

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.

					Jse PGO number if coo		e agreement, gr	ant, etc.)
Date submitt	ed: 09/13/2017							
Title of Proje	ect: National Tobacc	o Education Ca	ampaign					
Dates for pro			Dates for fundi	ing (if	f applicable):			
Beginning		•	Beginning:		пррисшоло).			
Ending:	09/28/2017		Ending:					
_			o o				_	
Project is (ch								
	vision, as used below, refers role of CDC staff member, a				e project including scop	pe of pro	oject, funding r	estrictions,
[X] Nev	v			[]	Revision			
[] Continuation, without revision(s)		n(s)			Continuation, with	nuation, with revision(s)		
Lead staff m	ember:	Contact info	rmation:	Ple	ease indicate your role	e(s) in tl	nis project:	
Name:	Michelle O'Hegarty	Division:	OSH	[]	Project officer	[]	Technical r	nonitor
User ID:	IZR0	_	770-488-5582	[]	Principal investigator	[]	Investigato	r
	Ethics number: 1611	-	770 100 0002	- []	Consultant	[X]	Other (plea	se explain)
		<u>-</u>		_			oject Lead for ivities	=
	list those activities which a		rtice (check all	that s	annly)?			
[]	Research	eric ireniui priid			alth practice			
.,	Check one:				that apply:			
	[] Human subjects i	nvolved	[]		mergency Response	[]	Surveillance	
	[] Human subjects i		[]		ogram evaluation	[X]	Other (please	e explain)
	ŭ						-	Public Health Campaign Developm nt
	EARCH involving human soprotection?	ubjects, has the	project or rese	earch	activities been review	ed by t	he CDC IRB f	or human
a. []	NO, New project, not yet r	eviewed	d. []	YES	S, Reviewed and appro	oved by	CDC	
b. []	NO, Existing project, not r	eady to submit]	If YES, please list pro		ımber and	
c. []		•			ii 1 E5, piease iist pro	tocol ni		
	NO, Submitted for approv	al			expiration date	tocol ni		
	NO, Submitted for approv	al	e. []	NO,	-			IRB not

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, Scientific ethics consultant, etc.) number Prin Michelle O'Hegarty 16113 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. 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 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 instrucational techniques, curricula or classroom management methods)? 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? 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; 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). 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: NO If NO skip to 6.4 Will this research involve human subjects that are elected or appointed public officials or candidates for 6.3.1 public office? [] NO [] 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). NO YES [] [] **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

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		6.4.1	Is this ma	aterial or info	rmation publicly	available?		
			[]	YES	[]	NO		
		6.4.2				in such a manner by the invidentifiers linked to the subj	vestigator that the subjects cannot be jects?	
							search purposes, this criterion is not mess to the data, this criterion is met).	et.
			[]	YES	(there are no ide	ntifying information and no	unique identifiers or codes)YES	
			[]	NO	(there are identi	iers (including codes))		
7.			e and attac	ch a short sum	ımary paragraph	(<1 page);		
	if this i	f 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 (researchnon-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.						
		Important NOTE/CONTEXT: OSH has developed rough cut advertisements for the 2018 National Tobacco Education campaign. Rough cut advertisements are near-final versions of advertisements with unedited photos, placeholder, and voiceovers. A. Purpose: Rough cut testing is a formative activity that evaluates participants' reactions to near final versions of advertisements to ensure they are clear, credible, believable, and persuasive. Rough cut testing is crucial to ensuing that the ads inform the target audience of the health consequences caused by smoking cigarettes and motivates them to take action (e.g., quit smoking cigarettes or talk to a loved one about the dangers of smoking cigarettes). The rough cut ads were developed by Arnold Worldwide and The Plowshare Group in collaboration with CDC which are designed to encourage smokers to quit. There are seven rough cut ads that will be tested among adult cigarette smokers and adult nonsmokers. The rough cut ads feature former smokers from the Tips® campaign and focus on the following: Brian (lung cancer); two executions featuring Christine (oral cancer); Sharon (throat cancer); a nicotine replacement therapy ad featuring Tiffany/Sharon (two versions will be tested with the call to action being the sole difference); and one ad (Brian, Christine, or Sharon) that features a participant voiceover for the call to action as opposed to the announcer voiceover featured in previous Tips® ads. Quantitative methods will be used to collect information with adult cigarette smokers and adult nonsmokers 18-54 years old to gather feedback on the ads. Information learned from the online quantitative test has immediate benefit for the program. The results from testing will be used to refine and finalize the ads for the 2018 campaign. B. Project status section: Public Health Practice. This activity is designed to inform the 2018 National Tobacco Education campaign.						
8.	Please	se list the primary project site and all collaborating site(s).						
	Explar	lanation of project components:						
9.		project involves research that is funded extramurally, list amount of award that should be restricted pending IRB oproval and describe which project components will be affected, if known:						

Approvals (signature and position title)	Date	Research Determination / Remarks
Lindsey McCarter - HEALTH COMMUNICATION SPECIALIST	09/13/2017	[X] Public health practice [] Research not involving human subjects [] Research involving human subjects, no CDC investigators [] Research involving human subjects, CDC investigators, exempt [] Research involving human subjects, CDC investigators, not exempt (check if applicable) [] Local IRB [] CDC Exemption [] CDC IRB
staff member completing this form		Comments:

Form 684R_NR (revised January 2003)

Diane Beistle - LEAD HEALTH COMMUNICATIONS SPEC.	09/13/2017	[X] Public health practice [] Research not involving human subjects [] Research involving human subjects, no CDC investigators [] Research involving human subjects, CDC investigators, exempt [] Research involving human subjects, CDC investigators, not exempt (check if applicable) [] Local IRB [] CDC Exemption [] CDC IRB	
Team Lead		Comments: approved	
Israel Terungwa Agaku - Senior Service Fellow	09/13/2017	[X] Public health practice [] Research not involving human subjects [] Research involving human subjects, no CDC investigators [] Research involving human subjects, CDC investigators, exempt [] Research involving human subjects, CDC investigators, not exempt (check if applicable) [] Local IRB [] CDC Exemption [] CDC IRB	
Division ADS		Comments:	
Joan Redmond Leonard - PUBLIC HEALTH ANALYST	09/13/2017	[X] Public health practice [] Research not involving human subjects [] Research involving human subjects, no CDC investigators [] Research involving human subjects, CDC investigators, exempt [] Research involving human subjects, CDC investigators, not exempt (check if applicable) [] Local IRB [] CDC Exemption [] CDC IRB	
CUC ADS, Deputy ADS, or Human Subjects Contact		Comments:	