CENTER FOR DATA INSIGHTS AND INNOVATION
CALIFORNIA HEALTH & HUMAN SERVICES AGENCY

View xForm - Project Application v6

This form is for new projects that have not been previously approved by CPHS.

Data entry
- Submitted 05/21/2026 1:35 PM ET by Doyoon Kim

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

June 2026

_____HSC New Project_____

Researchers from Emory University in collaboration with CDPH submitted this application to request approval for their study that is aimed to understand early TB infectiousness and transmission by evaluating people who are being assessed for TB or have early TB disease, collecting clinical information and biological samples, and linking participants to the California TB Registry to determine who later develops active TB. They want to identify biomarkers, aerosolized TB signals, and social contact patterns that can reveal how much transmission occurs before people feel sick and to improve early detection, screening, and prevention strategies for TB.
A Co-PI (Dr. Barry) from CDPH is listed in the application

• Data-Source Department:
CDPH—A LOS from "CDPH Tuberculosis Control Branch, Division of Communicable Disease Control, Center for Infectious Diseases" is attached.

• PROJECT SITE
Emory University—NO DSL??

• FUNDING
Federally Funded by NIH

• End-Product:
For dissemination of the study results, they will produce internal and external presentations, reports, and manuscripts.

• Linkage:

Yes

05/01/2026 • Sussan Atifeh • Internal

Email exchange with Neszka on this project:

05/20/2026 • Sussan Atifeh • Internal • Resolved

Neszka's Input on This Project	05/20/2026 3:25 PM ET
Informing Chairs about This Project	05/20/2026 3:26 PM ET

Internal Note:

Researchers clarified that, "NIH did not designate Emory IRB as a single or central IRB. We would like to move forward with CalHHS CPHS reviewing the study at the full board meeting on June 5th. " Please see the attached email to this note:

05/20/2026 • Sussan Atifeh • Internal

Researchers Provided Clarification	05/20/2026 6:39 PM ET

If personnel are not found by their email address while trying to complete the following questions, you can add them in the system with the link below. Click on the "New Contact Form" and complete it. Within a few minutes of completing the form, you will receive an email notifying you of the availability of the new contact. You should then be able to add them in the subsequent questions.

User had the option to start a different form here.

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Sarita Shah, MD, MPH

Email: sarita.shah@emory.edu **Business:** (404) 727-7326

Choose the institution with which the PI is affiliated (not the location at which the research is being conducted).

Emory University

Enter the city in which the PI's institution is located.
Atlanta

Enter the state in which the PI's institution is located.

Start typing in the state name to select the name from the list.

Georgia

Attach a copy of the PI's Curriculum Vitae.

Microsoft Word - CV -- Sarita Shah -- 6Feb26.docx.pdf PI Curriculum Vitae

CO-PRINCIPAL INVESTIGATOR (CO-PI)

Enter the Co-PI's email address by clicking on the "Add Contact" button.

It is not clear from the application whether the CDPH Co-PI will be actively involved in research activities specifically for this project, or whether their role reflects routine CDPH responsibilities (e.g., oversight of TB Registry matching or general program collaboration).

Please clarify in the "Purpose" or " Procedures" section of this application whether her involvement is limited to routine CDPH duties or whether they will have any role in study-specific activities such as data analysis, interpretation, manuscript preparation, or access to identifiable or coded study data. This information is needed to determine whether they should be listed as project personnel.

05/01/2026 • Sussan Atifeh • *Not* Internal • Resolved

If there are multiple co-principal investigators, repeat this action for all Co-PIs. If there are no Co-PIs for this project, skip this question.

Pennan Barry, MD

Email: pennan.barry@cdph.ca.gov **Business:** (510) 620-3041

Attach a copy of each Co-PI's Curriculum Vitae.

Pennan Barry CV 202508 No posters.doc Co-PI Curriculum Vitae

ADMINISTRATIVE CONTACT

Enter the email address(es) for the administrative contact(s). If you are the administrative contact, enter your email address, and enter anyone else you want listed as an administrative contact.

Doyoon Kim

Email: dki2299@emory.edu **Business:** (404) 706-6147

Angie Campbell, Master of Arts

Email: angie.campbell@emory.edu **Business:** (614) 499-4401

RESPONSIBLE OFFICIAL (RO)

Enter the RO's email address.

*The RO **cannot** be the same person as the PI or Co-PI. The RO must have supervisory authority, in the administrative structure of the institution, over the PI.*

Timothy Lash, DSc, MPH

Email: tlash@emory.edu **Business:** (404) 712-1270

OTHER RESEARCH STAFF

Enter the email address for any other research staff by clicking the "Add Contact" button.

In the last paragraph of the attached Cover Letter, you mentioned, "State and local TB program staff may assist with operational coordination and data linkage."

Please ensure that this section includes all research staff who have not been listed elsewhere in the application and who will:
• Interact directly with participants (e.g., interviews, focus groups), or
• Have access to study data at any stage.
This includes:
• Individuals who will access linked de identified data if any variables originate from state data.
• All staff involved in data management, processing, analysis, or report writing.

05/01/2026 • Sussan Atifeh • *Not* Internal • Resolved

Repeat this action for all other research staff not previously provided on this screen that should receive notifications about this project. If there are no additional research staff, skip this question.

Fay Willis, MPH

Email: fay.willis@emory.edu **Business:** (713) 502-7313

Emily Han, MPH

Email: emily.han@cdph.ca.gov **Business:** (510) 620-3019

Varsha Hampole, MPH

Email: Varsha.Hampole@cdph.ca.gov **Business:** (510) 620-3994

Check for PI same as RO (internal only question) *(Internal)*

False

Project Information

SUBMITTER

Application completed by:

Doyoon Kim
Email: dki2299@emory.edu **Business:** (404) 706-6147

PREVIOUSLY APPROVED EXEMPTION

Is there a previously-approved exemption from CPHS for this project?

No

PROJECT TITLE

Enter the project title (please capitalize each word in your title).

Infectiousness and Social Mixing in Asymptomatic TB as a Driver of Population-level Transmission (INSPIRE study)

PROJECT SITE

Indicate the primary site at which the research will be conducted.

The site(s) refer to the institution(s) responsible for the primary storage, receipt, and management of study data, as well as for ensuring data security and compliance with relevant regulations. This includes overseeing access controls, data encryption, and privacy safeguards. Typically, this is the Principal Investigator's and Responsible Official's institution, which houses and manages the servers through which the data is processed. Since in the case of an adverse event or loss of confidentiality, the PI and RO are accountable.

Please note that a Data Security Letter (DSL) must be provided for each study site and uploaded in the "Data Security Letter" section of the application.

Given that, please if the main site of the project is Emory University, select it from the dropdown menu.
Also, if this project has multiple sites, please clarify about it in the "Purpose" section of this application.

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05/01/2026 • Sussan Atifeh • *Not* Internal • Resolved

Emory University

STUDY PROCEDURES

Indicate the study procedures involved in this research. Check all that apply.

Data Registry
Interviews
Recruitment-Participant
Surveillance Data
Surveys

TYPE OF RESEARCH REQUEST

Indicate which of the following applies to this research. Check all that apply.

based on the clarifications provided by the research team in an email conversation, Emory IRB is not designated by NIH as the central IRB and this project will be discussed in the June 5th meeting. Please select "Common Rule/Human Subjects" and attach copies of all recruitment materials for this project in relevant sections of this application.

05/20/2026 • Sussan Atifeh • *Not* Internal • Resolved

*Death Data Only refers to health-related studies requesting existing mortality data from **within** the California Human Health Services Agency (CHHSA)*

*SB-13 (Information Practices Act) refers to health-related studies requesting existing data from **outside** the CHHSA (e.g. California Department of Corrections and Rehabilitation [CDCR], California Department of Education [CDE], etc.) **OR** studies requesting data **within** the CHHSA that are not state funded or involving state staff.*

Common Rule/Human Subjects refers to health-related studies that involve direct or indirect interaction with human subjects (e.g. recruitment, interviews, etc.)

*Common Rule Only refers to health-related studies requesting existing data from **within** the CHHSA (e.g. Office of Statewide Health Planning and Development [OSHPD], California Department of Public Health [CDPH], etc)*

SB-13 (Information Practices Act)
Common rule/Human subjects
Common rule only

PROJECT TYPE DETAILS

Indicate which, if any, apply to this research. Check all that apply.

IF you do not use any identifiable state data to recruit the subjects of this study, and if CDPH staff do not have any role in the subject's recruitment for this study, please de-select all options except "Minimal Risk."

Since you are working with Data, you should select "Minimal Risk."

05/01/2026 • Sussan Atifeh • *Not* Internal • Resolved

If the research does not involve any of following, choose "None of the above."

Minimal Risk

VULNERABLE POPULATIONS

Indicate which vulnerable populations, if any, will be involved with this research. Check all that apply.

If vulnerable populations are not part of the research, choose "Not applicable." Note regarding minors: in the United States, a minor is under 18 years of age. If research is conducted outside the United States, a minor is under the age of majority in the countries where research is to be conducted.

Minors
Economically or Educationally Disadvantaged Persons

Please click the link below to fill out the supplement involving children. After you've finished the form, you will need to save it locally and then attach in the space below.

Link to Children Supplemental Form

DRAFT - Checklist-For-Research-Involving-Children_revised-2-25-22_INSPIRE.pdf	Children Supplemental Form

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
Federally funded

Enter name of federally-funded source.
National Institutes of Health

EXPEDITED REVIEW CONSIDERATION

Please check the criteria below that you think your project meets to qualify for an expedited review. If none of these expedited criteria are appropriate for your project, choose 'not applicable'; your protocol will be reviewed by the full committee. Note that CPHS will make the final determination of whether the project meets the criteria for expedited review.

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

***The Departments within the California Health and Human Services Agency (CHHSA) are: Aging, Alcohol and Drug Programs, Child Support Services, Community Services and Development, Developmental Services, Emergency Medical Services Authority, Health Care Services, Mental Health, Public Health, Rehabilitation, Social Services and Statewide Health Planning and Development.*

Not applicable

ANTICIPATED PROJECT START DATE

Projects cannot begin before they have been reviewed. The earliest possible start date is always the date of the next public meeting at which the project will be heard.

Please select 6/5/26 or a date following this date within a few weeks.

05/01/2026 • Sussan Atifeh • *Not* Internal • Resolved

For a list of public meeting dates, see the CPHS website

06/05/2026

ANTICIPATED PROJECT END DATE

08/31/2030

Project Details

PURPOSE

Include a brief statement, less than 500 words, describing the research project. Be sure to address the background for the project, including relevant literature, the major research questions to be addressed, and the expected end product (e.g., article, report or other publications). Include the location(s) where the project will take place. The summary should be understandable to the general public.

Please name the site(s) of this study in this section, and note:

The site(s) refer to the institution(s) responsible for the primary storage, receipt, and management of study data, as well as for ensuring data security and compliance with relevant regulations. This includes overseeing access controls, data encryption, and privacy safeguards. Typically, this is the Principal Investigator's and Responsible Official's institution, which houses and manages the servers through which the data is processed. Since in the case of an adverse event or loss of confidentiality, the PI and RO are accountable.

Please note that a Data Security Letter (DSL) must be provided for each study site and uploaded in the "Data Security Letter" section of the application.

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Emory University will serve as the primary institution for the receipt, storage, management of study data as well as for ensuring data security and compliance with all applicable regulations.

Since asymptomatic tuberculosis (TB) remains undiagnosed for prolonged periods, during which time people maintain their normal activities, this may explain the large proportion of transmission occurring in community settings. Understanding social contact patterns during early stages of TB has important implications for determining where and when TB is spread.

We hypothesize that individuals in early TB stages may have sufficient TB bacillary burden to be infectious and contribute to transmission before they develop symptoms that prompt them to seek care. We will conduct a prospective cohort study to determine the onset of infectiousness (Aim 1) and measure social contact patterns (Aim 2) along the spectrum of TB disease. Aim 3 will utilize these data to model the proportion of TB transmission that occurs during early-stage disease, particularly in community settings.

We will prospectively enroll and follow 2,000 participants (12 years and older) who are evaluated for TB, B-1 immigrants, or close contacts of a microbiologically confirmed, pulmonary TB index case. Individuals with with active TB who are starting treatment (as a positive control group) also be enrolled. All participants will be enrolled through California local health department TB programs.

The duration of an individual participant's commitment to the study is one study

visit that will include symptom screening, TB exposure assessment, social contacts survey, sputum and blood collection for TB diagnosis. We will use available data from participants' medical records and test results obtained during routine standard care procedures.

At the end of the study, a list of study participants will be matched with California TB Registry to determine if participants developed active TB in California after completing the study visit.

All research activities involving participant enrollment will take place at the TB control program clinics; activities involving testing of research samples will take place at the CDPH Microbial Diseases Laboratory (MDL) and Emory research laboratory.

For dissemination of the study results, we will produce internal and external presentations, reports, and manuscripts.

MAJOR RESEARCH QUESTION

What is the major research question to be addressed in this project?

To describe the prevalence of early-stage, asymptomatic or minimally symptomatic TB, and to understand social contact patterns of these individuals in order to determine the proportion of TB transmission attributable to this disease state.

STUDY PROCEDURES

Describe in detail all procedures for this research. Do not attach grant applications or similar documents. Information in this application must be sufficient to fully explain the procedures without such documents

Emory University IRB has reviewed and approved this study.

The CDPH Co-PIs will be actively involved in study-specific activities such as study design, oversight, and implementation; coordination with CDPH jurisdictions; clinical consultation; analysis, interpretation, and dissemination of results. The CDPH staff do not any role in the subject's recruitment for this study. Other research staff (e.g., a microbiologist and research assistant) from the local TB program are yet to be determined.

We will not request the release and use of any directly identifiable data from state department (CDPH) for the purpose of conducting this study. Directly identifiable information including name, date of birth, residential address information (zip code) will be used to match with the California TB Registry at CDPH. We will not receive and use any identifiers from the CDPH to contact subjects. Instead, CDPH will be provided with subjects' identifiers to perform matching and will return results to Emory using study IDs only, without any identifiers. This request is not only for the data matching by the CDPH, but all human-subject contact activities described in this study can be completed before we receive deidentified TB Registry data from the CDPH.

The proposed study is observational, and no experimental intervention or treatment will be administered to study participants. All participants will complete a single study visit and will not be contacted by the study after completing this visit. The investigators and study staff will attempt to schedule the research visit on a day and time that is convenient to participants. The study will provide transportation incentives and compensation of time involved to participate in research activities.

We will prospectively enroll 2,000 close contact participants, person being assessed for TB, and/or recent immigrants (B-1 classification) evaluated at several TB clinics in California. Individuals with with active TB who are starting treatment (as a positive control group) also be enrolled.

Immigrants with a B-1 classification are those who are entering the country legally after TB screening in their country of origin revealed an abnormal chest X-ray (CXR) suggestive of TB, but no evidence of active TB (e.g. sputum cultures for TB negative). These immigrants are normally re-evaluated in TB clinic to ensure the TB has not become active in the ensuing months since their original evaluation.

All research activities involving participant enrollment will take place at the TB control program clinics; activities involving testing of research samples will take place at the CDPH MDL and Emory research laboratory.

RESEARCH PROCEDURES AND DATA COLLECTION:
As part of standard of care at TB clinics, tuberculin skin testing (TST) or Interferon-Gamma Release Assay (IGRA) will be used to determine participants' TB infection status. Only people with positive TST or IGRA will be approached by clinic staff for study enrollment. B1 arrivers will not get an additional IGRA, but the

results of their overseas IGRA will be used for study inclusion.

For this study, we will use the results from whichever test is used at the local clinic. Those with positive results (i.e., >5mm induration for TST or positive blood results for IGRA) will be eligible to be enrolled in the study. Contacts who are TST or IGRA negative at initial testing by the clinic should undergo repeat TST or IGRA testing at 8-12 weeks as part of standard of care. If they are positive at the 8-12 week repeat testing performed as part of standard of care, they will be eligible to be enrolled in the study at that time.

We will use available data from participants' medical records and test results obtained during routine standard care procedures. This includes demographics, medical history, TB risk factors, TB exposure assessment, IGRA/TST results, HIV test results, lung imaging findings (e.g,. CXR and/or chest CT), sputum testing results, pregnancy test results, and any other body fluid or tissue samples tested for TB. Additional information will be collected from available medical records at study site clinics for participants who subsequently are evaluated for or are diagnosed with active TB. These records may include actual images from imaging studies (e.g., x-rays, CT scans). Tests conducted outside of standard care for research purposes will not be shared with clinics, programs, or participants and, therefore, will not affect clinical care.

The structured interview will collect additional demographic data, medical history (e.g., HIV, diabetes), TB risk factors (e.g., tobacco), occupation, and incarceration history that is not already captured through the routine medical record data. TB exposure will be assessed with a validated questionnaire that asks: number of people with active TB in the household and other known TB contacts; relationship; number of hours spent together indoors; physical proximity (e.g., sharing a room or bed); and household characteristics (e.g., number of rooms).

Symptom screening using a structured questionnaire will start with an open-ended question asking participants about any symptoms they are concerned about. Then, specific symptoms will be probed including cough, fever, night sweats, weight loss, loss of appetite, fatigue, chest pain, hemoptysis. For any positive symptom, duration and severity will be recorded. We will query whether they have sought medical care, or if they have shared concern about the symptom(s) with a family member or friends.

Social contacts survey will query about contacts over a short recall period. The survey will be administered by study staff, who will query participants about their contacts in the 2 days before the study visit. Participants will be asked to report contacts with whom they had physical, non-physical, or casual contact. For each contact, participants will record age, sex, relationship to participant, as well as location (e.g., home, school, transport), duration, environment (indoors/outdoors), and proximity/type of contact. To determine the number of casual contacts, participants will be asked to report on locations where they spent time (i.e., bar, restaurant, market/grocery, public transportation) and the approximate number of people in each location but who do not meet the definition of physical or non-physical contact.

In addition to sputum specimens collected as part of standard care, each participant will have an additional sputum specimen collected and stored for the study. Additionally, we will obtain the results of sputum smear, NAAT, and culture done as part of standard care. Participants unable to produce mucoid sputum will be encouraged to make repeated cough efforts and spit what is in their mouth into the specimen container, repeating this process 3 times.

Blood will be collected for biomarkers and mRNA and will be sent to Emory for testing. For metabolomic biomarkers, the kynurenine/tryptophan ratio and retinol will be measured using commercially available ELISA kits. Additionally, targeted and untargeted high-resolution metabolomics will be performed at Emory. For mRNA signatures, we will perform RNA-Seq, for a comprehensive quantitative assessment of transcriptional profiles in whole blood.

For face mask sampling, participants will wear Avelo face masks for 45 minutes under direct observation by study staff. Following sample collection, the face mask filter will be placed into a buffer tube containing pathogen-inactivating DNA-stabilizing media and transported at ambient temperature to the local study site. Tubes will stored at -20°C and shipped to the CDPH MDL for testing per the manufacturer's instructions.

At the end of the study, a list of study participants will be matched with California TB Registry to determine if participants developed active TB in California after completing the study visit. This information will be recorded in the study record, including:
- Date of report
- Status at TB diagnosis (alive or dead)
- Initial reason evaluated for TB
- Smear, culture, NAAT, pathology/cytology results from sputum and nonsputum specimens
- Chest radiograph and chest CT scan results
- Date of illness onset
- The site of disease
- Case identified during the contact investigation of another case
- Case verification criteria (i.e., NAAT, culture, smear, clinical diagnosis, provider diagnosis).
- Immunosuppressive and other conditions increasing the risk of progression to active TB disease: HIV, organ transplant, anti-TNF alpha, end stage renal disease, other immunocompromise
- Date treatment started
- Date treatment stopped
- Reason treatment stopped or never started
- Deceased (e.g., did the patient die)

Participants will only complete activities during the baseline visit and will not be contacted at the time the database is reviewed.

Please upload here any tables or charts related to your study procedures and any materials (such as surveys or interview questions) that will be presented to participants.

INSPIRE Schedule of Assessments_0420_26.docx Other Documents

Deleted Attachments: 3 (Most Recent: INSPIRE Schedule of Assessments, 2-16-26.docx on 04/20/2026 3:09 PM ET)

RECORDING

Will audio or video recording occur?

No

DECEPTION

Will deception be used in this study?

No

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CHHSA) DEPARTMENTS LIST

Indicate any of the following CHHSA department(s)' involvement in providing research staff, funding and/or patients from State mental hospitals for this project.

CDPH: Department of Public Health

STATE DEPARTMENT DATA/SPECIMENS

Choose the department(s) from which you are requesting data and/or specimens and provide the formal name of the database or specimen registry. After you have selected the department from the drop down and entered the formal name of the database or specimen registry, click 'add' and repeat to add additional data and/or specimens if applicable.

Agency	Provide the formal name of the data base or specimen registry.
California Department of Public Health	California TB Registry

Study Population

POPULATION DESCRIPTION

Provide a full description of how human subjects will be involved in the research. Address characteristics of subjects such as: age; sex; ethnicity; and number of participants. Include requested participant number.

We will prospectively enroll approximately 2,000 participants. We will screen adults and adolescents 12 years and older who are being evaluated for TB, immigrants with a B-1 classification, or close contacts of a microbiologically confirmed, pulmonary TB index case for enrollment. Individuals with with active TB who are starting treatment (as a positive control group) also be enrolled. Only people with positive TST or IGRA will be approached by clinic staff for study enrollment.

Close contacts are defined as individuals who slept in the same house for >=1 night or spent >=5 hours indoors with the index case in the 1 month before diagnosis. Contacts will be identified through contact investigation procedures that normally take place with all confirmed pulmonary TB cases.

Immigrants with a B-1 classification are those who are entering the country legally after TB screening in their country of origin revealed an abnormal CXR suggestive of TB, but no evidence of active TB (e.g. sputum cultures for TB negative). B-1 immigrants are identified through electronic notification by Division of Global Migration and Health (DGMH) and are contacted and invited into clinic for evaluation. These immigrants are normally re-evaluated in TB clinic to ensure the TB has not become active in the ensuing months since their original evaluation.

People being evaluated for TB are individuals referred by outside providers with findings suggestive of possible TB disease (abnormal imaging, symptoms, and/or positive TB blood test).

People with active TB disease who are starting treatment are those who have been microbiologically confirmed to have TB on sputum testing through routine TB clinic procedures. This group will serve as a "positive control" for the research tests that are being conducted in this study.

Contacts, B-1 immigrants, people being evaluated for TB, and individuals with active TB who present to TB clinic for care will be informed about the study and referred by the local clinic staff to a research team member for enrollment if he/she is interested in participating.

We will include children ages 12-17 years in the proposed research. The investigators have experience with recruiting children <18 years for other similar latent TB and TB studies. For all minors age <18, written consent for study participation will be obtained from the participant's parent or guardian, and a concurrent assent form will be signed by the child, indicating his or her willingness to participate in the study.

DATABASE DETAILS

List the database(s) to be used and the time period(s) being requested. This may include requests for future data that is not available at this time.

List the variables being requested, including a brief description of each variable. Justify the need for each variable and for the quantity of data being requested. You may also attach a list of variables on the next question.

Also address if participants will be involved in any other studies.

Research staff will access surveillance systems and medical records solely for the purpose of screening eligibility and data abstraction relevant to the study objectives.

For eligibility screening, medical records and test results obtained during routine standard care will be used. As part of standard of care at TB clinics, tuberculin skin testing (TST) or Interferon-Gamma Release Assay (IGRA) will be used to determine participants' TB infection status. Only people with positive TST or IGRA will be approached by clinic staff for study enrollment. Participants will not be involved in any other studies.

We will prospectively enroll and follow 2,000 participants (12 years and older) who are evaluated for TB, individuals with active TB, B-1 immigrants, or close contacts of a microbiologically confirmed, pulmonary TB index case. For data abstraction, We will use available data from participants' medical records and test results obtained during routine standard care procedures. This includes sociodemographic (e.g., age, sex, country of birth), CXR film and interpretation, chest CT scan and interpretation, HIV status, pregnancy test result, TB infection (e.g., IGRA, TST) test, BCG status, medical history (comorbidities), TB risk factors, TB symptoms, TB exposure assessment, sputum smear, NAAT test, and culture results, contact investigation data, development of active TB disease, and TB treatment regimen and outcome. If any of the listed data are missing or incomplete, we will collect them for study purposes only if the participant provides informed consent; participants may choose to provide this information or decline without any penalty or impact on their care. Tests conducted outside of standard care will not be shared with clinics, programs, or participants and, therefore, will not affect clinical care.

Copies of CXR films will only be accessed for individuals with positive TB findings and will be reviewed retrospectively, not in real time, solely to assess clinical presentation for case definition during the study period.

For quality assurance purposes, copies of relevant source documents (such as laboratory results, radiographic images) with name, MRN, and date of birth removed, will be uploaded to the HIPAA-compliant local folder, the Emory REDCap database, and SharePoint study folder. Access to REDCap and SharePoint folder will only be provided to study staff.

At the end of the study, a list of study participants will be matched with the California TB Registry to determine if participants developed active TB in California after completing the study visit. This information will be recorded in the study record. Additional information will be collected from available medical records at study site clinics for participants who subsequently are evaluated for or are

diagnosed with active TB. These records may include actual images from imaging studies (e.g., x-rays, CT scans). Participants will not be contacted at the time the database is reviewed.

Participants' names and study ID numbers will be linked in a password-protected computer file that will be kept on a computer which can only be accessed by senior project staff. This link between the participant and the research study will be destroyed 6 months after study analyses are completed.

Study investigators at Emory and CDPH will be responsible for storage of study data for at least 10 years after completion of the study, and for overseeing sharing of data and specimens outside of the research team, in line with U.S. regulations and guidelines. Electronic study data will be stored indefinitely in the Emory REDCap database. De-identified data will be shared outside the study team only from those participants who consent to future use.

If you have a list of variables with the details requested in the above question, attach that here. If you provided all details on the database in the question above, skip this question.

INSPIRE Study List of Variables.docx List of Variables

RATIONALE

What is the rationale for studying the requested group(s) of participants?

Tuberculosis remains the leading infectious disease cause of death worldwide, with 1.3 million deaths each year (1). Despite being curable and preventable, TB incidence has decreased by <2% per year since 2015 and is far off track from reaching the global End TB goal of 90% reduction by 2035 (2). It is increasingly recognized that TB exists along a dynamic spectrum, rather than binary states of latent TB infection and active TB disease (3,4). Evolving understanding of TB pathophysiology has made clear that there are intervening stages characterized by an absence of symptoms, in the setting of ongoing Mtb replication and host response detected by microbiology, radiology, or biomarkers (3,5,6). TB prevalence surveys in high-burden settings estimate up to half of bacteriologically confirmed TB occurs among people who do not report symptoms (7,8), yet there is limited understanding of the infectiousness of asymptomatic TB disease. Recent studies have shown that cough may not be necessary for TB to be transmitted. TB bacilli have been detected in bioaerosols generated by even less forceful respiratory maneuvers, such as tidal breathing (9,10), and are associated with incident TB in close contacts (11,12). The higher frequency of breathing compared to coughing (e.g., 22,000 breaths/day vs. 500 coughs/day) is further hypothesized to explain up to 90% of TB that is aerosolized in a single day (13), including before symptoms develop. Since asymptomatic TB may be undiagnosed for an average of 2 years (6,14)—during which time people maintain their normal activities and social mixing behaviors—this may explain the large proportion of transmission occurring in community settings.

We will prospectively enroll approximately 2,000 participants. We are studying immigrants with a B-1 classification, close contacts, and other people being evaluated for active TB to recruit people already undergoing evaluation for TB with a reasonable likelihood of having active TB disease that is early in the disease course or is minimally or asymptomatic.

Individuals with active TB who are starting treatment (as a positive control group) also be enrolled. Individuals in this group have been microbiologically confirmed to have TB on sputum testing through routine TB clinic procedures. This group will serve as a "positive control" for the research tests that are being conducted in this study.

Other people undergoing evaluation for active TB disease will be included because these people may be more likely to have more advanced TB and so that the spectrum of TB disease is represented in the study participants. We are recruiting participants in experienced local health departments with high volumes of people undergoing evaluation for TB.

The overarching goal of this project is to describe the prevalence of early-stage, asymptomatic or minimally symptomatic TB, and to understand social contact patterns of these individuals in order to determine the proportion of TB transmission attributable to this disease state. The study findings may guide screening and diagnosis approaches for people at risk for TB in the US and globally, which has potential to improve outcomes for individuals through early diagnosis and for communities through reduced transmission. (See separate References file for citations)

RECRUITMENT DETAILS

Describe how potential subjects will be identified for recruitment. Examples include: class rosters; group membership; individuals answering an advertisement; organization position titles (e.g., presidents, web designers, etc.). How will potential participants learn about the research and how will they be recruited (e.g., flyer, email, web posting, telephone, etc.)?

Important to remember: subjects cannot be contacted before IRB approval.

We will prospectively enroll approximately 2,000 participants of close contacts, B-1 immigrants, individuals with active TB, and people who present to TB clinic for evaluation. Clinic staff will be informed about enrollment criteria for the study and will alert study staff about potentially eligible patients.

Potential participants will be informed about the study and referred to a study staff for enrollment if he/she is interested in participating. Study participants will be recruited and enrolled by a trained research team member who will be based in the several TB clinics in California.

At the time study staff approach potential participants, information about the study procedures and purpose will be explained in the preferred language. Most study participants will likely not speak English as the primary or preferred language; therefore, consent and assent forms will be translated into the most commonly-spoken languages at each clinical site, and consent process and interviews will be conducted by either a local staff member or online/telephonic translation service in the participant's preferred language. Study staff will emphasize that participation is completely voluntary, and withdrawal is possible at any time with no effect on their future care or risk of any other negative consequences. Written consent or assent (for minors under age of 18) will be required for study enrollment. Consent and assent discussions will be provided in the participant's preferred language.

Attach copies of all recruitment materials.

INSPIRE Adult Consent Form Short v1_CDPH IRB_APR02_2026_cleaned.docx	Recruitment Materials
INSPIRE Assent Form v2.1_CDPH IRB_04202026.docx	Recruitment Materials
INSPIRE study flyer_UPDATED.pdf	Recruitment Materials

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SCREENING

Will subjects be screened prior to entry into the research?

Yes

Please address the criteria for exclusion and inclusion in the research during the screening process. Provide reasons for not including women or minorities. Provide justification for including vulnerable populations such as children or prisoners. Please also provide a statement regarding what will happen to the information collected about the individual should they not enter into the study.

We will screen adults and adolescents 12 years and older who are being evaluated for TB, B-1 immigrants, individuals with active TB, or close contacts of a microbiologically confirmed, pulmonary TB index case for enrollment. Close contacts are defined as individuals who slept in the same house for >=1 night or spent >=5 hours indoors with the index case in the 1 month before diagnosis or during the index case infectious period as determined by the local program. Contacts will be identified through contact investigation procedures that normally take place with all confirmed pulmonary TB cases. B-1 immigrants identified through electronic notification by Division of Global Migration and Health (DGMH) are contacted and invited into clinic for evaluation. People undergoing TB evaluation are individuals referred by outside providers with findings suggestive of possible TB disease (abnormal imaging, symptoms, and/or positive TB blood test). Contacts, B-1 immigrants, individuals with active TB, and people who present to TB clinic for evaluation will be informed about the study and referred to a study worker for enrollment if he/she is interested in participating.

We will include children ages 12-17 years in the proposed research. The investigators have experience with recruiting children <18 years for other similar TB studies. For all minors age <18, written consent for study participation will be obtained from the participant's parent or guardian, and a concurrent assent form will be signed by the child, indicating his or her willingness to participate in the study.

At all sites, we will exclude:
• Children under the age of 12
• Participants treated for TB disease within the past 5 years or who received TB preventive treatment within the past 12 months
• Pregnant women
• Individuals with an active psychiatric condition or alcohol or drug dependence that might interfere with the ability to give true informed consent and to adhere to the study requirements
• Incarcerated (prisoners) or otherwise institutionalized individuals

We will exclude pregnant women because pregnancy may impact the biomarker signatures that this study seeks to identify. In addition, the radiographic procedures that are required at the study visit may pose a risk to pregnant women and fetuses. The study team will perform a urine pregnancy test for participants who are women of childbearing age at the beginning of the baseline study visit. Women who are pregnant at the time of enrollment will be excluded from the study and no study procedures will be initiated and no data collected. Exclusion from study enrollment will not influence a pregnant woman's ability to receive treatment through the clinical treatment program offered by the TB clinic.

All information accessed during the screening process will be used solely to determine eligibility and will not be collected or stored if the individual is not enrolled in the study.

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type
Gift card

Explain the amount and schedule of compensation that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.
Participants will receive $75 USD per study visit as reimbursement for transportation and compensation for time and inconvenience required for completion of the study visit in accordance with local guidelines established by CDPH and Emory University IRBs. Participants will be provided the study reimbursement in gift cards, per standard policy at the local study sites, and all participant compensation will be handled by the local study team.

STUDY DURATION

Estimate the probable duration of the entire study. This estimate should include the total time each subject is to be involved and the duration of each data collection about the subject.

E.G., This is a two-year study. Participants will be interviewed three times per year; each interview will last approximately two hours. Total approximate time commitment for participants is 12 hours.

This is a five-year study. All participants will complete a single study visit to complete activities and will not be contacted after completing this visit. The visit might require several hours, including travel time.

Risks and Benefits

RISK DESCRIPTION

Provide a description of possible risks to participants: physical, psychological, social, economic, loss of data security, and/or loss of confidentiality. Describe and justify whether the research is minimal risk or greater than minimal risk.

This study is associated with minimal risks as the only study-related intervention is phlebotomy, having an additional sputum collected, and wearing a facemask for 45 minutes. Additional risks associated with study participation include the potential loss of confidentiality, inconvenience of attending research visit, discomfort in answering personal questions, and discomfort in wearing a face mask and having blood drawn. There are no risks associated with collection of sputum.

Blood draws may cause some discomfort, bleeding, bruising or infection where the needle enters the body. Phlebotomy will be performed only by phlebotomists or study staff who are trained and experienced, to minimize the risk of unnecessary discomfort or bleeding.

The study requires an in-person study visit. The visit will take place at the local TB clinic or close by. The visit might require several hours, when including travel time. Participants will receive reimbursement for transportation and time and inconvenience required for the study visit, in accordance with local guidelines established by CDPH and Emory University IRBs and U.S. and California guidelines. Participants will also be told that they may withdraw from the study, if they so choose, at any point, without any impact on their medical care.

Because this project focuses on TB, confidentiality is an important concern. We will be collecting personal information from participants to facilitate follow-up and will be asking questions about sensitive data including health, TB and HIV status, and information about participants' social networks.

Discussing one's medical and social history may, in some cases, cause the participant to feel upset. However, the questionnaires have been validated and/or used in our previous studies and have been well-accepted by prior, similar participants. No social, legal, or long-term risks are foreseen.

MEDICAL SERVICE RISKS

Describe how medical services will be provided if subjects suffer adverse mental or physical effects as result of research activity. If no services provided, state that clearly.

Although medical service risk is minimal, any participant that suffers adverse mental or physical effects as a result of participating in the study will be encouraged to contact the study team if they experience side effects after the study visit, and study staff will either provide or refer the participant for treatment. The study will not provide specific additional medical services.

INTERNATIONAL RESEARCH

Will this research occur outside of the United States or U.S. territories?

Check with client to see if they consider territories to be outside the U.S. or not, as this can vary between institutions.

No

LESS RISKY METHODS

Describe any less risky methods and why they are not being used.

The current approach represents the lowest possible risk while still allowing the research questions to be adequately addressed. Further reduction of procedures (e.g., eliminating data collection or modifying methods) would compromise the scientific validity of the study without meaningfully reducing risk. Therefore, no less risky methods are feasible or appropriate for achieving the aims of this research.

BENEFITS

Describe the benefits, if any, to the subjects or to society that will be realized as a result of this project. Discuss the benefits that may accrue directly to the subjects as well as to society. If there is no direct benefit anticipated for the subjects, state that clearly.

There may not be a direct benefit to individual study participants. For individual study participants, the benefit will be the knowledge that they are contributing to the understanding of when people become infectious with TB.

JUSTIFICATION OF RISKS

Explain why study risks are reasonable in relation to the potential benefits to subjects and to society.

The risks to subjects are reasonable because the study has been intentionally designed to minimize or eliminate potential risks to participants. The procedures involve no deception, and no collection of sensitive information beyond what is necessary for the research objectives. Given the minimal risks involved for study participants, we feel the importance of expected results outweighs potential risks.

Adminstrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

If the researcher demonstrates that he or she is unable to comply with any of the requirements below, he or she may request an exception from these requirements. The researcher should indicate any measures that will be taken to address this requirement. The exception request should be made in the text box of the corresponding requirement. An exception will only be granted if the researcher can demonstrate that adequate alternative measures have been taken to minimize risks so as to justify the exception.

HIPAA IDENTIFIERS

Please identify which HIPAA Identifiers you plan to request as part of your submission.

Name
All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
Medical record number

TRAINING PROCEDURES

Describe the procedures for training all research staff who have access to PID on privacy and security. Indicate if staff are required to sign a confidentiality statement related to general use, security, and privacy.

Education for all study staff on the protection of human participant participants; all investigators and study staff will be required to complete and maintain CITI (Collaborative Institutional Training Initiative) training (www.citiprogram.org) accreditation. In addition, all staff and monitors will sign a confidentiality statement.

STAFF VETTING PROCEDURES

Describe procedures, either background check or thorough reference check, for vetting staff who will have access to PID.

Study staff based at California clinics who will have access to PID will be recruited based on their experience with human subjects research and training in Good Clinical Practice (GCP) and ethical protections. They will undergo pre-employment background and reference checks. They will be required to stay up-to-date with human subjects research ethics trainings, per California and U.S. regulations.

SUPPORT LETTER

Obtain and submit a department support/data release letter.

This is a statement from the state agency or department you are receiving data from. It must be on that agency's/department's letterhead and should include both

1) *that the release of the desired data is legal and*

2) *that the entity is willing to release the desired data to you, the researcher. If you are not receiving data, this letter should indicate that you are supported.*

***For VSAC requests, if you do not have a Departmental Letter of Support (LOS)/Data Release, you may upload a copy of the Data Request Form (application) from the department to secure a review for the upcoming cycle. The protocol will not be approved until the LOS is uploaded to the protocol.*

Please also review the CPHS Statement for Birth and Death Data.

INSPIRE CDPH-data-share-letter 20260220.pdf Department Letter of Support

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PREVENTING RE-USE AND UNAUTHORIZED ACCESS

Explain how you will ensure that data will not be reused or provided to any unauthorized person or entity.

Unauthorized means that the person or entity does not have a need to access the data for purposes of the research project approved by CPHS.

Participants' names and study ID numbers will be linked in a password-protected computer file that will be kept on a computer which can only be accessed by senior project staff. This link between the participant and the research study will be destroyed 6 months after study analyses are completed. Study records will be kept within limited access, password-protected computer files, available only to the investigators and study personnel. Analysis datasets will only include study ID, not personal identifiers. Publication or presentation of study results will not identify participants by name or other directly identifying information. The investigators have extensive experience in the performance of similar studies in people with TB.

Study data will be entered, cleaned, and archived in a password-secured online REDCap database, hosted on the Emory University server. REDCap is a HIPAA compliant online database service provided at no cost for use by Emory staff, faculty and external collaborators. Electronic copies of source documents and other forms of data may be preserved in secure, confidential servers located at CDPH sites and in Emory SharePoint folder accessible only by study investigators and staff. These servers comply with current safety and security protocols to ensure privacy and security of stored data (e.g., limited access, password protections, access roles, audit trails, data encryption, secure storage, and back-up/recovery).

Location and other identifying information will only be used for eligibility confirmation and for retention purposes and will only be accessible by the local study team. The study records and database will be accessible only to the investigators and study personnel. Directly identifying information including name, date of birth, residential address information (zip code) will be used to match with the California TB Registry at CDPH. CDPH TB Registry staff routinely match using personal identifiers and have extensive training and experience with handling datasets securely. Any matching records in the TB registry will be shared with study staff by study ID only. Match results with identifiers will be kept securely by TB Registry staff until instructed by study staff to destroy the data.

The Emory study team will only have access to data and specimens that are coded using the assigned study ID and contain no directly identifying information. Only the local site study investigator and CDPH study team members will have access to the participant's directly identifying information.

Study investigators at Emory and CDPH will be responsible for storage of study data for at least 10 years after completion of the study, and for overseeing sharing of data and specimens outside of the research team, in line with U.S. regulations and guidelines. Electronic study data will be stored indefinitely in the Emory REDCap database. De-identified data will be shared outside the study team only from those participants who consent to future use.

CONFIDENTIALITY OF PUBLISHED DATA

Indicate whether information will be published that could possibly be used to identify an individual subject.

De-identified scientific data included in published manuscripts will be made available to the larger scientific community at the time of publication or the end of the project, whichever comes first; all other generated scientific data will be shared no later than the end of the project. The data will be made available for an indefinite period or until Emory University or other study partners request that it be withdrawn. Publication or presentation of study results or study data will not include personal identifiers and will be reviewed and scored using the CDPH Data Deidentification Guideline v2.0 to reduce or eliminate the risk of potential reidentification.

DATA REQUEST JUSTIFICATION

Provide adequate justifications for the quantity of the data, the years and the variables being requested. Have you requested no more than the minimum necessary data to perform the research?

The proposed sample size is sufficient to support valid statistical analysis while avoiding the collection of excess data beyond what is required for reliable and interpretable results. The period of access to data requested were selected because they align directly with the timeframe relevant to the research objectives. Limiting the data to these specific period ensures consistency in measurement and avoids unnecessary inclusion of data that would not contribute meaningfully to the analysis. The study will collect only the minimum information necessary to meet the study objectives, using existing records whenever possible.

Only variables essential to the research questions are being requested. Variables not directly related to the study objectives, including sensitive information not required for analysis, have been excluded. This approach ensures that data collection adheres to data minimization principles and reduces potential risks to participants.

LIMITATIONS TO DATA ACCESS

Indicate if access to data is limited only to those with a need to know for purposes of implementing or evaluating the research.

Participant names and other directly identifying information that are entered into the data system will not be accessible to staff outside the local site. Only the local site investigator and CDPH study team members will have access to the participant's directly identifying information. Location and other identifying information will only be used for eligibility confirmation and for retention purposes and will only be accessible by the local study team. The study records and database will be accessible only to the investigators and study personnel.

The Emory study team will only have access to data and specimens that are coded using the assigned study ID and contain no directly identifying information. All study staff and monitors will sign a confidentiality agreement.

Electronic copies of source documents and other data, from which names, MRNs, and dates of birth have been removed, may be stored on secure, confidential servers at CDPH sites and within Emory REDCap and SharePoint folders accessible only to authorized study investigators and staff.

PROTECTION AGAINST SMALL CELL SIZES AND ASSOCIATED PROBLEMS

Describe appropriate and sufficient methods to protect the identity of individual subjects when small cells or small numbers and/or data linkage to another data set are involved in the research project.

Publication or presentation of study results or study data will not include personal identifiers and will be reviewed and scored using the CDPH Data Deidentification Guideline v2 to reduce or eliminate the risk of potential reidentification.

LINKAGES

Will the data set be linked with any other data sets?

Yes

Identify all data sets and each of the variables to be linked, with a brief description of each variable and justification for each linkage. If there is an extensive list, you may attach that list in the next question and indicate such here.
A list of study participants will be matched to the California TB Registry to determine whether participants were reported with active TB disease following their study visit. Matching will be performed by TB Registry Staff and only information from matched records will be returned to study staff using study ID. Limited information related to timing, TB risks, and clinical findings at the time of diagnosis will be returned.

Data sets and variables from medical records and TB Registry to be linked include:
- Sociodemographic indicators, including age, sex, education, race/ethnicity, origin of birth place
- Chest X-ray film and interpretation
- Chest CT scan and interpretation
- HIV status
- Pregnancy test result
- TB infection (e.g., IGRA, TST) test
- BCG status
- Comorbidities (lung disease, diabetes, etc.)
- TB risk factors (residency, employment, etc.)
- TB symptoms
- TB exposure assessment
- Smear, culture, NAAT, pathology/cytology results from sputum and nonsputum specimens
- Contact investigation data
- Development of active TB disease
- TB treatment regimen
- TB treatment outcome
- Date TB treatment started
- Date TB treatment stopped
- Reason treatment stopped or never started
- Date of report
- Status at TB diagnosis (alive or dead)
- Initial reason evaluated for TB
- Date of illness onset
- The site of disease
- Case identified during the contact investigation of another case
- Case verification criteria (ie, NAAT, culture, smear, clinical diagnosis, provider diagnosis)
- Immunosuppressive and other conditions increasing the risk of progression to active TB disease: HIV, organ transplant, anti-TNF alpha, end stage renal disease, other immunocompromise
- Deceased (e.g., did the patient die)

Attach a copy of the document detailing all data sets and each of the variables to be linked. If you provided this information in the answer to the above question, skip this question.

INSPIRE Study List of Variables.docx Other Documents

Will a third party be used for data linkage?
No

DESTRUCTION OF PID VERIFICATION

Indicate that you will provide CPHS with a letter certifying that PID has been destroyed and/or returned to the data source once research is concluded.

Yes

DATA SECURITY LETTER

You must obtain a Data Security Letter (DSL) from each site involved in the study (using the format specified on the CPHS website) and attach it in this section ("Data Security Letter" section) of the application.

Please note that the Data Security Letter (DSL) must be signed by the Chief Information Officer, Privacy Officer, Security Officer, or an equivalent representative of the researcher's institution, confirming that CPHS Data Security Standards are met. The signature should come from an IT professional who is knowledgeable about the data security measures in place and can confirm compliance with CPHS Data Security Standards.

For your convenience, you can access the relevant resources using the links below:

• Data Security Letter Template
https://www.cdii.ca.gov/wp-content/uploads/2024/03/Data-Security-Letter-Template-Accessible.pdf

• Data Security Requirements
https://www.cdii.ca.gov/wp-content/uploads/2023/04/Data-Security-Requirements-2012-04-20.pdf

Additionally, you can refer to the CPHS webpage for further information regarding the DSL and other resources by visiting CPHS Resources under "IRBMANAGER" and "FORMS AND BULLETINS."

05/01/2026 • Sussan Atifeh • *Not* Internal

Upload a certification/statement from the Chief Information Officer, Privacy Officer, Security Officer or equivalent position of the researcher's institution that CPHS Data Security Standards are met.

- *Data security letters cannot be signed by the Principal Investigator or Responsible Official.*
- *The data security letter must be on your institution's letterhead.*
- *Example of data security letter*

Data Security Requirements for CA Dept of HCAI (1) Dr Sarita_signed-Corrected.docx	Data Security Letter

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Physical Safeguards

DATA PROTECTION

Indicate that research records and physical samples will be protected through the use of locked cabinets and locked rooms; PID in paper form will not be left unattended unless locked in a file cabinet, file room, desk, or office.

Yes

DATA DESTRUCTION

Will data/samples will be destroyed or returned as soon as it is no longer needed for the research project.

Yes

RETAINED DATA

Will the retained data/samples have personal identifiers or be de-identified?

data will be de-identified

Explain what identifiers will be removed and how.
Each study participant's research data and specimens will be labeled only with a unique study identification number and contain no other individual identification. Diagnosis of TB requires special sensitivities with respect to confidentiality. Each participant will receive a unique study identification number, and all research data collection, data entry forms and study specimens will be labeled only with this number and contain no other individual identification. Only the written informed consent forms will have identifiable information in them, and these forms will be stored separately from documents that include study identification number.

Participants' names and study ID numbers will be linked in a password-protected computer file that will be kept on a computer which can only be accessed by senior project staff. This link between the participant and the research study will be destroyed 6 months after study analyses are completed. Study records will be kept within limited access, password-protected computer files, available only to the investigators and study personnel. Publication or presentation of study results will not identify participants by name or any other identifier. The investigators have extensive experience in the performance of similar studies in people with TB.

Directly identifying information including name, date of birth, residential address information (zip code) will be used to match with the California TB Registry at CDPH. CDPH TB Registry staff routinely match using personal identifiers and have extensive training and experience with handling datasets securely. Any matching records in the TB registry will be shared with study staff by study ID only. Match results with identifiers will be kept securely by TB Registry staff until instructed by study staff to destroy the data.

Study data will be entered, cleaned and archived in a password-secured online REDCap database, hosted on the Emory University server. REDCap is a HIPAA compliant online database service provided at no cost for use by Emory staff, faculty and external collaborators. Electronic copies of source documents and other data, from which names, MRNs, and dates of birth have been removed, may be stored on secure, confidential servers at CDPH sites and within Emory REDCap and SharePoint folders accessible only to authorized study investigators and staff. These servers comply with current safety and security protocols to ensure privacy and security of stored data (e.g., limited access, password protections, access roles, audit trails, data encryption, secure storage, and back-up/recovery).

Location and other identifying information will only be used for eligibility confirmation and for retention purposes and will only be accessible by the local study team. The study records and database will be accessible only to the investigators and study personnel. The Emory study team will only have access to data and specimens that are coded using the assigned study ID and contain no directly identifying information. Only the local site investigator and CDPH study team members will have access to the participant's directly identifying information.

DESTRUCTION METHODS

Describe how you will ensure the PID in paper form is disposed of through confidential means, such as cross cut shredding or pulverizing.

After all study analyses are completed, the PID in paper form will be destroyed in compliance with CDPH and Emory guidelines by the cross-cut shredding applicable document(s).

FAXING

Describe how you will ensure that faxes with PID are not left unattended and fax machines are in secure areas.

Not applicable - no faxes will be used in this study.

MAILING

Indicate whether mailings of PID are sealed and secured from inappropriate viewing; and whether mailings of 500 or more individually identifiable records of PID in a single package, and all mailings of PID to vendors/contractors/co-researchers, are sent using a tracked mailing method, which includes verification of delivery and receipt, such as UPS, U.S. Express Mail, or Federal Express, or by bonded courier.

Not applicable - no mailings of PID will be utilized in this study.

ELECTRONIC STORAGE

State whether PID in paper or electronic form, e.g., stored on laptop computers and portable electronic storage media (e.g., USB drives and CDs), will ever be left unattended in cars or other unsecured locations.

Personally identifiable data (PID), whether in paper or electronic form, will not be left unattended in cars or other unsecured locations. All physical records containing PID will be stored in locked cabinets within secured access-controlled offices when not actively in use. Electronic files containing PID will be stored only on password-protected, encrypted institutional computers or secure institutional servers approved for research data storage.

Portable electronic storage media (e.g., USB drives, CDs, external drives) containing PID will not be routinely used. If temporary transfer is necessary, only encrypted storage devices approved by the institution will be used. Laptop computers used for study activities will be password protected, encrypted, and maintained under the direct control of authorized study personnel at all times. PID will not be stored on personal devices or left unattended in unsecured environments.

Study data will be entered, cleaned and archived in a password-secured online REDCap database, hosted on the Emory University server. REDCap is a HIPAA compliant online database service provided at no cost for use by Emory staff, faculty and external collaborators. Only staff working on this study will have access to the study REDCap database, for which they will need a username and password which must be updated annually. Electronic copies of source documents and other data, from which names, MRNs, and dates of birth have been removed, may be stored on secure, confidential servers at CDPH sites and within Emory REDCap and SharePoint folders accessible only to authorized study investigators and staff. These servers comply with current safety and security protocols to ensure privacy and security of stored data (e.g., limited access, password protections, access roles, audit trails, data encryption, secure storage, and back-up/recovery).

Location and other identifying information will only be used for eligibility confirmation and for retention purposes and will only be accessible by the local study team. The study records and database will be accessible only to the investigators and study personnel. The Emory study team will only have access to data and specimens that are coded using the assigned study ID and contain no directly identifying information. Only the local site investigator and CDPH study team members will have access to the participant’s directly identifying information.

California TB Registry will receive and maintain a list of study participant names for the purpose of matching with the TB Registry. TB Registry data is kept on secure CDPH servers. No physical records will be kept by the TB Registry.

Study investigators at Emory and CDPH will be responsible for storage of study data for at least 10 years after completion of the study, and for overseeing sharing of data and specimens outside of the research team, in line with U.S. regulations and guidelines. Electronic study data will be stored indefinitely in the Emory REDCap database. Deidentified data will be shared outside the study team only from those participants who consent to future use.

PHYSICAL STORAGE

Describe whether facilities, which store PID in paper or electronic form, have controlled access procedures, and 24 hour guard or monitored alarm service.

Any paper or physical records or samples will be protected by storage in locked filing cabinets at each study site. Any records containing personal information will not be left unattended unless locked in a file cabinet, or otherwise physically secured with a lock. Physical records will be kept to a minimum with most study materials being in electronic form and not containing identifiable information.

Study investigators at Emory and CDPH will be responsible for storage of study data for at least 10 years after completion of the study, and for overseeing sharing of data and specimens outside of the research team, in line with U.S. regulations and guidelines. Electronic study data will be stored indefinitely in the Emory REDCap database. Deidentified data will be shared outside the study team only from those participants who consent to future use.

SERVER SECURITY

Provide a description of whether all servers containing unencrypted PID are housed in a secure room with controlled access procedures.

Study records will be kept in locked files and/or within limited access, password-protected computer files, available only to the investigators and study personnel. Electronic copies of source documents and other data, from which names, MRNs, and dates of birth have been removed, may be stored on secure, confidential servers at CDPH sites and within Emory REDCap and SharePoint folders accessible only to authorized study investigators and staff. These servers comply with current safety and security protocols to ensure privacy and security of stored data (e.g., limited access, password protections, access roles, audit trails, data encryption, secure storage, and back-up/recovery).

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Only the written informed consent forms will have directly identifiable information in them, and these forms will be stored separately from documents that include study identification number. The informed consent documents will not be uploaded to REDCap or SharePoint but will remain as electronic copies at the study site.

Participants' names and study ID numbers will be linked in a password protected computer file that will be kept on a computer which can only be accessed by senior project staff. This link between the participant and the research study will be destroyed 6 months after study analyses are completed. Study records will be kept in locked files and/or within limited access, password-protected computer files, available only to the investigators and study personnel. Publication or presentation of study results will not identify participants by name or other directly identifying information.

A list of study participants will be matched to the California TB Registry to determine whether participants were reported with active TB disease following their study visit. Matching will be performed by TB Registry Staff and only information from matched records will be returned to study staff using study ID. Limited information related to timing, TB risks, and clinical findings at the time of diagnosis will be returned.

DISK STORAGE

State whether all disks with PID will be destroyed.

Each study participant's research data and specimens will be labeled only with a unique study identification number and contain no other individual identification. Study investigators at Emory and CDPH will be responsible for storage of study data for at least 10 years after completion of the study, and for overseeing sharing of data and specimens outside of the research team, in line with U.S. regulations and guidelines. Electronic study data will be stored indefinitely in the Emory REDCap database. Deidentified data will be shared outside the study team only from those participants who consent to future use.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

State whether all computer access will be protected through the use of encryption, passwords, and other protections.

Study records will be kept within limited access, password-protected computer files, available only to the investigators and study personnel. Emory REDCap and SharePoint are accessible only through usernames and passwords, and data is encrypted in these HIPAA-compliant systems.

FIPS 140-2 COMPLIANCE: WORKSTATIONS

Indicate whether all workstations that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

Yes, all workstations and study computers containing PID will have full disc encryption that uses FIPS 140-2 compliant software.

FIPS 140-2 COMPLIANCE: LAPTOPS

Indicate if all laptops that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

Yes, all workstations and study computers containing PID will have full disc encryption that uses FIPS 140-2 compliant software.

FIPS 140-2 COMPLIANCE: REMOVABLE MEDIA DEVICES

Indicate if PID on removable media devices (e.g. USB thumb drives, CD/DVD, smartphones, backup recordings) are encrypted with software that is FIPS 140-2 compliant.

Yes, all removable devices containing PID will be encrypted with software that is FIPS 140-2 compliant software.

SECURITY PATCHES

Indicate if all workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame.

All workstations, laptops and other systems that process and/or store PID will have security software installed that is updated on a regular basis.

PASSWORD CONTROLS

Indicate if sufficiently strong password controls are in place to protect PID stored on workstations, laptops, servers, and removable media.

All study laptops and workstations must have strong passwords to be able to open and use them. Emory systems (such as SharePoint and REDCap) require the creation of passwords that meet stringent criteria and must be updated every 12 months. Criteria include:
-Must be at least 9 characters long and no more than 30 characters long
-Must include at least 2 letters.
-Must not repeat any character sequentially more than 2 times.
-Must include at least 2 non-alphabetic characters (spaces, numerals, punctuation, and/or special characters).
-Must not include part of your name or NetID (username).
-Must not include a common word or commonly used sequence of characters.
-Can be changed no more often than once every 1 day.
-New password may not have been used previously.

ELECTRONIC SECURITY CONTROLS

Indicate if sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews.

Study data will be entered, cleaned and archived in a password-secured online REDCap database, hosted on the Emory University server. REDCap is a HIPAA compliant online database service provided at no cost for use by Emory staff, faculty and external collaborators. Electronic copies of source documents and other data, from which names, MRNs, and dates of birth have been removed, may be stored on secure, confidential servers at CDPH sites and within Emory REDCap and SharePoint folders accessible only to authorized study investigators and staff. These servers comply with current safety and security protocols to ensure privacy and security of stored data (e.g., limited access, password protections, access roles, audit trails, data encryption, secure storage, and back-up/recovery).

FIPS 140-2 COMPLIANCE: ELECTRONIC TRANSMISSION

Explain whether all transmissions of electronic PID outside the secure internal network (e.g., emails, website access, and file transfer) are encrypted using software which is compliant with FIPS 140-2.

No PID will be transmitted electronically outside the secure internal network. PID will not be shared with Emory study personnel.

INTERNET ACCESSIBILITY

Note if PID in an electronic form will be accessible to the internet.

PID will be accessible only through abstraction of the data from the CDPH surveillance database. PID will not be transmitted through the internet as part of this study.

DISPOSING OF PID

When disposing of electronic PID, indicate whether sufficiently secure wiping, degaussing, or physical destruction will be used.

Participants' names and study ID numbers will be linked in a password-protected computer file that will be kept on a computer which can only be accessed by senior project staff. This link between the participant and the research study will be destroyed 6 months after study analyses are completed.

Conflict of Interest Information

CONFLICT OF INTEREST (COI) INSTRUCTIONS

A COI is defined as any financial or other relationships of the researcher(s) or the institution that could be perceived as affecting the objective conduct of the research, including the interpretation and publication of the findings. Researchers must disclose any COI, including perceived COI.

Financial relationships to be disclosed include but are not limited to the following:

- **Present or anticipated ownership of stock, stock options, or other financial obligations of the source of funding.**
- **Receipt or expectation of payment of any sort in connection with papers, symposia, consulting, editing, etc. from the source of funding.**
- **The sale or licensing or anticipated sale or licensing of medical or other products or intellectual property, such as patents, copyrights, or trade secrets to the source of funding or other entities.**
- **Any past, present or anticipated receipt of money or other valuable consideration from the source of research funding by the researcher(s), the family of the researcher(s), the research institution, or by an institution in which the researcher(s) or the family of the researcher(s) has an interest as owner, creditor, or officer.**

DISCLOSURES

Does any member of the study team, members' spouses, or members' dependent children have any significant financial interests related to the work to be conducted as part of the above-referenced project?

No

Informed Consent Procedures

INFORMED CONSENT PROCEDURES

Provide a description of procedures to be used in obtaining and documenting informed consent from participants.

See instructions and examples on CPHS website.

At the time of recruitment, research staff at each site will inform potential participants in-person of the purpose of the study; how long the consent and baseline visit will take; their choice to participate; that their care will not be affected by a choice not to participate; and that there will be no cost, compensation, or benefit to them from the screening. Individuals expressing interest in the study who may meet the inclusion criteria will be asked to complete the consent discussion.

A written informed consent to participate will be obtained from all study participants at the time of enrollment and prior to the administration of any study measures. At the time of the consent discussion, the study team member will sit with the potential participant in a private area, read the consent form to them and provide opportunities for questions to be asked and answered (this may take around 30 minutes). The participant may provide consent on this day, or be provided the opportunity to take the form with them and return at a later time to complete consent. After consent is completed and the form is signed by both the study team member and the participant, the participant will complete study procedures.

The informed consent forms will be provided in the primary languages used at each of the study sites, including Spanish, Vietnamese; the translation will be conducted by a certified translation company. The form will also be read aloud in the participant’s preferred language by the research assistant or a language translation service representation via phone or Zoom (if nobody at the site speaks the language), as many participants may be illiterate or vision impaired. Literacy will be verified by demonstration of reading and writing ability. For illiterate or vision-impaired participants, we will ask the participant to bring in an impartial witness (not affiliated with the study) who is literate. Following this, the participants will be asked if they are willing to participate in the study, and if so, will be asked to sign or make their mark on the informed consent form. A copy of the informed consent document will be offered to the participant so they may keep it and refer to it in the future.

CONSENT FORMS

Attach copies of consent forms and any other documents or oral scripts used to inform potential research subjects about the study. See examples of consent and assent forms on the CPHS website.

Be sure to include a concise explanation of key information for participants at the beginning of your consent form, as shown in the examples on the website. Also attach the Participant's Bill of Rights (download the revised version from the same CPHS website). CPHS may approve the use of a consent procedure which does not include, or which alters, some or all of the elements of informed consent. If a waiver or alteration of informed consent is being requested, attach a document that explains how all of the criteria below will be satisfied.

INSPIRE Adult Consent Form Short v1_CDPH IRB_APR02_2026_cleaned.docx	Consent Form

Deleted Attachments: 1 (Most Recent: INSPIRE Consent Form v2.1 28Jan26.docx on 04/20/2026 3:07 PM ET)

HIPAA Determination

HIPAA INSTRUCTIONS

To determine if this project is covered by HIPAA, answer the following questions.

COVERED ENTITY

Will health information be obtained from a covered entity, known as a clearinghouse, such as Blue Cross, that processes or facilitates processing health data from another entity, including but not limited to state databases?

No

HEALTHCARE PROVISIONS

Will the study involve the provision of healthcare by a covered entity, such as the UCD Medical Center?

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

Yes

HIPAA WAIVER

Are you requesting a waiver or alteration of HIPAA authorization?

Please check with CDPH to see if the data that they release to you is covered under HIPAA. IF not, please change your response in this section to "No."

05/01/2026 • Sussan Atifeh • *Not* Internal • Resolved

If you have already received a waiver/alteration from another IRB choose 'waiver/alteration approved by another IRB'. You do not need to apply for a waiver or alteration as the HIPAA waiver or alteration of authorization is only required from one IRB.

No

HIPAA AUTHORIZATION FORM

Upload a copy of the HIPAA Authorization form(s) or the documentation of the approval of a waiver/alteration from another IRB.

(Placeholder) Infectiousness and Social Contact Patterns Study Protocol_combined_waiver_consent_hipaa_elements_20JUN25.docx	HIPAA Documents

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

INSPIRE CDPH IRB Application Budget.xlsx Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

INSPIRE_Emory_Coverletter_CDPH_IRB_03262026_draft_V2_clean_signed.docx Cover Letter

In order for the PI to review and sign this form, you will need to click "Next" and on the next page, click "Submit." At that point the PI will receive notification that will need to review the application and if they request changes, they will return the form to you and you will receive an email notification.

Calculated Field for agency plus data set *(Internal)*

California Department of Public Health: California TB Registry

PI Signature for Coordinator Submission (Initial) - Submitted 05/21/2026 1:41 PM ET by Sarita Shah, MD, MPH

PI Review

Please click "Next" and "Submit" in order to submit this application, regardless of whether or not it is ready for review. If you indicated it is ready for review, it will go to the Responsible Official for review and signature, and if not, it will be returned to the individual who completed the form for changes.

Is this application ready to be reviewed by the IRB? If not, choose no to have the application sent back to the coordinator for revisions.

Yes

To sign this form, enter your IRBManager password. By signing this form, you are indicating that the information within this application is accurate and reflects the proposed research and that you attest to the conflict of interest disclosures for all study team members.

Signed Thursday, May 21, 2026 1:41:31 PM ET by Sarita Shah, MD, MPH

Responsible Official Signature
- Submitted 05/01/2026 3:08 PM ET by Nicholas Zadrozna

Responsible Official Signature

After reviewing this application, is it ready for submission to the CPHS IRB?

Yes, ready for submission to IRB.

Enter your password to sign this protocol. By signing this protocol, you are attesting that the information within is accurate and reflects the details of the proposed research project.

Signed Friday, May 1, 2026 3:07:48 PM ET by Timothy Lash, PhD

After choosing whether or not the submission is ready for CPHS IRB review, please click "next" and "submit" (on the next screen) to move the form forward to the CPHS IRB or back to the Researcher.

Notify IRB for Pre-Screening
- Submitted 05/21/2026 2:41 PM ET by Sussan Atifeh

Internal IRB Screening

CPHS Office: The questions on this page will appear every time the project is resubmitted to the CPHS IRB (even after review). Once the project has been reviewed by a committee member, unless researcher has changed questions on the form that impact the level of review, you do not need to update the questions here. If the changes made are not clear and require additional clarification change the 'ready for review' to 'no' and require changes. When you change the answer back to yes, it will remember your previous answers.

Is this study ready to be reviewed by the CPHS panel?

Yes

Choose the IRB committee to review this study (this defaults to CPHS)

CPHS

Level of Review Determination (once the level of review is assigned for this project, do not change this answer unless the reviewer/committee has decided that the study requires a different level of review)

Full Board Minimal Risk

Please provide a rationale for your level of review preliminary determination
The Chairs clarified that this project should be discussed in the June 5th full board meeting.

Choose the CPHS Chair
Catherine Hess, PhD

Select the vice chair of the committee
Larry Dickey, MD, MPH, MSW

Assign to Cycle

June

Assign to cycle year
2026

Load into IRBManager (Initial Submission)
- Submitted 05/21/2026 2:42 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 05/21/2026 2:44 PM ET by Sussan Atifeh

Full Board Set Up

Project number

2026-074

The office will complete the questions on this page and submit the form after the teleconference with the chairs regarding this project is completed.

Confirmation of level of review

Full Board Minimal Risk

Provide the rationale for the level of review determination
The Chairs clarified that this project should be discussed in the June 5th full board meeting.

Assign SME to study

John Schaeuble, PhD, MS

Enter the meeting date for this project

06/05/2026

SME Review

SME review

After reviewing the application, complete the question(s) below. If you wish to make comments on the application for the researcher, use the 'add note' feature on each question (be certain to unmark the internal only box and do not mark changes required). To navigate the application, you can either use the 'previous' button at the bottom of the page or from the drop down at the top of this page choose 'view previous stages'. Once you have completed the questions that appear on this page (different questions will appear depending on your answer to the first question), you will need to click 'next' (from either the top of the bottom of the screen) and then click 'submit'.

If you are requiring revisions before the full committee review, the form will be returned to the researcher for revisions and returned to you upon re-submission.

Does the researcher need to provide additional information/revisions before the committee meeting? If there is insufficient time for the researcher to make changes prior to the committee meeting, choose 'no' in order to route the form correctly.

No answer provided.

In order to either return this application to the researcher or to move forward for the full meeting review, click 'next' and 'submit' on the next screen.