the fringe rate for your institution) should be detailed for each year of requested funding. The FCS program supports a minimum of 75% and a maximum of 100% FTE.

A detailed budget for the anticipated research costs (not to exceed \$20,000/year) for each year requested must also be provided. A detailed budget is NOT required for the travel costs (not to exceed \$10,000/year) or educational costs (not to exceed \$10,000/year) in the budget section since these are cost reimbursable.

Organization Assurances

Validate

Signature Page

Submit

Documents to be uploaded as PDF or Word document attachments to the application workspace on ProposalCentral:

Please note that all attachments should be formatted as Arial size 12-point font. Margins should be ≥ 0.75 " on all sides.

I. PROFESSIONAL HISTORY (1 page maximum)

Provide information about your prior research and clinical training experiences beyond what is evident in the biosketch. Describe your past scientific experience, indicating how the FCS program fits into your past and future research career development. Please highlight the themes that have guided your previous work and how they have led to your current career status and future career goals. If your work is changing direction to focus on NF1, explain the reasons for the change. It is important to justify how this award will help you develop into a leader in the field of NF1 for both research and clinical care as well as help you achieve your overall career goals.

II. CAREER DEVELOPMENT PLAN (4 page maximum)

The career development plan should address how the planned activities (clinical care, research, program building, mentorship, education) of the two or three year period of the FCS award will support one another and fit together to support your development as a leader in the field of NF1. Include how you plan to extend these activities beyond the time of the FCS award to ensure ongoing success in NF1 research. This should include plans for future research, program building, and clinical care for people with NF1, as well as plans to secure additional support for such efforts during and after the period of the FCS award. Please emphasize the new, enhanced research skills and knowledge you will acquire as a result of being a Collins Scholar. Describe the structured activities such as coursework, internships, externships, workshops and other formal learning experiences that will be incorporated into your career development plan. It is important that you discuss what you will do differently if you are a Collins Scholar compared to your training without the award,

specifically in relation to the field of NF1 research. You must include a description of how you will meet the NIH requirements for instruction in the responsible conduct of research (<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html>).

Finally, you must include a detailed timeline that incorporates all elements of the career development plan (including but not limited to specific educational goals, enhancing clinical training in NF1, research skill development, regional, national and international program development, networking, speaking, writing, education and mentorship, etc.). The career plan should include plans to apply for additional grant support for your research and subsequent grant support to continue your NF1 focused clinical translational research at the conclusion of the FCS award. A table or graph is often helpful in conveying core aspects of the timeline for the elements of the career development plan.

In preparing the career development plan, please recall that the goal of the FCS program is to support people prepared to dedicate their time to perform groundbreaking work that will alter the field of NF1 and who are positioned to serve as leaders in the NF1 field. This should be reflected in the comprehensive career development plan.

III. RESEARCH PROJECT DESCRIPTION (10 page maximum, references are not included in the 10-page limit).

- A. **Title**
- B. **Technical Abstract:** Describe your proposed research project in 250 words or less.
- C. **Lay Abstract:** Describe the proposed research project for a lay audience in 250 words. Using plain language, emphasize what the proposed work would mean for a person with NF1.
- D. **Research Plan:**
 1. Hypotheses and Specific Aims of the research project.
 2. Significance of the problem(s) to be addressed and how the project will improve scientific knowledge and/or change the NF1 field.
 3. Preliminary Findings that help demonstrate feasibility. Highlight results that are specifically a result of the candidate's research and efforts as well as those of the mentorship team.
 4. Approach. Describe the strategy, methodology, and analyses to be used to accomplish the specific aims of the project, noting details about the proposed scientific methods including accuracy and reproducibility and a justification of how the work is clinical or translational.

Provide statistical justification for sample sizes and include statistical analysis plans appropriate to the work proposed.

Discuss potential problems and challenges to the successful completion of the research and propose alternative strategies to address challenges that will arise.

For projects with vertebrate animals and/or human subjects, please include details for addressing the variable of sex, as part of the research plan. Please consider the following:

If little is known about sex differences, the proposal should include both sexes. Sufficient numbers should be provided to inform the presence or absence of sex differences (or justification must be made for why this is not feasible or scientifically relevant) and findings should be reported separately by sex in future progress reports and publications

If sex differences are known not to exist, a justification should be provided if the project proposes to study just one sex.

If sex differences are known, experiments should be designed with appropriate group sizes to detect sex differences.

Specifically note the role the research mentor(s) will play in the execution of the research.

5. Milestones and deliverables. Create succinct, but appropriately detailed deliverables for each proposed aim with an associated timeline for expected completion of each deliverable. Please note that awarded FCS proposals follow a detailed schedule of milestones and deliverables throughout the course of the award. The milestones and deliverables proposed in the application will likely not be the final form used in any award, however, should be constructed to reflect a possible schedule. Further, please note that a condition of NTAP funding is that investigators upload all key data generated via their award into their designated Synapse Neurofibromatosis Open Science Initiative (NF-OSI) project space as soon as possible after data generation. This includes any information necessary to interpret the data, such as a description of the cohort or the model system, experimental protocols, descriptions of study instruments and equipment, and code used to generate processed data. This data will be embargoed from the public during the award period and for eighteen months after the end date of the award—or sooner, at the data contributors' discretion. Data

will be made publicly available to the broader research community through the Synapse platform, and displayed on the [NF Data Portal](#) at the completion of this time period and with the data contributor's consent. If there are any restrictions on openly sharing the data, the FCS grantees must specify those in writing to NTAP before receiving the FCS award.

6. Innovation. Explain how the project challenges current practice or creates a new approach to a problem within NF1 and why it has potential to improve outcomes for people with NF1.

IV. NIH FORMATTED BIOSKETCHES

- A. Applicant
- B. Lead Mentor
- C. All other members of your mentorship team or key personnel
- D. Formatting instructions can be found here:

<https://grants.nih.gov/grants/forms/biosketch.htm>

V. MENTORSHIP PLAN (3 page maximum)

- A. The mentorship plan should cover the two or three year period of the award with discussion of the role of **each** of the mentors during and after the period of this award.
 1. Research mentorship – discuss which of your mentors will serve as your lead research mentor, why they are suited for this role and their specific responsibilities and duties for completion of the research project as well as supporting each of the goals of the career development plan. Multiple research mentors are permitted. In this instance, the role of each mentor must be explained and one mentor must be identified as the lead mentor.
 2. Clinical mentorship – discuss which of your mentors will serve as your clinical mentor to support you in becoming an expert in NF1 clinical management and why they are suited for this role. (The research and clinical mentorship can be performed by one person if this is justified).
- B. The mentorship team must consist of a minimum of two members including a lead scientific mentor and a clinical mentor. Additional mentors are permitted if their role is defined and many FCS find it helpful to have a dedicated career development mentor. The lead mentor must be the scientific research mentor for the proposed project. This person must be a faculty member (or equivalent) expert in the candidate's area

of research. This mentor will guide the development and execution of the research proposal as well as play a key role in the development and execution of the career development plan. This person can be at the home institution or any other institution as long as the mentor choice is well justified and plan for mentorship interactions are well articulated including details for scheduled meetings and supervision by the lead mentor.

1. The lead/scientific mentor is responsible for:
 - a) Guiding the design and execution of an original, high quality, clinical or translational research project
 - b) Supervising the preparation and submission of research manuscripts and progress reports
 - c) Guiding and supervising the execution of the career development plan
 - d) Guiding and supporting the FCS in identifying opportunities to present their work and apply for additional support.
 - e) Ensuring that the mentorship committee meets a minimum of every 6 months (by video conference or in person), and coordinating with the Collins Scholar to provide minutes from these meetings to NTAP.
 - f) Attending NTAP sponsored events, including a mentor training program and the FCS Program in Neurofibromatosis Clinical and Translational Research annual meeting. The lead mentor must agree in his/her letter that they will meet these requirements.

2. The additional two or more members of the mentorship team should be identified and their specific roles and responsibilities relative to the career development, clinical care, education, program building and research goals should be stated.

The additional mentors are expected to provide expertise in the scientific area of research chosen for the project (complementary to the interests of the lead mentor), clinical practice expertise within NF1 or address specific aspects of career development. It is advisable that one mentor be within your discipline, one be outside of your discipline, and that at least one mentor be focused on your career development trajectory. A minimum of one mentor must have expertise in the clinical practice of caring for patients with NF1. This person can be at the home institution or any other institution as long as the mentor choice is well justified and a specific plan is provided for the logistics of meeting with this mentor.

3. You must provide the details of how the mentorship team will work together including their respective roles in designing and securing

the success of the research project, securing opportunities for your training in specific areas, oversight of your career development plan and ensuring that you successfully meet the requirements of the FCS Program in Neurofibromatosis Clinical and Translational Research. Please include specific details about how you will communicate with each mentor and how the mentors will communicate with each other to achieve all of the goals of the *Collins Scholar*. It is often helpful to add the mentorship meetings and interactions to your detailed timeline.

VI. BUDGET JUSTIFICATION (3 page maximum)

As detailed above, the personnel cost for the applicant's salary support (the percent support to include salary within the NIH salary cap, using the fringe rate from your institution) should be detailed for each year of requested funding. The FCS program can support between 75-100% FTE for the FCS. A detailed budget for the anticipated research costs (not to exceed \$20,000/year) for each year requested must also be provided. In contrast, a detailed budget is not required for the travel costs (not to exceed \$10,000/year) or educational costs (not to exceed \$10,000/year) in the budget section since these are cost reimbursable, but all of these items should be addressed in the budget justification.

The budget justification is a narrative of planned spending by the FCS that must be uploaded to ProposalCentral. This should include a detailed plan for each category of spending. For personnel this includes explanation/justification for the FTE requested for the FCS for each year of the award and justification for a two versus three year award period. The personnel description should expressly state the time the FCS will have available for FCS expected activities and how that time is guaranteed. Budget justification for research expenses (\$20,000 per year) should include anticipated research related costs and address any areas of leveraged support. Justification for education and travel (\$10,000 per year for each category) expenses should include anticipated coursework, specialty seminars, travel to expert centers, travel to professional meetings, investigator meetings, program building meetings for the regional center, etc. No justification is required for the mentor stipend (\$10,000/year).

Please describe what additional funds outside of the FCS program are available and will be applied to support any element of the work proposed. Applicants must provide details of current or expected support outside of the FCS program and describe areas of overlap and non-overlap. Please note the FCS are encouraged to apply for additional awards that support their research, program building, or clinical care in NF1 (but overlap must be justified). If successful in obtaining additional funding, they may re-purpose their awarded FCS funds for other uses for their NF1 efforts over a longer time course.

VII. SIGNATURE PAGES

- A. Applicant (Please click “Print Application” to review your application as a PDF. If no changes, please type your name in the “Applicant/PI” to certify and click sign in ProposalCentral in Section 12)
- B. Authorized official for the University. Please complete the name, email address, and role of authorized official in Section 6 in ProposalCentral. When you complete the section, the authorized official will receive an auto-generated email with information about your application and a direct link to access to the fillable form to be uploaded as a PDF or Word document.

Please access this section to select and share the form with your authorized representative early in the process of completing the application.

VIII. LETTERS OF SUPPORT

- A. **A minimum of three letters of support are required.** Please enter the name, email address, and role of mentor in Section 6 in ProposalCentral. When you complete the section, the mentor will receive an auto-generated email with information about your application and a direct link to upload the letter. When a letter is successfully submitted, you will receive an email confirmation.

These letters should be addressed to:

The Francis S. Collins Review Committee and be uploaded as a PDF or Word document by **December 9, 2022, 11:59p.m. EST**. These letters each have a specific area of focus (please see below); however, *all* letters should comment on the potential for the candidate to be a leader in clinical translational research in NF1, why they are excellent candidates for the FCS Program in Neurofibromatosis Clinical and Translational Research, and why being a Collins Scholar will secure their successful career in clinical translational science in NF1.

- B. **Mentor Letters**

Lead/scientific mentor

This letter should highlight why the mentor is suited to serve as the lead mentor for the candidate’s project. The letter should also include a statement about the mentor’s commitment to providing career development and counseling; guiding and encouraging the design and execution of an original, high quality, clinical or translational research project; supervising the preparation of reports to NTAP and for publication; and collaborating with the mentorship team to support the Collins Scholar in all aspects of the FCS program activities. The mentor should also agree to meet the requirements of the FCS Program in Neurofibromatosis Clinical and Translational Research including attending the required Collins Scholars education day and virtual science calls.

Clinical Mentor

This letter should highlight the clinical expertise in NF1 that the mentor has, how they will work for the FCS to support their development into an expert in NF1 clinical care, how they will introduce the FCS to clinical initiatives regionally, nationally and internationally and how they will work with the rest of the mentorship team to support not only the clinical goals but also the research, education, program building and career development goals.

Department Chairperson or Director

A letter from the department chairperson should detail the plan for the dedication of a minimum of 75% and a maximum of 100% of professional time to the FCS program for the duration of the award as well as what the candidate's expected activities outside of the FCS Program in Neurofibromatosis Clinical and Translational Research are likely to entail. This 75-100% effort may be divided across clinical, research, program building, educational, research, and career development activities as long as they are focused on NF1. It should also include discussion about the role of the candidate in the department, the departmental and institutional commitment to the candidate during and after the completion of the award including plans for faculty promotion in the short and long term. It should also discuss the department's position on the applicant's focus on NF1 research and clinical care, and the resources available to the candidate to further clinical translational science and program development in NF1 at the institution. This letter should be independent of any other mentor letter.

Additional letters of support may be submitted at the candidate's discretion. These letters should detail the role the mentor will play in the candidate's research project, NF1 clinical training, and career development, and specifically discuss how the mentorship team will be coordinated to ensure the candidate is performing optimally across all of the domains of the Collins Scholarship (education, clinical expertise, scientific expertise, leadership development).

Addendum 1: Additional Details of the FCS Program Requirements and Application Process

1. The award requires a minimum of 75% and a maximum of 100% effort for the FCS scholar focused on NF1 associated work (clinical, research, education, program building, participation in active mentorship).
2. The period of the award is a minimum of two years and a maximum of three years. Time commitment and the duration of the award must be well justified (see budget justification, IX).
3. In addition to salary support for the Collins Scholar (based on NIH cap) the following funds are available:
 - A total of \$10,000/year is provided as a mentor stipend
 - Up to a total of \$20,000/year is provided to support research costs
 - Up to a total of \$10,000/year is provided to support travel
 - Up to a total of \$10,000/year is provide to support education expenses.

These costs are all cost reimbursable based on milestone report and invoices submitted.

4. A maximum of 10% indirect costs are permitted. No indirect costs are permitted on patient care associated costs.
5. Milestone reports explaining progress (or limitations and requested changes) in research, clinical, educational, and career development activities will be required at six-month intervals. Each report will be structured using a template provided by NTAP, and consist of a detailed narrative, organized according to the deliverable tasks for the milestone period. Milestone payments are directly linked to the completion of milestone deliverable tasks. Prior FCS have shared that the process of creating and reporting with a detailed and consistent structure has improved the quality and efficiency of their work as a FCS. For example, it has enabled additional grant applications and ensured their projects proceeded successfully to completion, thereby directly supporting the successful career development of the FCS.
6. Several meeting opportunities are created for the Collins Scholars to meet the program mission of building community and advancing career development for clinical translational science in NF1. All efforts are made to maximize the value of these meetings by minimizing inconvenience and maximizing content. These meetings are required and include:
 - a. An annual scientific meeting of the Collins Scholars and mentors hosted by NTAP in or near Bethesda, Maryland. The day-long meeting consists of lectures from key opinion leaders from science and medicine on a chosen topic, short lectures from each of the Collins Scholars, recognition of new and completing scholars, and remarks

from Dr. Francis Collins when feasible.

- b. An annual academic meeting within their specialty
 - c. Semi-annual virtual laboratory meetings. NTAP will organize and oversee a 'virtual' laboratory meeting amongst ALL of the Collins Scholars and mentors, during which time two of the scholars who are in at least the 2nd year of the program will present their research findings to the entire group for discussion. The Collins Scholar and at least one member of their membership team are required to participate.
 - d. Quarterly NF Education/Mentorship program administered by Dr. Vic Riccardi. This will entail participation in a group call with Dr. Riccardi in which Dr. Riccardi will lead a discussion around a specific topic of interest that is germane to NF1. Topics are provided beforehand, and scholars are encouraged to suggest discussion topics from the list (or new ones) for the calls. Scholars are also given the opportunity for individual calls to review project progress and receive feedback about topics in NF1 clinical care and research as well as their specific projects.
7. The FCS Program in Neurofibromatosis Clinical and Translational Research is administered by the Neurofibromatosis Therapeutic Acceleration Program (NTAP) of Johns Hopkins University, Department of Neurology. All applications will undergo peer review by at least three reviewers orchestrated by NTAP. This is not a federally or institutionally sponsored award.
8. All applications will undergo initial review by NTAP staff and if the application is complete, it will be forwarded to a review panel for detailed review. Reviewers are senior medical and scientific leaders recruited across disciplines pertinent to NF1 research that have expertise in clinical or translational science. Some reviewers will also have expertise in NF1. Reviewers are instructed to evaluate each application for:

The strength of the applicants' research history including research training to date, evidence of commitment to clinical or translational research, publications and other demonstrations of scientific contributions as well as overall accomplishments to date.

The strength of the career development plan including clearly delineated plans to acquire critical research and clinical skills, structured activities that serve the career and project goals, plans for becoming an expert and leader in NF1, and a clear vision of the career trajectory in NF1 research and clinical care after completion of the FCS program.

The strength of the research proposal including feasibility, innovation, potential impact for patients with NF1, and ability to recognize and address problems that may arise.

The strength and applicability of the mentorship plan, the commitment of the mentors to the applicant and their FCS responsibilities, and the details

for mentorship interactions and responsibilities.

Appropriateness of budget and budget justification including complementary awards and support.

Applicants will be notified if they have been advanced for consideration of funding after completion of peer review. The applications advanced for consideration will be notified by January 13, 2023. The FCS tenure will start July 1, 2023.

Please note, applicants advanced for consideration of funding may be asked to address comments and revise their proposal based on the reviewers' comments prior to submitting a final project plan, scope of work, deliverables, timeline, and budget that will comprise the final project award. Such revisions occur as part of a constructive, collaborative process between NTAP leadership, the reviewer team and the applicant and their team.

9. Please note that a condition of NTAP funding is that funded investigators upload all key data generated via their award into their designated Synapse Neurofibromatosis Open Science Initiative (NF-OSI) project space as soon as possible after data generation. This includes any information necessary to interpret the data, such as a description of the cohort or the model system, experimental protocols, descriptions of study instruments and equipment, and code used to generate processed data. This data will be embargoed from the public during the award period and for eighteen months after the end date of the award—or sooner, at the data contributors' discretion. Data will be made publicly available to the broader research community through the Synapse platform, and displayed on the [NF Data Portal](#). If there are any restrictions on openly sharing the data, the FCS grantees must specify those in writing to NTAP before receiving the FCS award.
10. NTAP has a goal of appointing one to two scholars per year, however, only the most exceptional candidates will be awarded a position within the FCS Scholar Program in Neurofibromatosis Clinical and Translational Research. It is possible that greater or than less than one or two awards will be given in some years. All applicants will receive detailed reviewer comments regardless of the award decision. Applicants who are not selected are encouraged to re-apply the following year addressing the reviewer critiques (assuming that they still fulfill eligibility requirements).

Addendum 2: Application Checklist

Applicant Section (Complete in ProposalCentral)

Professional background history (page 2, upload as an attachment in ProposalCentral)

Career development plan including detailed timeline for the period of the reward (4 page maximum, upload as an attachment in ProposalCentral)

Research project description (10 page maximum, upload as an attachment in ProposalCentral)

NIH formatted biosketches (upload as a PDF in ProposalCentral)

- Applicant
- Mentorship team members

Mentorship plan (3 page maximum, upload as an attachment in ProposalCentral)

Budget and budget justification (3 page maximum, upload as an attachment in ProposalCentral)

Signature pages

Applicant (Please click “Print Application” to review your application as a PDF. If no changes, please type your name in the “Applicant/PI” to certify and click sign ProposalCentral in Section 12)

Authorized official for the University (Please complete the name, email address, and role of authorized official in Section 6 in ProposalCentral. When you complete the section, the authorized official will receive an auto-generated email with information about your application and a direct link to access to the fillable form to be uploaded as a PDF or Word document).

A minimum of three letters of support are required. Please complete the name, email address, and role of mentor in Section 6 in ProposalCentral.

Required letters are:

- Lead research mentor
- Clinical mentor
- Department chairperson
- Additional letters at your discretion

When you complete the section, each letter writer will receive an auto-generated email with information about your application and a direct link to upload the letter. When a letter is successfully submitted, you will receive an email confirmation. Applicant should follow up with each mentor or click on the button under “Actions” to send a reminder email to the mentor.

These letters should be addressed to:

The Francis S. Collins Review Committee and be uploaded as a PDF or Word document to ProposalCentral by **December 9, 2022, 11:59p.m. EST**. Although each letter will have a specific area of focus all letters should comment on the potential for the candidate to be a leader in clinical translational research in NF1, why they are excellent candidates for the FCS Program in Neurofibromatosis Clinical and Translational Research, and why being a Collins Scholar will secure their successful career in clinical translational science in NF1.

Please complete all sections of the application and submit requested documents as PDFs uploaded through ProposalCentral (<https://proposalcentral.com/GrantOpportunities.asp?GMID=229>). All materials must be received by **11:59p.m. EST on December 9, 2022**.

Please contact **Rhonda Jackson**, rjacks13@jhu.edu, for any questions or concerns. Applicants will receive confirmation upon receipt in ProposalCentral. Award notification will be by January 13, 2023 for a July 1, 2023 start of the period of performance.