



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

*Print Date: 9/28/22*

**Title:** LTSAE Milestone Tracker App Survey

**Project Id:** 0900f3eb81f5f0fd

**Accession #:** NCBDDD-LTSAE-6/15/22-581d0

**Project Contact:** ANA PAULA POHL DUARTE

**Organization:** NCBDDD/DHDD/CDD/LTSAE

**Status:** Pending Regulatory Clearance

**Intended Use:** Project Determination

**Estimated Start Date:** 09/30/2022

**Estimated Completion Date:** 06/30/2025

**CDC/ATSDR HRPO/IRB Protocol #:**

**OMB Control #:**

## 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	6/21/22	Campbell_Scott (sic3) CIO HSC

PRA: PRA Applies	6/21/22	Herron_Adrienne R. (xwj9) OMB / PRA
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## Description & Funding

### Description

Priority:	Standard
Date Needed:	07/05/2022
Determination Start Date:	06/21/22
Description:	Learn The Signs. Act Early. is conducting a in app survey to evaluate the Milestone Tracker app. The purpose of the Milestone Tracker app is to increase developmental disabilities screening by parents by using CDC's milestone checklist. The survey will consist of questions trying to understand app usage and behavior change by using the app.
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 goal of this project is to conduct an outcome evaluation of the Milestone Tracker app created by "Learn the Signs. Act Early" program in NCBDDD. The goal is to evaluate the app and how it's users interact with it, to potentially improve features of the app, and make sure that the app is increasing childhood development screening by parents. The Milestone Tracker app has been around for a couple of years, but has not been evaluated yet, this survey will allow the team to evaluate the app.
Objective:	The objective of this project is to increase developmental screening and surveillance for young kids. This is not a public health emergency since it is addressing developmental disabilities.
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

<b>Measuring Disparities:</b>	Not Selected
<b>Studying Social Determinants of Health (SDOH):</b>	Not Selected
<b>Assessing Impact:</b>	Yes
<b>Methods to Improve Health Equity Research and Practice:</b>	Not Selected
<b>Other:</b>	Not Selected
<b>Activities or Tasks:</b>	New Collection of Information, Data, or Biospecimens
<b>Target Populations to be Included/Represented:</b>	General US Population
<b>Tags/Keywords:</b>	Developmental Disabilities ; Parents ; Public Health Surveillance
<b>CDC's Role:</b>	CDC is the sole institution conducting activity
<b>Method Categories:</b>	Survey
<b>Methods:</b>	There will be two surveys administered to the target population. The population in this case are users of the Milestone Tracker app. App users will be sent a notification to complete the survey if they are interested. The first survey will be administered to all app users, which will consist of six questions about app usage and satisfaction. The second survey will be prompted to app users that have noted a developmental concern with their child. The second survey consists on asking about parents actions after indicating a developmental concern.
<b>Collection of Info, Data or Biospecimen:</b>	There will be two surveys administered to the target audience. The first survey will be administered to all app users. While the second survey will only be administered for app users that have indicated a developmental concern with their child after using the CDC Milestone Checklist. There will be no personally identifiable data collected or accessible as a result of this evaluation activity.
<b>Expected Use of Findings/Results and their impact:</b>	The outcome of this project are outcome evaluation findings that will help us to better understand how the app is being used, if users like the app/find it helpful, if the app helped them to identify a possible developmental concern, if they plan to use it again, and what happens as a result of using the app. We hope to be able to publish the results of this public health product evaluation.
<b>Could Individuals potentially be identified based on Information Collected?</b>	No

## Funding

Funding yet to be added .....

## HSC Review

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## HSC Attributes

Program Evaluation	Yes
Quality Assurance / Improvement	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

<b>Informed consent for adults</b>	No Selection
<b>Children capable of providing assent</b>	No Selection
<b>Parental permission</b>	No Selection

### **Consent process shown in an understandable language**

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

### **Clinical Trial**

<b>Involves human participants</b>	No Selection
<b>Assigned to an intervention</b>	No Selection
<b>Evaluate the effect of the intervention</b>	No Selection
<b>Evaluation of a health related biomedical or behavioral outcome</b>	No Selection
<b>Registerable clinical trial</b>	No Selection

### **Other Considerations**

<b>Exception is requested to PHS informing those tested about HIV serostatus</b>	No Selection
<b>Human genetic testing is planned now or in the future</b>	No Selection
<b>Involves long-term storage of identifiable biological specimens</b>	No Selection
<b>Involves a drug, biologic, or device</b>	No Selection
<b>Conducted under an Investigational New Drug exemption or Investigational Device Exemption</b>	No Selection

## Institutions & Staff

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### 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
ANA PAULA POHL DUARTE	04/21/2025				Co-Investigator		- -	LEARN THE SIGNS EARLY ACT TEAM
Katie Green	09/17/2023				Program Lead		404-498-3872	LEARN THE SIGNS EARLY ACT TEAM

## Data

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### DMP

**Proposed Data Collection Start Date:** 9/30/22

**Proposed Data Collection End Date:** 6/30/25

**Proposed Public Access Level:** Non-Public

#### Non-Public Details:

**Reason For Not Releasing Data:** Other - Data appropriate for internal use only to evaluate a CDC product

**Public Access Justification:** This project will have non-Public access due to the data being appropriate for internal use only to evaluate a CDC product.

**How Access Will Be Provided for Data:** There no plans to share the data outside of CDC; There will be no personal identifiable information collected from survey participants. There will be no questions asked in this survey that will be information that is personally identifiable. Additionally the link for the survey they will be provided for participants will be a protected link by REDCap that will not collect any personally identifiable information.

The data collected will be stored in the REDCap website that is managed by the CDC. Only "Learn The Signs. Act Early"(LTSAE)

Plans for Archival and Long Term Preservation:

evaluation team and project lead will have access to this data. The data from REDCap may be stored on a multiuser share drive only accessible to the LTSAE team.

Spatiality

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

Dataset

Dataset Title	Dataset Description	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...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
Current	POHL DUARTE_ANA PAULA (tdz8) Project Contact	06/17/2022	This is the NCBDDD research determination form	Other-Research Determination from	<a href="#">LTSAE_Research_Determination_Form_NCBDDD.docx</a>



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