



**U.S. Department of
Health and Human Services**
Centers for Disease
Control and Prevention

Print Date: 3/10/23

Title: Training for Home Assessment for Asthma Triggers Amendment 1

Project Id: 0900f3eb820becd8

Accession #: NCEH-ACHB-4/14/22-ef9b9

Project Contact: Maureen A Wilce

Organization: NCEH/ATSDR/DEHSP

Status: Pending Clearance : Amendment

Intended Use: Project Determination

Estimated Start Date: 10/31/2022

Estimated Completion Date: 03/31/2023

CDC/ATSDR HRPO/IRB Protocol #: N/A

OMB Control #: 0923-0047

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other <i>45 CFR 46.102(l)</i> Program Evaluation Quality Assurance / Improvement Other - training evaluation	3/10/23	Davis_Stephanie I. (sgd8) CIO HSC

PRA: PRA Applies	3/10/23	Davis_Stephanie I. (sgd8) CIO OMB / PRA
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Description & Funding

Description

Priority: Standard

Date Needed: 03/01/2024

Determination Start Date: 02/15/23

Description: The purpose of this amendment is to pursue a GenIC under the ATSDR Service Delivery Generic Clearance (OMB Control No. 0923-0047; expiration date 02/28/2025). Previously, we conducted a pilot among 9 respondents that included department of health staff participating in the evidence-based home assessment training on their experience taking the training. For this new GenIC, the information collected will be used to help CDC assess whether the training content and structure are appropriate for the target audience. We are evaluating an evidence-based home assessment training with a focus on asthma triggers. The training itself has been cleared (April 2019, eclearance ID# 0900f3eb81938081). The training slide set has three intended uses: to help home visitors (e.g., community health workers, nurses, asthma educators) understand the underlying factors that give rise to asthma triggers in the home; to facilitate communication with the resident/family about reducing environmental triggers of asthma; and to help the resident/family understand how to implement the most important evidence-based action steps to decrease asthma triggers in the home. If these custom assessment forms will be used beyond one year after GenIC approval, CDC will seek a standard Paperwork Reduction Act clearance for continuous collection.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission: No

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

Secondary Priority(s) of the Project: Not selected

Task Force Associated with the Response: Not selected

CIO Emergency Response Name: Not selected

Epi-Aid Name: Not selected

Lab-Aid Name: Not selected

Assessment of Chemical Exposure Name: Not selected

Goals/Purpose The purpose of this amendment is to pursue a GenIC. The purpose is to collect from federally funded home visit programs. Respondents will include participants taking the evidence-based home assessment training. Participation will be completely voluntary. The information will be used to help CDC assess whether the training content and structure are appropriate for the target audience.

Objective: The objective is to improve the training as necessary.

Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	Yes
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Not Selected
Studying Social Determinants of Health (SDOH):	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Yes
Other:	Not Selected
Activities or Tasks:	Programmatic Work
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Asthma
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided
Method Categories:	Survey
Methods:	Home Visit Program Staff from recipients of federal funding will fill out the survey on the CDC TRAIN platform . www.train.org/cdctrain/ .
Collection of Info, Data or Biospecimen:	The survey will be conducted on the CDC TRAIN platform www.train.org/cdctrain/
Expected Use of Findings/Results and their impact:	Internal evaluation use only. This will provide information to improve the training.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers (including coded data)?:	Yes
Is this project covered by an Assurance of Confidentiality?	No
Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	No
Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
Other-	staff time only				0.00

HSC Review

HSC Attributes

Program Evaluation	Yes
Quality Assurance / Improvement	Yes
Other - training evaluation	Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children

Protocol Page #:

Population - Minors

Protocol Page #:

Population - Prisoners

Protocol Page #:

Population - Pregnant Women

Protocol Page #:

Population - Emancipated Minors

Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process wavers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or	No Selection

behavioral outcome

Registerable clinical trial No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus No Selection

Human genetic testing is planned now or in the future No Selection

Involves long-term storage of identifiable biological specimens No Selection

Involves a drug, biologic, or device No Selection

Conducted under an Investigational New Drug exemption or Investigational Device Exemption No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Centers for Disease Control & Prevention	FWA00001413	07/30/26			
US Department of Housing and Urban Development	FWA00017325	05/23/14			

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Gene Pinzer	n/a	n/a	n/a	n/a	Project Officer	Eugene.A. Pinzer@hud.gov	978-502-4779	US Department of Housing and Urban Development
Ginger Chew	04/02/2024		08/28/2025	12/25/2025	Co-Investigator	gjc0@cdc.gov	770-488-3992	DIVISION OF ENVIRONMENTAL HEALTH SCIENCE AND PRACTICE

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Davis_Stephanie I. (sgd8) CIO OMB / PRA	03/10/2023	GenIC files ready to deliver to ICRO	Paperwork Reduction Act Form	GenIC Files to ICRO.zip
	Wilce_Maureen A. (muw9) Project Contact	03/08/2023	response to comments	Other	muw9_0900f3eb820becd8 (4) tracked.docx
	Wilce_Maureen A. (muw9) Project Contact	03/08/2023	zip file containing the clean files associated with this request	Other	Stephanie 3 8 23.zip
	Davis_Stephanie I. (sgd8) CIO HSC	03/07/2023	GenIC zipfile missing attachments	Paperwork Reduction Act Form	GenIC Files.zip
	Wilce_Maureen A. (muw9) Project Contact	03/06/2023	file with changes made and signed	Other	GenIC HomeAssmnt rev OS_2 clean signed.docx
	Wilce_Maureen A. (muw9) Project Contact	03/06/2023	responses to comments	Other	GenIC 0923-0047 HomeAssmntTrning rev OS_2 tracked.docx
	Wilce_Maureen A. (muw9) Project Contact	03/06/2023	the changes are in the STARS Platform, but here are the responses to comments.	Other	muw9_0900f3eb820ce247 tracked.docx
	Wilce_Maureen A. (muw9) Project Contact	03/06/2023	Part 2 form evaluation form with SORN added	Paperwork Reduction Act Form	Part 2 Form- Post-course Evaluation w SORN.pdf
	Wilce_Maureen A. (muw9) Project Contact	03/06/2023	Part 2 form pretest form with SORN added	Paperwork Reduction Act Form	Part 2 Form- Pre-test w SORN.pdf
	Wilce_Maureen		Part 2 form post test form with		

	A. (muw9) Project Contact	03/06/2023	SORN added	Paperwork Reduction Act Form	Part 2 Form- Post-test w SORN.pdf
	Davis_Stephanie I. (sgd8) CIO HSC	02/24/2023	GenIC files reviewed by OS	Paperwork Reduction Act Form	Files rev OS.zip
	Wilce_Maureen A. (muw9) Project Contact	02/23/2023	Revised and signed Gen IC form and attachments A, B, and C and Part 2 Forms are attached.	Other	revised home visiting training documents (3).zip
	Wilce_Maureen A. (muw9) Project Contact	02/23/2023	HUD NOFO	Other	HUD NOFO.docx
	Wilce_Maureen A. (muw9) Project Contact	02/23/2023	Gen IC package addressing Stephanie Davis's previous comments	Paperwork Reduction Act Form	GenIC zipfile (2-14-23).zip
	Davis_Stephanie I. (sgd8) CIO HSC	02/15/2023	GenIC Files reviewed by OS	Paperwork Reduction Act Form	Files rev OS.zip
	Wilce_Maureen A. (muw9) Project Contact	02/15/2023	Gen IC package addressing Stephanie Davis's previous comments	Paperwork Reduction Act Form	GenIC zipfile (2-14-23).zip
	Wilce_Maureen A. (muw9) Project Contact	02/15/2023	HUD NOFO	Other	HUD NOFO.docx
	Wilce_Maureen A. (muw9) Project Contact	02/14/2023	GenIC form and documents addressing Stephanie Davis's previous comments	Paperwork Reduction Act Form	GenIC zipfile (2-14-23).zip
	Wilce_Maureen A. (muw9) Project Contact	02/14/2023	HUD NOFO	Other	HUD NOFO.docx
Current	Wilce_Maureen A. (muw9) Project Contact	10/19/2022	This is a post-course 1) test of knowledge after taking the training and 2) an evaluation of the overall course itself	Other-post course evaluation	Home Assessment for Asthma Triggers post-course evaluation.docx
Current	Wilce_Maureen A. (muw9) Project Contact	10/19/2022	this is a pre-test before taking the training to assess previous knowledge	Other-pre-test	Home Assessment for Asthma Triggers pre-test.docx



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