

# **The Study of Disability Services Coordinators and Inclusion in Head Start, 2019-2024**

**OMB Information Collection Request  
New Collection**

## **Supporting Statement Part A**

**September 2021**

Submitted By:  
Office of Planning, Research, and Evaluation  
Administration for Children and Families  
U.S. Department of Health and Human Services

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**Alternative Supporting Statement for Information Collections Designed for  
Research, Public Health Surveillance, and Program Evaluation Purposes**

**Part A**

**Executive Summary**

- **Type of Request:** This Information Collection Request is for a new collection. We are requesting two years of approval.
  
- **Description of Request:** The Office of Planning, Research & Evaluation within the Administration for Children and Families at the Department of Health and Human Services proposes to conduct a study to provide a nationally representative picture of the Early Head Start (EHS) and Head Start (HS) Disability Services Coordinator (DSC) workforce, as well as services provided to children with disabilities and their families within these programs. This is the first study of the DSC workforce and will contain three phases of data collection. We will administer national web-based surveys to EHS/HS grantee and delegate agency (hereafter referred to as "EHS/HS program") directors (Phase 1) and to the DSCs identified by the EHS/HS directors (Phase 2). We will also conduct semi-structured interviews with purposively sampled subsets of DSCs (Phase 3). We do not intend for this information to be used as the principal basis for public policy decisions.

## Alternative Supporting Statement for Information Collections Designed for Research, Public Health Surveillance, and Program Evaluation Purposes

### A1. Necessity for Collection

According to the Head Start (HS) Performance Standards,<sup>1</sup> a minimum of 10% of children served must have an identified disability. HS standards go on to discuss the need for Disability Service Coordinators and programs to be given leeway in how they implement the standards. Very little HS administrative information is gathered about how the standards are implemented.

The Office of Planning, Research & Evaluation (OPRE) within the Administration for Children and Families (ACF) at the Department of Health and Human Services proposes to conduct the Study of Disability Services Coordinators (DSCs) and Inclusion in Early Head Start/Head Start (EHS/HS) to fill a gap in knowledge about the characteristics of DSCs, their roles and responsibilities, and how they collaborate to fulfill these duties. Given the flexibility in the HS standards, EHS/HS programs may have addressed the DSC requirements in varied and customized ways. A national study will be conducted to fully understand the range of DSC implementation as well as to examine subgroup approaches. ACF has contracted with NORC at the University of Chicago (NORC) to complete this work. There are no legal or administrative requirements that necessitate this collection. ACF is undertaking the collection at the discretion of the agency.

### A2. Purpose

#### *Purpose and Use*

The DSC study will provide a descriptive understanding of current practices and processes of the DSC role. Specifically, the study will provide ACF with a unique opportunity to better understand, support, and improve EHS/HS policies and practices for delivering disability services, as well as collaborating with local education agencies (LEAs), early intervention (EI) programs, health providers, and other community stakeholders who serve young children at risk for or with disabilities and their families. The study will be able to identify the staffing approaches, typical qualifications, and any challenges in retaining and hiring DSCs.

*Dissemination Plan.* Once the data collection is complete, a *full report* of summary and descriptive variables will be produced and shared with the public. In addition, five *briefs* will present on key topics of interest to OHS, including how the DSCs provide professional development for their programs; pathways to communications with families; transition practices for EHS/HS children with disabilities (e.g., to kindergarten); partnership and collaboration with local agencies; and cultural and linguistic responsiveness. Multiple additional products will be developed (e.g., summary presentations to OHS and training and technical assistance centers; scientific conference symposia; webinars for EHS/HS grantees; powerpoint slides for OHS use). In partnership with OHS, findings may be presented at various OHS events (e.g., MyPeers online collaborative learning system; OHS newsletters and training institutes; regional office presentations).

*Informing Training and Technical Assistance.* The Information gathered from this study is expected to inform the design and provision of ACF training and technical assistance for EHS/HS programs at the national and regional level. The study will identify training needs for staff and for DSCs about disabilities and disability services, including any needs for training in cultural and linguistic responsiveness, DSC management and staffing, partnership development with local agencies, professional development, family communication pathways, and transition methods. The data will allow ACF to examine variations in DSC implementation, and how these may be tailored for local communities.

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<sup>1</sup> <https://eclkc.ohs.acf.hhs.gov/policy/45-cfr-chap-xiii>

## Alternative Supporting Statement for Information Collections Designed for Research, Public Health Surveillance, and Program Evaluation Purposes

*Further Dissemination: Secondary Analyses.* The data will be archived in deidentified datasets. Once archived, the information may be used by qualified researchers addressing questions of value for children with disabilities and OHS. These could include a wide range of advocacy, technical assistance, management and administration, and stakeholder questions. For example, researchers may explore the associations between state policies and HS program implementation or examine variations in disability service coordinators' staffing, roles and processes. Further, HS programs may choose to examine their own approach to DSC and disabilities services and compare their internal approach to the national data to identify their unique strengths and weakness in DSC implementation. The archived data will serve as a valuable resource for understanding the roles and processes of EHS/HS programs in coordinating services for children with disabilities.

The information collected is meant to contribute to the body of knowledge on ACF programs. It is not intended to be used as the principal basis for decisions by federal decision-makers and is not expected to meet the threshold of influential or highly influential scientific information.

### *Research Questions*

The proposed study design will seek to answer research questions focused on EHS/HS DSCs and services provided to children with disabilities and their families within EHS/HS programs:

- **Research question 1:** What are the characteristics of the EHS/HS DSC workforce and related staff within EHS/HS programs across the country?
- **Research question 2:** What practices and policies do EHS/HS DSCs use to identify, recruit, screen, assess, and provide services, including implementation of Individual Family Service Plans (IFSPs) and Individual Education Plans (IEPs), to children with disabilities and their families?
- **Research question 3:** How do EHS/HS programs engage in capacity building with families (including providing or referring to supportive services) to ensure that they understand their rights and available resources, so that they can advocate for their children with potential or identified disabilities?
- **Research question 4**
  - **4a:** When children are identified as eligible for Individuals with Disabilities Education Act (IDEA) services, what services can EHS/HS programs provide them?
  - **4b:** What disability services do EHS/HS programs provide to children with needs who are not found eligible for services under IDEA?
- **Research question 5**
  - **5a:** How do EHS/HS programs engage and collaborate with internal team members: teacher/assistant teachers, mental health consultants (MHC), family support workers, education coordinators, health managers, policy council, and health services advisory committee (HSAC)?
  - **5b:** How do EHS/HS programs engage and collaborate with LEAs, IDEA Part B (preschool special education services), and Part C (early intervention services, birth to three)?
  - **5c:** How do EHS/HS programs engage and collaborate with other relevant services within their communities, including mental health providers and community programs?

**Alternative Supporting Statement for Information Collections Designed for  
Research, Public Health Surveillance, and Program Evaluation Purposes**

- **Research question 6**
  - **6a:** What types and range of training supports do EHS/HS DSCs and other staff receive and/or need?
  - **6b:** What supports do DSCs provide to teachers to individualize practices for children with disabilities?
  - **6c:** What strategies do DSCs provide to teachers to support the full inclusion of children with disabilities in the classroom?
- **Research question 7**
  - **7a:** How do EHS programs engage with HS programs and families to facilitate successful transitions to HS or pre-K for children with disabilities?
  - **7b:** How do HS programs engage with LEAs and families to facilitate successful transitions to kindergarten?

*Study Design*

ACF aims to address the research questions through a national survey of EHS/HS program directors<sup>2</sup> (Phase 1), a survey with DSCs identified by the directors (Phase 2), and a one-time qualitative interview with a subset of DSCs who respond to the web-based survey (Phase 3). Given the lack of administrative data about DSCs, it is essential that a national survey of EHS/HS directors be conducted to identify DSC respondents. We have no data regarding the population of the DSC workforce and subgroups, preventing us from setting a frame for selecting a nationally representative sample. A purposive sample of DSCs who completed the Phase 2 survey will be asked to participate in a semi-structured, qualitative interview. We will interview up to 36 EHS/HS DSCs.

Data collection activities will occur over fifteen months, beginning shortly after OMB approval. The three waves of data collection will overlap with staggered start dates: the Phase 1 survey will be fielded for approximately 8 months; the Phase 2 will be fielded for approximately 12 months; and the Phase 3 interviews will be conducted over 4 months. We provide additional details on the study design, its appropriateness for the intended use, and its limitations in Supporting Statement B.

**Exhibit A. Data Collection Activities**

<i>Data Collection Activity</i>	<i>Instruments</i>	<i>Respondent, Content, Purpose of Collection</i>	<i>Mode and Duration</i>
Phase 1	Survey of EHS/HS Program Directors <sup>1</sup>	<p><b>Respondents:</b> All EHS/HS grantee/delegate directors</p> <p><b>Purpose:</b> To collect contact information for DSCs and program-level information about the provision of disabilities and inclusion-related services. Phase 1 data will also inform weights for the Phase 2 survey data.</p> <p><b>Content:</b> Survey sections include: (1) director</p>	<p><b>Mode:</b></p> <p>Web-based survey (primary mode)</p> <p>Phone (option, as needed)</p>

<sup>2</sup> We use the term "EHS/HS program" to include EHS/HS grantees and delegate agencies.

**Alternative Supporting Statement for Information Collections Designed for  
Research, Public Health Surveillance, and Program Evaluation Purposes**

		background; (2) DSC contact information; (3) program-level characteristics; (4) training and other professional development; (5) external collaborations; and (6) transitions.	<p><b>Duration:</b></p> <p>25 minutes (web)</p> <p>40 minutes (phone)</p>
Phase 2	Survey of EHS/HS DSCs <sup>1</sup>	<p><b>Respondents:</b> DSCs provided by grantee/delegate directors in Phase 1</p> <p><b>Purpose:</b> To collect nationally-representative data to describe the characteristics of the DSC workforce and services provided to children with disabilities or suspected delays and their families.</p> <p><b>Content:</b> Survey sections include: (1) DSC characteristics; (2) screening, recruitment, referral, and evaluation; (3) capacity building and coordination with families; (4) disabilities services provided when children are or are not IDEA eligible; (5) collaboration with internal team and external partners; (6) supporting staff implementation of inclusion; and (7) transitions.</p>	<p><b>Mode:</b></p> <p>Web-based survey (primary mode)</p> <p>Phone (option, as needed)</p> <p><b>Duration:</b></p> <p>45 minutes (web)</p> <p>60 minutes (phone)</p>
Phase 3	DSC Interview	<p><b>Respondents:</b> Purposively selected DSCs from pool of DSCs who completed the Phase 2 web-based survey</p> <p><b>Purpose:</b> To collect qualitative information from DSCs about how they collaborate with community-based disability service providers, identify teacher training needs, recruit and enroll children with disabilities, communicate and build relationships with families or children with disabilities and suspected delays, successfully transition children with disabilities from an EHS/HS setting, and provide services that are responsive to the children’s and families’ racial, ethnic, cultural, and linguistic needs.</p> <p><b>Content:</b> The interviews will gather data on: a) partnerships with community-based disability service providers; b) teacher training and other professional development; c) recruitment and enrollment of children with disabilities and suspected delays; d) family collaboration; e) transitioning children with disabilities; and f) racial, ethnic, cultural, and linguistic responsiveness.</p>	<p><b>Mode:</b></p> <p>Semi-structured phone interviews</p> <p><b>Duration:</b>45 minutes</p>

## **Alternative Supporting Statement for Information Collections Designed for Research, Public Health Surveillance, and Program Evaluation Purposes**

1. *The primary mode for data collection will be online survey. However, both the Director and DSC Survey will include an option to complete by phone.*

### *Other Data Sources and Uses of Information*

*For Design and Data Collection.* The HS Enterprise System administrative data (HSES, 0970-0207 GABI), in combination with the HS Program Information Report (PIR, OMB #0970-0427) will be used to establish the list of the population of EHS/HS Directors as potential respondents to Phase 1. In addition, PIR and HSES population data will be used to assess response rates for subgroups over the course of the data collection.

*For Analyses and Reporting.* The DSC Study data will be used in combination with other data sources for analysis and reporting. The HSES and PIR, which contain program level disability data including the number of children with disabilities being served, referred, and evaluated, which will inform the study reports. HSES and PIR data may be used, for example, to identify subgroups of interest (e.g., Region XI, Region XII, rural and urban, larger and smaller programs). The study team will also utilize other publicly available state and disabilities relevant datasets (e.g., The Center for IDEA Early Childhood Data Systems (DaSy)) to examine HS/EHS DSC variability within the state context.

### **A3. Use of Information Technology to Reduce Burden**

The surveys (attached as Instruments 1: EHS/HS Director Survey and Instrument 2: EHS/HS DSC Survey) will be administered online via Qualtrics Survey Software. Collecting data in this manner reduces burden on respondents and improves data quality. The Phase 3 interviews will occur over the phone and will be recorded and transcribed.

### **A4. Use of Existing Data: Efforts to reduce duplication, minimize burden, and increase utility and government efficiency**

The proposed study does not duplicate any other work being done by ACF and does not duplicate any other data sources. Care was taken to not duplicate questions already asked within the HSES and PIR.

### **A5. Impact on Small Businesses**

The EHS/HS programs may be small organizations, including community-based organizations and other nonprofits. We will minimize burden for respondents by offering a web-based survey that respondents can complete at their convenience and by restricting the length of the survey. We will schedule the phone interviews at times that are convenient for the respondents.

### **A6. Consequences of Less Frequent Collection**

This is a one-time data collection.

### **A7. Now subsumed under 2(b) above and 10 (below)**

**Alternative Supporting Statement for Information Collections Designed for  
Research, Public Health Surveillance, and Program Evaluation Purposes**

**A8. Consultation**

*Federal Register Notice and Comments*

In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13) and Office of Management and Budget (OMB) regulations at 5 CFR Part 1320 (60 FR 44978, August 29, 1995), ACF published a notice in the Federal Register announcing the agency’s intention to request an OMB review of this information collection. This notice was published on July 22, 2021, Volume 86, Number 138, page 38722, and provided a 60-day period for public comment. During the notice and comment period, two sets of comments were received, one from the National Head Start Association and one from the Start Early organization. The comments and OPRE’s responses to these comments are summarized in Attachment G.

*Consultation with Experts Outside of the Study*

Stakeholders were briefed on the study and given opportunities to provide feedback on study constructs, instrument development, dissemination channels, and the tribal EHS/HS IRB process. For additional details on stakeholder activities, see Supporting Statement B, Section B3.

**Stakeholder Group**

Name	Organization
Angela Branch	FHI360, Region XII T/TA Center
Mary Beth Bruder	University of Connecticut A.J. Papanikou Center for Excellence in Developmental Disabilities Research, Education, and Service
Guadalupe Cuesta	National Migrant/Seasonal Head Start Collaboration Office
Amy Hunter	National Center on Early Childhood on Health and Wellness
Christy Kavulic	Office of Special Education Programs
Maria Pimentel	Disabilities & Mental Health Coordinator, Chicanos Por La Causa (CPLC)
Megan Vinh	Early Childhood TA Center
Mike Richardson	National American Indian and Alaska Native Head Start Collaboration Office
Maria Riestra-Quintero	Early Head Start Executive Director
Tina Routh	Mississippi Band of Choctaw (AIAN DSC)
Susan Sandall	National Center on Early Childhood Development, Teaching and Learning
Michelle Sarche	Colorado School of Public Health
Josh Sparrow	Brazelton Touchpoints Center (BTC)
Juan Carlos Tarango	FHI360, Disabilities Content Lead, Region XII
Sofia Zulema Thorp	Mental Health and Disabilities Specialist, Santa Fe Children’s Services-Flores Del Sol

**Region XI Workgroup**

Name	Organization and Title
Robert Pickens	<b>Chickasaw</b> - Director



**Alternative Supporting Statement for Information Collections Designed for  
Research, Public Health Surveillance, and Program Evaluation Purposes**

Judy Bryan	<b>Chickasaw</b> - DSC
-----*	<b>Chickasaw</b> -Primary caregiver of child(ren) with disabilities
Jennifer Russell	<b>Tanana Chiefs Conference</b> - Director
Evelyn Ekada	<b>Tanana Chiefs Conference</b> - DSC
Elvira Bitsoi	<b>Navajo Head Start</b> - Director
Lee Turney	<b>Ojibwe Leech Lake</b> - Director
Leila Goggeleye	<b>Ojibwe Leech Lake</b> - DSC
-----*	<b>Ojibwe Leech Lake</b> - Primary caregiver of child(ren) with disabilities
Kelly Spruce	<b>Seneca Nation</b> - Executive Director of HS Program
Lacy Nikola	<b>Seneca Nation</b> - DSC

\*name withheld for privacy

**A9. Tokens of Appreciation**

There are no tokens of appreciation proposed for respondents in this data collection

**A10. Privacy: Procedures to protect privacy of information, while maximizing data sharing**

*Personally Identifiable Information*

Contact information for Phase 2 participants will be collected from Phase 1 survey respondents (i.e., full name, phone number and email address). The collection of this personal information is necessary because no datasets currently exist with contact information for DSCs across all EHS/HS programs. Each DSC will be assigned a masked alphanumeric identifier to be used in any dataset with their individual responses from the Phase 2 survey or the Phase 3 interviews. After the completion of Phase 2 and 3, the DSC’s personal information will not be maintained in any paper or electronic system from which data are actually or directly retrieved. Any personal information that is shared by the respondent as part of the Phase 3 interview will be redacted from the transcript. All data will be stored on NORC secure servers.

Information will not be maintained in a paper or electronic system from which data are actually or directly retrieved by an individuals’ personal identifier.

*Assurances of Privacy*

Information collected will be kept private to the extent permitted by law. Respondents will be informed of all planned uses of data, that their participation is voluntary, and that their information will be kept private to the extent permitted by law. For the Phase 3 interviews, respondents will be asked permission to record. These assurances will be specified in the consent forms (see Appendix C). As specified in the contract, the Contractor will comply with all federal and departmental regulations for private information. The study has provided the informed consent forms to the Institutional Review Board (IRB) for the respondents not from tribal programs. The IRB has provided a preview and initial feedback on the consent forms. The informed consent forms in Attachment B incorporate this feedback. The complete clearance process has not been completed at the time of OMB submission, but data collection will not begin until IRB approval is received. In addition, the approval process with the applicable tribal

## **Alternative Supporting Statement for Information Collections Designed for Research, Public Health Surveillance, and Program Evaluation Purposes**

IRBs has yet to be initiated. Tribal IRB clearance will be completed before tribal data collection begins in the relevant communities.

### *Data Security and Monitoring*

As specified in the contract, the Contractor shall protect respondent privacy to the extent permitted by law and will comply with all Federal and Departmental regulations for private information. The Contractor has developed a Data Safety and Monitoring Plan that assesses all protections of respondents' PII. The Contractor shall ensure that all of its employees, subcontractors (at all tiers), and employees of each subcontractor, who perform work under this contract/subcontract, are trained on data privacy issues and comply with the above requirements.

As specified in the evaluator's contract, the Contractor will use Federal Information Processing Standard compliant encryption (Security Requirements for Cryptographic Module, as amended) to protect all instances of sensitive information during storage and transmission. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information, in accordance with the Federal Processing Standard. The Contractor shall: ensure that this standard is incorporated into its property management/control system; establish a procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive information. Any data stored electronically will be secured in accordance with the most current National Institute of Standards and Technology (NIST) requirements and other applicable federal and departmental regulations. In addition, the Contractor must submit a plan for minimizing to the extent possible the inclusion of sensitive information on paper records and for the protection of any paper records, field notes, or other documents that contain sensitive or PII that ensures secure storage and limits on access.

### **A11. Sensitive Information**<sup>3</sup>

The study does not intend to collect sensitive information. However, in the Phase 3 interviews it is possible that participants will voluntarily disclose sensitive information about themselves or the EHS/HS children and families with whom they work. All of this information will be protected as described in the Contractor's Data Security and Monitoring Plan.

The Contractor has submitted informed consents to the IRB for initial feedback and will obtain approval from applicable IRB approval prior to data collection.

### **A12. Burden**

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<sup>3</sup> Examples of sensitive topics include (but are not limited to): social security number; sex behavior and attitudes; illegal, anti-social, self-incriminating, and demeaning behavior; critical appraisals of other individuals with whom respondents have close relationships, e.g., family, pupil-teacher, employee-supervisor; mental and psychological problems potentially embarrassing to respondents; religion and indicators of religion; community activities that indicate political affiliation and attitudes; legally recognized privileged and analogous relationships, such as lawyers, physicians, and ministers; records describing how an individual exercises rights guaranteed by the First Amendment; receipt of economic assistance from the government (e.g., unemployment, WIC, SNAP); and immigration/citizenship status.

**Alternative Supporting Statement for Information Collections Designed for  
Research, Public Health Surveillance, and Program Evaluation Purposes**

*Explanation of Burden Estimates*

We estimate that the Phase 1 Survey of EHS/HS Program Directors will take approximately 25 minutes to complete, the Phase 2 Survey of EHS/HS DSCs will take an estimated 45 minutes to complete, and the Phase 3 DSC interviews will last approximately 45 minutes. Phone versions of each of the surveys we expect to take approximately 15 minutes longer, to carefully pace the reading and presentation of the survey questions and responses. This request is for two years of information collection.

Currently, there are 1600 HS agencies nationally, so 1600 directors will be invited to respond to our Phase 1 survey and we estimate a 79% response rate: 1264 responses. We expect those directors to refer us to 1 to 3 DSCs (average 2 per director). Out of the universe of 2528 DSCs, we expect a 75% response rate: 1896 survey responses. We plan to select only 35 DSCs to complete the Phase 3 interviews. We expect a minimal number of respondents to select the phone survey option (5 of the 1264 directors and 5 of the 1896 DSCs). These response rates are comparable to those achieved for the HS Health Manager Survey (2016) and the T/TA Center Study (2019), both with similar designs (i.e., surveying directors in Phase 1 and gathering information on Phase 2 respondents).

*Estimated Annualized Cost to Respondents*

The wage rates are from the May 2020 National Occupational Employment and Wage Estimates from the U.S. Bureau of Labor Statistics. For Program Directors we utilized 11-9030 Education and Childcare Administrators rates and for DSCs we utilized 11-9031 Education and Childcare Administrators, Preschool and Daycare.

**Estimated Burden and Costs to Respondents**

Instrument	Mode	No. of Respondents (total over request period)	No. of Responses per Respondent (total over request period)	Avg. Burden per Response (in hours)	Total Burden (in hours)	Annual Burden (in hours)	Average Hourly Wage Rate	Total Annual Respondent Cost
Survey of EHS/HS Program Directors (Phase 1)	Web	1259	1	0.42	529	265	\$47.25	\$12,521.25
	Phone	5	1	1.0	5	3	\$47.25	\$141.75
Survey of EHS/HS DSCs (Phase 2)	Web	1891	1	0.75	1418	709	\$25.81	\$18,299.29
	Phone	5	1	1.0	5	3	\$25.81	\$77.43
DSC Interview (Phase 3)	Phone	36	1	0.75	27	14	\$25.81	\$361.34
Totals						994 hours		\$31,401.06

**Alternative Supporting Statement for Information Collections Designed for  
Research, Public Health Surveillance, and Program Evaluation Purposes**

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**A13. Costs**

There are no additional costs to respondents.

**A14. Estimated Annualized Costs to the Federal Government**

<b>Activity</b>	<b>Detail</b>	<b>Estimated Cost</b>
Survey Design Instrument Development Pilot and User Testing OMB Clearance	<ul style="list-style-type: none"> <li>• FTE time</li> <li>• Operational expenses (such as equipment, overhead, printing, and staff support)</li> <li>• Other expenses that would not have been incurred without this collection of information</li> </ul>	\$236,860
Survey Administration	<ul style="list-style-type: none"> <li>• FTE time</li> <li>• Operational expenses (such as equipment, overhead, printing, and staff support)</li> <li>• Other expenses that would not have been incurred without this collection of information</li> </ul>	\$274,266
Analysis and Initial Dissemination	<ul style="list-style-type: none"> <li>• FTE time</li> <li>• Operational expenses (such as equipment, overhead, printing, and staff support)</li> <li>• Other expenses that would not have been incurred without this collection of information</li> </ul>	\$338,048
<b>Total costs over the request period</b>		\$849,174
<b>Annual costs</b>		\$424,587

**A15. Reasons for changes in burden**

This is a new information collection request.

**A16. Timeline**

Data collection will start after receiving OMB approval and NORC IRB approval. We will await the necessary clearances from tribal IRBs and school districts before collecting data from the EHS/HS programs in those areas. Our goal is to begin Phase 1 and Phase 2 data collection in January 2022. The collection will take place in three waves throughout the 2022 calendar year: Phase 1 will be fielded over 8 months; Phase 2 will be fielded over 12 months; and Phase 3 will be fielded over 4 months. Additional details on the study timeline are provided in the table below.

**Alternative Supporting Statement for Information Collections Designed for  
Research, Public Health Surveillance, and Program Evaluation Purposes**

**Study Timeline for Months after OMB approval**

Activity	Study Timeline for Months after OMB approval																																																				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33																				
Phase 1: Data Collection	█																																																				
Phase 2: Data Collection	█																																																				
Phase 3: Data Collection								█																																													
Analysis and Tabulation												█																																									
Report and Briefs													█																																								
Publication and Dissemination																	█																																				
Data Archiving																																																					

**Alternative Supporting Statement for Information Collections Designed for  
Research, Public Health Surveillance, and Program Evaluation Purposes**

**A17. Exceptions**

No exceptions are necessary for this information collection.

**Attachments**

Instrument 1: Survey of EHS/HS Program Directors (Phase 1)

Instrument 2: Survey of EHS/HS DSCs (Phase 2)

Instrument 3: DSC Interview (Phase 3)

Attachment A: Crosswalk Mapping Study Goals to Research Questions, Constructs, Instruments, and Item numbers

Attachment B: Informed Consent Forms

Attachment C: Phase 1 Recruitment

Attachment D: Phase 2 Recruitment

Attachment E: Phase 3 Recruitment

Attachment F: Study Awareness

Attachment G: OPRE Response to Comments