

# Application Requirements 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 **Marigo Stathis, mstathi1@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 <u>info@n-tap.org</u> with the subject line "Last,First-FCS-application-documents". The video clip should be submitted to the same address with the subject line as "Last,First-FCS-application-video". Letters of support should be submitted directly by the author to <u>info@n-tap.org</u> with the subject line "Candidate name Last,First-LOS-Mentor name Last, First". A checklist is included for your convenience (Addendum 1). The fully completed application and ALL supporting materials (including letters of support, video clip and signature pages) must be received by **April 4, 2016 by 5:00p.m. EST.** 

#### **ELIGIBILITY REQUIREMENTS**

- 1. Hold a health-professional degree that permits patient care.
- 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 commitment to the candidate's training, expertise in the research skill set proposed in the application and in the clinical management of NF1.
- 7. 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.

#### **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 (page 1)

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

## II. **PROFESSIONAL HISTORY** (page 2)

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 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 cover the two or three year period of the award and discuss how this plan will be extended to ensure ongoing success in NF1 research beyond the time of the award. Stress 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 wil 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 (<u>http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html</u>).

Finally, you must include a **detailed timeline** that incorporates all elements of the career development plan (education, clinical training in NF1, research skill development, program development, networking and speaking, 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.

Recall that the goal of this funding 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.

# IV. RESEARCH PROJECT DESCRIPTION (10 page maximum)

For the Project Description, please use Arial size 12 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 and its significance for improving outcomes for patients with NF1 for a lay audience in 250 words or less.

# D. Research Plan:

- 1. <u>Hypotheses and Specific Aims</u> of the project.
- 2. <u>Significance</u> of the problem(s) to be addressed and how the project will improve scientific knowledge and/or change the NF1 field
- 3. <u>Preliminary Findings</u> that help demonstrate feasibility. Highlight results that are a result of the candidate's research and efforts specifically.
- 4. <u>Approach</u>. Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project, noting in particular how it is clinical or translational.
  - a) Specifically note the role the research mentor will play in the execution of the research.
  - b) Discuss potential problems and challenges to the successful completion of the research and propose alternative strategies to address challenges that will arise.
  - c) Provide statistical justification for sample sizes and include statistical analysis plans appropriate to the work proposed.
- 5. <u>Milestones and deliverables.</u> Create specific and finite deliverables for each of the aims and an associated timeline for expected completion.
- 6. <u>Innovation.</u> 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: <u>http://www.grants.nih.gov/grants/funding/2590/biosketchsample.pdf</u> A template biosketch form can be found here: <u>http://grants.nih.gov/grants/funding/phs398/biosketch.pdf</u>

# 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 the 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(s) and why they are suited for this role.
  - 2. Clinical mentorship discuss which of your mentors will serve as your clinical mentor 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 at least three members: a lead mentor and two other mentors. The lead mentor must be the scientific research mentor for the proposed project. This person must be a faculty member expert in the candidate's area of clinical or translational research. This mentor will guide the development and execution of the research proposal as well as play a key role in the development of your career development plan. This person can be at the home institution or any other institution as long as the mentor choice is well justified.

Your lead/scientific mentor is responsible for:

- 1. Guiding and encouraging the design and execution of an original, high quality, clinical or translational research project
- 2. Supervising the preparation and submission of research and progress reports
- 3. Guiding and supervising the execution of the career development plan
- 4. Coordinating other members of the mentorship team
- 5. Attending NTAP sponsored events, including a mentor training program and the FCS Program in Neurofibromatosis Clinical and Translational Research annual meeting.
- C. At least two, and up to three, additional members of the mentorship team should be identified.
  - 1. 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) as well as clinical practice within the field of NF1 mentorship and career development within NF1 mentorship. 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.

2. 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 the 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 may be helpful to add the mentorship interactions to your detailed timeline (see section III).

### VII. SIGNATURE PAGES (Addendum 2)

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

#### VIII. BUDGET AND BUDGET JUSTIFICATION

A. A detailed budget addressing the personnel cost 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. Please also describe what additional funds outside of the FCS program will be used to support the research program.

#### IX. LETTERS OF SUPPORT

A. Three letters of support are required. These should be addressed to Dr. Jaishri Blakeley and emailed in PDF format by April 4, 2016 5pm EST toinfo@n-tap.orgwith the subject line "Candidate name Last, First.LOS.Mentor 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; and collaborating with the mentorship team to support the Collins Scholar. The mentor should also agree to meet the requirements of the FCS Program in Neurofibromatosis Clinical and Translational Research including 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

The 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 the candidate's 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 be. It should also include discussion about the role of the candidate in the department, the department's commitment to the candidate during and after the completion of the award and their focus on NF1 research and the resources available to the candidate to further clinical translational science and program development in NF1.

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

#### **ADDITIONAL INFORMATION**

The applicants advanced for consideration of the FCS Program in Neurofibromatosis Clinical and Translational Research will be notified in May 2015. The position will start July 2015.

- The award requires a minimum of 75% and a maximum of 100% effort for the FCS. 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).
- In addition to salary support for the *Collins Scholar*, 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 and up to a total of \$10,000/year is provide to support education expenses. All costs must be justified (see budget justification, IX).
- 3. A maximum of 10% indirect costs are permitted. No indirect costs are permitted on patient care associated costs.
- 4. Scholars must attend an annual meeting of the *Collins Scholars*, the annual Children's Tumor Foundation CoNFerence and an annual academic meeting within their specialty.
- 5. Scholars and mentors will attend an orientation that will review the specific requirements for clinical translational science training, including didactic course work, exposure to pharmaceutical industry, and regulatory agencies pertinent to their research focus, as well as the additional training and reporting requirements specific to the Francis S. Collins Scholars Program in Neurofibromatosis Clinical and Translational Research.
- 6. Brief progress reports outlining progress in research, clinical and career development activities will be required at six-month intervals.
- 7. Scholars and mentors are required to participate in virtual laboratory meetings at least quarterly.
- 8. 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 orchestrated by NTAP. This is not an NIH sponsored award and NIH is not involved in the selection process or administration of the program.
- 9. 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 accomplishments
- 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, plan for becoming an expert and leader in NF1, and a clear vision of the career trajectory after completion of the FCS program
- c. the strength of the research proposal including feasibility, innovation, potential impact on patients with NF1, ability to recognize and address problems that may arise
- d. the strength of the mentorship plan and the commitment of the mentors to the applicant and their FCS responsibilities

After initial review, applicants will be notified if they have been advanced for consideration of funding. Applicants advanced for consideration of funding may be asked to address comments and revise to proposal based on the review prior to submitting a final project plan, scope of work, deliverables timeline and budget. Such revisions occur as part of a constructive, collaborative process between the reviewer team and the applicant and their team.

10. 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 no awards will be given in some years. All applicants will receive reviewer comments. Applicants who are not selected are encouraged to re-apply the following year (assuming that they still fulfill eligibility requirements).

## Addendum 1: Checklist

- □ Cover sheet with demographics (page 1)
- □ Professional history (page 2)
- Personal introduction and mission statement video
- Career development plan including detailed timeline for the period of the reward (4 page maximum)
- □ Research project description (10 page maximum)
- NIH formatted biosketches
- □ Mentorship plan (3 page maximum)
- Budget and budget justification
- □ Signature pages

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 make sure that you have completed 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: "Last,First.FCS.application". Please send the video clip as a separate email to info@n-tap.org with the subject line:"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 April 4, 2016**. Please contact **Marigo Stathis, mstathi1@jhmi.edu**, for any questions or concerns.

## Addendum 2: Signature pages

#### a. 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: \_\_\_\_\_

## b. Authorized official for the University

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 this individual 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 will support the individual's salary, benefits, and research support as provided through the Francis S. Collins Scholars Program in Neurofibromatosis Clinical Research starting July 1, 2015, without overlap, for the length of the award if the individual is named a *Collins Scholar*.

Signature of university authorized official:

Date: \_\_\_\_\_