

# Evaluation of non-invasive fingerprinting methods for healthcare recording in newborns and infants

<b>Submission date</b> 16/03/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/03/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/05/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Biometrics is the measurement and statistical analysis of people's unique physical and behavioral characteristics. The technology is mainly used to identify individuals based on these characteristics. Although there are many validated technologies to recognize adults, these technologies have been ineffective in newborns and young children. The present work describes the development and clinical testing of a fingerprint capture system designed for biometric recognition of newborns and young children for vaccination and clinical follow-up. This study aimed to test the new system in a newborn ward and immunization clinic at an urban hospital in Baja California, Mexico.

### Who can participate?

Healthy infants aged less than 35 weeks

### What does the study involve?

Prototypes of a biometric device are used to capture several images of an infant's finger, foot, and/or hand prints. The study team may take photos and videos of the interactions. Parents /guardians will be asked to sign a separate consent to allow the team to record and/or photograph the infant's movements.

### What are the possible benefits and risks of participating?

Participation in this study will not involve any physical risks or discomforts. There is the risk of loss of confidentiality due to the child's participation in this study. To minimize this risk, the team will assign each participant a study ID number and this will be used rather than the parent /guardian or child's name.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. Participants will be informed of any significant new findings. There is no direct benefit to the child participating in this study. The investigators, however, may learn more about biometric identification of infants that will be very important to children's health around the world.

Where is the study run from?  
UC San Diego (USA)

When is the study starting and how long is it expected to run for?  
July 2015 to December 2020

Who is funding the study?  
Bill and Melinda Gates Foundation (USA)

Who is the main contact?  
Dr Eliah Aronoff-Spencer  
earonoffspencer@health.ucsd.edu

## Contact information

**Type(s)**  
Principal investigator

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
BMGF OPP1159073

## Study information

**Scientific Title**  
Biometric recognition of newborns and young children for vaccinations and health care using non-contact fingerprinting: a non-randomized prospective clinical trial

**Study objectives**  
Reliable infant (0-12 months) biometric identification is critical for effective healthcare yet has historically proven difficult to carry out. While the fingerprint is completed at around 4 months of gestation, accurate and reliable infant fingerprinting has posed significant problems over

adult identification in many settings. This study is testing a device developed using principles of human-centered design to reliably capture and identify infant fingerprints.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 09/03/2015, University of California San Diego (UCSD) Human Research Protections Program (9500 Gilman Drive, La Jolla, CA 92093, USA; +1 (0)858 657 5100; hrpp@ucsd.edu), ref: 151400

### **Study design**

Observational cohort study

### **Primary study design**

Observational

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Biometric recognition of newborns and infants

### **Interventions**

Participating parents are consented and enrolled. Fingerprints from each infant finger are captured using a non-contact imaging device. Multiple images are taken for each finger. Enrollment of fingers occurs on the first visit and takes 10-20 minutes. On subsequent visits the child's finger is again scanned multiple times. Matching and processing are carried out retrospectively after encounter completion.

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Not applicable

### **Primary outcome(s)**

Enrollment goal reached, assessed using a target of 500 participants - consented parents and at least one participant encounter between 01/01/2018 and 31/12/2020

### **Key secondary outcome(s)**

1. Failure to enrol rate, assessed using an image quality cutoff score and defined as no fingers with images of quality equal to or greater than this threshold from any image taken at time of encounter
2. Detection error tradeoff, assessed using standard methods for calculation of true positive and negative versus false positive and negative rates to determine thresholds optimizing sensitivity and specificity using data calculated after session encounters
3. Identification rates assessed using comprehensive match characteristics method ranking an

individual match across many participants at 0-720 days time between enrollment and identification

**Completion date**

31/12/2020

## **Eligibility**

**Key inclusion criteria**

1. Age minimum 34 weeks gestational age up to 1 year since birth
2. Male or female
3. Any ethnic background
4. Health status: well
5. Available for a minimum of two visits (to allow repeat identification)

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Total final enrolment**

494

**Key exclusion criteria**

1. Infants older than 6 months of age
2. Active health issues
3. Trauma or parental concerns

**Date of first enrolment**

01/01/2018

**Date of final enrolment**

31/12/2019

## **Locations**

**Countries of recruitment**

Mexico

**Study participating centre**

**General Hospital of Tijuana**

Department of Research  
Centenario 10851  
Zona Urbana Rio, Tijuana  
Mexico  
22000

**Study participating centre****Grupo Pediatrico de Tijuana / Dr Enrique Chacon-Cruz**

Germán Gedovius 10489  
Zona Urbana Rio, Tijuana  
Mexico  
22010

## Sponsor information

**Organisation**

Bill & Melinda Gates Foundation

**ROR**

<https://ror.org/0456r8d26>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Bill and Melinda Gates Foundation

**Alternative Name(s)**

Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United States of America

# Results and Publications

## Individual participant data (IPD) sharing plan

All reasonable efforts will be made to keep the neonate’s personal information confidential. The video recordings will be used for device development and destroyed at the completion of the study. The researchers will not collect any other protected health information (PHI) or any personal information that might lead to individual identification. No PHI will be used in any reports or publications about this study. There is the risk of loss of confidentiality due to disclosure is required by law or through University of California San Diego organizations that may inspect and/or copy research records for quality assurance and data analysis.

Several methods will be used to ensure confidentiality. Patient identifiable information will not be recorded in the study database or in any subsequent analysis. All collected data will be recorded with a sequential patient identification number. The key linking study ID to identifiable information will be retained in a password-protected file and/or in a locked location, accessible only to the research team and separate from other study data. The study database will be password protected and stored on a secure server. The information will not be disclosed without consent except where required by law. The results of the study when published will have no patient identifying PHI. Videos will also be maintained in a password-protected file and/or in a locked location accessible only to the research team.

Patients will be assigned a study ID number which will be used for study purposes. The key linking study ID numbers to identifiable information will be kept in a password-protected file and /or in a locked location separate from all other study data. Upon completion of the publication of findings, the key that links PHI data to subject ID will be destroyed. The study database will be stored on a password-protected computer file on a secure server with access restricted to study members. No PHI will be presented or published. PHI will be destroyed after the study /manuscript is complete and no further analysis will be performed.

## IPD sharing plan summary

Stored in non-publicly available repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		29/12/2022	22/05/2023	Yes	No