



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

Please read these instructions carefully before preparing and submitting your application. Please contact **Sharad Verma, sverma20@jhmi.edu**, if you have any questions.

All application materials (with the exception of letters of support and the video clip) must be completed and submitted as a single PDF to info@n-tap.org with the subject line "Candidate Name Last,First-FCS-application- documents". The video clip should be submitted to the same address with the subject line as "Candidate Name Last,First-FCS-application-video". Letters of support should be submitted directly by the author to info@n-tap.org with the subject line "Candidate name Last,First-LOS-Mentor name Last, First". A checklist is included for your convenience (Addendum 2). The fully completed application and ALL supporting materials (including letters of support, video clip and signature pages) must be received by **March 15, 2019 by 5:00p.m. EST**. Applicants will be notified of award by April 30, 2019. The FCSs tenure starts in July 2019.

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 explained 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 three 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.
9. Applications are encouraged from people around the world from all disciplines of science and medicine as long as all of the above criteria are met.

APPLICATION COMPONENTS

Please include a header with the candidate name “Last, First” as well as page numbers throughout sections I-VIII.

I. COVER SHEET WITH DEMOGRAPHICS

- A. Name
- B. Address
- C. Current position
- D. Current affiliation and department
- E. Mail address
- F. Email address
- G. Phone

II. PROFESSIONAL HISTORY (1 page maximum)

Written background: 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 award fits into your past and future research career development. Please highlight the themes that have guided your previous work. If your work is changing direction to focus on NF1, explain the reasons for the change. It is important to justify the award and how it will help you **develop into a leader in the field of NF1** research as well as help you achieve your overall career goals.

Personal introduction and mission statement video: Please provide a video clip (up to 2 minutes) in which you discuss your clinical and research focus, the rationale for training in NF1 clinical translational research, why you have the potential to be a leader in the NF1 research field, and how you will use the time and resources of the FCS Program in Neurofibromatosis Clinical and Translational Research to accomplish these goals.

III. CAREER DEVELOPMENT PLAN (4 page maximum)

The career development plan should address how the planned activities 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. Mention should be made of how you plan to extend these activities beyond the time of the award to ensure ongoing success in NF1 research. 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, 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, program development, networking, speaking, writing, education and mentorship skills, 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 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.

IV. **RESEARCH PROJECT DESCRIPTION** (10 page maximum)

For the Project Description, please use Arial size 12 point font. Margins should be 1" on all sides, 10 page limit. 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 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.
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 patients with NF1.

V. **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:

<http://www.grants.nih.gov/grants/funding/2590/biosketchsample.pdf>

A template biosketch form can be found here:

<http://grants.nih.gov/grants/funding/phs398/biosketch.pdf>

VI. **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 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.

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 three members including: a lead mentor and up to three additional mentors. 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) 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.
- e) Attending NTAP sponsored events, including a mentor training program and the FCS Program in Neurofibromatosis Clinical and Translational Research annual meeting. Lead mentors must agree in their letter that they will meet these requirements (see section IX).

2. The additional two (and up to three) members of the mentorship team should be identified and their specific roles and responsibilities relative to the career development and research goals should be stated.

The additional mentors complete the mentorship team and are expected to provide expertise in the scientific area of research chosen for the project (complementary to the interests of the lead mentor) or 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 (see section III).

VII. BUDGET AND BUDGET JUSTIFICATION

A detailed budget addressing the personnel cost (within NIH cap) for the applicant’s salary support (the percent salary support and the duration of support) as well as the anticipated research costs (not to exceed \$20,000/year), travel costs (not to exceed \$10,000/year) and educational costs (not to exceed \$10,000/year) per year must be included. Please include a detailed budget justification for each category of spending (personnel, research, travel and education). No justification is required for the mentor stipend (\$10,000/year). Please also describe what additional funds outside of the FCS program will be used to support the research program. Applicants must provide details of current or expected support outside of the FCS program and describe areas of overlap and non-overlap.

VIII. SIGNATURE PAGES (Addendum 3)

- A. Applicant
- B. Authorized official for the University

IX. LETTERS OF SUPPORT

- A. A minimum of three letters of support are required. These should be addressed to:

The Francis S. Collins Review Committee and be emailed in PDF format by March 15, 2019 5pm EST to info@n-tap.org with the subject line “Candidate name Last,First.LOS.Letter Writer Name Last, First”. 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. 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 a required orientation session for mentors and attendance of the annual meeting (see section VI B).

- C. A second mentor of your mentorship team.

This letter 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).

- D. 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. 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 position as appropriate. 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.

- E. Additional letters of support may be submitted at the candidate's discretion.

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 program.
2. The period of the award is a minimum of 2 years and a maximum of 3 years. Time commitment and 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.**All costs must be justified and supporting invoices submitted (see budget justification, IX).**
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 and career development activities will be required at six-month intervals. Each report will consist of a detailed narrative, organized according to the deliverable tasks for the milestone period. Please note: milestone payments are directly linked to the completion of milestone deliverable tasks.
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 orientation meeting that will review the requirements of the FCS program as well as topics such as the state of the field for NF1, specific requirements in clinical translational science training, and an overview of the end to end process for drug discovery and medicines development with exposure to experts in the pharmaceutical industry and regulatory agencies.
 - (b) an annual scientific meeting of the *Collins Scholars* (often scheduled with the annual Children's Tumor Foundation CoNFerence)
 - (c) an annual academic meeting within their specialty
 - (d) 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. Emphasis should be placed on focused presentations which highlight interesting observations and/or recent challenges that will inspire discussion amongst the group. Presentations will follow a template to be provided by NTAP, should be no more than 20 minutes in duration, and should be made available to NTAP at least 2 days before the meeting, for dissemination to the group. The *Collins Scholar* and at least one member of their membership team are required to participate.
 - (e) 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 with Dr. Riccardi to review project progress and receive feedback from Dr. Riccardi about topics in NF1 clinical care and research as well as their specific projects.

10. 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 (see point 10, below). This is not an NIH sponsored award and the NIH is not involved in the selection process or administration of the program.
11. 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:
 - a. 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.
 - b. 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.
 - c. 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.
 - d. 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.
 - e. 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 April 30, 2019. The FCS tenure will start July 2019.

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.

12. NTAP has a goal of appointing two scholars each year, however, only the most exceptional candidates will be awarded a position within the FCS Scholars Program in Neurofibromatosis Clinical and Translational Research. It is possible that greater or than less than 2 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

- Cover sheet with demographics (page 1)
- Professional background history (page 2)
- Personal introduction and mission statement video (max 2 min)
- Career development plan including detailed timeline for the period of the reward (4 page maximum)
- Research project description (10 page maximum)
- NIH formatted biosketches
 - Applicant
 - Mentorship team members
- Mentorship plan (3 page maximum)
- Budget and budget justification (including competing and complementary funding)
- Signature pages
- At least three letters of support to be submitted via email to info@n-tap.org from your:
 - Lead mentor
 - Another member of your mentorship team
 - Department chairperson
 - Additional letters at your discretion

Please complete all sections of the application saved as a single PDF (except for the video and letters of recommendation) and load to an email addressed to info@n-tap.org with the subject line: "Candidate Name Last,First.FCS.application". Please send the video clip as a separate email to info@n-tap.org with the subject line:"Candidate Name Last,First.FCS.video". Please have all letters of recommendation sent by their authors to info@n-tap.org with the subject: "Candidate Last,First.LOS.Mentor Last,First". All materials must be received by **5pm EST on March 15, 2019**. Please contact **Sharad Verma, sverma20@jhmi.edu or Rhonda Jackson, rjacks13@jhu.edu**, for any questions or concerns. Applicants will be notified when completed applications are received. Award notification will be by April 30, 2019.

Applicant:

I certify that the statements herein are true and complete to the best of my knowledge and that I will comply with all applicable NTAP terms and conditions governing my potential appointment. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

Applicant's signature:

Date: _____

Authorized official for the University or Institute

This individual is qualified for this program and will receive immediate priority for clinic coverage (if applicable), all requirements for protected time, and all financial needs according to the program announcement. As an authorized official of

I, _____, agree to grant _____ the required _____% dedicated time to NF1 related clinical care and research as required by the Francis S. Collins Scholars Program in Neurofibromatosis Clinical and Translational Research and agree that the University or Institute will support the individual's salary, benefits, and research support as provided through the Francis S. Collins Scholars Program in Neurofibromatosis Clinical and Translational Research starting _____ without overlap, for the length of the award if the individual is named a *Collins Scholar*.

Signature of university authorized official:

Title

Date: _____