



# Project Determination

## Evaluating Deep Learning Algorithm Assessment of Digital Photographs for Dental Public Health Surveillance

**Project ID:** 0900f3eb8218c113  
**Accession #:** NCCDPHP-ST-6/14/23-8c113  
**Project Contact:** Susan Griffin  
**Organization:** NCCDPHP/OD/OMS  
**Status:** Pending Clearance  
**Intended Use:** Project Determination  
**Estimated Start Date:** 11/01/23  
**Estimated Completion Date:** 10/31/24  
**CDC/ATSDR HRPO/IRB Protocol#:** NA  
**OMB Control#:** Currently undergoing OMB approval

### Description

#### Priority

Standard

#### Date Needed

08/01/23

#### Determination Start Date

06/16/23

#### Description

Please note that this project was been determined to be research in 2023. The purpose of this form is to determine if CDC needs to obtain CDC IRB approval to receive and store de-identified data and digital images of teeth. CDC is funding an outside institution, Purdue University, and the Colorado Department of Public Health to collect and analyze data for this project. Purdue University has submitted an IRB that includes the Colorado dental examiners. This project will examine the feasibility and validity of using digital photos taken by non-dental professionals, which in turn would be analyzed by deep learning algorithms to assess youth's oral health status in lieu of human examination. This deep learning assessment tool ultimately could be used by public health officials for dental public health

surveillance at the local, state, and national level. In order to train and test the deep learning algorithms to identify caries, sealants, and fluorosis, data on these conditions as assessed by standardized examiners and corresponding photos are required. CDC requests a one-year OMB approval for the one-time collection of oral health data from 1,000 middle- and high-school students in Colorado communities with naturally occurring fluoride in the tap water at or exceeding 1 part per million. The Colorado state health department will implement the collection by recruiting selected schools and dental examiners, gaining consent, arranging logistics, and collecting data from dental examination and photos taken by the dental examiners. CDC will provide dental examination and photo taking protocols and train the examiners. Data collected for each student will include 1) human assessment of fluorosis severity in the 6 upper anterior teeth and caries/sealant assessment of the occlusal surfaces of the 8 permanent molars and 2) 9 smartphone digital photos of the upper anterior teeth and 24 intraoral camera digital photos of the occlusal surfaces of the 8 permanent molars. Only de-identified data will be collected. All de-identified data—digital photos of the teeth and the completed paper screening form—will be uploaded to a HIPAA compliant cloud storage box that only can be accessed by examiners and designated CDC researchers with administrative rights. CDC is authorized to collect this information under the Public Health Service Act, Title 42, Section 247b-14, Oral health promotion and disease prevention; and the Public Health Service Act, Title 42, Section 301.

**IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission**

No

**IMS Activation Name**

Not selected

**Select the primary priority of the project**

Not selected

**Select the secondary priority(s) of the project**

Not selected

**Select the 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**

Develop effective and efficient tool that would provide public health practitioners with valid and reliable national, stat, and local estimates of youth's dental health.

**Objective**

Obtain dental data from youth including digital photos and human assessment of oral health status that can be used to develop tool.

**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**

Yes

**Studying Social Determinants of Health (SDOH)**

Not selected

**Assessing Impact**

Not selected

**Methods to Improve Health Equity Research and Practice**

Not selected

**Other**

Not selected

**Activities or Tasks**

New Collection of Information, Data, or Biospecimens

**Target Population to be Included/Represented**

Children

**Tags/Keywords**

Dental Care for Children; Dental Fissures; Dental Caries

**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**

Convenience Sample

**Methods**

The Division of Oral Health (DOH) proposes using data collected from 1000 Colorado middle- and high-school students to train and test deep learning algorithms to identify caries, sealants, and fluorosis from digital photos. The following data will be collected for each child: 1) human assessment of fluorosis severity in the 6 upper anterior teeth and caries/sealant assessment of the occlusal surfaces of the 8 permanent molars and 2) 9 smartphone digital photos of the upper anterior teeth and 24 intraoral camera digital photos of the occlusal surfaces of the 8 permanent molars. Data from 750 students will be used to train the deep learning algorithms to assess caries, sealants, and fluorosis and data from 250 students to evaluate the accuracy of the algorithms in terms of agreement with standardized

examiner assessment. All de-identified data—digital photos of the teeth and the completed paper screening form—will be uploaded to a HIPAA compliant cloud storage box that only can be accessed by examiners and designated CDC researchers with administrative rights. CDC is authorized to collect this information under the Public Health Service Act, Title 42, Section 247b-14, Oral health promotion and disease prevention; and the Public Health Service Act, Title 42, Section 301.

### Collection of Info, Data, or Bio specimens

Data will be collected at approximately 50 Colorado middle- and high-schools. Dental examiners who have been calibrated to a standardized examiner will be examining 1,000 youth and taking digital photos of their teeth. The human assessment portion of the data collection is quite similar to that used for the Basic Screening Survey, which the Division of Oral Health funds states to perform. Only de-identified data will be collected. All de-identified data—digital photos of the teeth and the completed paper screening form—will be uploaded to a HIPAA compliant cloud storage box that only can be accessed by examiners and designated CDC researchers with administrative rights.

### Expected Use of Findings/Results and their impact

This deep learning assessment tool ultimately could be used by public health officials for dental public health surveillance at the local, state, and national level. It is anticipated that obtaining information on dental conditions via deep learning assessment of digital images as opposed to human assessment will 1) be more cost-effective as it would not require dental personnel and 2) improve the accuracy of assessment due to minimal bias and less confounding factors associated with the examiner (e.g., subjective index and thresholding). This tool also would offer mobility, simplicity, and affordability for rapid and scalable adaptation in community-based settings.

### Could Individuals potentially be identified based on Information Collected?

No

## Funding

Funding Type	Funding Title	Funding #	Original Fiscal Year	# of Years of Award	Budget Amount
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## HSC Review

### Additional Ethical Considerations

may have potential for human subjects research; CDC is not engaged in human subjects research.

## Regulation and Policy

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

Yes

### Estimated number of study participants

1000

### Population - Children

## Regulation and Policy

<b>Targeted</b>	Page:
<b>Population - Minors</b>	
<b>N/A</b>	Page:
<b>Population - Prisoners</b>	
<b>N/A</b>	Page:
<b>Population - Pregnant Women</b>	
<b>N/A</b>	Page:
<b>Population - Emancipated Minors</b>	
<b>N/A</b>	Page:
<b>Suggested level of risk to subjects</b>	
Minimal	
<b>Do you anticipate this project will be exempt research or non-exempt research</b>	
Non-Exempt	
<b>Requested consent process waivers</b>	
<b>Informed consent for adults</b>	
No Selection	
<b>Children capable of providing assent</b>	
No Selection	
<b>Parental permission</b>	
No Selection	
<b>Alteration of authorization under HIPPA Privacy Rule</b>	
No Selection	
<b>Requested Waivers of Documentation of Informed Consent</b>	
<b>Informed consent for adults</b>	
No Selection	
<b>Children capable of providing assent</b>	
No Selection	
<b>Parental permission</b>	
No Selection	
<b>Consent process shown in an understandable language</b>	

## Regulation and Policy

### Reading level has been estimated

Yes

### Comprehension tool is provided

No Selection

### Short form is provided

Yes

### Translation planned or performed

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 identifiable biological specimens

No Selection

### Involves a drug, biologic, or device

No Selection

### Conducted under an Investigational New Drug exemption or Investigational Device Exemption

## Regulation and Policy

No Selection

## Institutions

Institution	FWA #	FWA Exp. Date	IRB Title	IRB Exp. Date	Funding #
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## Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/Institution
Lorena Espinoza	03/10/2026				Co-Investigator	lee6@cdc.gov	770-488-5319	DIV OF ORAL HEALTH

## DMP

<b>Proposed Data Collection Start Date</b>	11/30/23
<b>Proposed Data Collection End Date</b>	06/29/24
<b>Proposed Public Access Level</b>	Non-Public
<b>Reason for not Releasing the Data</b>	CIO conducting this project does not fund or own the data and is not responsible for making it available
<b>Public Access justification</b>	These de-identified data will be used to develop learning algorithms to identify dental conditions with digital images. They will not be used after that.
<b>How Access Will Be Provided for Data</b>	De-identified data obtained at collection site will be automatically uploaded to HIPPA compliant box that can only be accessed by authorized researchers.
<b>Plans for archival and long-term preservation of the data</b>	

## Spatiality (Geographic Location)

Country

State/Province

County/Region

## Determinations

Determination	Justification	Completed	Entered By & Role
HSC: <b>Does NOT Require HRPO Review</b>	Non-Exempt Human Subjects Research when CDC is not engaged  <i>45 CFR 46.102(a) HHS/OHRP 2008 Engagement Guidance at III B(1-11)</i>  Research that involves de-identified/unlinkable data or biospecimens, but not involving FDA investigational products  <i>45 CFR 46.102(e)</i>	07/21/23	Redmond Leonard_Joan (jrl3) CIO HSC
PRA: <b>PRA Applies</b>		07/25/23	Still-LeMelle_Terri (cse6) OMB / PRA