



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: List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products

Dates for project period:

Beginning: 01/01/2019

Dates for funding (if applicable):

Ending: 12/31/2022

Beginning: _____

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.

[X] New

[] Revision

[] Continuation, without revision(s)

[] Continuation, with revision(s)

Lead staff member:

Name: Leslie Norman

Contact information:

Division: OSH

Please indicate your role(s) in this project:

[X] Project officer

[] Technical monitor

User ID: LAN0

Telephone: 770-488-5469

[] Principal investigator

[] Investigator

Scientific Ethics number: _____

Mailstop: F79

[] Consultant

[] Other (please explain)

1. Are any or all of the activities within this project DESIGNED to contribute to generalizable knowledge (i.e., research)?

[] YES [X] NO

If YES, list those activities which are research:

2. Is this CDC project research or public health practice (check all that apply)?

[] Research

[X] Public health practice

Check one:

Check all that apply:

[] Human subjects involved

[] Emergency Response

[] Surveillance

[] Human subjects not involved

[] Program evaluation

[X] Other (please explain)

Comprehensive
Smoking
Education
Act of 1984
(15 U.S.C.
1335a(a))

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

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)

Tracking NO. No Funding

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).

- [] 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)?

Tracking NO. No Funding

<input type="checkbox"/>	YES	<input type="checkbox"/>	NO	If NO skip to 7
6.4.1 Is this material or information publicly available?				
<input type="checkbox"/>	YES	<input type="checkbox"/>	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).				
<input type="checkbox"/>	YES	(there are no identifying information and no unique identifiers or codes) YES		
<input type="checkbox"/>	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 Congressionally mandated Comprehensive Smoking Education Act of 1984 (15 U.S.C.' 1335a(a)) requires each commercial entity that manufactures, packages, or imports cigarettes to provide HHS (through CDC) with a list of ingredients added to tobacco in the manufacture cigarettes. Respondents are commercial cigarette manufacturers, packagers, or importers. Manufacturers submit a summary report to CDC with the ingredient information for of 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 cigarette 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
Leslie Norman - PUBLIC HEALTH ANALYST	05/25/2018	<p><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</p> <p>(check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u></p> <p>staff member completing this form</p>

Leslie Norman - PUBLIC HEALTH ANALYST	06/04/2018	<p><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</p> <p>(check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB</p>
Team Lead		<u>Comments:</u>
Israel Terungwa Agaku - Senior Service Fellow	06/04/2018	<p><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</p> <p>(check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB</p>
Division ADS		<u>Comments:</u>
Joan Redmond Leonard - PUBLIC HEALTH ANALYST	06/07/2018	<p><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</p> <p>(check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB</p>
CUC ADS, Deputy ADS, or Human Subjects Contact		<u>Comments:</u>