Attachment 10 - Research Determination Form

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

Print Date: 2/12/20

Title: Asthma Information Reporting System (AIRS) Revision ICR

Project Id: 0900f3eb81a32f63

Accession #: NCEH-DEHSP-10/1/19-32f63

Project Contact: Etheredge_Alisha (epq5)

Organization: NCEH/ATSDR/DEHSP

Status: **Project In Progress**

Intended Use: **Project Determination**

Estimated Start Date: 10/01/2019

Estimated Completion Date: 10/01/2023

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0920-0853

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research	10/3/19	Davis_Stephanie I. (sgd8) CIO HSC
PRA: **PRA Applies**		10/3/19	Davis_Stephanie I. (sgd8) CIO OMB / PRA

ICRO: **Returned with No Decision**		2/4/20	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Date Needed:	10/15/2019
Determination Start Date:	10/01/19
Description:	The purpose of this information collection (IC) is to continue CDC#??s monitoring of funded programs#?? planning and delivery of public health activities and the programs#?? collaboration with health care systems. AIRS is the system by which state asthma programs report their progress on National Asthma Control Program developed performance measures (PM), as well as state-level asthma emergency department (ED) visit and hospital discharge (HD) data. Recipients receive funding to implement a variety of public health strategies and activities. CDC collects information related to each recipient's strategies and activities, and the process and outcome PM outlined by the cooperative agreement program.
Goals/Purpose	The National Center for Environmental Health#s National Asthma Control Program (NACP) supports state, local and territorial health departments to better understand the impact of asthma and to encourage a comprehensive public health approach to asthma control. The purpose of this information collection (IC) is to continue NACP#s monitoring of recipient programs# planning and delivery of public health activities and the programs# collaboration with health care systems under a new cooperative agreement (EH19-1902). CDC collects information related to each recipient#s strategies and activities, and the process and outcome PMs outlined by the cooperative agreement program. NACP-funded asthma programs report their progress on NACP developed performance measures (PMs), as well as state-level asthma emergency department (ED) visit and hospital discharge (HD) data. A new PM electronic reporting tool has been developed, which will allow recipients to report PM information. Recipients receive funding to implement a variety of public health strategies and activities.
Objective:	The objective of this information collection is to 1) monitor state and national progress toward achieving the outcomes identified in the National Asthma Control Program#s logic model; 2) facilitate aggregate reporting of outcomes to state and national stakeholders; 3) identify and respond to technical assistance needs; and 4) promote continuous quality improvement at the state program and CDC level.
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	Awardee Program Managers
Tags/Keywords:	Asthma, AIRS
CDC's Role:	CDC is providing funding, CDC is recipient of materials/services FROM an institution
Method Categories:	Other
Methods:	Respondents include up to 30 cooperative agreement recipients (state, local, and territorial health departments). Information will be collected from recipients on an annual basis. Recipients will submit standardized PM data on an annual basis via a newly developed electronic reporting tool in SharePoint. The

Collection of Info, Data or Biospecimen:	SharePoint site was created to allow recipients to electronically input information for eight core PMs. State-level ED visit and HD surveillance data will be submitted electronically by recipients to a dedicated electronic mailbox.
Expected Use of Findings/Results:	Information will be used for multiple purposes: 1) monitoring state and national progress toward achieving the outcomes identified in the National Asthma Control Program#s logic model; 2) facilitating aggregate reporting of outcomes to state and national stakeholders; 3) identifying and responding to technical assistance needs; and 4) promoting continuous quality improvement at the state program and CDC level.
Could Individuals potentially be identified based on Information Collected?	Yes

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award
CDC Cooperative Agreement	A Comprehensive Public Health Approach to Asthma Control through Evidence-Based Interventions	CDC-RFA-EH19-1902	2019	5

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office

Estimated number of study participants

Population - Children

Population - Minors

Population - Prisoners

Population - Pregnant Women

Population - Emancipated Minors

Suggested level of risk to subjects Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

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 documents 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 behavioral outcome	No Selection
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 identfiable 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

Institutions yet to be added .....

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
Alisha Etheredge	12/26 /2021	03/10/2019			Project Officer	epq5@cdc.gov	770-488-7884	DIVISION OF ENVIRONMENTAL HEALTH SCIENCE AND PRACTICE

Data

DMP

Proposed Data Collection Start Date:	10/1/20
Proposed Data Collection End Date:	10/1/23
Proposed Public Access Level:	Public
Public Access Justification:	Data will be made accessible to the public. Aggregate, de-identified performance measures data will be shared with the public (posted on CDC webpage) and presented at the American Evaluation Association conference. The hospitalizations and emergency departments visits data is publicly available data

How Access Will Be Provided for Data:	previously collected by the recipient, not at the request of CDC. This de-identified data is shared with the public on the CDC website.
Plans for Archival and Long Term Preservation:	The data will be stored within the SharePoint site for at least ten years. Each state, local and territorial asthma program recipient has access to its own information and surveillance data. The state, local, or territorial cooperative agreement recipient decides the level of access for each user, and to what extent local partners may access that information. State, local, and territory cooperative agreement recipients are required to report periodically as a condition of their award from CDC. The information collected will be neither sensitive nor proprietary in nature. Reporting spreadsheets containing emergency department visit and hospitalization data will be uploaded and stored on the ACHB#s SharePoint site for at least ten years.

Spatiality

Spatiality (Geographic Locations) yet to be added .....

Dataset

Dataset Title	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...								