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 09/05/2025 1:42 PM ET by Elon Ullman, M.S. Industrial Hygiene

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

October 2025 cycle

09/05/2025 • Nicholas Zadrozna • Internal

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.

Elon Ullman, M.S. Industrial Hygiene

Email: elon.ullman@cdph.ca.gov **Business:** (510) 684-1142

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

California Department of Public Health

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

Richmond

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

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

California

Attach a copy of the PI's Curriculum Vitae.

Elon Ullman CV 2025.pdf PI Curriculum Vitae

CO-PRINCIPAL INVESTIGATOR (CO-PI)

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

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.

No answer provided.

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.

Elon Ullman, M.S. Industrial Hygiene

Email: elon.ullman@cdph.ca.gov **Business:** (510) 684-1142

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.*

Kristin Cummings, MD, MPH

Email: Kristin.Cummings@cdph.ca.gov **Business:** (510) 393-2643

OTHER RESEARCH STAFF

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

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.

Kyle Peerless, MPH

Email: kyle.peerless@cdph.ca.gov **Business:** (831) 333-6556

Constancia Dominguez-Voong, Bachelor of Science (BS), Master of Science (MS)

Email: constancia.dominguez-voong@cdph.a.gov **Business:** (279) 667-2160

Constancia Dominguez-Voong, Bachelor of Science (BS), Master of Science (MS)

Email: constancia.dominguez-voong@cdph.a.gov **Business:** (279) 667-2160

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

False

Project Information

SUBMITTER

Application completed by:

Elon Ullman, M.S. Industrial Hygiene
Email: elon.ullman@cdph.ca.gov **Business:** (510) 684-1142

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).

Comparing The Effectiveness of N95, KN95, and KF94 Respirators

PROJECT SITE

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

California Department of Public Health

STUDY PROCEDURES

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

Recruitment-Participant

TYPE OF RESEARCH REQUEST

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

*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)*

Common rule/Human subjects

PROJECT TYPE DETAILS

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

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

Minimal Risk
Consent form

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.

Not applicable

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
State funded

Enter name of state-funded source.
Emerging Workplace Hazards Unit, Occupational Health Branch, California Department of Public 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.

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

10/15/2025

ANTICIPATED PROJECT END DATE

10/14/2026

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.

Background

During the COVID-19 pandemic, the use of masks and respirators as personal protective equipment was recommended to the public by leading public health agencies in the United States. After it was recognized that the SARS-COV-2 virus is airborne, the messaging changed to promote the use of tight-fitting respirators over loose-fitting cloth and surgical masks.

Although loose-fitting masks are no longer being recommended as respiratory protection, international respirators such as KN95 and KF94 continue to be recommended alongside CDC-certified N95 respirators by leading public health agencies. This messaging continues despite several studies showing that international respirators provide significantly less protection than N95s. More research is needed on the effectiveness of N95 vs. international respirators to inform public health messaging on how the public can best protect themselves from airborne hazards such as respiratory diseases and wildfire smoke.

Study

The major research question to be addressed is:

1. How much protection do individuals get from N95 vs international respirators.

This study will add to the scientific literature by comparing the effectiveness of N95, KN95, and KF94 respirators. Effectiveness will be evaluated using quantitative fit testing equipment (TSI PortaCount) that measures the level of particles inside vs outside a respirator when worn by study participants. Participation will be open to the public. Fit testing will take place at the CDPH Richmond campus and other locations such as UC Berkeley and UCSF.

The expected end product is a peer-reviewed research paper.

MAJOR RESEARCH QUESTION

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

What is the difference of protection that individuals achieve from N95 respirators with head straps vs. international respirators such as KN95 and KF94s with ear loops.

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

Methods

Forty individuals (Twenty male and twenty female) will be recruited to participate in this study. Individuals expressing interest in the study will be pre-screened via telephone. During the pre-screening process, the researcher will go over:

- The purpose of the study
- The fit testing procedure
- Inclusion criteria
- Exclusion Criteria
- Compensation

Inclusion criteria for participants:

- Being 18 years of age or older
- Ability to be clean shaven (face only)
- English Speaking

Exclusion criteria for participants includes history of:

- Claustrophobia
- Cardiovascular Disease
- Chronic Respiratory Disease
- Uncontrolled hypertension
- Diabetes

All persons who choose to participate will sign a written consent form and be given a participant ID number.
Participants will receive quantitative fit testing (TSI PortaCount Respirator Fit Tester 8048 with FitPro Plus software) on 5 different respirators using an OSHA-approved modified fit testing procedure. The respirators will be 2 N95s (Trifold shaped 3M 9205, cup shaped 3M 1860), 2 KN95 models (Powecom, one earloop model and headstrap model) and 1 KF94 model (BOTN). The 3M 1860 comes in two sizes (small and regular). The BOTN KF94 comes in three sizes (small, medium and large).

Before each test, the participant will be instructed on how to put on the respirator properly by the tester. For the 3M 1860 and the BOTN, the participants will try on the different sizes and choose the one that fits them best without causing discomfort or obvious gaps. The rationale for the participant choosing their own size is to reflect real world conditions of buying a respirator for themselves without professional help.

After putting on each model, the participant will wait five minutes to assess the comfort level. The comfort level of the respirator will be recorded by the tester on a scale of 1-10. 1 being that they find it to be unbearably uncomfortable, and 10 being that they could wear it all day with no discomfort. Any rating from 1-3 will result in a termination of the test to avoid participant discomfort.

The modified fit test will include four test exercises (bending over, talking, head side to side, head up and down). The modified procedure is less time intensive compared to the full fit testing procedure which includes eight exercises, and is currently approved by OSHA after validation testing.

During each fit test, a nontoxic salt (NaCl) aerosol will be generated in the room (TSI Particle Generator 8026). At the end of each fit test, a fit factor will be automatically calculated using the FitPro Plus software. The fit factor is calculated as the ratio of salt particles (number of particles per cubic centimeter) inside vs outside the respirator. This shows the effectiveness of each respirator model by calculating the relative reduction of aerosol that each respirator model provides. For example, a fit factor of 100 means the individual is breathing in 100 times less aerosol than if they were not wearing a respirator.

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.
No answer provided.

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

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.

Participation in the study will be open to the public.

Number of participants will be forty, twenty male and twenty female. Participants will be English-speaking adults (age 18 and over); all ethnic and racial groups are eligible.

RATIONALE

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

Adults from the public are being studied as respirators are made specifically for adults, and no child size respirators are being used. An equal number of females and males are being studied as previous studies have found that respirators fit male faces better than female faces. An equal number of females and males is important to ensure the results are not being skewed by an uneven ratio of sexes. 40 participants are being requested based on the output of power statistics that were calculated to significantly reduce the chance of a type II error.

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.

Individuals will be identified for recruitment using flyers on the CDPH Richmond campus, flyers on college campuses, and emails sent to both CDPH and Public Health listservs by the PI. The contact information for individuals interested in the study will be the PI's email address.

Attach copies of all recruitment materials.

Recruitment email N95 vs international respirator study_Final.docx	Recruitment Materials
Study Flyer IRB.pdf.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.
Exclusion criteria for participants includes history of:

- Claustrophobia
- Cardiovascular Disease
- Chronic Respiratory Disease
- Uncontrolled hypertension
- Diabetes

Inclusion criteria for participants:

- Being 18 years of age or older
- Ability to be clean shaven (face only)
- English Speaking

No records will be kept of information collected about the individual if they do not enter 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.
All participants will receive a $30 cash gift card after completion of the study. Payment will not be prorated.

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 study involving a single block of dedicated time to fit testing.

1. Informed consent: 5 minutes
2. Training to put on respirator: 5 minutes
3. Assessing comfort: 5 minutes for 5 models, 25 minutes total
4. Fit test: 4 minutes for 5 models, 20 minutes total

Total approximate time commitment is 1 hour.

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.

Respirators should not be worn by individuals with certain respiratory and cardiovascular medical conditions. These conditions are cardiovascular disease, chronic respiratory disease, uncontrolled hypertension and diabetes. All individuals will be pre-screened and those with any of these conditions will be excluded from the study.

Respirators can cause discomfort or claustrophobia in some wearers. This is minimal risk. The highest risk is discomfort if the model is too tight, in which case the trial for that model will be terminated without fit testing.

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.

No services provided.

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.

A user seal check is the only less risky method to assess respirator fit. This involves an individual putting on a respirator, and then breathing in and out to subjectively check if there are any noticeable gaps between the respirator and the face. However, user seal checks are not reliable enough to assess respiratory effectiveness nor do they give a quantitative estimate of effectiveness.

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.

Anticipated benefits for the subjects are increased education on respiratory protection. This includes how to put them on effectively and potentially finding a model that fits them well.

The main benefit to society is adding to the literature on the comparison of effectiveness between different types of respirators. This is crucial for the development of educational material for the public to decide what type of respirator or mask to wear for different scenarios. For example, the California Department of Public Health has relied heavily on peer-reviewed research when developing and updating our masking page:

https://go.cdph.ca.gov/masking

JUSTIFICATION OF RISKS

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

The risks are minimal, and quantitative fit testing is standard procedure and commonly used across workplaces worldwide where respirators are worn. Potential benefits are increasing to the publicly available knowledge on effectiveness of different types of respirators to inform public health recommendations on respiratory protection for public health emergencies. This includes proper protection from wildfire smoke, viruses, and other airborne hazards where respiratory protection is needed.

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
Telephone numbers
Email address

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.

All researchers involved in the study will be trained in proper procedures for storing the consent forms and subject name/subject ID sheet. For the subject ID master sheet, the subject will be given an ID number before each trial starts. Subject name, and ID will always be written on the subject ID master sheet outside of the room where trials are taking place and immediately stored in a locked cabinet. All consent forms will be immediately taken to the locked cabinet at the end of each trial.

The last four digits of the gift card will also be written on the master sheet to indicate who got the card and ensure no duplicates were given out. Telephone numbers and email addresses will be collected as contact information during recruitment process. Staff will be instructed to not copy contact information outside of the initial recruitment email.

Staff will sign a confidentiality statement related to general use, security, and privacy.

STAFF VETTING PROCEDURES

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

All staff with access to PID will be researchers doing the fit testing trials. All will be either CDPH employees or a CDPH intern from UC Berkeley. All staff will be trained in what information is PID (name, email, telephone number) and proper procedures for PID privacy and security.

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.

CDPH Letter of Support_KC.docx 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.

No data will be reused or provided to any unauthorized person or entity. All data will be stored on a secure SharePoint site and only accessible to research team members from CDPH conducting data analyses. Data on SharePoint is stored on Microsoft’s cloud storage. SharePoint will only be accessible to CDPH staff logging in through an authentication protocol established by the CDPH Information Technology Services Division and reviewed and approved by the CDPH Information Security Office.

CONFIDENTIALITY OF PUBLISHED DATA

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

No information will be published that could be used to identify an individual subject.

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?

No data is being requested.

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.

Access to data is limited only to those involved in data collection (fit testing).

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.

Analyses of subgroups with small numbers will be reported in such a way that individuals cannot be identified, following the CHHS Data De-identification Guidelines.

LINKAGES

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

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

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*

CDPH_CPHS_Data_Privacy_Letter2025_Signed.pdf 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.
No data will have personal identifiers. All participants will be given a participant ID number.

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.

All PID in paper form will be disposed of through cross cut shredding.

FAXING

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

No PID will be faxed.

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.

No PID will be mailed.

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.

No PID in paper or electronic form will ever be left unattended in cars or other unsecured locations.

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.

All PID in paper form (name) will be held in a locked cabinet on CDPH Richmond campus which has controlled access procedures and a 24 hour guard. All PID in electronic form (name, email and phone number) will be on CDPH laptops (emails in Outlook used for recruitment). Per state of California policy, all user computers are fully encrypted. CDPH also has eliminated passwords for nearly all staff and adhere to FIDO standards for authentication and access to CDPH systems and data. CDPH has a zero-trust security framework, which encompasses addition protections at various levels of use.

SERVER SECURITY

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

All servers containing PID are housed in a secure room within a locked, controlled access building on secure campus. Data at rest or in transmission is encrypted per FIPS 140-2 standards.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

All names will be kept on a master Subject Name/Subject ID master physical sheet of paper. All analysis data will be digital. Only the Subject ID and no identifiers will be attached to the analysis data.

DISK STORAGE

State whether all disks with PID will be destroyed.

Data with PID will not be stored on disks or any removable media.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

Per state of California policy, all user computers are fully encrypted. CDPH also has eliminated passwords for nearly all staff and adhere to FIDO standards for authentication and access to CDPH systems and data. CDPH has a zero-trust security framework, which encompasses addition protections at various levels of use.

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.

All CDPH's user computers have FIPS 140-2 compliant, full-disc encryption.

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.

All CDPH's user computers have FIPS 140-2 compliant, full-disc encryption.

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.

CDPH only allows the use of thumb drives that are FIPS 140-2 compliant. We have phased out CD/DVD use. State smartphones, and employee smartphones accessing CDPH systems, are managed with mobile device management (MDM) software that enforces encryption and containerizes CDPH content/data. PID in this study will not be stored on any removable media devices.

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.

CDPH utilizes an enterprise patching system that automatically updates user computers on a set cycle, or as needed, and does the same for servers and infrastructure systems. Staff are blocked from downloading and installing executables and software is available through the CDPH Software Center, which has vetted and approved software that can be updated to all staff as needed.

PASSWORD CONTROLS

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

CDPH has eliminated passwords for nearly all staff and adhere to FIDO standards for authentication and access to CDPH systems and data. CDPH has a zero-trust security framework, which encompasses addition protections at various levels of use.

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.

Yes, CDPH has these controls in place, and they are implemented and monitored by our Security Operations Center (SOC) team. The systems are installed through specific, automated, task sequences when computers are "built" to CDPH standards.

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.

Yes, encryption is used for all data transfers by default. CDPH also has a secure feature for sending email. These systems meet FIPS 140-2 requirements.

INTERNET ACCESSIBILITY

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

Name, email address and phone number will be stored on a Outlook and only shared with research team members from CDPH conducting data analyses. Data on Outlook is stored on Microsoft's cloud storage. All email communication will only be accessible to CDPH staff logging in through an authentication protocol established by the CDPH Information Technology Services Division and reviewed and approved by the CDPH Information Security Office.

DISPOSING OF PID

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

Since CDPH user systems are encrypted to FIPS standards, the deletion of encryption keys and a drive wipe are sufficient for data destruction.

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.

All participants will be given the attached consent form. The beginning of the consent form will be verbally explained to the participant, including:

1. the fact that consent is being sought for research and that participation is voluntary.
2. the purpose and procedures of the research and how much time altogether this will require from the participant.
3. reasonably foreseeable risks or discomforts to the participant.
4. reasonably expected benefits for the participant or others; and
5. alternative procedures or treatments, if any, that might be advantageous to the participant.

Prospective participants will be given the opportunity to have all questions answered by study personnel. Each person who chooses to participate will read and sign the informed consent document.

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.

Consent Form.docx Consent Form

Deleted Attachments: 3 (Most Recent: Consent Form.docx on 09/05/2025 1:39 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?

No

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

N95 vs Int Resp Budget.xlsx Project Budget

Deleted Attachments: 1 (Most Recent: Budget.xlsx on 09/04/2025 1:08 PM ET)

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

Cover Letter.docx Cover Letter

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 Friday, September 5, 2025 1:42:45 PM ET by Elon Ullman, M.S. Industrial Hygiene

In order to submit this form, click "Next" and "Submit." At that time, the application will be routed to the Responsible Official (if this is the first submission) for review and signature.

Responsible Official Signature
- Submitted 09/05/2025 2:05 PM ET by Kristin Cummings, MD, MPH

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, September 5, 2025 2:05:08 PM ET by Kristin Cummings, MD, MPH

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

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?

No answer provided.