



REQUEST FOR DETERMINATION OF RESEARCH STATUS

To be completed by the staff member with lead responsibility for the project and approved by branch chief (if applicable) and Division ADS. A separate PGO funding memo is required if project is research and involves human subjects regardless of the CDC staff role.

- Instructions:**
- (1) Use this form to declare: (a) the research status of any project, (b) role or roles of CDC staff
 - (2) A short summary should be attached offering specific details about the project and the role of staff.
 - (3) Be sure to complete all applicable items, obtain appropriate signatures and submit this form for approval.

Tracking Number: _____
 (Use PGO number if cooperative agreement, grant, etc.)

Date submitted: 05/25/2018
Title of Project: Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S.

Dates for project period: **Dates for funding (if applicable):**

Beginning: 01/01/2019 **Beginning:** _____
Ending: 12/31/2022 **Ending:** _____

Project is (choose one):

NOTE: Revision, as used below, refers to any substantive change made to the project including scope of project, funding restrictions, personnel, role of CDC staff member, determination of research status, etc.

- New** **Revision**
 Continuation, without revision(s) **Continuation, with revision(s)**

Lead staff member:	Contact information:	Please indicate your role(s) in this project:	
Name: <u>Leslie Norman</u>	Division: <u>OSH</u>	<input checked="" type="checkbox"/> Project officer	<input type="checkbox"/> Technical monitor
User ID: <u>LANO</u>	Telephone: <u>770-488-5469</u>	<input type="checkbox"/> Principal investigator	<input type="checkbox"/> Investigator
Scientific Ethics number: _____	Mailstop: <u>S107-7</u>	<input type="checkbox"/> Consultant	<input type="checkbox"/> Other (please explain)

- 1. Are any or all of the activities within this project DESIGNED to contribute to generalizable knowledge (i.e., research)?**
 YES **NO**
If YES, list those activities which are research:

- 2. Is this CDC project research or public health practice (check all that apply)?**
- | | |
|---|--|
| <input type="checkbox"/> Research | <input checked="" type="checkbox"/> Public health practice |
| <i>Check one:</i> | <i>Check all that apply:</i> |
| <input type="checkbox"/> Human subjects involved | <input type="checkbox"/> Emergency Response <input type="checkbox"/> Surveillance |
| <input type="checkbox"/> Human subjects not involved | <input type="checkbox"/> Program evaluation <input checked="" type="checkbox"/> Other (please explain) |

Comprehensive
Smokeless
Tobacco
Health
Education
Act of 1986
(15 U.S.C. '4401 et
seq.; Public
Law 99-
252)

- 3. If RESEARCH involving human subjects, has the project or research activities been reviewed by the CDC IRB for human subjects protection?**
- a. **NO, New project, not yet reviewed** d. **YES, Reviewed and approved by CDC**

Tracking NO. No Funding

- b. NO, Existing project, not ready to submit If YES, please list protocol number_and
c. NO, Submitted for approval expiration date _____
e. NO, RESEARCH, no CDC investigators (CDC IRB not required)
f. N/A (Not Applicable)

If RESEARCH, list any other CDC staff involved in this project, please include the name, role, and scientific ethics number

Name	Role (project officer, investigator, consultant, etc.)	Scientific ethics number Prin
Leslie Norman		

IF YOU THINK THE RESEARCH PROJECT MIGHT QUALIFY AS EXEMPT RESEARCH (as identified in 45CFR46.101), PLEASE ANSWER questions 4-6, OTHERWISE SKIP TO question 7.

4. Does the proposed research involve prisoners?
 YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7).
 NO
5. Does the proposed research involve fetuses, pregnant women, or human in vitro fertilization as targets (such that Subpart B would apply)?
 YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7).
 NO

Educational Research

- 6.1 Is this research conducted in established or commonly accepted educational settings, AND does the research involve normal educational practices (e.g., research on regular and special education strategies or research on the effectiveness of, or comparison among instructional techniques, curricula or classroom management methods)?
 YES NO

Research Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational Tests

- 6.2 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior?
 YES NO If NO skip 6.3
Will children (<18 years of age) be research subjects?
 YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to item 7)
 NO
- 6.2.1 Is the information obtained recorded in such a manner that human subjects can be identified directly or indirectly through identifiers (such as a code) linked to the subjects;
 YES NO
- 6.2.2 Will any disclosure of the human subjects' responses outside of the research setting have the potential to place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability or reputation? (Examples here may include: the collection of sensitive data regarding the subjects' (or relatives' or associates') possible substance abuse, sexuality, criminal history or intent, medical or psychological condition, financial status, or similarly compromising information).
 YES NO
- 6.3 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior but the research is not exempt under paragraph 6.2 of this section:
 YES NO If NO skip to 6.4
- 6.3.1 Will this research involve human subjects that are elected or appointed public officials or candidates for public office?
 YES NO
- 6.3.2 Does federal statute(s) require(s) without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter? (Note: CDC can use this exemption criterion only in the case where a 308(d) Assurance of Confidentiality has been obtained to cover the research).

Tracking NO. No Funding

YES NO

Existing Data Which Is Publicly Available or Unidentifiable

6.4 Does this research involve only the collection or study of existing* data, documents, records, pathological or diagnostic specimens? (* 'existing' means existing before the study begins)?

YES NO If NO skip to 7

6.4.1 Is this material or information publicly available?

YES NO

6.4.2 Is this material or information recorded in such a manner by the investigator that the subjects cannot be identified directly or indirectly through identifiers linked to the subjects?

(Note: If a link is created by an investigator even temporarily, for research purposes, this criterion is not met. If a temporary link is created by clinical staff who already have access to the data, this criterion is met).

YES (there are no identifying information and no unique identifiers or codes)YES

NO (there are identifiers (including codes))

7. Please prepare and attach a short summary paragraph (<1 page); if this is new:

a. Be sure to include the purpose of the project, specific details about the project and the role of the CDC staff member (s) in the project. In explaining one's role as a consultant be particularly careful to identify involvement in things like: study design decisions, oversight of protocol development, participation in review of data collection procedures, and participation in data analysis and/or manuscript preparation, as well as whether there will be access to identifiable or personal data.

b. Explain your project status selection (research--non-exempt, exempt, no CDC investigator or not involving human subjects; public health practice). If you selected research not involving human subjects be sure to indicate if the data includes any personal information (e.g., name, SSN), linkable study identification numbers or codes, or geographical information.

This public health project data collection is Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. ' 4401 et seq.;;) requires each commercial entity that manufactures, packages, or imports smokeless tobacco products to provide HHS (through CDC) with a list of ingredients added to tobacco in the manufacture of smokeless tobacco products. Respondents are commercial smokeless tobacco product manufacturers, packagers, or importers. Manufacturers submit a summary report to CDC with the ingredient information for multiple products. This ICR has been reviewed by staff in CDC who have determined that the Privacy Act is not applicable.

Respondents are business entities, not individuals. Each respondent entity is represented by a contact person; however, no personal information is being collected. All information is filed and retrieved by name of the smokeless tobacco product manufacturer or the attorney representing the manufacturer, therefore, the information does not fall under the purview of the Privacy Act.

CDC staff members on this project include a project officer, information collector and a data analyst.

8. Please list the primary project site and all collaborating site(s).

Explanation of project components:

9. If project involves research that is funded extramurally, list amount of award that should be restricted pending IRB approval and describe which project components will be affected, if known:

Approvals (signature and position title)	Date	Research Determination / Remarks
Ruth Hayes - Carter Consulting Inc	06/04/2018	<input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt (check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB

staff member completing this form		<u>Comments:</u>
Elizabeth Reimels - PUBLIC HEALTH ANALYST Team Lead	06/04/2018	<input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt (check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB <u>Comments:</u>
Brian Armour - ASSOCIATE DIRECTOR OF SCIENCE Division ADS	07/09/2018	<input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt (check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB <u>Comments:</u> Approved.
Joan Redmond Leonard - PUBLIC HEALTH ANALYST CUC ADS, Deputy ADS, or Human Subjects Contact	07/12/2018	<input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt (check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB <u>Comments:</u>