

Mini Supporting Statement A

The Interagency Oncology Task Force Fellowship (IOTF) Program

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

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List of Attachments

Attachment 1: IOTF Application Tracks 1-4

Attachment 2: IOTF Emails

Mini Supporting Statement A

A.1 Circumstances Making the Collection of Information Necessary

The Interagency Oncology Task Force Fellowship (IOTF) program trains scientists in research and research-related regulatory review, policies, and regulations to develop a skill set that bridges the two disparate processes. Fellows learn to build awareness of regulatory requirements into the early stages of the medical product development process and will develop strategies to improve planning throughout research and regulatory review. The purpose of the application is to assure that candidates for the IOTF program meet the basic eligibility requirements, assess their potential as oncology product research reviewers, 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 decisions about the prospective fellows that could benefit from the IOTF program.

The fellowship is offered as a partnership of the National Cancer Institute (NCI), 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 purpose of the application is to assure that candidates for the IOTF program meet the basic eligibility requirements, assess their potential as oncology product research reviewers, 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 decisions about the prospective fellows that could benefit from the IOTF program.

Participation in the IOTF 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.

The Interagency Oncology Task Force Fellowship program has the following 4 Program Tracks:

Track 1: Oncology Product Research and Review for M.D. Oncology Fellows

This fellowship will train physicians in aspects of clinical trials methodology and analysis, epidemiology, clinical aspects of medical product development, and regulation to facilitate the movement of drugs, biologics, and devices from the basic bench science to commercialization.

Track 2: Oncology Product Research and Review for B.C. Oncologists

This fellowship will train physicians in aspects of drug, biologic, or device development and related issues and standards to facilitate movement from basic bench science to commercialization.

Track 3: Oncology Product Research and Review for Postdoctoral Research Fellows

This fellowship will train individuals with postdoctoral research experience in aspects of research and review of the medical product development process to facilitate the movement of drugs, biologics, and devices from the bench to the bedside.

Track 4: Cancer Prevention Product Research and Review

This fellowship will train individuals in aspects of the cancer prevention drug, biologic, or device development processes, including their application to study populations, to facilitate the movement of novel approaches from the bench to the community.

This request is to implement the application process involving approximately a total of 32 applicants (for all four tracks). Prospective IOTF fellows must apply directly to NCI. The application process is conducted via email, where the applicant submits their Curriculum Vitae, Personal statement of research goals, and three letters of reference to the IOTF Program Manager at the Center for Cancer Training (CCT). All communications post-submission are typically conducted via email communication.

A.3 Use of Information Technology to Reduce Burden

Prospective fellows must apply directly to the CCT IOTF Program Manager for admission. The application is electronically based, with guidelines accessible through the IOTF website: <https://www.cancer.gov/grants-training/training/at-nci/iotf> under the pages specific to each Track.

The application is electronically based (e.g. email). The applicant will submit their application materials to the CCT IOTF Program Manager, and the applicant will receive an email confirming receipt and prompt further action (if needed) (Attachment 2).

A.4 Efforts to Identify Duplication

This information will not be collected anywhere else 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

This information will be voluntarily collected once per year.

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

This information collection is consistent with these guidelines.

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

Neither payments nor gifts will be provided to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

All information 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 to the applications. All applications, which include 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 Privacy Act is applicable. The applicable System of Record Notice (SORN) is NIH Privacy Act SORN 09-25-0014; "Clinical Research: Student Records."

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 Annualized Hourly Costs

The estimated total number of respondents is 32. The instrument listed is the application, with an estimated average time to complete at 1 hour. It is estimated that a total of 32 people will apply (for all four tracks).

The total estimated burden hour included for this information is 32 hours (Table A.12-1) and the cost to the respondents is estimated to be \$778.88 (Table A.12-2).

Table A.12-1 Estimated Annualized Burden Hours

Category of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hours
Individuals Applications	32	1	1	32
Totals		32		32

Table A.12-2 Annualized Cost to the Respondents

Category of Respondents	Total Annual Burden Hours	Hourly Wage Rate*	Respondent Cost
Individual (Application)	32	\$24.34	\$778.88
Total			\$778.88

*Source of the Hourly Wage Rate is provided by the Bureau of Labor Statistics, for job code title "All Occupations" 00-0000. https://www.bls.gov/oes/2018/May/oes_nat.htm#00-0000.

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

There are no additional costs to report.

A.14 Annualized Cost to the Federal Government

The annual cost to the Federal Government is estimated to be \$12,860.61 (Table A.14.1). The federal personnel are responsible for the review of applications collected.

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					
Director	15/7	\$170,800	3%		\$5,124.00
Program Manager	13/5	\$116,353	3%		\$3,490.59
Scientist	14/6	\$141,534	3%		\$4,246.06
Contractor Cost					\$0
Travel					\$0
Other Cost					\$0
Total					\$12,860.61

**The salary in the table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB.pdf>

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 IOTF programs. The data will also be used for annual program assessments, reviews, and reports to NCI leadership. It is anticipated that the data may be analyzed to better understand the training needs of early career scientists.

Table A.16.1 Project Time Schedule

Activity	Time
Applications accepted	Months 0 – 2
Analysis of information received	Months 3 – 4
Summarize Results	Months 5 – 6

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 survey will comply with the requirements in 5 CFR 1320.9.