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 07/27/2026 9:13 PM ET by Kristin Cummings, MD, MPH

Amendment Header

Amendment Submitter

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

Instructions for amending your approved application:

This is a copy of the project application in order to amend the project. You must answer all the amendment questions. After you've answered those questions, you will have to update all answers on the form that related to your proposed changes. You may leave other questions with their original answer. If you do not update the appropriate responses on the form related to your proposed amendment, you will be required to make additional changes.

Note that the contacts listed on this page are output only questions that cannot be changed. If you need to request personnel changes, you will be prompted later on within this form to enter the new contact information.

PI:

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

Administrative Contacts:

Name	Role

Protocol Number:

2022-084

Protocol Title:

California Artificial Stone and Silicosis (CASS) Enhanced Medical Monitoring Study

Indicate what types of changes you are requesting to this project. Select all that apply

Addition and/or removal of project personnel

Clearly summarize and justify your proposed changes to the protocol in layman's terms for all selections made above

This amendment makes the following changes:

1) removes one investigator (Sandra Garcia) -- Dr. Garcia is no longer involved in the study

2) changes the end date to 8/31/28 -- due to slower than anticipated recruitment rate and an additional year of funding, we need to extend the study end date to complete recruitment, data analysis, and write-up

3) increases the total number of study participants from 100 to 150 -- an additional year of funding allows us to recruit more participants than originally planned

Indicate the Level of Risk involved with the changes proposed.

If level of risk has changed, please update the "Risks" section in the protocol form.

Level of Risk has not changed

PI City Output *(Internal)*

Richmond

PI Location State Output *(Internal)*

California

Personnel Information for Amendment

Please complete the questions below.

If while trying to complete those questions, personnel are not found by their email address, you can add them in the system by completing the 'new contact form'. Click on the 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.

New Contact Form

Existing Personnel

Name	Role
Amy Heinzerling, MD, MPH	Research Team
ANDREA OH, MD	Research Team
Anh Hoang, MD MPH	Research Team
Cyrus Rangan, MD	Responsible Official
Erika Escobedo	Research Team
Fernanda Florez, BA	Research Team
Jane Fazio, MD	Co-Principal Investigator
Karoly Viragh, MD	Research Team
Kristin Cummings, MD, MPH	Principal Investigator
Nader Kamangar, MD	Co-Principal Investigator
Robert Harrison, MD	Co-Principal Investigator
Roxana Hixson, MD	Research Team
Sandra Garcia, PhD	Research Team
Sheiphali Gandhi, MD	Research Team
Sundus Lateef, MD	Research Team

Will you be making any changes to the makeup of research personnel?

Removal of any research personnel

REMOVE CONTACT(S)

Click 'Add Contact' button to enter in the email address of any staff (including co-PI or RO) from the above list that are being removed from the study.

Sandra Garcia, PhD

Email: sangarcia@irle.ucla.edu **Business:** (323) 629-7435

Project Information

SUBMITTER

Application completed by:

Kristin Cummings, MD, MPH

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

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).

California Artificial Stone and Silicosis (CASS) Enhanced Medical Monitoring Study

STUDY PROCEDURES

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

Interviews
Recruitment-Participant
Surveys

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."

Non-English translation required
Consent form
Reliance Agreement with another IRB
Greater than Minimal Risk

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

Link to Authorization Agreement with Another IRB

AuthAgree_Cummings_2022-084_dd.pdf Misc/Other

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.

Economically or Educationally Disadvantaged Persons

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
Federally funded

Enter name of federally-funded source.
National Institute of Occupational Safety and 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

07/01/2022

ANTICIPATED PROJECT END DATE

08/31/2028

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.

Workers who fabricate countertops using engineered stone are at risk of developing accelerated silicosis, a severe, incurable, and potentially fatal lung disease that is completely preventable. The Occupational Health Branch (OHB) of the California Department of Public Health (CDPH) has been instrumental in characterizing this emerging occupational health issue in California, reporting two fatal cases of silicosis in countertop fabrication workers in their 30s and documenting silicosis in 12% of their coworkers, with workplace investigation revealed silica exposures many times the permissible exposure limit.

Under Cal/OSHA's silica standards, employers are required to provide silica-exposed workers with medical surveillance, including a chest radiograph (chest X-ray) and spirometry (a lung function test). However, there is growing evidence that these tests are inadequately sensitive for early detection of silicosis. In two Australian case series, 35-43% of countertop fabrication workers with silicosis detected by chest computed tomography (CT) had normal chest x-rays and the majority had normal spirometry. In an Italian study, abnormalities consistent with silicosis were noted on 42% of chest x-rays and 33% of spirometry tests, compared to 100% of chest CTs and 50% of tests measuring another lung function parameter, diffusing capacity of the lung for carbon monoxide (DLCO). Such findings prompted the Thoracic Society of Australia and New Zealand to recommend the addition of low-dose chest CT (LDCT) and DLCO to screening protocols for countertop fabrication workers.

To date, most cases of silicosis among California's countertop fabrication workers have been identified at a late stage, when the worker has already become disabled or has died from the disease. In contrast, earlier identification of silicosis is an important preventive tool, as it can prompt changes in the workplace to lower silica exposures. Such surveillance-motivated intervention has the potential to limit disease progression in the workers with early silicosis and to prevent disease in current and future co-workers without silicosis.

To our knowledge, early detection of silicosis has not been attempted in California's countertop fabrication industry. In this study, we will offer standard (chest x-ray and spirometry) and enhanced (including LDCT and DLCO) medical surveillance to countertop fabrication shop workers and compare the performance of the two testing strategies.

MAJOR RESEARCH QUESTION

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

The overarching aim of this project is to promote respiratory health among vulnerable workers in California's countertop fabrication industry. This project aims to facilitate medical monitoring of silica-exposed workers in the countertop fabrication industry, including both promotion of currently mandated medical surveillance with chest radiography and spirometry, as well as investigation of the use of potentially more sensitive radiological, functional, and laboratory diagnostic tools. Specifically, the major research question is: Does enhanced medical monitoring of silica-exposed countertop fabrication workers using LDCT, DLCO, lung volume testing, and inflammatory biomarkers better detect silicosis than standard medical surveillance using chest radiography and spirometry? We will investigate the feasibility of enhanced medical monitoring and examine results from standard and enhanced protocols to compare sensitivity for early detection of silicosis.

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

Eligible workers for this study are non-pregnant adults who are currently working in California's countertop fabrication industry, have worked in the industry for at least two years, and live in Los Angeles County. All study testing and any necessary follow-up care will be provided at Olive View-UCLA Medical Center, which is a county hospital operated by the Los Angeles County Department of Health Services. The requirement for Los Angeles County residency ensures that all study participants can receive study testing as well as any necessary follow-up care at Olive View-UCLA Medical Center. If needed, follow-up care will be provided through the county's enhanced Medi-Cal program, which includes coverage for undocumented immigrants. If the subject needs follow up care and has private health insurance, which is highly unlikely given the study population, study investigators will make every effort to ensure patient follow up is available at UCLA or other health care center.

We will recruit participants through one of two main mechanisms. First, we will share information about the study via our study recruitment flyer posted online and distributed in neighborhoods, newspapers, and at Olive View-UCLA Medical Center clinics, as well as through identification of worker representatives including union members and labor rights organizations, who can share information with workers. Second, we may work with employers in the industry to coordinate visits to their workplaces to share information with their employees. While employers may facilitate employee participation by allowing study staff to visit the workplace and share study information with employees, employers will not be involved in employee recruitment, and information gathered during the recruitment and enrollment process will not be shared with employers. All conversations about the study and participation will be conducted in private. The employer may be aware of who is participating (to provide paid time off, for instance), but information about why a particular worker did or did not participate is not shared with the employer or anyone else outside of the study staff. Study staff will emphasize with employees and employers that study participation is voluntary, and choosing to participate or not participate will have no effect on their employment status.

Potential participants will be screened for eligibility by study staff. Female workers of menstrual age (through age 50 years) who are interested in participating will be asked about pregnancy status by study staff; those who are or may be pregnant will be considered ineligible at that time. This precaution will be taken to avoid risks of radiation and lung function testing to the fetus. If an individual is eligible to participate, study staff (principally the study's research assistants, Fernanda Florez and Erika Escobedo, who are bilingual in English and Spanish) will review the consent form with them,

and they will have the opportunity to ask any questions. Potential participants will provide verbal consent before completing the interviewer-administered questionnaire and written informed consent prior to undergoing any study medical tests. Please see attached "Participant Recruitment from Contact to Enrollment" protocol for additional details about the recruitment and informed consent processes.

The study components are: interviewer-administered questionnaire, standard medical surveillance tests (spirometry and chest radiography), and enhanced medical surveillance tests (LDCT, DLCO, lung volume test, and blood biomarkers). Participants will be encouraged to participate in all components of the study. While undergoing all tests offered is not a requirement to participate, the study is not intended solely as a service to employers who are required to provide standard tests to their employees. Thus, workers must be willing to undergo at least one of the enhanced medical surveillance tests, specifically LDCT or DLCO, to be eligible to participate.

The questionnaire addresses respiratory symptoms and diagnoses, current tasks, work history in stone fabrication and in other industries, and history of exposure to other lung hazards including cigarette smoking. The questionnaire includes several voluntary questions about immigration status, which are standard questions taken from the California Health Interview Survey. These questions are highly relevant to the worker population that comprises this industry and will be used descriptively and to document any disparities in exposure and disease by immigration status. The questionnaire will be administered in person or over the phone in English or Spanish. Participants who report a diagnosis of silicosis on the questionnaire will be asked to release relevant medical records to CDPH for review. Release of these records is not required for participation in the other study components. Transmitting records with identifiable information will be done via CDPH secure email, where possible. Alternatively, providers may submit information via secure fax, or via secure, tracked delivery service. All paper records will be stored in a locked file cabinet at CDPH. All electronic data used in this project will be maintained on the password-protected CDPH network in a secure, limited-access folder and on the password-protected Olive View-UCLA Medical Center in a secure, limited-access folder. Only project staff will be granted access to the study folders. Please see attached "Data Security and Data Management Plan," as well as responses to questions below, for additional details about data security.

Participants who had standard medical surveillance testing through their employers in the preceding 12 months will be asked to release the records of that testing to CDPH. Such participants will be offered only the enhanced medical surveillance tests. Otherwise, participants will be offered both the standard and enhanced medical surveillance tests. All imaging and lung function tests will be ordered by Dr. Jane Fazio, who is a research collaborator on this study and a bilingual (English/Spanish) pulmonologist at Olive View-UCLA Medical Center. All testing and clinical interpretations will be conducted at Olive View-UCLA Medical Center. Chest radiography will include classification by a NIOSH-certified B Reader and LDCT will include classification according to the International Classification of HRCT for

Occupational and Environmental Respiratory Diseases (ICOERD). Results of study tests and LDCT images will be released by Olive View-UCLA Medical Center to CDPH, with the participant's written consent. At the time of enrollment, workers unwilling to provide written consent to have employer-provided standard medical surveillance test results, study test results, and/or LDCT images released to CDPH will be considered ineligible to participate. Dr Fazio will share clinical interpretations of test results with participants; any abnormal findings will be discussed with participants, who will be referred for appropriate medical follow-up. Results will be communicated in the participant's preferred language. Because B reading and ICOERD classification are intended for epidemiologic rather than clinical purposes, participants will not receive these results.

Please see attached "Participant Experience from Consent to Study Completion" protocol for additional details about stepwise participation in the study for participants.

Blood will be collected and processed at the Olive View-UCLA Medical Center clinical laboratory. Some processed samples will be analyzed by the Olive View-UCLA Medical Center for tests of autoimmunity, given the evidence in the scientific literature that exposure to engineered stone may lead to autoimmune disease. Results of these blood tests will be released by Olive View-UCLA Medical Center to CDPH, with the participant's written consent, as described above for imaging and lung function test results.

Other processed blood samples will be shipped to the National Institute for Occupational Safety and Health (NIOSH) or UCLA School of Medicine for analysis in a research (not clinical) laboratory. Analyses will characterize global gene expression. These assays have been examined in animal models of silicosis previously. Samples will be marked with unique participant codes known only to study staff. Research laboratory staff will not have access to identifying information or the key linking identifiers to the participant codes. Results of the blood tests will be provided to study staff using the participant codes.

The autoimmunity and global gene expression blood tests are not standard clinical tests for silica-exposed workers and the significance of the results cannot be interpreted for an individual at this time. However, the autoimmunity blood tests will be available in the medical record and may have clinical implications, therefore the results of the autoimmune tests will be provided to individual participants. The results of the global gene expression blood tests will not be provided to individual participants. This information will be included on the consent form.

The data collected in the study will be analyzed for evidence of silicosis among participants. Evidence of silicosis will include: restrictive pattern on spirometry; chest radiograph classification of 1/0 or greater by NIOSH-certified B Reader, low diffusing capacity on DLCO, low lung volumes on lung volume test, or ICOERD classification of LDCT consistent with silicosis. We will compare the proportions of participants identified as having silicosis by each test and by the standard and enhanced testing protocols. We will use the questionnaire responses to examine risk factors for silicosis, including

employment tenure, job title, and tasks, and as well as facility characteristics from Cal/OSHA inspection records, when these are available. In addition, in collaboration with NIOSH researchers, we will examine the levels of the blood biomarkers to determine associations with silicosis as assessed by the other tests. Only non-identifiable data about disease classification with be shared with the NIOSH researchers.

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.

CASS_Data security and data management plan_CLEAN COPY_7_11_23.docx	Other Documents
CASS_Data security and data management plan_TRACK CHANGES_7_11_23.docx	Other Documents
Instructions for using CDPH secure email.docx	Other Documents
Participant Experience from Consent to Study Completion_CLEAN COPY_4_27_23.docx	Other Documents
Participant Experience from Consent to Study Completion_TRACK CHANGES_4_27_23.docx	Other Documents
Participant Recruitment from Contact to Enrollment_CLEAN COPY_4_27_23.docx	Other Documents
Participant Recruitment from Contact to Enrollment_TRACK CHANGES_4_27_23.docx	Other Documents
Participant screening questions_CLEAN COPY_4_27_23.docx	Other Documents
Participant screening questions_TRACK CHANGES_4_27_23.docx	Other Documents
Release of health information.docx	Other Documents
Release of study records.docx	Other Documents
CASS questionnaire_CLEAN COPY_7_11_23.docx	Questionnaires
CASS questionnaire_TRACK CHANGES_7_11_23.docx	Questionnaires

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.

Adult (age 18 years and older), non-pregnant current workers in the countertop fabrication industry with at least two years' tenure in the industry and who live in Los Angeles County, California will be eligible for participation in the study. Based on prior studies of workers in this industry in California and Texas, in addition to CDPH surveillance of workers with silicosis in this industry in California, we anticipate that the majority of participants in the study will be male and Hispanic. In a prior study of workers at a single large employer in California, all workers screened for silicosis were Hispanic men, with a median age of 37. In a Texas study, 76% of workers were male, with a median age of 44; race/ethnicity information was unavailable. We plan to offer study documents and the questionnaire in English and Spanish.
We plan to recruit 150 participants. We expect to have more than adequate power to compare the two testing protocols for detection of silicosis. With a sample size of 16 subjects, we would be able to detect a difference between the two testing protocols if the routine protocol has a sensitivity of 40% and the enhanced protocol has a sensitivity of 90%. With a sample size of 84 subjects, we will be able to detect a difference between the two testing protocols if the routine protocol has a sensitivity of 60% and the enhanced protocol has a sensitivity of 80%. With 150 participants, we therefore expect to have adequate power to compare the two testing protocols for detection of silicosis.

RATIONALE

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

As described above, silicosis is a preventable occupational disease that has been identified among workers who fabricate engineered stone countertops. Early detection of silicosis can allow for better management of future exposures and earlier access to appropriate healthcare. Although employers are required to provide medical monitoring for silicosis to exposed workers, evidence to date indicates that required medical monitoring, which includes chest x-ray and spirometry, may be insufficiently sensitive for timely detection of silicosis. Comparing the sensitivity of routine and enhanced silicosis screening protocols and evaluating the feasibility of enhanced screening in this participant group will help inform future recommendations for appropriate silicosis screening protocols in this worker population.
We chose an age cutoff of 18 years because although silicosis is a chronic lung disease that typically occurs after many years of exposure to silica dust, cases of silicosis in the countertop fabrication industry are notable for young age at diagnosis and relatively short employment tenure. Thus, we want to include younger adults who may be at risk for early-onset disease in this industry.
We are excluding pregnant workers primarily because of the radiation risk to the fetus associated with chest radiography and LDCT. In addition, by reducing the space available for lung inflation, pregnancy can affect spirometric parameters and could falsely suggest smaller than normal lungs (restrictive pattern). Thus, spirometry may be unreliable at detecting silicosis in pregnant workers. Finally, DLCO requires inhalation of a small amount of carbon monoxide, which is generally harmless to the patient being tested but of unknown effect on the fetus. Thus, for pregnant workers, the risks of participating in the study outweigh the benefits.

The requirement for Los Angeles County residency ensures that all study participants can receive study testing as well as any necessary follow-up care at Olive View-UCLA Medical Center. If needed, follow-up care will be provided through the county's enhanced Medi-Cal program, which allows coverage for immigrants without sufficient documentation status.

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 recruit participants through one of two main mechanisms. First, we will share information about the study via our study recruitment flyer posted online and distributed in neighborhoods, newspapers, and the Olive View-UCLA Medical Center clinics, as well as through identification of worker representatives including union members and labor rights organizations, who can share information with workers. Second, we may work with employers in the industry to coordinate visits to their workplaces to share information with their employees. While employers may facilitate employee participation by allowing study staff to visit the workplace and share study information with employees, employers will not be involved in employee recruitment, and information gathered during the recruitment and enrollment process will not be shared with employers. Study staff will emphasize with employees and employers that study participation is voluntary, and choosing to participate or not participate will have no effect on their employment status.

Attach copies of all recruitment materials.

CASS_study flier_word_CLEAN COPY_4_27_23.docx	Recruitment Materials
CASS_study flier_word_TRACK_CHANGES_4_27_23.docx	Recruitment Materials

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.
Individuals eligible to participate will be current workers in engineered stone fabrication occupations who live in Los Angeles County, California. Eligible individuals will be aged 18 years and over, employed for a minimum of two years in the stone fabrication industry, and able to provide informed consent and undergo medical surveillance as part of the study.

Pregnant workers will be excluded due to potential risks of radiation and lung function testing to the fetus, as noted above. Potential participants who are women of childbearing age will be screened for pregnancy prior to study enrollment using a screening method endorsed by the American College of Radiology for studies with ionizing radiation. This screening method has been used previously by the PI in an IRB-approved study of workers that included chest CT. While we expect most study participants to be male, given our knowledge about worker demographics in this industry, we prefer to include women of childbearing age, with appropriate screening for potential pregnancy, as a matter of equity, rather than exclude all women from the study, as women have not been well-represented in clinical studies and occupational research.

Children and prisoners will not be included in the study, as participation will be limited to current workers in engineered stone fabrication occupations.

Please see attached study screening document for additional details about the study screening process.

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.
Subjects will be compensated with a $200 gift card for participating in the study.

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.

The total study duration, from initiation of recruitment, through completion of enrollment and data collection, through analysis of results, is estimated to last around four years. Duration of the study for individual participants will be more limited; total time to complete enrollment and participate in the medical survey, including the interview questionnaire and medical testing, is estimated to take approximately 100 minutes, in addition to travel time to and from medical testing sites and any time waiting for the tests.

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.

Physical Risks:
Spirometry: This test may be tiring, and participants may feel momentary lightheadedness or chest discomfort.
Diffusing Capacity: Participants may feel momentary lightheadedness.
Lung volume test: Participants may develop temporary cough, shortness of breath, or claustrophobia.
Blood tests: This test may result in discomfort, minor bleeding, bruising, and, rarely, fainting.
Low-dose CT: This test exposes participants to ionizing radiation (X-rays). Ionizing radiation can lead to DNA damage and is thus a risk factor for cancer. The risk of cancer is thought to be related to radiation dose. The dose of radiation to each participant in this study is expected to be 1.5 millisieverts (mSv). For comparison, the radiation dose associated with chest X-ray is 0.1 and the average natural background radiation dose is about 3 mSv per year. Thus, the radiation dose of the CT used in this study will be equivalent to that of 15 chest X-rays or 6 months of natural background radiation. The American College of Radiology estimates that the approximate additional risk of fatal cancer for an adult from a low-dose chest CT is about 1 in 10,000 to 1 in 100,000. In comparison, the overall lifetime risk of fatal cancer is 1 in 5. To avoid any radiation risk to an unborn fetus, as well as for the additional reasons outlined under study exclusion criteria, pregnant women will not be enrolled in this study.

It is important to note that the alternative to low-dose CT is conventional chest radiography, which is offered as part of standard medical surveillance for silicosis. Although conventional chest X-ray offers lower radiation dose, it has been shown to be less sensitive than CT scan in artificial stone exposed workers; studies from Australia have found that 35-43% of workers diagnosed with silicosis via chest CT had normal chest x-rays.

Other psychological and medical risks: As with any diagnostic imaging, the low-dose chest CT that participants will undergo as part of this study may identify abnormal findings, including silicosis, as well as other possible incidental findings, such as lung masses. If such incidental findings are identified, they would require additional diagnostic work-up. While such incidental findings and any required work-up may incur additional physical and psychological risk to participants, the benefits of early detection and intervention in any identified abnormalities, including silicosis, would likely outweigh these risks.

Privacy risks: Study staff will follow data privacy and security protocols outlined elsewhere in this application. Results of study tests will not be shared with employers without the participant’s permission; providers will

follow privacy requirements in Cal/OSHA's silica regulations, which dictate that providers may share information about work restrictions with employers, but may not share results of medical assessments without employee permission. In addition, this federally-funded research is protected by a Certificate of Confidentiality, meaning that identifying information cannot be disclosed without the individual's permission, even in the event of a subpoena. Risk to study participants' privacy is therefore expected to be minimal.

The inclusion of chest CT scanning in this study makes the research more than minimal risk. To minimize the radiation risk related to chest CT scanning, we have chosen a low-dose protocol that delivers a radiation dose of 1.5 mSv. For comparison, a standard chest CT has a radiation dose of 7 mSv. The low-dose protocol we will use is comparable to what is routinely used to screen patients for lung cancer in the U.S.

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.

The potential risks associated with most study procedures are minor and unlikely to result in adverse mental or physical effects. If potential work-related or other medical findings are identified on diagnostic imaging, participants will be referred to additional medical care and/or workers' compensation resources as appropriate.

If a participant's study results indicate a potential diagnosis of silicosis, information will be shared with the study participant about silicosis and workers' compensation resources, and referral to Dr. Fazio or another pulmonary specialist at Olive View-UCLA Medical Center will be 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.

Currently mandated silica medical surveillance includes chest x-ray alone, which, as described above, involves a lower dose of radiation than LDCT. However, as outlined above, chest x-ray has been demonstrated elsewhere to have lower sensitivity for silicosis detection than LDCT. Early detection of silicosis can limit disease progression in the workers identified as having early silicosis, through modification of work activities and/or removal from silica dust exposure, and referral to appropriate clinical care.

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.

Participation in this study offers several potential benefits. The primary benefit is that participants will receive high-quality tests free of charge, including tests otherwise not available through standard mandated surveillance to workers in this industry. The individual results of these tests may allow for early detection of silicosis and allow workers with silicosis to better manage their future exposures and healthcare. A secondary benefit to society is that the information derived from the study may answer questions about the feasibility and benefits of enhanced medical surveillance that can inform future preventive strategies.

JUSTIFICATION OF RISKS

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

Though physical risks exist, these are in line with what is required by OSHA guidelines for medical surveillance of workers exposed to respirable silica dust. The increased radiation risk of LDCT used in this study is comparable to what is considered acceptable for screening for other exposure-related lung diseases, namely lung cancer in smokers. Early diagnosis of silicosis can delay rapid progression through early removal from exposure and adequate implementation of engineering controls in workplaces.
With confidentiality safeguards in place, the risks to privacy are very low. In contrast, the potential benefits to subjects and society are great. This research study has the potential to stimulate new preventive measures for silicosis in California and nationwide.

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
Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
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)
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.

Research staff will undergo required CDPH trainings on information privacy and security, including proper handling of PID. As a condition of employment, CDPH employees are required to follow procedures outlined in these trainings. Research staff based at Olive View-UCLA Medical Center also will undergo training on information privacy and security and follow the Medical Center's requirements for proper handing of PID as a condition of employment.

STAFF VETTING PROCEDURES

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

All study staff with access to PID will undergo thorough reference check as per CDPH standard practices.

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.

Letter of support_not applicable.docx Department Letter of Support

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.

The Occupational Health Branch is located within a secure, gated State facility with restricted entry via guard-controlled kiosk. The Branch is further secured in a key-card controlled building staffed by another security guard who prevents unauthorized access to the building and the removal of all office equipment without written authorization. Electronic study records will be stored on CDPH's network in limited-access files accessible only by essential study personnel, trained on data security. Paper study records will be stored in a locked file cabinet. Study personnel will be trained on the legal data protections in place.

Similarly, Olive View-UCLA Medical Center is located within a secure facility with restricted entry. Research offices are secured in key-card entry. Electronic study records will be stored on Olive View-UCLA Medical Center's network in limited-access files accessible only by essential study personnel, trained on data security. Paper study records will not be stored at Olive View-UCLA Medical Center. Study personnel will be trained on the legal data protections in place.

Any proposed use of the data beyond that described herein, such as future follow-up of the participants to assess clinical outcomes, will be submitted to the applicable Institutional Review Board for approval prior to study initiation. Once data are no longer necessary, they will be destroyed as permissible by state law.

CONFIDENTIALITY OF PUBLISHED DATA

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

Statistical summaries of data will be presented in an aggregate manner, in accordance with the CHHS Data De-Identification Guidelines, so that individuals cannot be identified. Personal identifiers will not be used in these analyses.

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 collected data will be the minimum necessary to perform the research. We are collecting patient identifiers and contact information to contact participants for study enrollment, coordinate study logistics, request relevant medical records, and administer the interview questionnaire. We are collecting basic demographic and work history information so that we can describe the group of participants and understand their demographic characteristics and occupational risk factors. We will collect the minimum amount of medical diagnostic data to provide adequate information for diagnosis and summary statistics regarding clinical aspects of the disease.

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.

There are multiple levels of security to limit data access only to those with a need to know for purposes of implementing the research. First, data will be stored at OHB and Olive View-UCLA Medical Center in secure electronic files only accessible by essential project personnel. Second, review and editing of data containing identifiers will be performed by authorized project personnel who will be trained in the proper procedures to maintain confidentiality of the data. Any paper records generated or obtained during the study will be transmitted only by secure, tracked delivery service. All paper records will be stored in a locked file cabinet at OHB.

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 so 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*

CDPHLetter2022CPHS_CASS_signed.pdf	Data Security Letter
Data Security Letter_Olive View UCLA Medical Center_5_23_SIGNED.pdf	Data Security Letter

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 contain personal identifiers

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.

PID in paper form will be disposed of by cross-cut shredding.

FAXING

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

We do not anticipate receipt of study data containing PID via fax. If an unanticipated need to transmit PID by fax occurs, we will use our branch fax, which is located in a secure area and monitored by branch administrative assistants, who will provide the faxes to research study staff.

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.

We do not anticipate receipt of study data containing PID via mail. If an unanticipated need to transmit PID by mail occurs, we will use a tracked mailing method that includes verification of delivery and receipt, such as UPS, US Express Mail, Federal Express, or bonded courier.

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.

PID in paper or electronic form will never 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.

OHB is located within a secure, gated State facility with restricted entry via guard-controlled kiosk. The Branch is further secured in a key-card controlled building staffed by another security guard who prevents unauthorized access to the building. Olive View-UCLA Medical Center is located within a secure facility with restricted entry. Research offices are secured with password-protected entry.

SERVER SECURITY

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

All data will be stored in an electronic database on the CDPH server and on the Olive View-UCLA Medical Center server. Access to these networks is limited to those with logon credentials. Study data will be located in study limited-access files. At each site, access to these files will be granted to essential study personnel only.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Identifiers will be stored separately from analysis data. The analysis dataset will use assigned research subject numbers rather than personal identifiers.

DISK STORAGE

State whether all disks with PID will be destroyed.

All disks with PID will be destroyed.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

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

All computer access will be protected through the use of encryption, passwords, and secure files accessible only to designated study personnel.

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 workstations that contain PID 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.

All laptops that contain PID 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.

PID will not be stored on 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.

All workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame as per CDPH's Information Technology department's protocols and Olive View-UCLA Medical Center's Information Technology department's protocols.

PASSWORD CONTROLS

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

Sufficiently strong password controls are in place to protect PID, as per CDPH's Information Technology department's protocols and Olive View-UCLA Medical Center's Information Technology department's protocols.

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.

Sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews, as per CDPH's Information Technology department's protocols and Olive View-UCLA Medical Center's Information Technology department's protocols.

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.

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

INTERNET ACCESSIBILITY

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

PID in an electronic form will not be accessible to the internet.

DISPOSING OF PID

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

When disposing of electronic PID, sufficiently secure wiping, degaussing, or physical destruction will be used as per protocols of CDPH's IT department in place at that time.

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.

Participation in this study is voluntary, and verbal and written informed consent will be obtained for participation. All prospective participants will be provided with an informed consent document. Prospective participants will have the opportunity to have all questions answered by study personnel. Prospective participants will be informed that they may voluntarily terminate a test at any point without prejudice to themselves and that research personnel may terminate a test at any time if they feel it is indicated. Each person who chooses to participate will provide verbal consent for the questionnaire and sign the informed consent document for the medical tests. In all cases, all procedures requiring informed consent will be performed after consent is obtained.

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.

OV Informed Consent Form_CASS_4_27_23.doc Consent Form

TRANSLATED DOCUMENTS

Provide copies of the non-English version of consent/assent forms and/or scripts to be used in this research.

CASS questionnaire_CLEAN COPY_7_11_23_SP.docx	Assent Forms
CASS_study flier_word_SP_5_2_23.docx	Assent Forms
Participant screening questions_7_11_23_SP.docx	Assent Forms
Release of health information_SP.docx	Assent Forms
Release of study records_SP.docx	Assent Forms
OV Informed Consent Form_CASS_7_11_23_SP.doc	Consent Form

TRANSLATOR

Provide a copy of the curriculum vitae of the translators(s) and/or proof of certification of the translation firm.

CPHS may reject poorly written documents or documents from translators lacking adequate proof of training or expertise. For studies using documents translated into Spanish, the translation should use formal language.

Translation Accuracy Affidavit.pdf Translator Curriculum Vitae

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?

Yes

BILLING/ELIGIBILITY

If the study involves the provision of healthcare, will a health insurer or billing agency be contacted for billing or eligibility?

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

HIPAA WAIVER

Are you requesting a waiver or alteration of HIPAA authorization?

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.

IRB - HIPAA Auth for Use Letter + Rights Spanish CURRENT.doc	HIPAA Documents
IRB - HIPPA Auth for Use Letter + Rights English CURRENT.doc	HIPAA Documents

Amendment Changes

List the pages and questions that have been changed.

This amendment:
Page 2: personnel (removed Sandra Garcia)
Page 3: project end date (changed to 8/31/28)
Page 5: study population (changed "100" to "150" where number of participants mentioned)

In addition, I noticed that some previously approved changes and attachments were inadvertently dropped from recent protocols because of my operator error in using IRB Manager (I mistakenly duplicated the original protocol rather than the latest approved one). To ensure that this amended version contains all of the most recent language and attachments, I have used the version of protocol approved on 6/14/24 and added the more recently approved amendments:
Page 3: UCLA reliance attachment (approved 11/27/24)
Page 4: language adding UCLA School of Medicine as a site for research blood tests in addition to NIOSH (approved 3/3/26)

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

Budget Summary.docx Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

Cover letter_7_11_23.docx Cover Letter

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.

Notify IRB for Pre-Screening
- Submitted 07/28/2026 11:09 AM ET by Sussan Atifeh

Internal IRB Screening

The questions on this page will be blank when an amended copy is submitted. If the form is returned during the amendment review, the questions on this page will appear as answered previously during the amendment review (responses from the initial review will not appear)

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
Dr. Hess requested this amendment to be scheduled for discussion in the August 7th, 2026, 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

August

Assign to cycle year
2026

Load into IRBManager (Amendment)
- Submitted 07/28/2026 11:11 AM ET by The System

Chair Review and Full Board Set-Up
- Submitted 07/28/2026 11:16 AM ET by Sussan Atifeh

Full Board Set Up

Project number

2022-084

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 Greater than Minimal Risk

Provide the rationale for the level of review determination
Dr. Hess requested this amendment to be scheduled for discussion in the August 7th, 2026, full board meeting.

Assign SME to study

Catherine Hess, PhD

Enter the meeting date for this project

08/07/2026

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.