United States Food and Drug Administration

Center for Tobacco Products, Food and Drug Administration Funded Trainee/Scholar Survey

OMB Control No. 0910-NEW

SUPPORTING STATEMENT PART A

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Tobacco Control Act (Pub. L. 111-31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant the U.S. Food and Drug Administration (FDA) authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. This is a new Information Collection Request (ICR) for implementation of a survey to evaluate tobacco regulatory science (TRS) training programs and their impact on TRS knowledge, skills, and future career interests. Through a web-based survey, this effort will collect quantitative information on the characteristics, activities, and impact of TRS training programs and activities. Findings will be used to inform and improve future training programs that help develop and encourage TRS researchers to pursue careers in TRS-related fields and contribute to science that informs tobacco regulatory policy and practice.

Regulatory decisions, health communications, and premarket application review depend upon scientific research. The Tobacco Regulatory Science Program (TRSP) is an interagency partnership between the National Institutes of Health (NIH) and the FDA CTP to foster tobacco regulatory research. CTP's Office of Science relies on TRS to inform regulatory decisions. FDA uses TRS findings to educate the public, assert jurisdiction over new products, and develop regulations and guidance materials. TRS research explores the effect of regulations on tobacco product initiation, cessation, exposure to harmful and potentially harmful constituents (HPHCs), and public health impact. TRS research also informs FDA's tobacco product application reviews. Furthermore, FDA's investment in TRS research also aims to directly and indirectly increase the number of scientists in this field.

The current project addresses evaluation questions regarding how FDA-funded research contributes to TRS and informs tobacco regulatory policy and practice. This information collection will address the impact of the FDA CTP's investment in TRS training programs and focus on how CTP supports emerging scientific leadership in TRS research. To implement this evaluation, CTP is contracting with RTI International. The Center for Tobacco Products, Food and Drug Administration Funded Trainee/Scholar Survey will inform the larger CTP portfolio evaluation by assessing how training through CTP-funded TRS projects is developing and preparing new researchers for TRS.

As stated in CTP's report, *Tobacco Regulatory Science Research Program at FDA's Center for Tobacco Products: Summary and Highlights*,

> "To make the most effective regulatory decisions, CTP must increase critical knowledge in evolving areas of regulatory science including the population health effect of the rapidly changing tobacco product market. Regulatory science research is critical to understanding the impact of manufacturing, marketing, and distribution of tobacco products on public health so that effective product review decisions can be made and other critical authorities granted by Congress to FDA can be used most effectively to reduce the death and disease resulting from tobacco use" (Center for Tobacco Products, 2018, p. 1).

This information collection is necessary to assess the effectiveness of TRS training programs to help facilitate career development of future generations of tobacco regulatory science researchers.

Appendices C-J provide copies of the data collection instruments and materials.

2. Purpose and Use of the Information Collection

FDA CTP will use findings from this study to determine whether its TRS training support investments lead to meaningful change that supports CTP aims, and to inform decisions about potential future investments. CTP's training support intends to build additional capacity for TRS that establishes an evidence base related to CTP's research priorities so that FDA regulations, communications, and application review are founded on rigorous, relevant scientific study.

3. Use of Improved Information Technology and Burden Reduction

Because this is a web-based study, 100 percent of the respondents will submit the information in an electronic format. Respondents will respond to questions using a web-based survey on their personal computers or mobile devices. Web-based surveys reduce respondent burden, minimize possible administration errors, and expedite the timeliness of data processing. Furthermore, web-based surveys are less intrusive and less costly compared with face-to-face interviews and mail and telephone surveys. Because there is no interviewer present, participant responses to a web-based survey are less prone to social desirability bias.

4. Efforts to Identify Duplication and Use of Similar Information

There are no other current or prospective studies of CTP TRS trainees that can address the purpose of this study. FDA partners with NIH on TRS activities, and NIH is not conducting related data collection. FDA conducted a similar survey in the past, but ongoing data collection is important to the study aims.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

FDA is collecting this survey data annually, as the study assesses changes over time in how trainees use the TRS training program and consider TRS as a career field for the future.

FDA and RTI will launch data collection during 2020 and conduct annual surveys through 2021. If the survey was not conducted annually, FDA would not be able to assess changes in trainee characteristics, training program needs, trainee attitudes or intentions related to a TRS career.

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

There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of 09/12/2019, 84 FR 48148. No comments were received.

The survey was designed in collaboration with researchers at CTP, the National Institutes of Health Tobacco Regulatory Science Program (TRSP), Center for Evaluation and Coordination of Training and Research (CECTR), and RTI International.

9. Explanation of Any Payment or Gift to Respondents

This data collection does not involve any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Privacy Analysis & Design
In developing this study, CTP consulted the FDA Privacy Officer to identify potential risks to the privacy of participants and other individuals whose information may be handled by or on behalf of FDA in the performance of this study. FDA designed the study to minimize privacy risks in keeping with the Fair Information Practice Principles (FIPPs) and applying controls selected from the National Institute of Standards and Technology (NIST), Special Publication 800-53, *Security and Privacy Controls for Federal Information Systems and Organizations*. CTP also identified privacy compliance requirements and coordinated with FDA's Privacy Officer to ensure responsible offices in CTP satisfy all in accordance with law and policy. FDA submitted a Privacy Impact assessment to the privacy office that is currently under review.

PII Collection
As part of this study, RTI International (RTI), on behalf of FDA will collect and/or maintain personally identifiable information (PII) about TRS trainees/scholars. The PII about TRS trainees/scholars consists of names and email addresses and is collected from the Center for Coordination of Analytics, Science, Enhancement, and Logistics (CASEL) (formerly CECTR). Annually, on behalf of FDA, CASEL emails Tobacco Centers of Regulatory Science (TCORS) administrators/coordinators and CTP-funded principal investigators (PIs) (**Appendix D and E**) requesting trainee names and email addresses. CASEL will compile this information and share the full list with the contractor conducting the data collection, RTI.

All data collection activities will be conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents and to protect the rights and welfare of human research subjects as provided in its regulations. Respondents will receive

information about privacy protections as part of the informed consent process. All project staff are required to complete trainings in privacy and confidentiality practices.

Privacy Act Applicability
The information collection is not subject to the Privacy Act of 1974. Hence, no Privacy Act Statement is required to be displayed on the form, website, mobile application or other point at which individuals submit their information.

Data Minimization
The PII collected or used for this study (i.e., names and email addresses) is limited to the minimum necessary to achieve the authorized purpose and produce a valid study. The purpose of the study is to gather data on the characteristics, activities, and impact of training programs funded by the CTP and other partners. This evaluation will also determine how CTP-funded research and associated training programs increase knowledge and skills related to TRS and interest to pursue careers in a TRS-related field. The study is authorized under the Family Smoking Prevention and Tobacco Control Act and Federal Food, Drug, and Cosmetic Act. The PII is necessary to track trainees over time to assess changes in knowledge and skills related to TRS and interest to pursue careers in a TRS-related field. PII is also necessary to follow-up with only respondents who have not completed the survey. The PII will be maintained in a document that is separate from respondent data and separate from the linking file which will contain only respondent study identification number, so that response data remain de-identified.

Likewise, the potentially sensitive information gathered from respondents in association with their PII is limited to that which is essential for the study. The only potentially sensitive questions in the survey assess how useful and helpful respondents' FDA TCORS or CTP-funded training mentors have been, as part of the study's characterization of the utility of components of the training program overall. The survey does not capture the name or contact information about any mentors. Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.

FDA has minimized the risk of unnecessary access, disclosure, use or proliferation PII about respondents. FDA and other parties involved in the study maintain study records containing PII only as long as required. After project completion (September 2023) all PII and the linkage file will be destroyed. The deidentified data will be archived on RTI's secure project share drive for five years and then deleted permanently. This follows FDA IRB's requirement for data storage for a minimum of three years. Destroying the linkage file after project completion increases protections and reduces any risk of breaches. Although the data collection contractor will have temporary access to identifiable information for recruitment purposes, response data will not be recorded in a manner that is linkable to respondent identifiers. The contractor will assign a unique identifier code to each survey respondent. Survey response data will be stored and analyzed by identifier code. Only RTI staff conducting the data collection will have a crosswalk that links study IDs to trainee names. After project completion the crosswalk will be destroyed. No survey participant names or other identifying information will be included in any reports or data sets.

Neither CTP, CASEL, nor RTI share PII gathered via this collection with any other individuals or entities. Presentation and any publication of the survey data will be presented in aggregate form and will be reviewed by CTP to ensure protection and appropriate

safeguards. Further to this no PII will be included when aggregating data further safeguarding the PII used to administer the survey.

Notice and Transparency
All PII subjects are provided notice regarding the collection and use of the information they submit. The survey invitation links respondents to a webpage with an informed consent. Agreement to the consent is necessary to access the survey. Webpages and other study materials are clearly branded as FDA products.

Individual Participation and Control
The initial invitation to participate will state that participation in the survey is voluntary. Individuals who use the web address in the recruitment materials to access the survey will be shown the informed consent. Only those who click "yes" below the consent to indicate that they agree to participate will proceed to the survey questions. The informed consent document is included as **Appendix C**. Individuals can stop taking the survey at any time. Using Microsoft Word's Flesch-Kincaid reading level assessment, the informed consent document's reading level is 9.2. This level is appropriate, as respondents in the sample will have advanced degrees.

Third-Party Accountability
Contract agreements include clauses that hold prime and their service providers to federal standards and the laws and policies specifically applicable to this study. FDA reviewed the privacy policies of all third parties to confirm that it does not conflict with HHS/FDA and/or is superseded by contract content.

Data Security
CASEL will share the list of contact information for potential respondents with RTI by sending a password-protected file to RTI via email, and RTI will save the list in a restricted-access electronic file. As mentioned above, PII (i.e., names and email addresses) will be maintained in a document that is separate from respondent data and separate from the linking file which will contain only respondent study identification number, so that response data remain de-identified.

Data is transmitted from encrypted Qualtrics storage using SSL, accessible only after authentication to the Qualtrics server either via direct login or an API authentication. RTI will store the survey dataset on secure servers in RTI's headquarters in the Haynes Building at 3040 East Cornwallis Road, Research Triangle Park, NC 27709. Data will only be accessible by project staff trained in human subjects. At the completion of data collection, the databases will be deleted from the RTI's Qualtrics account and remain only on RTI's secure shared drive.

The study is currently being reviewed by FDA's IRB (RIHSC).

11. Justification for Sensitive Questions

The only potentially sensitive questions in the survey assess how useful and helpful respondents' FDA TCORS or CTP-funded training mentors have been, as part of the study's characterization of the utility of components of the training program overall. The survey does not capture the name or contact information about any mentors. Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer. Web-based surveys are entirely self-administered

and maximize respondent privacy without the need to verbalize responses. Respondents complete the survey at the time and location of their choosing and can choose not to be in a location where their coworkers or mentors will see their entries. Personal identifiers will not be saved with the survey data, and datasets will be stored in a secure server.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Respondents include current and former TCORS or other CTP-funded trainees and trainee PIs or training directors. PIs and training directors will be asked to provide trainee names and email addresses and encourage trainees to participate in the survey. Current and former trainees will be asked to read an informed consent and take a brief web-based survey. There will be no cost to participants other than their time. A total of approximately 350 trainees will be invited to participate in the web survey and, based on previous trainee surveys, we estimate an 85 percent response rate.

Burden was estimated based on experience with prior similar survey activities and information obtained from informal testing by contractor staff.

CASEL will email TCORS administrators/coordinators and CTP-funded PIs (**Appendix D and E)** requesting trainee names and email addresses. CASEL will compile this information and share the full list with RTI. RTI will email potential trainee respondents a lead letter (**Appendix F**) describing the study and letting them know about a forthcoming email invitation to participate in the survey (**Appendix G**). Respondents will use the email link to enter the survey portal and read the informed consent (**Appendix C**). Respondents will be asked to read the consent and click “yes” to provide consent to participate, and then will access the trainee survey (**Appendix H**). Around the same time trainees receive the email invitation, PIs and training directors will receive an email asking them to encourage trainees to participate (although these communications will not indicate whether trainees have participated or not) (**Appendix I**). After the survey is launched, weekly reminder emails will be made to all trainees who have not yet started the survey (**Appendix J**). The online survey will be available for up to 6 weeks from the time of the initial invitation.

The total estimated burden to respondents is 143 hours, as summarized in Table 1.

Table 1. Estimated Annual Reporting Burden

Type of Respondent/ Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
	Current or former trainee/scholar				
Lead Letter	350	1	350	.025	9
Email invitation	350	1	350	.016	6
Informed consent	298	1	298	.033	10
Survey	298	1	298	.16	48
Follow-up email	176	3	528	.016	8

Table 1. Estimated Annual Reporting Burden

	PI or Training Director				
Trainee list email	350	1	350	.16	56
Notification email	350	1	350	.016	6
Total					143

12b. Annualized Cost Burden Estimate

To derive wage estimates, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2018 National Occupational Employment and Wage Estimates. We have adjusted the PI/training director hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. For trainees, we have not adjusted wage estimates for fringe benefits and overhead because direct wage costs represent the "opportunity cost" to trainees for time spent on survey completion (Table 2).

For trainees, we use the adjusted hourly wages from "Life, Physical, and Social Science Occupations" and for PIs and training directors we use "Postsecondary Teachers."

Table 2. Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Life, Physical, and Social Science Occupations	19-0000	$36.62	N/A	$36.62
Postsecondary Teachers	25-1000	$40.82*	$40.82	$81.64

Source: "Occupational Employment and Wage Estimates May 2018," U.S. Department of Labor, Bureau of Labor Statistics. http://www.bls.gov/oes/current/oes_nat.htm

* Wages for some occupations that do not generally work year-round, full time, are reported either as hourly wages or annual salaries depending on how they are typically paid. Annual mean wage for Postsecondary Teachers is $85,190. Utilizing the Office of Personnel Management's 2,087 annual standard work hours, mean hourly wage for Postsecondary Teachers was calculated to be $40.82.

The estimated annualized cost to respondents is $8,027.90, as summarized below in Table 3.

Table 3. Estimated Annualized Cost to Respondents

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Current or former Trainee/scholar	81	$36.62	$2,966.22
PI or Training Director	62	$81.64	$5,061.68
Total			**0**

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The cost estimate for this information collection will be $76,150 (Table 4). This total cost covers all data collection activities including survey revisions, survey programming, survey hosting and licensing, testing, email list compilation and maintenance, sending initial invitation and follow-up emails, information collection, tabulation, data cleaning, analysis and reporting.

Table 4. Estimated Annualized Cost to the Federal Government

Activity/Personnel		Total Cost
Evaluation Contractor		
Collecting, summarizing and analyzing data, writing final reports		$70,000
Subtotal		**$70,000**
FDA Personnel		
• COR at 5% FTE (project management and oversight)		$6,150
Subtotal, Federal Personnel		**$6,150**
Grand Total		**$76,150**

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data will be collected annually between April 2020 and May 2022. Data will be tabulated and presented to FDA annually by early-September. See Table 5 for the anticipated schedule.

Table 5. Estimated Schedule for the Evaluation

Activity	Start date	End date
Invite trainees to participate	-	April 2020, 2021, 2022
Data collection	April 2020, 2021, 2022	May 2020, 2021, 2022
Data analysis	May 2020, 2021, 2022	June 2020, 2021, 2022
Evaluation report	June 2020, 2021, 2022	September 2020, 2021, 2022

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

FDA is not requesting an exemption for display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection. The OMB approval and expiration date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

Center for Tobacco Products (2018). Tobacco Regulatory Science Research Program at FDA's Center for Tobacco Products: Summary and Highlights. https://www.fda.gov/downloads/TobaccoProducts/PublicHealthScienceResearch/UCM613046.pdf. Retrieved on January 28, 2019