

Print Date: 8/28/23

Title: APPLETREE Performance Measures and ICRs PRA Revis	sion
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Project Id: 0900f3eb8215d7a0

Accession #: NCEH-DCHI-11/13/19-61974

Project Contact: Audra E Henry

Organization: NCEH/ATSDR/OCDAPS

Status: Pending Regulatory Clearance : PRA Revision

Intended Use: Project Determination

Estimated Start Date: 10/01/2023

Estimated Completion Date: 09/30/2026

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0923-0057

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other 45 CFR 46.102(1)	11/15/19	Davis_Stephanie I. (sgd8) CIO HSC
PRA: PRA Applies		6/15/23	De Leon Salazar_Alfonsina (wvg4) CIO OMB / PRA

ICRO:	
PRA Applies	

OMB Approval date: 9/28/20 OMB Expiration date: 9/30/23 6/16/23

Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

06/30/2023 Date Needed:

Determination Start Date: 05/16/23

APPLETREE performance measures and Information Collection forms to be submitted for the 60-day Federal Register Notice and Description:

to OMB for approval in accordance with the Paperwork Reduction Act.

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

Not selected **Epi-Aid Name:**

Lab-Aid Name: Not selected

Assessment of Chemical Exposure Name: Not selected

Goals/Purpose

prevent harmful chemical exposures in the environment.

Collect information from APPLETREE recipients to inform performance measures, demonstrate impact, and report progress. Objective:

Does your project measure health disparities among

populations/groups experiencing social, economic,

geographic, and/or environmental disadvantages?:

Does your project investigate underlying contributors to health inequities among populations

/groups experiencing social, economic, geographic,

and/or environmental disadvantages?:

Does your project propose, implement, or evaluate

Not Selected

Demonstrate, through regular reporting, the impact and effectiveness of APPLETREE recipients' work to reduce, eliminate, or

Not Selected

Not Selected

an action to move towards eliminating health inequities?:

Activities or Tasks: New Collection of Information, Data, or Biospecimens

Target Populations to be Included/Represented: Other - Awardee Program Managers

Tags/Keywords: APPLETREE; Program Evaluation; Mandatory Reporting

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: Other - Required reporting under cooperative agreement

Methods: Data will be reported on various forms developed by ATSDR

Collection of Info, Data or Biospecimen: Data will consist of programmatic activity tracking, event reporting, and process measurement.

Expected Use of Findings/Results and their impact:ATSDR will compile information collected to report attainment of programmatic performance measures. Achieving programmatic

goals will result in a demonstration of the return on investment and positive impact on public health.

Could Individuals potentially be identified based on

Information Collected?

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	ATSDRs Partnership to Promote Local Efforts to Reduce Environmental Exposure (APPLETREE)	TS-23- 0001	2023	5	69800000.00

HSC Review

HSC Attributes

Quality Assurance / Improvement

Regulation and Policy

Do you anticipate this project will need IRB review by the CDC IRB, NIOSH IRB, or through reliance on an external IRB?

Estimated number of study participants

Population - Children Protocol Page #:

Population - Minors Protocol Page #:

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 waviers

Informed consent for adults

No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Alteration of authorization under HIPPA Privacy No Selection

Rule

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 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
Audra Henry	03/13 /2026				Program Lead	ate1@cdc. gov	770- 488- 3758	OFFICE OF CAPACITY DEVELOPMENT AND APPLIED PREVENTION SCIENCE
Trent Lecoultre	12/17 /2023				Program Lead	tll7@cdc. gov	770- 488- 3799	DIVISION OF COMMUNITY HEALTH INVESTIGATIONS

Data

DMP

Proposed Data Collection Start Date: 10/1/23

Proposed Data Collection End Date: 9/30/26

Proposed Public Access Level: Public, Restricted

Restricted Details:

Data Use Type:

Data Use Type URL:

Data Use Contact:

Public Access Justification: This data can be made available upon request. The data will be aggregated and summarized to be used in public-facing reports.

How Access Will Be Provided for Data:

This data can be made available upon request. The data will be aggregated and summarized to be used in public-facing reports. No

PII, confidential information, secure information, or intellectual property will be collected.

Plans for Archival and Long Term Preservation: Data will be stored in ATSDR's Request Management System and in files held by the Project Officer.

Spatiality

United States	
Critica Clates	

Dataset

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

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	06/16/2023	NOA 0923=0057 (2020)	Notice of Action	NOA 0923-0057.pdf
	De Leon Salazar_Alfonsina (wvg4) CIO OMB / PRA	06/15/2023	60-day FRN documents reviewed by OS and ready for ICRO review	Other	0923-0057 60D FRN files to ICRO.zip
	De Leon Salazar_Alfonsina (wvg4) CIO HSC	06/15/2023	60-day FRN documents reviewed by OS and ready for ICRO review	Other	0923-0057 60D FRN files to ICRO.zip
	Henry_Audra L. (ate1) Project Contact	06/13/2023	Appletree 2023 Revision 60-day FRN request documents rev by OS.	Other	Appletree OMB package rev OS for 60D FRN.zip
	Henry_Audra L. (ate1) Project Contact	06/13/2023	Draft 60-day FRN notice	Paperwork Reduction Act Form	0923-0057 APPLETREE Revision 60- Day_FRN_20190801.docx

(at	enry_Audra L. te1) roject Contact	06/13/2023	Supporting Statement A	Paperwork Reduction Act Form	SSA APPLETREE PMs 103019.docx
(at	enry_Audra L. te1) roject Contact	06/13/2023	ICR package forms for 60-day notice	Other	Clean Copies to upload to STARS for 60 days - Copy.zip
(at	enry_Audra L. te1) roject Contact	06/13/2023	60-day FRN package - clean copy	Other	Clean copies for 60 day.zip
(at	enry_Audra L. te1) roject Contact	06/13/2023	Notice of Funding Opportunity	Notice of Funding Opportunity	Foa_Content_of_CDC-RFA-TS-23-0001 (1) (1).pdf
(at	enry_Audra L. te1) roject Contact	06/13/2023	Supporting Statement B	Paperwork Reduction Act Form	SSB APPLETREE PMs 103019.docx
(at	enry_Audra L. te1) roject Contact	06/13/2023	Appletree 2020 Revision Wrksht1 and wrksht2.	Other	Appletree 2020 revision Wrksh1 Wrksh2s.zip
(at	enry_Audra L. te1) roject Contact	06/13/2023	Appletree 2023 Revision 30-day FRN request documents rev by OS.	Other	Appletree OMB package rev OS for 30D FRN.zip
Sa (w	e Leon alazar_Alfonsina vyg4) IO HSC	05/19/2023	Appletree 2023 Revision 60-day FRN request documents rev by OS.	Other	Appletree OMB package rev OS for 60D FRN.zip
Sa (w	e Leon alazar_Alfonsina vvg4) IO HSC	05/19/2023	Appletree 2020 Revision Wrksht1 and wrksht2.	Other	Appletree 2020 revision Wrksh1 Wrksh2s.zip
Sa (w	e Leon alazar_Alfonsina rvg4) IO HSC	05/19/2023	Appletree 2023 Revision 30-day FRN request documents rev by OS.	Other	Appletree OMB package rev OS for 30D FRN.zip
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Henry_Audra L. (ate1) Project Contact	05/16/2023	ICR package forms for 60-day notice	Other	Clean Copies to upload to STARS for 60 days - Copy.zip
LeCoultre_Trent D (tll7) Project Contact	11/15/2019	Draft 60-day FRN notice	Paperwork Reduction Act Form	0923-0057 APPLETREE Revision 60- Day_FRN_20190801.docx
LeCoultre_Trent D (tll7) Project Contact	11/15/2019	Supporting Statement A	Paperwork Reduction Act Form	SSA APPLETREE PMs 103019.docx
LeCoultre_Trent D (tll7) Project Contact	11/15/2019	Supporting Statement B	Paperwork Reduction Act Form	SSB APPLETREE PMs 103019.docx



U.S. Department of Health and Human Services

Centers for Disease Control and Prevention