

# Frequently Asked Questions

Last updated February 07, 2020

## **K01—Mentored Research Scientist Career Development Awards in Tobacco Regulatory Research:**

- K01—Independent Clinical Trial Not Allowed, [RFA-OD-20-008](#)
- K01—Independent Clinical Trial Required, [RFA-OD-20-011](#)

## **K99/R00—Pathway to Independence Awards in Tobacco Regulatory Research:**

- K99/R00—Independent Clinical Trial Not Allowed, [RFA-OD-20-009](#)
- K99/R00—Independent Clinical Trial Required, [RFA-OD-20-010](#)

## **Clinical Trial Option**

1. How do I know if I need to apply to the Independent Clinical Trial option Request for Application (RFA)?
  - A. Note that the National Institutes of Health (NIH) [defines](#) a clinical trial as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.” As this definition can apply to studies that investigators may not have previously considered to be a “clinical trial,” we highly recommend investigators review the resources available at <https://grants.nih.gov/policy/clinical-trials/definition.htm>. There you will find [Case Studies](#), [Frequently Asked Questions \(FAQs\)](#), and a [Decision Tree](#) that will help determine if your investigation is considered a clinical trial or not. Additionally, we encourage you to discuss your proposals and research ideas with the appropriate scientific contacts listed in Section VII of the funding opportunity announcement (FOA) to which you plan on applying.

## **Eligibility**

### **Eligible Organizations**

2. Are NIH intramural scientists eligible to apply?
  - A. **K01**: No. The NIH Intramural Research Program is not an eligible applicant organization. At the time of award, the candidate must have a full-time appointment at the applicant institution.
  - B. **K99/R00**: Yes. The NIH Intramural Research Program is an eligible applicant organization.
3. Are foreign institutions eligible to apply for the Tobacco Regulatory Research K01 and K99/R00?
  - A. No.

## Eligible Individuals

4. Under what conditions may people in tenure track positions apply to these K01 and K99/R00 RFAs?
  - A. Individuals who are in tenure track positions may not apply to the Pathway to Independence (K99/R00) RFAs because the purpose of both is to allow the awardee to secure a tenure track position. Potential applicants to the K01 award who are in tenure track positions are still eligible if, at the time of application, they have not been and are not currently the Principal Investigator (PI) on an NIH research project (R01), program project (P01), center grant (P50), sub-project of a program project (P01), sub-project of a center grant (P50), other career development awards (K awards), or the equivalent.
5. Are NIH Intramural Research Training Award (IRTA) program trainees eligible to apply for the K99/R00 RFA?
  - A. Postdoctoral trainees in the IRTA program are eligible to apply for the K99/R00 career awards. IRTA trainee applicants must, of course, also meet the other eligibility criteria for these tobacco regulatory research career awards.
6. Are foreign individuals eligible to apply as PIs for the Tobacco Regulatory Research K01 and K99/R00 RFAs?
  - A. For K01: By the time of award, the individual must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card U.S. Citizenship and Immigration Services (USCIS) Form I-551, or other legal verification of such status).
  - B. For K99/R00: There is no citizenship requirement for K99 applicants. An applicant may be a citizen or a non-citizen national of the United States, have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status), or be a non-U.S. citizen. For applications submitted on behalf of non-U.S. citizens with temporary U.S. visas, visa status during each phase of the K99/R00 award must allow the Program Director (PD)/PI to conduct the proposed research at the applicant institution. For the K99 phase of the award, the applicant institution is responsible for determining and documenting, in the K99 application, that the candidate's visa will allow him or her to remain in the United States long enough to complete the K99 phase of the award. For the R00 phase of the award, the U.S. institution at which the R00 phase of the award will be conducted is responsible for determining and documenting, in the R00 application, that the PD/PI's visa will allow the PD/PI to remain in the United States for the duration of the R00 award.
7. What are the required degrees to apply to these RFAs?
  - A. For K01: Candidates for the K01 award must have a research or health-professional doctoral degree. In addition, this funding opportunity may support individuals who propose to train in a new field or individuals who have had a

hiatus in their research career because of illness or pressing family circumstances.

- B. For K99/R00: Candidates for the K99/R00 award must have a clinical or research doctorate (including Ph.D., M.D., D.O., D.C., N.D., D.D.S., D.M.D., D.V.M., Sc.D., D.N.S., Pharm.D. or equivalent doctoral degrees). Clinicians (including those with M.D., D.D.S., D.V.M. and other licensed health professionals) in a clinical faculty position that denotes independence in clinical responsibilities but not in research may also be eligible for the K99/R00 award.

8. What are the general eligibility requirements for K01 applicants?

- A. Current and former PDs/PIs on an NIH research project (R01), program project (P01), center grants (P50), sub-projects of a program project (P01), sub-projects of center grants (P50), other major individual career development awards (e.g., K01, K07, K08, K22, K23, K25, K76, K99/R00), or the equivalent are not eligible. Current and former PDs/PIs of an NIH Small Grant (R03), Exploratory/Developmental Grant (R21), Dissertation Award (R36), or Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) (R41, R42, R43, R44) remain eligible, as do PDs/PIs of Transition Scholar (K38) awards and individuals appointed to institutional K programs (K12, KL2).

9. What are the general eligibility requirements for K99/R00 applicants?

A. **Individuals are NOT eligible if they:**

- Have currently or previously held an independent research faculty or tenure-track faculty position, or its equivalent, in academia, industry or elsewhere; or
- Have more than 4 years of related postdoctoral research training at the time of initial application or resubmission; or
- Have been an independent PD/PI on NIH research grants (e.g., R01, R03, R21), NIH career development awards (e.g., K01, K07, K08, K23, K25), or other peer-reviewed NIH or non-NIH research grants over \$100,000 direct costs per year, or have been project leaders on sub-projects of a program project (P01) or center grant (P50).

- B. The following is provided as an aid to distinguish independent from non-independent positions. However, it is not sufficient merely to cite one or more of the following items to document eligibility.

Evidence for non-independence may include:

- The candidate's research is entirely funded by another investigator's grants.
- The candidate's research is conducted entirely in another investigator's assigned space.
- According to institutional policy, the candidate cannot hire postdoctoral fellows or technical staff or be the responsible supervisor of graduate students.

- According to institutional policy, the candidate is not allowed to submit an application as the PD/PI of an NIH research grant application (e.g., R01).
- The candidate lacks other rights and privileges of faculty, such as attendance at faculty meetings.

Conversely, evidence for independence, and therefore lack of eligibility, includes:

- The candidate has a full-time faculty position.
- The candidate received a start-up package for support of his/her independent research.
- The candidate has research space dedicated to his/her own research.
- The candidate may attend faculty meetings, be the responsible supervisor for graduate students, and/or hire technical support or postdoctoral fellows.
- The candidate is eligible to apply for independent research funding as the PD/PI of an NIH research grant.

10. How do I determine if my years of research experience since I received my terminal research or clinical doctorate are within the specified years allowed (4 years for the K99)?

- A. The critical issue is the number of years of the applicant's research experience since the terminal doctorate was obtained. Under special circumstances, individuals who received terminal doctorates more than the specified number of years in the FOA may be eligible. For example, a clinical faculty member who does not hold an independent research faculty position or individuals who have experienced a career interruption may need to request consideration of their unique situation. Examples of qualifying interruptions would include a complete or partial hiatus from research activities for child rearing; an incapacitating illness or injury of the candidate, spouse, partner, or member of the immediate family; relocation to accommodate a spouse, partner, or other close family member; pursuit of non-research endeavors; and military service. Potential applicants with clinical non-research positions or who have had research career interruptions should consult with NIH staff at the earliest possible stage.

## Mentoring

11. Do I need a mentor in order to apply for the K01 and K99/R00 awards?

- A. **K01**: Yes. You must identify a primary mentor, or co-mentors, to develop your application. Note that at least one supervising mentor must have expertise in tobacco regulatory research. The mentoring team must demonstrate they not only have the scientific knowledge but the professional knowledge to guide you to research independence.
- B. **K99/R00**: Yes. Before submitting the application, you must identify a primary mentor who will supervise the proposed K99 career development and research experience.

You may identify a mentor and co-mentors to jointly supervise you. Note that at least one supervising mentor must have expertise in tobacco regulatory research. The mentor and co-mentors offer specific expertise that is needed to launch your career as an independent researcher. The mentor and co-mentors are also collaborators who might provide you with expertise and other scientific needs to complete your research.

12. Is it required that mentor(s) have been funded by the Food and Drug Administration (FDA) Center for Tobacco Products (CTP)?

- A. No. It is acceptable for the mentor's experience to be relevant to tobacco regulatory science and not necessary have been funded by the FDA CTP.

### Application

13. What letters are needed for mentored career award applications, and who needs to write them?

- A. Letters of reference are needed from three–five people who have supervised you and know your work. They may not also be mentors or consultants on your proposal.
- B. Letters of support are needed from anyone who has a key role on your project, including mentor(s), consultants, and people providing special materials (e.g., transgenic mice, ligands). It is recommended that they state their role on the project, what resources they will make available specifically to you, and in the case of a mentor, take the opportunity to describe their impression of you. Some use institutional letterhead on the first letter of support (from the primary mentor), and then not for subsequent ones in order to comply with space limitations.
- C. A letter of institutional commitment is needed—usually written by the department chair. It describes the environmental resources and facilities as well as the institution's commitment to your career. As with the other letters, this should be tailored to you and should be fairly detailed in order to avoid the impression of a generic letter. This letter must be on institutional letterhead.
- D. A cover letter needs to accompany your application.

### Budget

14. What are allowable salary and research costs for awarded Tobacco Regulatory Science Research K01 and K99/R00? And are there any other costs?

- A. **K01:** Up to \$90,000 per year toward the salary and \$60,000 toward research development costs of the career award recipient. Indirect costs, also known as facilities and administrative (F&A) costs, are reimbursed at 8% of modified total direct costs.
- B. **K99/R00:** Up to \$90,000 per year toward the salary and up to \$60,000 per year toward research development costs are allowed for the K99 phase. Intramural scientist applicants should not request salary and related fringe benefits. Indirect

costs, also known as F&A costs, are reimbursed at 8% of modified total direct costs. The total cost for the independent investigator (R00) phase may not exceed \$249,000 per year. This amount includes salary, fringe benefits, research support allowance, and applicable F&A costs. Indirect costs will be reimbursed at the extramural sponsoring institution's indirect cost rate.

15. What is the basis of determining the salary of the Tobacco Regulatory Science Research award recipient?

- A. **K01:** At the time of award, the candidate must have a "full-time" appointment at the applicant institution. The award requires the candidate to devote a minimum of 9 person-months (75% of full-time professional effort) to conducting tobacco regulatory research. The remaining effort may be devoted to other research pursuits and activities consistent with the objectives of the award.
- B. **K99/R00:** The K99 salary must be justified by the applicant as consistent with the stage of development of the candidate and the proportion of time to be spent in research or career development activities. The R00 salary should be based on the person-months effort to be devoted to the R00. For both the K99 and R00 phases, candidates must devote a minimum of 9 person-months (75% of full-time professional effort) to conducting tobacco regulatory research. The remaining effort may be devoted to other research pursuits and activities consistent with the objectives of the award.

16. Can mentors be paid from the budget?

- A. As stated in the RFAs, salary for mentors, secretarial and administrative assistants, etc. is not allowed.

### **Attendance at Meetings**

17. Am I expected to attend tobacco regulatory science meetings?

- A. Yes, you are expected to attend and present your research results at a conference or workshop appropriate to furthering your tobacco regulatory research career.

### **Travel**

18. Must funds from the award be used for travel to the two required meetings per year?

- A. Yes

### **Application Requirements/Submission**

19. Where can the applicant find additional information regarding application submission?

- A. The NIH provides multiple resources for applicants with submission questions. Below is a list of resources, depending on the type of question being asked:

- For questions regarding Grants.gov registration and submission, as well as downloading forms and application packages, please contact Grants.gov Customer Support at [support@grants.gov](mailto:support@grants.gov).
- For questions regarding application instructions, process, and finding additional NIH grant resources, please contact [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).
- For questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, and post-submission issues, please see [Need Help?](#)
- For peer review questions, contact Dr. Weijia Ni from the Center for Scientific Review at [weijia.ni@nih.gov](mailto:weijia.ni@nih.gov).
- For financial/budgetary questions, contact the appropriate grants management contact listed in Section VII of the RFA.
- For mechanism-specific, scientific, and responsiveness questions, contact the appropriate scientific contact listed in Section VII of the RFA.
- For information regarding the Tobacco Regulatory Science Program visit <http://prevention.nih.gov/tobacco/>.

20. Am I required to submit a letter of intent (LOI)?

- A. An LOI is not required, and it does not enter into the review process. However, it allows NIH staff to estimate the potential review workload and plan the review. Investigators are encouraged to communicate with NIH scientific contacts to discuss their research ideas and specific aims prior to submitting applications, as all proposed research-specific aims must be within the regulatory authority of the FDA CTP in order to be deemed responsive to this FOA. Applications that are non-responsive will not be reviewed.

Suggested content of an LOI:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity
- Specific aims

21. Where do I send the LOI?

- A. The letter may be sent by email to [TRSP@mail.nih.gov](mailto:TRSP@mail.nih.gov), or by regular mail to:

Tobacco Regulatory Science Program  
 Office of Disease Prevention  
 6100 Executive Boulevard  
 Room 3B01, MSC 7530  
 Bethesda, MD 20892-7530 (Use Rockville, MD 20852 for Express Mail)  
 Tel: 301-451-7464  
 Fax: 301-480-2230

## Responsiveness

22. How do I know if my application is responsive to this FOA?

A. This is a critical question, as each of the specific aims in the application must meet the following criteria to be considered responsive. The project must:

- Address one or more of the eight interest areas listed in the RFAs, and
- Fall within scope of the FDA CTP's regulatory authority.

As such, applicants are strongly encouraged to contact the scientific research contacts listed in Section VII of the RFAs for feedback about responsiveness prior to submitting an application.

Note that upon receipt, applications will be evaluated for responsiveness by the FDA CTP and participating NIH Institutes. Only applications that are within the scope of the eight areas listed in the RFAs and the FDA CTP's regulatory authority will be peer reviewed. Your application title, abstract, and specific aims are used to make this determination, so it is important that you are clear about your proposed scientific aims and how they may potentially inform the CTP's regulatory authority. Staff reviewing your application will refer to other parts of the application if responsiveness is unclear based on title, abstract, and specific aims. If your application is deemed responsive, it will undergo scientific peer review by experts convened specifically for these RFAs (by the NIH Center for Scientific Review). If your application is deemed non-responsive, it will be withdrawn prior to evaluation of its scientific merit (i.e., peer review).

23. The FDA CTP has regulatory authority over the manufacture, marketing, and distribution of tobacco products. What are some examples of these authorities?

A. [The Family Smoking Prevention and Tobacco Control Act](#) gave the FDA responsibility and authority to, among other things:

- Restrict cigarettes and smokeless tobacco retail sales to youth.
- Restrict the sale and distribution of tobacco products, including advertising and promotion, as appropriate to protect public health.
- Review modified-risk tobacco products, such as those marketed for use to reduce harm, prior to their introduction to the market.
- Adjust warning labels for cigarettes and smokeless tobacco products in order to promote greater public understanding of the risks of tobacco use.
- Establish standards for tobacco products (for example, setting limits on harmful and potentially harmful constituents and nicotine levels) as appropriate to protect the public health.
- Review new tobacco products prior to their introduction to the market.



For more information, see [Family Smoking Prevention and Tobacco Control Act—an Overview](#).

24. What are the research interest areas for these RFAs?

- A. These RFAs are focused on the following eight FDA CTP interest areas. Only applications proposing research projects relevant to one or more of these eight areas will be considered for funding. Refer to the RFA for full descriptions of these domains.
1. Chemistry and Engineering
  2. Toxicity
  3. Addiction
  4. Health effects
  5. Behavior
  6. Communications
  7. Marketing influences
  8. Impact analysis

25. Are the eight research priorities in the RFA listed in order of priority to the FDA, or are they of equal priority?

- A. The research priorities are not listed in priority order. They are of equal priority to the FDA CTP.

26. What topics are non-responsive to these RFAs?

- A. Although the following research topics may be within FDA CTP's regulatory authority to fund, they are not to be included in these RFAs and will be deemed out of scope and not reviewed:
- Studies of short-term health effects and/or acute toxicology/clinical pharmacology testing of early generation electronic nicotine delivery systems (ENDS) products.
  - Mechanistic studies (i.e., basic science of disease development) unless biomarkers of harm with predictive value for disease development associated with tobacco product use is an outcome.
  - Short-term studies of the acute effects of reduced nicotine content cigarettes.
  - Graphic health warnings for cigarette packages and advertisements.
  - Communicating harmful and potentially harmful constituents to the public.
  - Impacts of marketing restrictions on adults.
  - Descriptive studies of demographics and/or risk perceptions that describe only exposure to advertising without linking exposure to tobacco use behaviors.

27. May researchers include foreign populations in their proposed research?

- A. Foreign populations may be included if the product under study is the same as the one(s) used in the United States. Results from foreign populations must be relevant to the U.S. population and U.S. regulation of tobacco.

28. In general, what areas of research are not within the FDA CTP's regulatory authority?

- A. The Family Smoking Prevention and Tobacco Control Act gives the FDA the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by youth. In general, the CTP's regulatory authorities do NOT extend to the following:

- Setting tax rates and prices for tobacco products.
- Regulating therapeutic products, such as those marketed to treat tobacco dependence.
- Setting clean indoor air polices.

29. Is a research proposal in which the primary outcome identifies differential effects of various tobacco products on disease risk, incidence, or progression of disease considered responsive?

- A. Yes. A proposal identifying differential effects of various tobacco products on disease would be responsive. Examples\* might include:
- Pulmonary function-testing outcomes following use of various combustible tobacco products
  - Oral manifestations following use of various tobacco products, especially new and emerging tobacco products.

*\* The examples provided are illustrative and should not be viewed as definitive or comprehensive.*

30. Within the scientific domains of "toxicity" or "health effects," is a research proposal that investigates the mechanisms and/or etiology of tobacco-related disease responsive?

- A. It depends. Mechanistic and/or etiologic research is largely relevant to disease prevention or treatment, neither of which is within the CTP's regulatory authority, so would not be considered responsive. These types of research may in some cases be responsive, but only if the outcomes of the research inform the mandate of the FDA CTP. For example, research comparing the mechanistic processes or underlying disease etiology of different tobacco products or their constituents may be considered responsive. As such, it is important to discuss your research concept with an NIH Scientific/Research Contact and to consider submitting an LOI.

31. Within the scientific domains of "addiction," "toxicity" or "health effects," is a treatment intervention study designed to compare the effectiveness of various tobacco products on tobacco cessation considered responsive?

- A. No. The CTP's regulatory authority does not extend to regulating therapeutic uses of tobacco products as this authority rests with other Centers within the FDA. Examples of research projects that would be considered responsive include an observational study to examine the natural history of whether participants quit smoking cigarettes while using a different tobacco product, and assessing if communications regarding the health consequences of using tobacco products have an impact on usage rates.\* In many of its key regulatory areas, the CTP is charged with assessing the impact of tobacco products on the health of the population as a whole, taking into account both users of tobacco products and people who do not currently use tobacco products, as well as the increased or decreased likelihood that existing users of tobacco products will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using such products.

*\* The examples provided are illustrative and should not be viewed as definitive or comprehensive.*

32. Within the scientific domains "toxicity" or "health effects," is a research proposal in which the primary outcome informs treatment of disease considered responsive?

- A. No. The CTP does not regulate products or support development of clinical interventions intended for the treatment of disease. For example, pharmacotherapy for treatment of cancer or emphysema, screening, physical activity, or dietary interventions for heart disease would all be considered non-responsive.\*

*\* The examples provided are illustrative and should not be viewed as definitive or comprehensive.*

33. What types of biomarker research may be appropriate for FDA CTP funding?

- A. Proposals identifying biomarkers of specific tobacco product exposure and/or disease and those with the potential to differentiate exposure of differing tobacco products could be considered responsive.

Examples\* include:

- Biomarkers to measure exposure to new and emerging tobacco products.
- Biomarkers of disease (e.g., cancer, cardiovascular disease, pulmonary disease, reproductive and developmental effects) that can be associated with specific measures of tobacco exposure.
- Development of a non-clinical biomarker of disease coupled to traditional toxicology and/or pharmacology studies to provide a relevant framework for the regulatory application.
- Studies linking biomarkers of disease in non-clinical models that translate to biomarkers that are measurable in the clinical setting.
- Magnitude of changes in biomarkers that translates into clinically meaningful impacts on human health outcomes.

Biomarker research may fall within the scope of one or more of the eight interest areas, depending on the intended use of the biomarker. However, there is research

that will remain outside of FDA CTP authorities such as biomarker research for which the primary focus is to inform treatment.

*\* The examples provided are illustrative and should not be viewed as definitive or comprehensive.*

34. What types of research on nicotine and/or nicotinic receptors are appropriate for consideration of funding by the CTP?

A. If the research provides information on outcomes such as motor activity, memory, or neuronal responses to particular ligands, the research is likely not appropriate. Research to rapidly screen tobacco constituents for activity at the nicotinic receptor to determine their dependence potential would be considered responsive.\*

*\* The examples provided are illustrative and should not be viewed as definitive or comprehensive.*

35. Are studies on the impact of state and local tobacco control policies responsive?

A. It depends upon the specific policies being examined and whether they fall under the purview of the FDA CTP. Studies evaluating the impact of a tobacco tax increase are not responsive, as the CTP does not have regulatory authority regarding tax rates on tobacco products. Similarly, the CTP does not have authority over the sale of tobacco cessation medications. For example, a study evaluating the effectiveness of providing free nicotine replacement therapy for tobacco cessation would not be considered responsive. Studies evaluating the impact of a tobacco advertising restriction, a ban on the sale of flavored tobacco products, or restrictions on the sale of single serving products, however, may be considered responsive.\*

*\* The examples provided are illustrative and should not be viewed as definitive or comprehensive.*

36. Are public opinion polls about tobacco regulations responsive to FDA CTP regulatory authorities?

A. Unlike state or local policymaking, where public support can be an important factor in the adoption and implementation of policies, public opinions cannot be used to support federal regulations.

37. Is the CTP interested in graphic health warning research given that the U.S. government did not seek Supreme Court review of the court decision that blocked the implementation of graphic health warnings on cigarette packages and advertising?

A. No, as indicated in the non-responsive research topics in the RFA, studies on graphic health warnings for cigarette packages and advertisements are not allowed. However, the FDA is committed to funding and conducting research on graphic health warnings on alternative tobacco products.

38. What topics are considered responsive within the scientific domain of “impact analysis”?

A. The following types of analyses are examples\* of topics that would be considered responsive under “impact analysis”:

- Computational/mathematical modeling and simulation and/or statistical modeling of the public health impact of potential FDA CTP action.
- Health and economic impact of tobacco use and/or tobacco regulatory policies on vulnerable populations.
- Economic burden (e.g., health care cost, productivity loss) of tobacco-related diseases on users and non-users (e.g., secondhand and thirdhand exposure).
- Studies evaluating the impact of tobacco regulatory actions (e.g., mandated changes in product characteristics) on consumer behavior or behavioral intentions.

*\* The examples provided are illustrative and should not be viewed as definitive or comprehensive.*

39. Will applications that propose to study products not yet available in the United States be considered responsive?

A. Yes, if the product(s) meets the statutory definition of a “tobacco product” under the Tobacco Control Act (i.e., any product made or derived from tobacco and intended for human consumption, including any component, part, or accessory of a tobacco product), then studies examining these products could be considered responsive to the RFA. However, the application must demonstrate that the proposed research can directly contribute to the FDA’s regulatory authority over the manufacture, marketing, and distribution of tobacco products within the United States. As the relevance may be dependent on not only the product, but also the types of research being conducted, we recommend that you discuss any particular proposed research with one or more of the Scientific/Research Contacts listed in Section VII of the RFAs.

40. Would an application that proposed to study a heat-not-burn product that is already included in a modified-risk tobacco product (MRTTP) application be considered responsive?

A. Potentially, yes. While heat-not-burn products would be considered a “tobacco product” under the Tobacco Control Act and would fall under the regulatory authority of the FDA CTP as a result of the [deeming rule](#), both the responsiveness of a research proposal investigating this product and its relevance to the FDA CTP priorities would depend upon the type of research being proposed. As such, we recommend that you discuss any particular proposed research with one or more of the Scientific/Research Contacts listed in Section VII of the RFAs.

41. The RFA states that “short-term studies of the acute effects of reduced nicotine content cigarettes” would be deemed non-responsive to the RFA. What does this RFA consider “short-term”?
- A. There is not a specific timeframe that defines “short-term” or acute outcomes. However, the appropriate length for any study is dependent upon the research question. Applicants are encouraged to familiarize themselves with the funded research and published literature in this area through the [NIH](#), the [Tobacco Regulatory Science Program \(TRSP\)](#), and other [CTP-supported tobacco regulatory research projects](#) and see how their proposed research could expand on the current understanding of reduced nicotine cigarette use.
42. The RFA states that when addressing chronic toxicity, short-term studies of acute or subchronic toxicity would be deemed non-responsive to the RFA. What does the RFA consider “short term”?
- A. 90 days or less would be considered short term unless the applicant provides a rationale explaining how shorter studies are relevant to long-term effects.

## **Review**

43. Will more weight be assigned in the review for applications that address more than one of the eight priority areas?
- A. No. Reviewers will be looking to see if the research question is addressed adequately and appropriately. When approaching which research priorities to address, we recommend that investigators think about what scientific evidence the FDA would need to support a product review process or regulatory decision.
44. On what basis are applications selected for funding?
- A. Applications will be selected for funding based on scientific merit, current availability of funds, and FDA CTP current research priorities.

## **Post-Award Management and Reporting**

45. Which NIH Institute/Center will manage my award?
- A. It depends on the nature and scope of the research projects proposed. Applicants may request assignment to a particular Institute in their cover letter, but the NIH will make the final determination regarding Institute assignment.
46. Are the reporting requirements for these awards the same as other NIH grants?
- A. No. A mid-period progress report will be due every 6 months following the project start date, as well as the annual progress report and all reports required by the NIH at the time of grant close-out. Mentors must also provide evaluations in the mid-year progress reports.

47. Are policies and procedures different for these awards?
- A. Yes. This includes exclusion from Streamlined Non-Competing Award Procedures (SNAP) and all carryover requests requiring prior approval from both the NIH and FDA CTP.
48. Some researchers are under limitations with respect to accepting funds from the tobacco industry. How will these FDA research awards be funded?
- A. As mandated in the Tobacco Control Act, the FDA is authorized to collect fees from tobacco product manufacturers and importers for its activities related to the regulation of the manufacture, distribution, and marketing of tobacco products. Although the tobacco user fees are specified in statute, Congress must actually appropriate the funds before the FDA can obligate them. The tobacco industry has no control over FDA CTP funding decisions. The FDA uses some of these funds to award research grants.
49. What will be the availability of confidential information obtained by the FDA—for example, product and constituent reporting?
- A. Several laws govern the confidentiality of tobacco product information submitted to the FDA, including sections 301(j) and 906(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Trade Secrets Act, and the Freedom of Information Act, as well as the FDA's implementing regulations. The FDA's general regulations concerning the public availability of FDA records are contained in 21 Code of Federal Regulations (CFR) Part 20. Regarding the reporting of constituents, the FD&C Act requires tobacco product manufacturers and importers to report quantities of harmful and potentially harmful constituents (HPHCs) in tobacco products or tobacco smoke by brand and sub-brand. The FD&C Act also directs the agency to publish a list of HPHCs by brand and by quantity in each brand and sub-brand, in a format that is understandable and not misleading to a layperson.
50. If a scientific study proposes to make ANY change to a commercialized tobacco product (e.g., manipulating the size of the product; putting the tobacco product in different colored packaging), then an investigational tobacco products (ITP) request is recommended by the FDA (Reference: [Draft Guidance Use of Investigational Tobacco Products](#)). What information is required in the ITP request?
- A. The information needed in an ITP request may vary depending on the proposed ITP and the type of study. The FDA needs to determine whether the product is a tobacco product, whether the tobacco product is within our current jurisdiction, whether the tobacco product is an ITP, and whether the study products will be provided to human subjects. For example, if one makes a change in labeling of a commercially marketed tobacco product and it will not be used by human subjects, no ITP request is needed. If one makes a change in labeling of a commercially marketed tobacco product and there will be actual use by human subjects, then the FDA recommends that an ITP request come to the FDA CTP for review, but it is likely that chemistry, engineering, and manufacturing will not be needed. If you have questions about ITP, please contact Debbie Cordaro ([debbie.cordaro@fda.hhs.gov](mailto:debbie.cordaro@fda.hhs.gov)).

## Research Resources

51. What is the PhenX Toolkit, and why does the RFA encourage its use?
- A. The [PhenX Toolkit](#) is a web-based catalog of freely-available standard measures that are intended to serve as common data elements across research studies. The measures span many scientific domains and include Specialty Collections in Tobacco Regulatory Research. As noted in [NOT-OD-17-034](#), the Tobacco Regulatory Research Collections provide a common set of recommended measures that, when incorporated across studies, will facilitate data sharing, comparing, and integration, as well as replication and validation of findings. The measures that are included in the PhenX Toolkit were identified by working groups of experts within each of the scientific domains, followed by outreach to the relevant scientific communities to establish a consensus for the prioritized, recommended measures. PhenX Toolkit measures are typically well-established, broadly validated measures that are low-burden to the participant and investigator. The Tobacco Regulatory Research Collections include standard measures like the Fagerstrom Test for Nicotine Dependence and questions found in large and/or nationally-representative surveys like the Population Assessment of Tobacco and Health (PATH) and the National Youth Tobacco Survey (NYTS). For more information about the Tobacco Regulatory Research Collections in the PhenX Toolkit, see the [TRSP website](#).
52. Will the National Institute on Drug Abuse (NIDA) research cigarettes (e.g., SPECTRUM) be available for research funded through this RFA on a similar basis as currently?
- A. Yes. Nicotine Research Cigarettes, SPECTRUM Cigarettes, will be available for these awards. Please visit [Nicotine Research Cigarettes Drug Supply Program](#) for updated information on the NIDA Drug Supply Program and the application process.
53. Might it be possible to obtain other research tobacco products (e.g., cigars, roll-your-own tobacco, or e-cigarettes) with known nicotine concentrations for use in research funded through this RFA?
- A. At this time, we are aware of one additional research tobacco product, the [standardized research e-cigarette \(SREC\)](#) developed by NIDA. Unlike the SPECTRUM combustible cigarettes provided by NIDA to researchers at no cost, the SREC was developed under a small business contract issued by NIDA to NJOY, LLC. Please visit the website for additional information.

NIH-FDA Tobacco Regulatory Science Program website: <http://prevention.nih.gov/tobacco/>