

## 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.				
<b>Instructions:</b>	(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 pro-	oject and the role of staff.		
	(3) Be sure to complete all applicable items, obtain appropriate signatures and	l submit this form for approval.		
	Tracking Number:	To Be Determined		

<b>Date submitted:</b> 06/23/2015								
Title of Pr	roject:	Working with Pub Vulnerable Popul		Health Cen	ters to Re	educe Teen Pregnar	ncy amo	ng Youth from
Dates for	project	t period:		Dates for fu	unding (if	applicable):		
Beginni	ing:	09/30/2015		Beginning: Ending:		09/30/2015		
Ending	<b>;:</b>	09/29/2020				09/29/2016		
Project is	(choos	se one):						
		on, as used below, refers to e of CDC staff member, de				e project including sco	pe of pro	eject, funding restrictions,
[X] N	New					[] Revision		
[] Continuation, without revision(s)			(s)		[]	Continuation, with revision(s)		
Lead staff	f memb	ber:	Contact info	rmation:	Ple	ase indicate your role	e(s) in th	uis project:
Name:	Tr	risha Mueller-peterson	Division:	DRH	[X]	Project officer	[]	<b>Technical monitor</b>
	_		_		[]	Principal	[]	Investigator
User II	_	ZJ5	Telephone:	770-488-6		investigator		
		1	Mailstop:	F74	[]	Consultant	[]	Other (please explain)
<b>1.</b> Are a	any or a	all of the activities within the second of the s	chis project DE				wledge (i	.e., research)?
1. Are a	any or a YI ES, list	all of the activities within the ES [X] No those activities which are	chis project DE.  O e research:	SIGNED to	contribute	e to generalizable knov	vledge (i	.e., research)?
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Name						Scientific ethics number Prin				
Trisha Mueller-peter				erson					14399	
				EARCH PRO					I (as identified in 45CFR46.101),	
4.			•	sed research			•			
	[]	YES			-			ted and must be reviewed b	oy an IRB (skip to question 7).	
	[]	NO		, .					, and the second second	
5.	Does			arch involve	fetuses, p	oregnant v	women, o	r human in vitro fertilizati	on as targets (such that Subpart B	
	[]	YES								
	[]	NO								
Eď	ucation	al Resea	<u>rch</u>							
	6.1	norma	ıl educati	onal practice	es (e.g., re	search on	regular :	and special education strat	gs, AND does the research involve regies or research on the sroom management methods)?	
		[]	YES	•	[]	NO		• /	,	
Re	search l		g Surveys	<u>, Interview</u> F		s (includi	ing Focus	groups), Observation of P	ublic Behavior, or Educational	
Tes			-	•				2		
	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, th	is researc	h cannot	be exemp	ted and must be reviewed	by an IRB (skip to item 7)	
		[]	NO							
		6.2.1		nformation obtained recorded in such a manner that human subjects can be identified <u>directly or</u> <u>thy</u> through identifiers (such as a code) linked to the subjects;						
			[]	YES		[]	NO			
		6.2.2	the subj employa subjects	ects at risk o ability or rep s' (or relative	of crimina outation? es' or asso	l or civil (Example ciates') p	liability, o es here ma ossible su	or be damaging to the subj ny include: the collection of	f sensitive data regarding the riminal history or intent, medical	
			[]	YES		[]	NO			
	6.3								nt), survey procedures, interview or paragraph 6.2 of this section:	
	[]	YES		[]	NO		If NO skip to 6.4			
	6.3.1	Will this	ffice?	volve hur	nan subje	ects that a	re elected or appointed pu	blic officials or candidates for		
		[]	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			
Exi	isting D	ata Whi	ch Is Pub	licly Availab	le or Uni	<u>dentifiabl</u>	<u>e</u>			
	6.4							f existing* data, documents e the study begins)?	s, records, pathological or	
		[]	YES		[]	NO		If NO skip to 7		
		6.4.1	Is this n	naterial or in	formatio	n publicly	y availabl	e?		
			[]	YES		[ ]	NO			

		6.4.2					in such a manner by the investigator that dentifiers linked to the subjects?	at the subjects cannot be		
							tor even temporarily, for research purpo staff who already have access to the data			
			[]	YES	·		ntifying information and no unique identi			
			[]	NO			iers (including codes))	•		
7.			re and att	tach a short sur	mmary parag	raph (	<1 page);			
	if this	s is new:	:			_				
	a.	the pr design partic	roject. In n decision	n explaining one ns, oversight of n data analysis	e's role as a cor f protocol deve	onsultai elopme	ecific details about the project and the rol ant be particularly careful to identify invo- ent, participation in review of data collec preparation, as well as whether there wil	volvement in things like: study ction procedures, and		
	b.	subjec includ	ects; publi	ic health practi	ice). If you sele	ected r	non-exempt, exempt, no CDC investigato research not involving human subjects bo SN), linkable study identification number	e sure to indicate if the data		
		primar youth a systen	ary strategion aged 15-1 ms to sexu	ies: 1) increased 19; 2) developme	d availability and nent and implem	d acces nentatio	ns to decrease teen pregnancy rates in Chat essibility of youth-friendly sexual and reprodu on of a system to link vulnerable youth ages and 3) increase awareness of youth-friendly	uctive health services targeting s 15 to 19 enrolled in youth-serving		
		CDC s	staff will se ort. CDC wi	serve as project o	officers on this of	coopera	ractice. All assessment activities support pro rative agreement. CDC staff will provide prog identifiable data. All program evaluation data	ogrammatic, technical and scientific		
8.	Please	e list the	e primary	y project site an	nd all collabor	ating s	site(s).			
				Site Name			Site Location	Assurance Number (FWA, MPA or SPA) i applicable		
		Prima	ary Site		Association fo Tealth Care	or	Decatur, GA			
	Expla	anation (	of project	et components:						
9.				search that is fu roject compone			list amount of award that should be rest if known:	tricted pending IRB approval		
Арј	provals	(signati	ure and p	position title)	Date	Rese	earch Determination / Remarks			
	Trisha Mueller-peterson - EPIDEMIOLOGIST		06/23/2015	[X] [] [] []	Public health practice Research not involving human subjects Research involving human subjects, no Research involving human subjects, Cl Research involving human subjects, Cl	CDC investigators, exempt				
						(chec [ ] [ ]	cck if applicable) Local IRB CDC Exemption CDC IRB			
eta	staff member completing this form				1	Cor	Comments			

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Violanda Grigorescu - Branch Chief	06/23/2015	[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: I approve for the branch
David Warner - RESEARCH SCIENCE OFFICER	06/26/2015	[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	06/30/2015	[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: