

## 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.

					-		- T T	Be Determined	
					1	racking Number:	101	Be Determined	
					J)	Jse PGO number if coo	perative	agreement, grant, etc.)	
te submit	ted:	06/23/2015							
le of Proj	ect:		licly Funded I	Health Cei	nters to R	educe Teen Pregnar	ncy amo	ng Youth from	
		Vulnerable Popul	ations						
tes for pr	oject pe	riod:		Dates for f	funding (i	f applicable):			
Beginning:         09/30/2015           Ending:         09/29/2020			Beginni	ing:	09/30/2015		<u>_</u>		
			Ending	:	09/29/2016		_		
oject is (c	hoose on	ie):							
NOTE: Re	evision, a	is used below, refers t	o any substanti	ve change i	made to th	e project including sco	pe of pro	eject, funding restrictions	
		CDC staff member, de							
[X] Ne	w				[]	Revision			
] Co	ntinuati	on, without revision(	(s)	[] Continuation, with			revision(s)		
ad staff n	ambare		Contact info	rmetion	DI	ease indicate your role	n(c) in th	nic project:	
au stait ii Name:		Mueller netereen	Division:	DRH	[X		[]	Technical monitor	
vaille.	THSHE	Mueller-peterson	- Division:	שאם		Principal	[]	Investigator	
J <b>ser ID:</b>	CZJ5		Telephone:	770-488-6		investigator		investigator	
Cientifi	c Ethics	number: 14399	Mailstop:	F74		C 14 4	[]	Other (please explain	
			- Manstop.	174		Consultant	- []	Other (please explan	
			_						
Are any	or all of	f the activities within	this project DE			e to generalizable know			
Are any	or all of	f the activities within to [X] No.	this project DE						
Are any	or all of	f the activities within	this project DE						
Are any	yes, list thos	f the activities within to [X] No se activities which ar	this project DE.  O re research:	SIGNED to	o contribut	e to generalizable knov			
Are any  [ ]  If YES	or all of YES , list those	f the activities within to [X] No se activities which are object research or pub	this project DE.  O re research:	SIGNED to	o contribut	e to generalizable know			
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Form 684R\_NR (revised January 2003)

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Name					Scientific ethics number Prin					
Trisha Mueller-pet			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		,					C P I I I	
5.	Does			arch involve	fetuses, p	regnant v	women, o	r human in vitro fertilizatio	on as targets (such that Subpart B	
	[]	YES								
	[]	NO								
<u>Ed</u>	<u>ucation</u>	al Resea	<u>rch</u>							
	6.1	norma	l educati	onal practice	es (e.g., re	search on	regular	and special education strat	gs, AND does the research involve egies or research on the sroom management methods)?	
		[]	YES	-	[]	NO		- '		
Res	search l	Involving	Surveys	, Interview I	Procedure	s (includi	ng Focus	groups), Observation of Pr	ublic Behavior, or Educational	
Tes	<u>sts</u>									
	6.2			ch use educa observation o				· -	nt), survey procedures, interview	
		[]	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 tly</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 reps' (or relative	of crimina outation? es' or asso	l or civil l (Example ciates') p	liability, o es here ma ossible su	or be damaging to the subj ay include: the collection of	f sensitive data regarding the riminal history or intent, medical	
			[]	YES		[]	NO			
	6.3								nt), survey procedures, interview r paragraph 6.2 of this section:	
		[]	YES		[]	NO		If NO skip to 6.4		
		6.3.1	Will this public o		volve hur	nan subje	ects that a	re elected or appointed pu	blic officials or candidates for	
		[]	YES		[]	NO				
	6.3.2	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	availabl	e?		
			[]	YES		[]	NO			

		6.4.2					in such a manner by the investigator that dentifiers linked to the subjects?	the subjects cannot be			
							or even temporarily, for research purpos staff who already have access to the data,				
			[]	YES	·		tifying information and no unique identi	· · · · · · · · · · · · · · · · · · ·			
			[]	NO			ers (including codes))				
7.			re and att	tach a short sur	mmary parag	raph (	<1 page);				
	if this	this is new:  Be sure to include the purpose of the project, specific details about the project and the role of the CDC staff member(s)									
	a.	the pr design partic	roject. In n decision	n explaining one ns, oversight of n data analysis	e's role as a con f protocol devel	onsultai elopme	cific details about the project and the rol nt be particularly careful to identify invo ent, participation in review of data collect preparation, as well as whether there will	olvement in things like: study tion procedures, and			
	b.	subjec includ	ects; publi	lic health practi	tice). If you sele	ected r	non-exempt, exempt, no CDC investigator research not involving human subjects be 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 ssibility of youth-friendly sexual and reproduc on of a system to link vulnerable youth ages and 3) increase awareness of youth-friendly	ctive health services targeting 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 ative agreement. CDC staff will provide prog identifiable data. All program evaluation data	grammatic, 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) it applicable			
		Prima	ary Site		Association fo Health Care	or	Decatur, GA				
	Expla	anation (	of project	ct components:							
9.				search that is fu roject componer			list amount of award that should be restrif known:	ricted 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, CI Research involving human subjects, CI	DC investigators, exempt					
						(chec [ ] [ ]	ck if applicable) Local IRB CDC Exemption CDC IRB				
eta	staff member completing this form			1	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: