

## Pfizer-NCBiotech Distinguished Postdoctoral Fellowship in Gene Therapy Application Guidelines & Instructions (UPDATED 6-7-18)

### REVISIONS:

- 1) New deadline for submission of application (page 1).
- 2) The restriction has been removed requiring completion of Ph.D. within three years prior to submission (page 2).

### Application Essentials

**Revision:** The deadline to submit applications to the Pfizer-NCBiotech Distinguished Postdoctoral Fellowship in Gene Therapy (Pfizer-GTF) program for fiscal year 2018-2019 is:

**NOON, Wednesday, July 18, 2018**

Award decisions will be announced for the FY2018-2019 Pfizer-GTF cycle in mid- September 2018.

Funds will be available beginning November 1, 2018. Fellows must be in place by January 11, 2019.

**IMPORTANT - New for the FY2019 Application Cycle:** The Faculty Mentor must be registered in the NCBiotech Funding Portal in order to submit a GTF proposal. See Step 5, page 8. Instructions will be posted by March 1, 2018 at [www.ncbiotech.org/pfizer-fellowships](http://www.ncbiotech.org/pfizer-fellowships).

### Program Details

#### Purpose

North Carolina is a leading hub for gene therapy research. The North Carolina Biotechnology Center (NCBiotech) and Pfizer, Inc. have partnered to create a program intended to expand North Carolina's gene therapy research and development capabilities and to grow the scientific workforce trained in gene therapy disciplines.

The Pfizer-NCBiotech Distinguished Postdoctoral Fellowship in Gene Therapy (Pfizer-GTF) program provides scientific and professional development training to exceptional postdoctoral fellows interested in establishing research careers related to gene therapy. Competitive awards support two-year fellowships that enable early-career scientists to conduct gene therapy research at North Carolina universities.

Fellowship awardees will conduct research in a Faculty Mentor's laboratory that will:

- Develop adeno-associated virus (AAV)-based gene therapy platforms or address challenges (*e.g.*, immunogenicity) associated with the use of these platforms;

#### **and/or**

- Develop AAV gene therapy-enabling technologies/methodologies, such as gene editing, vector delivery, or gene therapy product manufacturing;

#### **and/or**

- Explore novel applications of AAV-based gene therapies, such as target validation and preliminary testing of AAV constructs in monogenic/rare disease models.

### Program Features

Pfizer-GTF awards support Fellow salary, benefits, project expenses, meeting travel, and professional development for the duration of the two-year appointment.

Professional development is a distinguishing feature of this program. Fellows will be required to participate in training modules coordinated by NCBiotech on topics including FDA regulations related to biological therapies, project management skills, leadership and supervisory development, scalable manufacturing of gene therapy products,

and intellectual property. Fellows will also have opportunities to engage with other Pfizer-NCBiotech Distinguished Fellows, as well as with the broader technology development and entrepreneurship communities in North Carolina.

Applicants are encouraged to review the *Evaluation Criteria* section for more details.

## **Gene Therapy Fellowship Requirements**

Applications shall be developed jointly by the candidate Fellow and the Faculty Mentor (see eligibility requirements for Fellows and Faculty Mentors to follow).

The fellowship application is submitted by the Faculty Mentor through his/her institution (*e.g.*, a North Carolina university or non-profit research institute). An authorized representative of the institution's sponsored programs office must sign the application cover sheet.

- ⊗ *Applications lacking a named Fellow Candidate, Faculty Mentor, or evidence of institutional endorsement will not be considered.*

The Pfizer-GTF Fellowship requires the following:

- The Fellow and Mentor independently commit to the research project outlined in the application, as indicated by Letters of Interest/Support from each.
- The Fellow becomes an employee of the sponsoring university or research institution and will be subject to institution policies for postdoctoral fellows.
- The Fellow will be offered the institution's standard benefits package (healthcare insurance, *etc.*) available to other postdoctoral fellows.
- The Fellow must participate in the professional development modules programmed by NCBiotech and is encouraged to take part in other career development opportunities provided.

- The Fellow and Mentor must submit annual reports and be available for periodic interviews with Pfizer-GTF program staff.

### **For the Postdoctoral Fellow Candidate:**

- The Pfizer-GTF Candidate must have attained a doctoral degree (Ph.D. or equivalent) in a life science discipline relating to gene therapy. **(Revision: Restriction has been removed requiring completion of Ph.D. within three years prior to application.)**
- Fellow Candidates must show exemplary potential as independent researchers as demonstrated by publication record, letters of support, inventorship, or other measures of research productivity and potential.
- Fellows must be U.S. citizens or must demonstrate the legal right to work in the U.S. upon acceptance of the award, per the awardee institution's policies regarding eligibility and visa sponsorship. **The North Carolina Biotechnology Center does not sponsor work visas.**

### **For the Faculty Mentor:**

- The Faculty Mentor must hold a full time tenured, tenure-track, or equivalent full-time research faculty appointment at a North Carolina-based university or non-profit research institute.
- The Faculty Mentor must maintain an active research program relating to gene therapy (preferably adeno-associated viral [AAV] platforms), gene therapy enabling methodologies, or the biology underlying a genetic disease that may be amenable to treatment via gene therapy.
- The Faculty Mentor agrees to provide the Fellow with a positive training environment, access to all necessary project resources, supervision, and career development support in order to maximize the benefit of this experience to the Fellow.
- The Faculty Mentor agrees to provide the Fellow with the necessary time away from

the lab to participate in all required professional development modules provided by NCBiotech as part of this fellowship.

## **Funding & Matching Requirements**

See the *Budget Guidelines* section for full details.

### **Fellowship Package**

The Pfizer-NCBiotech Distinguished Postdoctoral Fellowship package provides \$190,340 for two-year post-doctoral fellowships, including salary support, benefits, project supplies, travel and professional development training, as follows:

#### *Salary & Benefits*

NCBiotech provides a total of \$78,000 in Year 1 to cover the Fellow's base salary (\$65,000 per year) plus benefits (calculated as 20% of salary). These funds will be provided directly to the university or institution for disbursement to the Fellow. A cost-of-living increase of 3% is provided in Year 2. Salary requests are fixed and non-negotiable.

- ⊗ *NCBiotech funds do not provide salary support for the Faculty Mentor or other project personnel.*

#### *Project Expenses & Travel*

NCBiotech provides funds to cover project expenses, including supplies, minor lab equipment, and core laboratory fees at a rate of \$15,000 per year. Additionally, \$2,000 is allocated for approved travel to a scientific conference(s) (see the *Budget Guidelines* for allowable expenses).

#### *Professional Development*

NCBiotech will provide a series of mandatory professional development modules for Fellows. The Center will directly fund these courses/activities and their costs should not be included in the Application Budget.

### **Institutional Support**

A full budget for the successful completion of the research project described in the application must be prepared, using the budget form provided. *Any research project costs not covered by the fellowship MUST be itemized and committed as match by the institution.* See details in the *Budget Guidelines*.

## **Preliminary Consultation**

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Although not required, a pre-submission consultation is encouraged. Please contact us at least **two weeks prior** to the application deadline if you would like to schedule a consultation.

When contacting Center staff to schedule a preliminary consultation, please provide the following information:

- Name and current university affiliation of the Fellow Candidate
- Name, title, and university affiliation of the Faculty Mentor
- Brief description of the research project

## **Evaluation Criteria**

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Applications will be reviewed competitively based on an assessment of each Fellow candidate's potential as a researcher, the match between the Fellow and the Faculty Mentor, the project's degree-of-fit with the aims of the Program, and the impact that the fellowship will have towards the career development goals of the Fellow.

Specifically, the review criteria will include, but may not be limited to, the following:

### **A. Fellow Candidate**

Has the Fellow candidate demonstrated evidence of potential as an independent researcher in a gene therapy-related discipline, as demonstrated through publications, grants, awards, inventorship, or other measures of scientific productivity?

### **B. Fellow-Mentor Match**

Does the Faculty Mentor demonstrate a commitment to the success of both the project and the career development of the Fellow?

Does the Mentor have the project-specific expertise and resources to devote appropriate oversight to the Fellow?

Does the Fellow have sufficient scientific understanding and familiarity with gene therapy-related methods to initiate and complete the research project in a timely fashion? If not, has the Mentor outlined a training plan for the Fellow to acquire these skills?

Are all necessary resources for the successful completion of the project available in the

Mentor's lab or elsewhere within the university?

### C. Project

Are the goals of the project consistent with the eligible gene therapy-related research areas outlined on page 1 (see *Purpose section, p.1*)?

Is the project innovative? Does it address a current problem? Is the project described in sufficient detail to assess the probability of success?

Is completion of the project feasible within the allotted two-year timeframe and budget?

## Post-award Reporting

Technical and financial reports are required throughout the term of the fellowship. In addition, both the Fellow and the Faculty Mentor will be required to complete post-award surveys to track subsequent employment, funding, patents, licenses, publications, companies created, *etc.* that directly result from the award. We will periodically collect these data for up to 10 years to demonstrate the impact of this program.

## Early Termination

If, for any reason, the Fellow does not complete the full two-year term of the fellowship, the Mentor must notify NCBiotech in writing within 15 days and the fellowship will be terminated. Unused funds are not transferrable with the Fellow to other institutions nor to other projects or trainees within the Mentor's lab.

## Information Release

NCBiotech announces its awards through press releases and other publications. These communications typically include the Project Title and Public Information Summary that is provided by the applicant with the online application. We do not release information on declined proposals.

## Confidentiality

As part of our grants review process, the Biotechnology Center routinely shares the contents of grant applications with both internal and/or external experts to assess the merits of each application. The Biotechnology Center will endeavor to maintain the confidentiality of all information provided by the applicant. While

measures are in place to assure the appropriate handling of all information provided, the applicant is responsible for limiting the disclosure of any sensitive information that should not be shared outside of the Biotechnology Center.

We encourage applicants to consult with their university's technology transfer office (academic applicants) or an intellectual property professional for more specific counsel as necessary.

## Application Instructions

Application materials are located on the Pfizer-GTF webpage at [www.ncbiotech.org/pfizer-fellowships](http://www.ncbiotech.org/pfizer-fellowships).

The Pfizer-GTF application is comprised of **four** application files containing the following **eleven** sections:

### File 1 (PDF): Personnel and Proposed Research Project

1. Letter of Interest from Fellow Candidate
2. Letter of Support from Faculty Mentor
3. Research Project Narrative
4. Curriculum Vitae - Fellow Candidate
5. Curriculum Vitae - Faculty Mentor
6. Curriculum Vitae - Other Key Personnel (if applicable)
7. Use of Human or Animal Research Subjects authorization (if applicable)

### File 2 (PDF): Supporting Documentation

8. University Letter of Commitment (required)
9. Other letters of support (optional)

### File 3 (PDF): Budget

10. Budget Form (includes budget justification)

### File 4 (PDF): Cover Sheet

11. Signed Cover Sheet

Please use the checklist above to make sure all components of the proposal application are included. Refer to the instructions below for completing each section.

### General Proposal Formatting Guidelines

- Use standard font (such as Times New Roman, Calibri, or Cambria) no smaller than 11 point.
- Page set-up should be for single-spacing on

8½"x11" paper.

- Number each page.
- Margins should be ¾" to 1".
- Each section should be titled using the header sections listed below and should match the Table of Contents.
- Do **not** use logos or letterhead on any pages of the Proposal *except* for support letters.
- Judicious use of headings and white space for ease of reading is appreciated.

### **Step 1: Prepare the Personnel and Proposed Research Project Documents**

#### **1. Letter of Interest (Fellow Candidate)**

This letter should identify the project and the Fellow Candidate by name.

- Summarize your scientific interests, accomplishments to date and awards received.
- Describe your gene therapy-related experience.
- Describe your career goals.
- Where do you expect to be in five years?
- How will this fellowship advance your career?

#### **2. Letter of Support (Faculty Mentor)**

This letter should identify the project and the Fellow Candidate by name.

- Briefly describe your research interests as they relate to gene therapy. Explain how the proposed project fits within the research goals of your lab.
- Summarize the activities that the Fellow will perform on the project.
- Describe the resources in your lab or the university that will be available to the Fellow for the execution of the project.
- Describe the training and professional development opportunities that you will provide to the Fellow for the successful execution the project as well as for a successful career following the completion of the fellowship. Confirm that the Fellow will be granted time away from the lab to participate in the periodic professional development activities that will be provided by NCBIotech.

**3. Research Project Narrative** The Research Project Narrative must include the sections listed below. Use the **headings** provided to identify the sections.

#### **a. Table of Contents**

*(separate page; does not count toward page limit)*

Include research project title, names of Fellow Candidate and Faculty Mentor, Faculty Mentor's institution, and section headings with page numbers.

#### **b. Project Description**

The total page limit for the project description below is 9 pages.

The proposal **Abstract** will be submitted online as a section of the application form . *(character limited to approximately ½ page.)* Provide a brief description of the technology and relevance to gene therapy as defined under *Program Details* (p.1).

- **Background** *(suggested 3 pages)*  
Briefly summarize the relevant science and current state of the art that supports the proposed research project. Please include preliminary data, if available.
- **Project Plan** *(suggested 5 pages)*  
Outline the research goals of the Fellowship project and describe in detail each research aim to be performed during the course of this award. Include detailed information on the following:
  - Specific aims
  - Study design; instrumentation and facilities that will be used for the project
  - Endpoints to be measured
  - Data analysis method(s) employed
  - Milestones to be achieved
  - Criteria used to define project success *a priori*
  - Potential challenges with the project and associated contingency plans.
  - If animals/human subjects will be used, provide evidence (power analysis) that the studies will be sufficiently powered to yield statistically significant results (80% confidence interval).

- **Roles and Responsibilities**

*(suggested ½ page)*

Describe the roles and responsibilities of

the key personnel on the project.

**c. Project Timeline**

*(does not count toward page limit)*

Provide a Gantt chart or other graphic or table that illustrates a detailed timeline for completion of the project milestones over the two-year fellowship.

**d. Bibliography**

*(does not count toward page limit)*

Give full citation including title and complete author list. If complete author list is extensive, include only the first three (3) authors listed.

**4. Curriculum Vitae – Fellow Candidate**

Provide a brief CV using the *Fellow Biosketch Form* provided online.

*The maximum length is 5 pages. Full CVs of excessive length will not be considered.*

*Required:* Provide the information as listed on the biosketch form,

**5. Curriculum Vitae – Faculty Mentor**

Provide a brief CV using the *Mentor Biosketch Form* provided online.

*The maximum length is 5 pages. Full CVs of excessive length will not be considered.*

*Required:* Provide the information as listed on the biosketch form, which includes current and pending grants and mentorship experience.

**6. Curriculum Vitae – Other Personnel**

If there are other key personnel involved with the project, provide a brief CV using the one-page *Other Personnel biosketch form* provided online.

**7. Use of Human or Animal Research Subjects Authorization** (if applicable)

For projects involving human subjects or animal studies:

- Provide a power analysis demonstrating that the studies proposed have the correct number of human or animal subjects required to achieve a confidence level of at least 80%.
- Provide documentation demonstrating that

notification of the research has been made to the institution's IRB or IACUC.

**Step 2: Convert Your Personnel and Proposed Research Project Documents into ONE PDF Document**

Convert your personnel and research project documents into **ONE** PDF file.

- ⊗ *Do not print and scan the proposal to PDF – this causes the PDF to be significantly larger.*

**Step 3: Gather Supporting Documents and Convert Them into ONE PDF Document**

Combine the following Supporting Documents into a **ONE** PDF file.

These documents represent items 8-9 on the checklist on page 4.

**8. University Letter of Commitment (required)**

This letter must confirm the institution's commitment to hosting a Pfizer-GTF Fellow according to these guidelines and if applicable, to providing any matching funds as they appear on the budget form. The nature and dollar value of any match (cash or in-kind) must be stated. This letter must be on letterhead and signed by an institutional representative authorized to commit the matching funds (*e.g.*, Vice Chancellor for Research, Dean, Department Chair, *etc.*).

**9. Other Letters of Support (optional)**

You may include letters of support from other key personnel who will contribute to the success of the Fellowship and/or the project.

**Step 4: Complete the Budget**

**10. Budget Form**

Prepare your Budget using the Pfizer-GTF Budget Form provided on the Pfizer-GTF webpage. Use of the GTF Budget form is **required**.

The Budget Form is provided as an Excel workbook consisting of two worksheets. **Both must be completed:**

- GTF 2-yr Budget (Tab 1)
- GTF budget justification (Tab 2)

Certain fields on the Budget Form corresponding to grant funding provided by NCBiotech are prepopulated (*e.g.*, Fellow Salary) and cannot be altered. Enter the amount of any additional support provided by the university in the University match column per the guidelines below.

The names of the Fellow candidate and Faculty Mentor must be included in the spaces at the top of the Budget Form.

The completed Budget Form must be submitted as a PDF file.

### **Budget Guidelines**

All items entered on Tab 1 of the Budget Form must be justified using Tab 2 of the Budget Form.

### **GTF Grant Request**

NCBiotech will provide a total of \$190,340 per GTF grant award, based on the following:

#### *Salary & Benefits*

NCBiotech provides a total of \$78,000 in Year 1 to cover the Fellow's base salary (\$65,000 per year) plus benefits (calculated as 20% of salary). These funds will be provided directly to the university or institution for disbursement to the Fellow. A cost-of-living increase of 3% is provided in Year 2. Fellow salary requests are fixed and non-negotiable.

The salary request for the Fellow is entered into the Budget Form.

- ⊗ *GTF grant funds do not provide salary support for the Faculty Mentor.*

#### *Project Expenses*

Funds will be provided to cover project expenses, including project supplies, minor lab equipment, and core laboratory fees at a rate of \$15,000 per year.

Use the Budget Form to itemize these expenses, not to exceed a total of \$30,000. Enter any other

project costs into the university match column (see below).

#### *Travel*

The GTF grant provides \$2,000 for approved travel to a scientific conference(s).

#### **Allowable** project expenditures for GTF funds provided by NCBiotech:

- Research project materials and supplies required by the project
- Core facility or equipment use
- Minor lab equipment
- Contracted research service fees

#### **Unallowable** expenditures from GTF funds provided by NCBiotech:

- salary or benefits costs for the Faculty Mentor or other research personnel
- publication costs
- tuition and/or any other student costs
- legal fees or patent costs
- indirect costs/overhead/facilities and administrative costs

- ⊗ *Biotechnology Center grants do not support any type of overhead, F&A or indirect costs.*

### **Institutional Support**

It is understood that the research project costs may exceed project funds provided by the fellowship. Project costs exceeding the total grant allocation of \$30,000 **MUST** be itemized and committed as a match by the institution.

Examples of expenses appropriate for institutional support (but not grant funding) include dedicated Faculty Mentor effort, additional project supplies, equipment usage, other personnel required for the completion of the project, or additional salary and benefits beyond that provided by the fellowship.

The total amount committed by the institution must appear and be consistent in the following documents:

- Cover Sheet
- University Letter of Commitment
- Budget Form (under University match column)

## Step 4: Complete the Cover Sheet

### 11. Cover Sheet

Complete the Cover Sheet provided on the Pfizer-GTF webpage located at:

[www.ncbiotech.org/pfizer-fellowships](http://www.ncbiotech.org/pfizer-fellowships).

## Step 5: Complete the Online Application Form

### **IMPORTANT - New for the FY2019 Application**

**Cycle:** The Faculty Mentor must be registered in the NCBiotech Funding Portal in order to submit a GTF proposal. Instructions will be posted by March 1, 2018 at [www.ncbiotech.org/pfizer-fellowships](http://www.ncbiotech.org/pfizer-fellowships).

**After the Mentor's registration is complete**, use the GTF application available through the Mentor's Funding Portal account. Complete all fields as instructed.

The online application form includes a field for the **Public Information Summary**. If your proposal is funded, this concise, easy-to-read summary may be used in Biotechnology Center press releases and other publications.

This summary is intended for a general audience, allowing the Biotechnology Center to share granting information with the general public and other interested parties.

- This summary should not include complex scientific terminology.
- The summary should convey to the citizens of North Carolina why the project is important.
- The maximum allowable length for this summary is **50 words**.

## Step 6: Attach the Required Documents

A GTF application is comprised of four files: **Cover Sheet, CVs and Research Proposal, Supporting Documentation, and Budget Form**. Follow the online instructions for attaching the required documents to the application form.

**Important note:** Only **ONE of each** of the proposal files may be attached to the application for a **total of four attachments**.

## Step 7: Review and Submit

Carefully review your application package using the checklist provided on page 4 and then submit your Pfizer-GTF application prior to the Program Deadline.

Submission of your grant application indicates that:

- A. You have read and understand the information and directions in this Application Package and agree to be bound by the conditions stated herein.
- B. You release the North Carolina Biotechnology Center from any claim for damages caused by:
  - i. Disclosures required under the provisions of any North Carolina or United States law, statute, or regulation,
  - ii. Disclosures made in connection with the North Carolina Biotechnology Center's funding review and approval process,
  - iii. Disclosures required by rule or order of any court of competent jurisdiction, or
  - iv. Any other non-negligent, inadvertent, unintentional, unknowing, or immaterial disclosure.
- C. All research conducted during the proposed project is performed in accordance with established university policies and procedures, including—but not limited to—policies and procedures applicable to research involving human subjects, laboratory animals, or hazardous agents and materials.

If the project proposed involves vertebrate animals, the project complies with federal guidelines for vertebrate animal care and experimentation.

You will receive a confirmation email notifying you that the Biotechnology Center has received your application. Any Center request for additional information must be addressed promptly.

## **Contact Information**

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