DI

Instructions:

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.

(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:		06/12/2019	06/12/2019									
Title of Pr	oject:	Templates for extra	Templates for extramural Data Management Plans									
Dates for	project	period:		Dates for fu	nding (i	f applicable):						
Beginni	ng:	01/01/2020		Beginnin	g:			_				
Ending	:	1254.272		Ending:								
	Revisior	one): a, as used below, refers to of CDC staff member, dete				e project including sco	pe of pro	oject, funding re	estrictions,			
[X] N	lew				[]	Revision						
		ation, without revision(s)			Continuation, with	revision	(s)				
			,			Continuation, with		(3)				
Lead staff	membe	er:	Contact info	rmation:	Pl	ease indicate your role	e(s) in th	is project:				
Name:	Ra	chel Kaufmann	Division:	OD	[]	Project officer	[X]	Technical n	nonitor			
User II	D: RB	K8	Telephone:	404-498-23	[]	Principal investigator	[]	Investigator	r			
		ics number: 7214	Mailstop:	S107-8	<u> </u>	Consultant		Other (plea	se evolain)			
Scienci	ne Lui	<u> </u>	manstop.	3107-0		Consultant	Ľ	Other (pica	se explain)			
		hose activities which are project research or publi		ctice (check	all that :	apply)?						
[]	[] Research			[X] P	ublic he	ic health practice						
	Ch	eck one:			Check all that apply:							
	[]	Human subjects inv	olved	[]	E	mergency Response	[]	Surveillance				
	[]	Human subjects not	involved		P	rogram evaluation	[X]	Other (please	explain)			
									This is an administrati ve task: Collection of data manageme nt plans from CDC funding awardees.			
		CH involving human sub tection?	jects, has the	project or 1	esearch	activities been review	ed by th	e CDC IRB fo	or human			
a. []	NO,	New project, not yet revi	ewed	d. []	YES	5, Reviewed and appro	oved by	CDC				
b. [] NO,	Existing project, not read	dy to submit			If YES, please list pro	tocol nu	mber and				

c. [] NO, Submitted for approval

If YES, please list protocol number_a expiration date Tracking NO. <u>No Funding</u>

[] YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7). [] NO								e. []	NO, RESEARCH, no Cl required)	DC investigators (CDC IRB not
Name Role (project officer, investigator, consultant, etc.) Scientific ethics number Prin Rachel Kaufmann 7214 ?YOU THINK THE RESEARCH PROJECT MIGHT QUALIFY AS EXEMPT RESEARCH (as identified in 4SCFR46.101), LEASE ANSWER questions 4.6, OTHERWISE SKEPT 00 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 I would apply)? [] YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7). [] NO NO ducational Research If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7). [] NO NO ducational Research If YES, this research on anong instructional techniques, curricula or classroom management methods)? [] VES If YES [] VES NO 6.1 Is this research soundected in established or commonly accepted education strategies or creater in nolve of proving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational Educational Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational. 6.2 WIII this research soundected in such a manner that human subjects ca								f. []	N/A (Not Applicable)	
number Prin Rachel Kaufmann 7214 ? YOU THINK THE RESEARCH PROJECT MIGHT QUALIFY AS EXEMPT RESEARCH (as identified in 45CFR46.101), LEASE 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 I would apply)? [] YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7). [] NO decation of the research involve fetuses, pregnant women, or human in vitro fertilization as targets (such that Subpart I would apply)? [] YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7). [] NO NO decation all restablished or commonly accepted education at strategies or research involve receivers of, or comparison among instrucational techniques, curricula or classroom management methods)? [] YES [] NO (II NO (IN Will this research suce ducational tects (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? [] YES If NO skip 6.3 (II YES, If YES, this research cann	I	f RES	EARCI	H, list any	other CDC st	aff invo	lved in thi	is projec	t, please include the name,	role, and scientific ethics number
PAGE THINK THE RESEARCH PROJECT MIGHT QUALIFY AS EXEMPT RESEARCH (as identified in 45CFR46.101), PLASE ANSWER questions 4-6, OTHERWISE SKIP TO question 7. Dass 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 I would apply)? YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7). NO NO ducational Research 6.1 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 instructuland techniques, curricula or classroom management methods)? If YES I NO eccarrch Involving Surveys, Interview Procedures (including Focus groups). Observation of Public Behavior. or Educational. 62 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures on barers (such as a code) linked to the subjects? I YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to item 7) I NO If NO skip 6.3		Name								
LEASE 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 I would apply)? YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7). NO NO detectional Research 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 earch Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational ests 6.2 Will this research use ducational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to item 7) NO YES YES If NO If YES, this research cannot be exempted and must be reviewed by an IRB (skip to item 7) YES NO If YES If NO static hidren (<18 years of age) be research subjects?		Rac	hel Ka	ufmann						7214
LEASE 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 I would apply)? YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7). NO NO detectional Research 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 earch Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational ests 6.2 Will this research use ducational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to item 7) NO YES YES If NO If YES, this research cannot be exempted and must be reviewed by an IRB (skip to item 7) YES NO If YES If NO static hidren (<18 years of age) be research subjects?	F VO	птн		HE RESE	ARCH PROJ	– ECT M	IGHT OU	ALIFY	AS EXEMPT RESEARCH	(as identified in 45CFR46.101).
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 I would apply)? YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7). NO NO ducational Research 6.1 6.1 Is this research conducted in established or commonly accepted education at 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 instructuational techniques, curricula or classroom management methods)? [YES [NO escarch Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational ests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? [YES [NO 6.2 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? [YES [NO 6.2.1 Vill this research as a code linked to the subjects; [] YES [YES [] NO 6.2.1 Is the information obtained recorded in such a manner that human										
Image: Severation of the severatis and the severation of the severation of the severatis			Does t	he propo	sed research in	volve p	risoners?			
Does the proposed research involve fetuses, pregnant women, or human in vitro fertilization as targets (such that Subpart I would apply)? [] YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7). [] NO ducational Research 6.1 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 esearch lavolving Surveys, Interview Procedures (including Focus groups). Observation of Public Behavior, or Educational setts 6.20 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? [] YES [] NO [] YES [] NO [] YES [] NO [] NO If NO skip 6.3 Will children (<18 years of age) be research subjects?	{]	YES		If YES, this r	esearch	cannot be	e exempt	ed and must be reviewed b	y an IRB (skip to question 7).
would apply? YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7). NO ducational Research 6.1 Is this research conducted in established or commonly accepted educational settings, AND does the research involve normal educational practices (c.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 essearch Involving Surveys. Interview Procedures (including Focus groups). Observation of Public Behavior, or Educational estis (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? [] YES [] NO If YES If YES, this research subjects? [] NO [] YES [] NO If NO skip 6.3 Will children (<18 years of age) be research subjects?										
question 7). [] NO ducational Research 6.1 Is this research conducted in established or commonly accepted educational settings, AND does the research involvommal ducational 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)? [] YES [] NO NO cesarch Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational. ests 6.2 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?										
ducational 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)? [] YES [] NO essearch 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 support on 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; [] NO 6.2.1 Ste 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; [] 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' franacial 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, fina	[]	YES			resear	ch canno	t be exe	mpted and must be revi	ewed by an IRB (skip to
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)? [] YES [] NO essearch Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? [] YES [] NO If NO skip 6.3 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation 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 in the subject 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 relative?) or associater's) possible substance abuse, sexuality, criminal bistory or intent, medical or psychological condition, financial status, or similarly compromising information). [] YES [] NO 6.3.1 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures; or observation of public behavior to util lability, or be damaging to the subjects' financial standing, employability or reputation? (Examples	[]	NO							
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)? [] YES [] NO essearch Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? [] YES [] NO If NO skip 6.3 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation 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 in the subject 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 relative?) or associater's) possible substance abuse, sexuality, criminal bistory or intent, medical or psychological condition, financial status, or similarly compromising information). [] YES [] NO 6.3.1 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures; or observation of public behavior to util lability, or be damaging to the subjects' financial standing, employability or reputation? (Examples										
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)? [] YES [] NO essearch Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? [] YES [] NO If NO skip 6.3 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation 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 in the subject 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 relative?) or associater's) possible substance abuse, sexuality, criminal bistory or intent, medical or psychological condition, financial status, or similarly compromising information). [] YES [] NO 6.3.1 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures; or observation of public behavior to util lability, or be damaging to the subjects' financial standing, employability or reputation? (Examples	duca	tional	Resear	rch						
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 essearch Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational ests 6.2 6.2 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior? [] YES [] NO If YES [] NO If NO skip 6.3 Will children (<18 years of age) be research subjects?					conducted in e	stablish	ed or con	imonly a	ccepted educational setting	gs. AND does the research involve
essearch Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational ests 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 thier (<18 years of age) be research subjects?	U	•1	norma	l educati	onal practices	(e.g., res	search on	regular a	and special education strat	egies or research on the
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 YES YES NO 6.2.2. Will any disclosure of the human subjects' response 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 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 6.3.1 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview probublic office?			[]	YES		[]	NO		0	
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?		rch In	volving	Surveys	, Interview Pro	ocedure	s (includir	g Focus	groups), Observation of P	ublic Behavior, or Educational
procedures or observation of public behavior? [] YES [] NO If NO skip 6.3 Will children (<18 years of age) be research subjects?			XX/211 41	ic recom	ah usa adusati	anal tost	te (ag aniti	vo dioan	astic antituda achiavama	nt) survey procedures interview
Will children (<18 years of age) be research subjects?	0	.2						ve, utagi	ostic, aptitude, activement	it, survey procedures, interview
 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 <u>directly or indirectly</u> through identifiers (such as a code) linked to the subjects: YES 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 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		If NO skip 6.3	
 [] NO 6.2.1 Is the information obtained recorded in such a manner that human subjects can be identified <u>directly or indirectly through identifiers (such as a code) linked to the subjects;</u> [] YES [] 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 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 			Will cl	hildren (<	<18 years of ag	e) be res	search sub	jects?		
 6.2.1 Is the information obtained recorded in such a manner that human subjects can be identified <u>directly or indirectly</u> 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 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 			[]	YES	If YES, this	researc	h cannot b	e exemp	ted and must be reviewed	by an IRB (skip to item 7)
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 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			[]	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 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 			6.2.1							ts can be identified <u>directly or</u>
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 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 []<				[]	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 			6.2.2	place th employs subjects	e subjects at ri ability or reput ' (or relatives'	sk of cr ation? (or asso	iminal or (Examples ciates') po	civil liab here ma ssible su	ility, or be damaging to the ay include: the collection of bstance abuse, sexuality, co	e subjects' financial standing, f sensitive data regarding the riminal history or intent, medical
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 [] [] YES []				[]	YES		[]	NO		
 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 YES NO 	6	.3	Will th procee	nis resear lures, or	ch use educatio observation of	onal tes public l	ts (cogniti behavior l	ve, diagn out the re	ostic, aptitude, achievemen esearch is not exempt unde	nt), survey procedures, interview r paragraph 6.2 of this section:
public office? [] YES [] YES 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			[]	YES		[]	NO		If NO skip to 6.4	
 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 			6.3.1			olve hun	nan subjee	cts that a	re elected or appointed pu	blic officials or candidates for
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				[]	YES		[]	NO		
			6.3.2	informa criterio	tion will be ma n only in the ca	aintaine	d through	out the r	esearch and thereafter? (N	Note: CDC can use this exemption
				[]	YES		[]	NO		
	Xisti	ng Dat	ta Whi		licly Available	or Unic				

Tracking NO. <u>No Funding</u>

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 particpation 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.

Goal of the project: To provide Cooperative Agreement applicants and awardees with templates for the creation of Data Management Plans (DMP).

Intended use of the resulting data: DMPs are required of entities using federal funds to collect or generate data. DMPs will be submitted to CDC by grant and cooperative agreement awardees for assessment to verify that they are concordant with CDC's data sharing policy.

Methods to be used to collect: DMPs will be submitted as standalone sections of the NOFO and annual continuation applications; revisions can also be submitted by the awardees whenever needed.

How data will be analyzed: Once DMPs are received, the DMP is then assessed for completeness and adherence to CDC policy and guidelines.

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			
Rachel Kaufmann - Assoc Director Science	06/12/2019	 [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 [] Research involving human subjects, CDC investigators, not exempt [] Local IRB [] CDC Exemption [] CDC IRB 			
staff member completing this form		<u>Comments:</u> please approve			

Rachel Kaufmann - Assoc Director Science Team Lead	06/13/2019	 [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 [] Local IRB [] CDC Exemption [] CDC IRB
- Division ADS	MM/dd/yyyy	 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 Research involving human subjects, CDC investigators, not exempt (check if applicable) Local IRB CDC Exemption CDC IRB
Joan Redmond Leonard - PUBLIC HEALTH ANALYST CUC ADS, Deputy ADS, or Human Subjects Contact	06/27/2019	 [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 [] Local IRB [] CDC Exemption [] CDC IRB