

Mini Supporting Statement A

Translational Science Interagency Fellowship (TSIF) Application

Sub-study under
“Generic Clearance for Application Information for
Fellowship, Internships, Training Programs, and Specialty Positions
(National Cancer Institute)”

OMB# 0925-0761

Expiration Date: 07/31/2022

October 1, 2020

Contact Information

Name: Brittany Haynes

Address: 6701 Democracy Blvd

BG 1DEM RM 971

Bethesda MD 20892

Telephone: 301-480-7927

Email: Brittany.haynes@nih.gov

List of Attachments

Attachment 1: Fellowship Application

Attachment 2: Privacy Act Memo

Attachment 3: Privacy Impact Assessment

Attachment 4: TSIF Email Correspondences

Attachment 5: TSIF Webpage Content

Mini Supporting Statement A

A.1 Circumstances Making the Collection of Information Necessary

The objective of the TSIF program is to train a cadre of postdoctoral and staff scientists in translational science research and research-related to regulatory science and review. This effort will create a workforce with a combined skill set that will be able to work across the translational science spectrum and move new technologies, products, or processes forward more efficiently. Fellows in this program will learn to build awareness of regulatory and drug development science and review requirements into the early stages of the technology development, preclinical, and clinical translational science process and will develop strategies and tools to improve the assessment and review of drug development submissions. The purpose of the TSIF program application is to facilitate the selection and onboarding of fellows. The application will be used to assure that candidates meet the basic eligibility requirements, determine where mutual scientific interests exist, and to make decisions regarding which applicant will be approved for participation in the fellowship program. All applications will be voluntary, low-burden, non-controversial, and will not raise issues of concern to Federal agencies. The results are not intended to be disseminated to the public. The information is for internal use to make decisions about candidates invited to participate in the TSIF program.

The fellowship is offered as a partnership of the National Center for Advancing Translational Sciences (NCATS) National Institutes of Health (NIH), and U.S. Food and Drug Administration (FDA), and the U.S. Department Health and Human Services (HHS).

A.2 Purpose and Use of the Information Collection

The TSIF program is jointly sponsored by NCATS and the FDA and aims to provide training in both translational science research and research-related regulatory review. The common goal of NCATS and the FDA is to bring safe and effective drugs, regimens, and devices from the bench to the bedside as quickly and efficiently as possible. To that end, fellows will be trained in preclinical translational science research, technology development, and other regulatory research and review aspects. Fellows in this program will develop skills of value to academia, the pharmaceutical industry, and government agencies.

The purpose of the TSIF program application is to assure that candidates for the TSIF program meet the basic eligibility requirements, determine where mutual scientific interests exist, and to make decisions regarding which applicant will be proposed and approved for fellowship awards. The information is for internal use to make decisions about the prospective fellows that could benefit from the TSIF program. The application will include an on-line application, a CV, personal statement, transcript, and three reference letters.

Participation in the TSIF program includes U.S. citizens and U.S. permanent residents. Individuals from underrepresented populations, consistent with NIH's Notice of Interest and Diversity ([NOT-OD-18-210](#)), are encouraged to apply for the program.

A.3 Use of Information Technology to Reduce Burden

Information will be collected electronically through secure email (Attachment 4) except for the reference letters which may be emailed or sent by mail. The following is the URL for the webpage where the applicant will be able to get details about the program and the application process, including a link to the application which will be a PDF that could be downloaded: <https://ncats.nih.gov/training-education/TSIF>. The URL is currently under

development and a draft of the webpage content has been submitted as Attachment 5. The Privacy Impact Assessment (Attachment 3) is being prepared by the Acting NCATS Privacy Coordinator for finalization.

A.4 Efforts to Identify Duplication

This information will not be collected anywhere else within NCATS and is unique to this program.

A.5 Impact on Small Businesses or Other Small Entities

This information collection will have no impact on small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

The information will be voluntarily collected once per year.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with 5 C.F.R. 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

N/A

A.9 Explanation of Any Payment of Gift to Respondents

There will be no payments or gifts to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

This information collection does request Personally Identifiable Information (PII) including name, contact information, education, citizenship/visa information, and employment history. All information is subject to the Privacy Act as detailed in the Privacy Act Memo, attachment 2, and will be kept private to the extent allowable by law. Review committees within the Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) will be able to access the applications. All applications, which include a CV, personal statement, and letters of recommendation, will be sent to reviewers via encrypted email. Applicants and contributors submit their information via email or postal service.

The information collected is subject to the Privacy Act System of Records Notices, including:

- 09-25-0014 – Clinical Research: Student Records, HHS/NIH/OD/OIR/OE

A.11 Justification for Sensitive Questions

No sensitive questions are contained in this information collection. Personally Identifiable Information (PII) will be collected including name, contact information, education, citizenship/visa information, and employment history. Federal regulations for the protection of human subjects do not apply to this activity

A.12 Estimates of Hour Burden Including Hourly Costs

The estimated total number of respondents is 20. The instrument attached is the TSIF program application (adapted from the IOTF program application), with an estimated average time to complete at 1 hour. The total estimated burden hour included for this information is 20 hours.

Table A.12-1 Estimated Burden Hours

| Type of Respondent | Number of Respondents | Number of Responses per Respondent | Average Time Per Response (in hours) | Total Burden Hours |
|--------------------|-----------------------|------------------------------------|--------------------------------------|--------------------|
| Individual | 20 | 1 | 1 | 20 |
| Totals | | 20 | | 20 |

Table A.12-2 Cost to the Respondents

| Type of Respondents | Total Annual Burden Hours | Hourly Wage Rate* | Respondent Cost |
|---------------------|---------------------------|-------------------|-----------------|
| Individual | 20 | 24.98 | \$499.60 |
| Totals | | | \$499.60 |

*Source of the Hourly Wage Rate is provided by the Bureau of Labor Statistics, Occupation title "All Occupations" 00-0000. https://www.bls.gov/oes/2019/May/oes_nat.htm#00-0000.

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There is no capital, operating, or maintenance costs to report.

A.14 Annualized Cost to the Federal Government

The estimated cost to the Federal government is \$12,924.39. This includes FTE and contract costs.

A.14-1 Annualized Cost to the Federal Government

| Staff | Grade/Step | Salary** | % of Effort | Fringe (if applicable) | Total Cost to Gov't |
|--------------------------|------------|-----------|-------------|------------------------|---------------------|
| Federal Oversight | | | | | |
| NCATS | | | | | |
| Director | 15/7 | \$170,800 | 3% | | \$5,124.00 |
| Program Manager | 12/2 | \$89,213 | 3% | | \$2,676.39 |
| FDA | | | | | |
| Director | 15/7 | \$170,800 | 3% | | \$5,124.00 |
| Contractor Cost | | | | | |
| Travel | | | | | \$0 |
| Other Cost | | | | | \$0 |
| | | | | | |
| Total | | | | | \$12,924.39 |

**The salary in the table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/20Tables/html/DCB.aspx>

A.15 Explanation for Program Changes or Adjustments

This is a mini Supporting Statement for a generic information collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Applications will be used to determine the eligibility of applicants for the TSIF program. The data will also be used for annual program assessments, reviews, and reports to NCATS leadership. It is anticipated that the data may be analyzed to better understand the training needs of fellows. The opening and closing times for the application is October 15 and January 15.

Table A.16.1 Project Time Schedule

| Activity | Time |
|----------------------------------|-------------|
| Applications accepted | Month 0 - 3 |
| Analysis of information received | Month 4 - 6 |
| Summarize Results | Month 6 - 7 |

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

We are not requesting an exemption to the display of the OMB Expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

This request will comply with the requirements in 5 CFR 1320.9.