

View xForm - Project Application v6

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

Data entry

Amendment Header

Amendment Submitter

August 2025 cycle

07/02/2025 • Nicholas Zadrozna • Internal

Matthew La Rocque, MPP

Email: mlarocque@socialfinance.org **Business:** (310) 923-2482

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:

Catherine Dun Rappaport, MPP

Email: cdunrappaport@socialfinance.org **Business:** (617) 596-5064

Administrative Contacts:

Name

Role

Protocol Number:

2025-004

Protocol Title:

Evaluation of Community Response Initiative to Strengthen Emergency Systems (C.R.I.S.E.S) Act Grant Pilot Program

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

Recruitment strategy and/or materials
Research methodology and/or research questions
Additional data sets requested
Data collection
Other (examples such as, but not limited to: budget changes, project site and project title)

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

This IRB amendment is proposing three changes to the C.R.I.S.E.S. Evaluation that relate to human subjects:

1. Changes to Service Delivery Data Template (updated procedures)
2. Spanish Translation of Client Satisfaction Survey, Survey Consent Form, and Survey Recruitment Materials (new procedures)
3. Interviews of Service Recipients (new procedures)

1. CHANGES TO SERVICE DELIVERY DATA TEMPLATE (UPDATED PROCEDURES):

CPHS originally approved the Service Delivery Data Template in May 2025. Pilots will use this template to gather data during crisis response activities. As part of this amendment, Social Finance is modifying the service delivery template to incorporate additional fields that enable pilots to capture screening, service and referral data they routinely collect during crisis response activities. These additions will enable Social Finance to collect additional data that will better capture the full range of services pilots are providing, and help us better answer our research questions. However, the data sets will continue to omit all PID data and all previously approved data security provisions remain in effect.

Impacts to data sets requested: The updated service delivery data template includes the following changes:

A. Social Finance has added three additional referral data fields to accommodate different types of services and referrals that pilot sites track: Additional fields for "Screening: Abuse", "Other service provided" and "Referral to other support" have been added to track additional types of screening, services and referrals sites may provide, which were not included in our original data template. We are also requesting that these three field names be added to our HIPAA waiver for the study. However, the data collection procedures are otherwise the same as described in the original application.

B. Social Finance is updating the Call Origin data field to include a response option for "On the street" interactions, which entail emergency responses that start not with a call, but an on-the-street interaction with a crisis response team member. These "on the street" interactions represent a large share of the Oakland pilot's crisis response incidents. All other data elements detailed in the template remain the same for these interactions.

2. SPANISH LANGUAGE SURVEY TRANSLATION (NEW PROCEDURES)

CPHS originally approved the English-language client satisfaction survey materials in May 2025. Social Finance has translated survey materials to improve accessibility for Spanish-speaking participants. This amendment includes a Spanish-language translation of the survey recruitment script, survey consent form, and survey questions that were originally approved in

May 2025.

3. INTERVIEWS OF SERVICE RECIPIENTS (NEW PROCEDURES):

Social Finance will conduct follow-up interviews in English with approximately 24 individuals (6 from each of four pilots) who previously received crisis response services. The purpose of these interviews is to collect more in-depth qualitative data about clients' experiences with receiving crisis response services.

Impacts to recruitment strategy and materials: Social Finance will recruit these individuals from the pool of client satisfaction survey respondents who agree to be contacted for a potential follow-up interview. The client satisfaction survey approach, including the process for requesting consent to be contacted for a potential follow-up interview, was approved by CPHS in May 2025. Recruitment scripts and the informed consent form for the interview are part of this amended application (see Attachments 5 and 6). All clients who agree to be contacted for an interview must complete an informed consent form prior to the interview. Participation in the interview will be voluntary, and the client can stop the interview at any time. Two members of the evaluation team will conduct each interview.

Impacts to data collection: Social Finance will collect additional qualitative information from clients about their experiences receiving crisis response services. Each interview will take approximately 45 minutes and will take place virtually via Microsoft Teams, reachable by weblink or phone number.

Impacts to research methodology: Social Finance will review, code, and analyze interview data using Dovetail, a third-party software for analyzing qualitative data, to identify themes and insights that address our research questions. For analysis purposes, data from Microsoft Teams and Dovetail will be downloaded onto a secure, password-protected SharePoint site. The evaluation team will strip all PID (such as name, email, phone number) from interview notes and transcripts prior to coding and analysis. For all data types, access to data will be limited to three authorized staff members (one of the study's Principal Investigators and two additional research staff). The evaluation team will permanently delete study data from all storage locations in accordance with data retention and privacy protocols at the conclusion of the study.

Impacts to budget: Social Finance will compensate each interview participant with a \$55 gift card. Social Finance has updated the evaluation budget to account for interview compensation and staff time associated with recruiting participants, conducting interviews, coding interview data, and conducting analysis.

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)*

Boston

PI Location State Output *(Internal)*

Massachusetts

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
Alina Xu, MBA/MPA	Co-Principal Investigator
Amber Ivey, JD / MPA	Research Team
Catherine Dun Rappaport, MPP	Principal Investigator
Jake Segal, BA	Responsible Official
Matthew La Rocque, MPP	Research Team
Sarah Osborn, BA	Research Team

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

Add new Administrative Contacts

Please enter the email address(es) of the new administrative contact(s)

If you are removing an administrative contact, remember to include that individual in the 'removal of personnel'.

Sarah Osborn, BA

Email: sosborn@socialfinance.org **Business:** (781) 999-1919

Project Information

SUBMITTER

Application completed by:

Matthew La Rocque, MPP

Email: mlarocque@socialfinance.org **Business:** (310) 923-2482

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).

Evaluation of Community Response Initiative to Strengthen Emergency Systems (C.R.I.S.E.S) Act Grant Pilot Program

STUDY PROCEDURES

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

Interviews
Program Evaluations
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."

Minimal Risk
Non-English translation required
HIPAA waiver
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.

Individuals with Impaired Decision-Making Abilities
Economically or Educationally Disadvantaged Persons

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.

State funded

Enter name of state-funded source.

California Department of Social Services

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

08/01/2025

ANTICIPATED PROJECT END DATE

10/31/2026

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.

In accordance with the C.R.I.S.E.S. Act statute (AB-118), the California Department of Social Services (CDSS) Office of Equity (OOE) is working with the national nonprofit, Social Finance, to conduct a descriptive study of Community Response Initiative to Strengthen Emergency Systems (C.R.I.S.E.S.) Act Grant Pilot Program. C.R.I.S.E.S. grantees and their community-based organization (CBO) partners will conduct “pilots” that provide services from October 1, 2023, through June 30, 2026.

The evidence base on alternative emergency response programs, such as C.R.I.S.E.S., is still emerging and there are few rigorous evaluations (RTI International, 2022). However, existing literature demonstrates that successful programs require multi-disciplinary partnerships and project champions; jurisdiction-level goals and study-designs; credible, culturally responsive outreach teams; and community engagement in shaping crisis response models. (Harvard Kennedy School Government Performance Lab (GPL), Results for America, RTI International, Science Advances, the International Association of Chiefs of Police).

To fulfill evaluation requirements in AB-118, Social Finance’s study will explore the extent to which C.R.I.S.E.S. pilots employ effective strategies and will answer the following research questions outlined in further detail in the MAJOR RESEARCH QUESTION section:

- Were individuals satisfied with the services they received from pilots?
- How effective was the implementation process (i.e., did the program achieve its intended results)?
- Before and after the emergency response pilots took place, were there any changes in community-level indicators such as the volume of traditional law enforcement response or psychiatric hospitalizations?
- What did pilots and CDSS learn from the process of designing and implementing the pilot program?
- How can lessons learned from this pilot program inform the development of future community-based emergency response programs?

Social Finance will help CDSS answer these research questions by analyzing data from four pilot sites across California: City of Oakland, Marin County, Sacramento County, and Santa Cruz County (see STUDY PROCEDURES for more detail). We expect the study participants to be California residents. Social Finance will produce a final report that synthesizes learnings and answers key research questions.

MAJOR RESEARCH QUESTION

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

AB-118 requires grantees to “report at least annually to the department on the use of program funding, which shall include data reporting on clients served and program outcomes, as determined by the department in consultation with stakeholder workgroup.” It further requires CDSS to “issue a public report, to be posted on its internet website six months following the end of the program, on the programmatic and fiscal savings associated with the program, key conclusions, populations served and the benefits conferred or realized, using quantitative and qualitative data, and resulting policy recommendations to provide guidance to the Legislature and Governor in fully implementing and scaling a permanent program.”

To fulfill these statutory requirements, the following research questions were defined at the outset of this work. The questions were designed to explore critical dimensions of the pilot's implementation, impact, and future scalability and improvement.

1. Were individuals satisfied with the services they received from pilots, especially members of populations disproportionately impacted by law enforcement emergency response? These may include Black, Indigenous, and people of color (BIPOC); low-income; disabled; neurodivergent; unhoused; immigrant; Lesbian, Gay, Bisexual, Trans, and Queer (LGBTQ), and other marginalized communities.
2. How effective was the implementation process (i.e., did the program achieve its intended results)? Sub-questions related to effectiveness include the following:
 - a. Who received community-based emergency response services, in terms of number and demographics of clients served?
 - b. How timely was the emergency response?
 - c. Did clients receive referrals to additional services, utilize those services, and benefit from them?
 - d. Before and after the emergency response pilots took place, were there any changes in the volume of traditional law enforcement response?
 - e. Before and after the emergency response pilots took place, were there any changes in health indicators, such as psychiatric hospitalizations?
 - f. How much did the pilot program cost and how does this compare to the cost of traditional emergency response services?
 - g. Did other community members know about the pilot program? If so, how did they hear about it?
 - h. What role did community members play in shaping the pilot program?
3. What did pilots and CDSS learn from the process of designing and implementing the pilot program?
 - a. What aspects of design and implementation were most successful?
 - b. What aspects were most challenging?

4. How can lessons learned from this pilot program inform the development of future community-based emergency response programs?

5. How can pilots and CDSS support the expansion of community-based emergency response programs in California following the conclusion of this pilot?

See Attachment 1 for additional information on how different types of data will be used to answer the above research questions.

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

You state that interview requirement is to be able to speak/respond to prompts in English. Please elaborate on this exclusion criteria. The client survey satisfaction survey for Spanish-speaking clients asks them if they would be interested in a follow up interview, but does not mention that this interview's requirement is for English speaking only. Is it possible to add the stipulation that is on the consent form for English speaking to the client survey satisfaction portion instead?

How are staff screening Spanish-version of client satisfaction survey (are these participants included in the random sampling?).

Is it your intent to collect 6 full interviews (e.g., if 6 interviews are administered but 2 are stopped before completion - would you recruit additional persons to get to 6? Depending on response this may impact the upper range of who you will contact and budget amount allocated for participant payment).

07/24/2025 • Jonni Johnson, PhD • *Not Internal*

The recruitment and consent process - where are these responses going? Or how are they collected and kept secure? How is research team notified when consent form is completed?

There's concern about the timing of consent being next to the interview scheduled time may cause undue pressure. This will be a discussion about a highly distressing event for your participants. Is it feasible to provide them with the preview of the questions during recruitment? Or once they respond to the recruitment - can they be taken to the consent form and provided the questions for their consideration for participating further? Or provided the consent form and times to schedule?

There is risk with discussing traumatic events without explicit prior knowledge of what will be discussed - and I am wondering if there is a way for you to re-work the order of information provided to reduce surprise/re-triggering, increase transparency, reinforce voluntary participation, etc. by providing the short list of questions beforehand.

You also mention that there will be two people in the interview, but the script implies there will be only 1.

07/24/2025 • Jonni Johnson, PhD • *Not Internal*

Can you explain more about the use of Dovetail? What is this software providing you with? Dovetail is not a HIPAA-compliant software and there is risk there. It seems that you plan to remove details from the transcript prior to uploading to Dovetail - can you describe this in more detail of the information that is being redacted? Is it just names? Or also dates? medical information/diagnoses that may be mentioned, HIPAA covered entities that provided services, locations.

Can you confirm that SF will be manually removing information from Dovetail?

Does SF have some level of user access with Dovetail to control usability/third party analysis by Dovetail/auditing trail of access?

Can information be deleted immediately from Dovetail once it is qualitatively coded by the software?

Is it needed to be kept until the end of the study?

Is it just interview transcripts that are uploaded to Dovetail?

Or if someone declines recording will interview notes be uploaded as well?

The uploading of the interview content is not disclosed in your consent form - is it possible to add this but that no identifying information about the participants and services will be included in the upload?

07/24/2025 • Jonni Johnson, PhD • *Not Internal*

There should be a documented plan for missed interview appointments, including brief script and number of contact attempts to be made.

07/24/2025 • Jonni Johnson, PhD • *Not Internal*

DATA COLLECTION FROM HUMAN SUBJECTS

This study is a program evaluation of C.R.I.S.E.S. Act Pilot Program, in which four pilot organizations are implementing alternative emergency response programs. To answer the study's research questions, Social Finance will analyze three types of data that are collected through engagement with human subjects: (1) service delivery data; (2) client satisfaction survey data; and (3) interview data.

Note: The Committee for the Protection of Human Subjects (CPHS) approved the procedures for collecting service delivery and survey data in May 2025. This amendment proposes three updates: additions to the attached service delivery data collection template, the addition of a Spanish language version of the client satisfaction survey and consent form, and new study procedures for conducting follow-up interviews with clients.

1. Service delivery data: De-identified information gathered from individuals who receive C.R.I.S.E.S. program services at pilot sites, collected during the administration of crisis services.

Note: While none of the data collection and reporting processes for service delivery data detailed in this section and approved in May 2025 have been changed, tab 2 of Attachment 2 contains the following changes, which are noted in orange text in the attachment:

- Three additional referral data fields are being added to accommodate different types of screening, services and referrals that pilot sites track: Additional fields for "Screening: Abuse" (e.g. domestic violence), "Other service provided" and "Referral to other support" have been added to track additional types of services and referrals sites may provide, which were not included in our original data template. We are also requesting that these three field names be added to our HIPAA waiver for the study.
- The Call Origin data field is being updated to include a response option for "on the street" interactions, which entail emergency responses that start not with a call, but an on-the-street interaction with a crisis response team member. These "on the street" interactions represent a large share of the Oakland pilot's crisis response incidents. All other data elements detailed in the template remain the same for these interactions.

a. Data collection: In accordance with the C.R.I.S.E.S. Act statute (AB-118), pilots must collect data on the delivery of crisis response services and submit it to CDSS. The statute requires that pilots provide "data reporting on clients served and program outcomes, as determined by the department in consultation with stakeholder workgroup." CDSS mandates this data reporting in the administration of the C.R.I.S.E.S. program and Social Finance does not determine how pilots collect service delivery data.

b. Data reporting: CDSS' agreement with Social Finance to conduct an evaluation of the C.R.I.S.E.S. Act Pilot Program, as required by statute, enables Social Finance to access data submitted by pilot sites to CDSS for purposes of the research. Attachment 2 is a data template that outlines the service delivery data that CDSS is asking sites to report, which will be shared with Social Finance. Specific data fields to be reported by sites have

been determined in consultation with the stakeholder workgroup, as required by statute, and include: call screening details, response time and duration, details of what happened during the response, referrals to services offered, and whether or not the response team followed up with clients at a later date. Because service delivery models and data collection approaches vary between pilots, sites may choose to omit data from certain fields when reporting this data to CDSS. In addition, because we do not know how many individuals will request and receive alternative crisis response services, we do not know how many records will be generated from service delivery data.

c. HIPAA considerations: While no personally identifiable data (PID) or HIPAA fields will be reported as part of these quarterly data submissions, some pilots will use data elements from records covered by HIPAA to compile the data submissions to CDSS, which Social Finance will subsequently access. In order to access CDSS service delivery data obtained from records covered by HIPAA, Social Finance is requesting a HIPAA waiver as part of this IRB application (see HIPAA Waiver section below for more detail).

d. Secure data submission and storage: Each quarter, pilots will upload service delivery data to a secure SharePoint site owned by CDSS, with access limited only to the pilot site submitting data, CDSS, and members of the Social Finance evaluation team via Microsoft username and password that uses multi-factor authentication. Please see report sections covering Study Duration, Administrative Safeguards, Preventative Use and Unauthorized Access, Physical Safeguards, Electronic Safeguards, and HIPAA Determination for more information on how Social Finance will secure and destroy this data after use for this evaluation.

e. Training procedures for data reporting: Social Finance will hold online trainings with pilot site staff responsible for data collection to ensure pilot sites do the following when submitting data to CDSS:

(i) Make consistent use of templates to submit service delivery data on a quarterly basis to CDSS, such that the structure of the data included in the templates (number of rows, number of columns, column names and categories) never changes.

(ii) Submit de-identified quarterly service delivery data. Quarterly service delivery data will include individual records that are de-identified by excluding from the data collection template all PID and HIPAA fields. To ensure data are de-identified, valid data to entry on data templates will be limited to simple categories (e.g., “Yes” / “No” binary fields, and other forced choice categories); and time stamps (i.e., time of call, time of arrival on scene, time of departure from scene). We will instruct pilots not to share any service delivery data beyond the fields described in Attachment 2.

(iii) Clarify reasons for missing or incomplete data. If a response team does not collect a particular piece of data, the team should select “Unknown” if a data point that is normally captured was unable to be captured, or “Not part of data collection” if the data is not part of the site’s data collection process.

(iv) Double check data templates being filled out to ensure that there is no unintentional disclosure of PID or HIPAA identifiers in data fields that will be shared with CDSS and the evaluation team.

As needed, Social Finance will work with pilots to troubleshoot data submission issues on an ongoing basis.

f. Data cleaning: To the extent there are differences in the structure and quality of service delivery data that pilots will share with CDSS and the evaluation team each quarter, Social Finance will first harmonize and clean data submissions across pilots to maximize data quality. We will identify inconsistencies and gaps and follow up with sites to clarify the reasons for missing or incomplete data. Specific follow-up questions and corrections from pilot sites will be exchanged within CDSS' secure SharePoint site. Sites will submit any revisions in a revised data file representing an amended version of the original submission, which both pilots and Social Finance will have access to. If necessary, clarifying detail on the nature of corrections needed may be discussed over the phone and manual changes may be inputted into the amended file on the secure SharePoint site.

g. Ensuring de-identification: As part of the data cleaning process, Social Finance will ensure that no PID or HIPAA data fields are included in individual data sets. If they are accidentally included, the evaluation team will follow Social Finance's organizational policies for handling PID: 1) delete the file containing PID or HIPAA fields immediately, 2) notify our IT team to help confirm that copies of the data no longer exist on our server or on any devices; and 3) communicate reminders to pilots to avoid including these fields in the future. Given the limited nature of the data to be submitted, Social Finance believes that the risk of re-identification of individuals from de-identified data is very low.

h. Analysis: Using service delivery data collected by pilots, we will develop summary statistics (e.g., totals, distribution of responses across question types) that seek to answer research question (2) "How effective was the implementation process?", and in particular, the following sub-questions:

- (i) What was the number of clients served?
- (ii) How timely were emergency responses?
- (iii) Did clients receive referrals to additional services?

Analysis will consider differences across sites. Individual data will also enable Social Finance to analyze patterns within sites, such as whether types of crises vary over the course of the service delivery period as community awareness about the pilot increases, and whether call outcomes (e.g., calls to 9-1-1, responder safety) and types of referrals depend on the type of crisis.

2. Client satisfaction survey data: Feedback and perspectives collected from eligible individuals who engaged with or were present during a CRISES pilot site crisis response, and received a follow-up interaction conducted in person, over the phone, by text message, or by email.

a. Context for administering client satisfaction surveys: As part of pilots' crisis response service model, pilots will conduct follow-up interactions with individuals who interact with C.R.I.S.E.S. services. This group includes:

- (i) Individuals in crisis who receive services from crisis responders
- (ii) Individuals who called for crisis response services (for themselves or someone else)
- (iii) Bystanders who are on scene, including friends, family and other community members who are present at the time of the crisis response.

The purpose of follow-ups is to check in on individuals' well-being following the crisis response and provide any additional support. It is possible that pilots may attempt to follow up with a client who does not respond. Pilots, in their discretion, may also elect not to follow up with an individual who received crisis response services if the responder felt unsafe or if additional contact with the client would be counterproductive to the wellbeing of the client. The follow-up interaction presents an opportunity to invite feedback on the services received, after the response team has worked to address the client's crisis. Social Finance has developed the following client satisfaction survey procedures, which sites will help to administer.

b. Eligibility criteria: Individuals will be invited to participate in the survey at the conclusion of follow-up conversations conducted by pilot staff. Pilot staff will invite individuals to fill out the survey for individuals who:

(i) Interact with C.R.I.S.E.S. services (identified in 2.a. above) and receive a follow-up

(ii) Agree to be contacted to fill out the survey

(iii) Do not fall into any of the following exclusion criteria:

(a) Do not have a follow-up interaction with the pilot (e.g., client was unreachable after crisis response, pilot staff did not follow up because crisis responder did not feel safe during response, or pilot staff did not follow up because they believe additional contact would be counterproductive to the wellbeing of the client)

(b) Are currently in crisis or have particularly sensitive needs (e.g. an individual who is experiencing signs of severe emotional distress during the follow up call such as uncontrollable crying, panic attacks, or expressing thoughts of self-harm will not be asked to take survey)

(c) Made pilot staff feel unsafe at the point of follow-up

(d) Decline to share feedback with Social Finance or do not consent to share their responses

(e) Are under the age of 18

c. Survey invitation procedure: Social Finance will provide a link to pilots to share with clients that includes an informed consent form and survey questions hosted on Qualtrics. The survey invitation will be integrated into follow-up calls conducted by pilot staff and the language that will be used for inviting eligible individuals to take the survey is included in Attachment 3. When pilot staff members offer the survey to eligible clients, pilot staff members must state that the survey is optional, that individuals may skip any question they do not want to answer, and that choosing not to participate will not impact their access to services. If the client agrees to complete the survey, the staff member will share the survey link with the client via text or email within 24 hours of follow-up conversations using the same contact information that was used to initiate the follow-up conversation. Social Finance will train pilot staff on survey invitation procedures before they are implemented. A Spanish language version of the verbal invitation script and survey invitation text will be provided for clients who prefer Spanish. Social Finance will provide the Spanish language script to sites with Spanish language speaking staff who are equipped to communicate with Spanish speaking clients.

d. Survey consent: When clients open the survey link on their phone or

computer, the first screen explains the purpose of the survey and asks them to provide consent to take the survey. The consent form includes the purpose of the study, potential risks or discomforts related to participating in the survey, potential benefits of participation, resources the client can access if they experience distress during or after participation, confidentiality of data records, an explanation of whom to contact for questions about the research, a statement that participation is voluntary, and a statement that not participating in the survey will not impact their access to services (see Attachment 4 for consent form and survey questions). Clients will also be given the opportunity to consent to participate in an incentive lottery for survey respondents (more detail below) and to be contacted for a compensated one-on-one follow-up interview. If they want to participate in the incentive lottery and/or are willing to be contacted for follow-up, they only need to provide a first name and phone number or email address. If they do not consent to enter the incentive lottery or to be contacted for follow-up, they are not asked to provide their name or contact information. Social Finance plans to seek IRB approval for research procedures involving interviews and informed consent for interviews at a later date. We will not contact any clients before obtaining IRB approval for interview procedures. A Spanish language version of the survey consent form will be provided for clients who prefer Spanish. Sites will send a link to the Spanish language consent form to Spanish speakers using the translated recruitment text in Attachment 3.

e. Survey completion: If the client consents to take the survey, they will then respond to survey questions in the Qualtrics form. At no point during the completion of this survey will the client directly interact with research staff from Social Finance or with staff from CDSS. A Spanish language version of the survey will be provided for clients who prefer Spanish. The link to the Spanish language consent form will direct respondents to the Spanish language survey once they consent.

f. Secure data submission and storage: Social Finance will collect client satisfaction survey responses in Qualtrics and store data on a secure server with password-protected access limited to one of the study's Principal Investigators and two additional research staff. Social Finance will keep names, phone numbers, and email addresses secure and confidential. When analyzing survey data, PID fields (such as name, email, phone number) will be stripped from the analysis file and stored separately and securely. This limits access and exposure to sensitive information for only those times where it is necessary (such as conducting follow-up outreach for interviews). Names and contact information will only be used to issue survey incentive payments and/or reach out to respondents at a later stage in the evaluation for an interview (provided they have consented to being contacted for an interview and the IRB has approved subsequent interview and interview consent procedures). Upon conclusion of the study, the raw survey data will be deleted.

g. Incentive payments for time spent completing the survey: Social Finance will conduct an incentive lottery, which awards a \$25 incentive payment to one respondent for every 10 survey submissions that enter the optional lottery, to be distributed via phone number or email address (see details in

the Compensation section). At every 10 surveys submitted that agree to enter the optional lottery, Social Finance will randomly select one survey and issue a gift card to the respondent. The research team will select a recipient by using a random number generator to assign a random number to each of the 10 surveys submitted, sorting the responses by the random number, and selecting the smallest random number. This approach was chosen for its equitable nature, which ensures that each random selection gives participants the same chance of being selected.

h. Analysis: Using client satisfaction survey responses, we will analyze several dimensions of client feedback to glean insights into all of the study's research questions. Feedback will tell us about how clients learned about and connected with pilot programs, clients' experiences with the crisis response services, the extent to which clients were referred to and used additional services after the response occurred, and how services could be improved. To the extent possible, we will also conduct subgroup analyses based on client satisfaction survey data to determine whether there were any disparities in pilot implementation by subgroups, including age, gender identity, and race/ethnicity. We are cognizant that demographic data available from client satisfaction data may be incomplete and subgroup sizes may be small. We will exercise caution in reporting and interpreting any disparities from subgroup analyses to avoid suggesting that meaningful differences in implementation exist where there is insufficient data to support such conclusions. As much as possible, we have also reduced our ability to connect survey data with service delivery data; none of the same variables are collected across the two data types, and Social Finance staff will be instructed to store them in separate files and separate folders.

3. Client interviews: Social Finance will conduct qualitative interviews with individuals who have received crisis response services through one of the C.R.I.S.E.S. pilot programs. Interviews will take approximately 45 minutes and will take place virtually via Microsoft Teams, reachable by weblink or phone number. Interviews are designed to help us understand client experiences with crisis response services in order to answer some of our key research questions, including: Were individuals satisfied with the services they received from pilots? How effective was the implementation process (i.e., did the program achieve its intended results)?

a. Eligibility: Participants will be eligible for an interview only if they meet all of the following criteria:

- 1) Received services from a C.R.I.S.E.S. pilot program during a crisis or called the hotline for someone in need of crisis response
- 2) Received at least one follow-up call or visit from the pilot site (as part of their service model, pilots conduct follow-ups with clients who received crisis response services to check on their well-being)
- 3) Were offered the opportunity to complete the client satisfaction survey during that follow-up interaction, in accordance with the eligibility criteria described in section 2b
- 4) Received, consented to, and completed a client satisfaction survey; and
- 5) Explicitly consented to be contacted for a potential follow-up interview with Social Finance by selecting "Yes, you may contact me for an interview" in response to the survey question, "Can we contact you for a 1:1 interview"

in the future to learn more about your experiences with [program name]? If so, you can provide your first name and a phone number or email address on the following screen so we can follow up with you to share more information. You can choose not to participate at that time. We will not share your contact information with anyone else."

6) Provided valid and complete contact information (e.g., first name and either a working phone number or email address) in the client satisfaction survey

7) Can be reached by Social Finance within 2 contact attempts by phone or email and confirm continued interest in participating in the interview

8) Are 18 years of age or older at the time of scheduling the interview

9) Are able to complete the interview in English

b. Recruitment and Participant Selection: Social Finance plans to conduct approximately 24 interviews with individuals who have received crisis response services (6 from each pilot). The evaluation team will recruit potential interviewees from clients who complete the client satisfaction survey between July 2025 and June 2026 and indicate their willingness to be contacted for a follow-up interview. We will conduct interviews on a rolling basis to capture participants' experiences while their memory of the crisis event is still recent. The recruitment process will follow these steps:

1) At the end of each month, the evaluation team will review that month's completed client surveys from each pilot site and identify clients who agreed to be contacted for an interview. We expect a relatively low survey response rate consistent with prior studies in the field of alternative crisis response (e.g. the Urban Institute's evaluation of Denver's Support Team Assisted Response (STAR) Program). Additionally, not all survey respondents will agree to an interview.

2) If there is more than one client per pilot site in a given month who agrees to an interview, we will randomly select one to reach out to for an interview by assigning a unique identifier to each client, using a random number generator in Excel to assign a corresponding random number to each identifier, and selecting the client corresponding to the lowest random number.

3) We will reach out to the selected client via email or text message, depending on the contact method the client provides in their survey response. The outreach message will clearly state that the interview is optional and completely voluntary, that their feedback will be kept confidential, and that choosing not to participate will have no impact on the services they receive. The message will also include details about compensation, directions for consenting to participation, and a link to a scheduling form and informed consent form (see Attachments 5 and 6 for recruitment language and informed consent form).

4) If the selected client does not respond to the initial outreach through email or phone call, we will send one follow-up message after seven days. If there is still no response to the follow-up message after an additional seven days, and there are additional clients who agreed to an interview, we will randomly select another individual to reach out to, via the methodology described in step 2.

5) We will conduct interviews with clients from each pilot site until we reach 6 per site. Because the survey response rate, interview acceptance rate, and response rate to interview outreach will vary by site, we may complete all 6

interviews at some sites earlier than others.

c. Consent: Social Finance will contact selected clients for an interview via the method they indicated in the client satisfaction survey (text or email) to share information about the follow-up interview. This message will include a link to an electronic informed consent form, along with a scheduling form for participants to indicate their availability. Participants must review and sign the electronic informed consent form before the interview can be scheduled. The form outlines the purpose of the study, what participation involves, that the interview will take place virtually, the voluntary nature of participation, potential risks and benefits, confidentiality protections, and information about compensation. At the start of each interview, the interviewer will verbally confirm that participation is voluntary, confirm they still want to participate in the interview, remind the participant that they can skip any questions they do not wish to answer, and they can stop the interview at any time without penalty.

d. Recordings and transcriptions: With consent from participants, the evaluation team will record interviews with participants' explicit consent using Microsoft Teams' recording and transcription tool (see below for details on data security). These recordings are essential for creating accurate, verbatim transcripts that help minimize errors, reduce bias, and support consistent analysis of participant responses. Recordings will allow the team to better identify key themes and ensure the integrity of the data. Recording is not required for participation. If a participant does not wish to be recorded, they may still take part in the interview, and the interviewer will take detailed notes instead. We may see an interview participant's first and last name, as well as their face, when they come on screen. Before we record, we will ask them for permission to record, request that they change their display name on Teams to just their first name, and ask them to go off camera so that we capture only an audio recording. We will not record an interview without these conditions being met. All recordings and transcriptions will be securely stored in Microsoft Teams, and will only be made accessible to authorized members of the evaluation team. The evaluation team will download the transcripts from Microsoft Teams to a secure, password-protected SharePoint Site, and then upload to Dovetail for coding and analysis (see 3f and 3i for more detail). Recordings and transcriptions will only be used for qualitative analysis related to this study. Recordings will not be used for any future research, training, or public dissemination. All recordings and transcripts will be permanently deleted within 30 days of the completion of the study.

e. Confidentiality: Social Finance will ensure that all data gathered during interviews is kept confidential. Information shared by participants will be securely stored and access limited to authorized members of the evaluation team (see 3f for more detail on data security). No personal identifiers such as names and contact information will be included in any reports. We will store participants' contact information separately from interview data. This information will only be used for scheduling and for compensation. Contact information will be shared with the third-party payment vendor, Tremendous, solely to issue gift cards, and the vendor will not retain this information beyond what is needed to complete the payment. All identifiable

data will be deleted within 30 days of the completion of the study.

f. Data security: To facilitate coding and analysis, our team will utilize Dovetail to upload transcripts and analyze the data (as noted in section 3i below). Dovetail utilizes multiple data security techniques to ensure that third party data is stored securely, such as regular data backups and recovery tests, encryption of all data at rest and in transit, static code analysis and third-party vulnerability scanning, and many other cloud security techniques. Interview notes will be securely stored on a password-protected SharePoint site and deleted permanently once the evaluation is complete. For analysis purposes, transcripts from Microsoft Teams will be downloaded to SharePoint and uploaded to Dovetail. Interview coding data from Dovetail will be downloaded back to SharePoint. The evaluation team will strip all PID fields (such as name, email, phone number) from interview notes and transcripts prior to coding and analysis. Access to data will be limited to three authorized staff members (one of the study's Principal Investigators and two additional research staff). Any information from interviews shared in data we report will exclude personally identifiable details associated with any individuals, including names, contact information, and other information that could reveal participant identity. Upon completion of the study, all data with PII will be permanently deleted from all storage locations.

g. Risks: The primary risk to participants is the potential for psychological discomfort, emotional distress, or re-traumatization when discussing their experiences with crisis response services. These experiences may involve sensitive or triggering topics related to mental health, trauma, or crisis events. Social Finance will prioritize the interviewee's safety and well-being throughout the interview process by applying a trauma-informed approach. To mitigate risks, the interview guide only includes the questions that are necessary to collect data that will help the evaluation team answer our research questions. The interviewer will remind participants at the beginning of the interview, and again as needed, that participation is entirely voluntary and that they can skip any questions or stop the interview at any time without penalty. Additionally, members of the evaluation team who conduct interviews will first undergo training on trauma-informed interviewing techniques, including how to recognize signs of trauma and avoid actions that could re-traumatize the individual. The training would be provided by an organization such as JT Consulting (www.consulting-jt.com), which has previously trained Social Finance staff members on trauma-informed approaches to engaging community members. JT Consulting specializes in training organizations to bring a trauma-informed lens to responding to and supporting individuals impacted by interpersonal or community violence. If participants express a need for additional support, the interviewer will provide the 24/7 Suicide and Crisis Lifeline (9-8-8) as an additional resource. No physical, legal, or financial risks are anticipated. All data collected will be de-identified in analysis and reporting to mitigate any risk related to participant confidentiality. Loss of data security and associated loss of confidentiality may be a risk if data collected through the project is not secured appropriately. This risk is very low due to data security efforts we are taking to secure PID, which include storing survey responses and interview data in password-protected locations that are only accessible to

three Social Finance staff members, and ensuring that service delivery data collected by pilots does not contain any PID or HIPAA identifiers. Additional information on data security is provided in more detail below.

h. Compensation: Participants will be compensated for their time and participation in the interview with a \$55 gift card. Compensation will be provided following the interview via the secure payment platform, Tremendous, either through text message or email, based on the participant's preference. Participants will be informed that receipt of compensation is not contingent upon answering all questions and they are still eligible to receive the gift card even if they choose to skip questions or end the interview early.

i. Analysis: Interview transcripts will be analyzed in Dovetail to help answer key research questions including: Were individuals satisfied with the services they received from pilots? How effective was the implementation process (i.e., did the program achieve its intended results)? and to explore differences across pilot sites in service delivery. Transcripts and interview notes will be reviewed for accuracy and cleaned to remove PII prior to analysis. The evaluation team will use both deductive and inductive coding approaches. A preliminary codebook will be developed based on the interview guide and research questions, with initial codes focused on service access, interaction with response teams, perceived impact, and overall experience. As themes emerge during initial coding, the codebook will be updated accordingly. Two trained members of the research team will independently code a subset of transcripts to ensure consistency and establish inter-coder reliability. Discrepancies will be discussed and resolved by consensus. Once reliability is established, the remaining transcripts will be divided and coded by the trained research in Dovetail. Coded data will be analyzed by authorized research staff to identify recurring patterns, key themes, and site-specific variations in experience. All findings will be reported in aggregate form. Any quotations used will be anonymized to ensure participant confidentiality.

REPORTING OF DATA AND RESULTS

Social Finance will adhere to the following approaches in data reporting:

1. Confidentiality in reporting: No information that could be used to identify an individual respondent will be used in any public report. The evaluation team will comply with CalHHS Data De-identification guidelines, including presenting data as a whole if the cell size is less than 11.

2. Quarterly data summaries: Social Finance will share quarterly summaries of data (including information collected in the course of service delivery, client surveys, and client interviews) with CDSS and pilots, using aggregated, de-identified data, in order to provide stakeholders with timely feedback on program implementation. To do this, the evaluation team will create de-identified data files for analysis, which exclude all personally identifiable details associated with any individual, including names and contact information.

Each pilot will only have access to results for their own surveys and interviews; i.e., the Oakland pilot will only see summaries of survey results and interview insights from Oakland crisis response clients. We will not share individual-level survey data or interviews with CDSS or pilots, and details from free responses or interviews may be condensed for brevity and privacy -- i.e., we will ensure that no text from free response answers contains PID, HIPAA identifiers, or other data (or combinations of data) that could conceivably be used to identify an individual. This includes any details related to a crisis response scenario, such as references to the location of response, that could be connected to an individual. For example, if a survey or interview respondent provides their identity, location, or other PID/HIPAA information when responding to the question "How can we improve this program to better meet your needs?", we would not be able to share that response with pilots or CDSS, since those details would have already been scrubbed from our analysis file.

3. Produce a final public-facing report, to be reviewed and approved by CDSS before publicizing, that includes but is not limited to descriptions of how the pilot program was implemented and programmatic and fiscal savings associated with the program, syntheses of lessons learned and key conclusions from the implementation; and policy considerations for implementing and scaling a more permanent program for community-based emergency response. The report will also include the key research questions, methodologies used to answer those questions, and limitations of the research. The report will be developed with an eye toward accessibility, including a focus on plain language and visual aids, to ensure that a wide audience can interpret the results of the pilot program.

ADDITIONAL DATA COLLECTION EXCLUDING HUMAN SUBJECTS

In addition to service delivery data collection and survey procedures involving engagement with human subjects at an individual level, this study will collect the following additional data that do NOT involve human subjects and therefore does not need to be reviewed by the IRB:

Pilot-level data on program design and implementation, including data on:

- Pilot design processes: Summary of pilot design decision making process, including brief descriptions of community engagement activities
- Team structure: Composition and roles of the team implementing the crisis response pilot
- Team demographics: Summary of client-facing crisis response team demographics at an aggregate level, including race/ethnicity and gender identity
- Grant budget actuals: Budget actuals showing how grant funds were allocated over the course of the grant period for operations/administration, service delivery, recruiting/hiring, training, and other costs.
- Training summaries: Summaries of any training that the client-facing crisis response team receives

Aggregate data from staff member shifts at Oakland pilot site:

- Social Finance plans to collect quarterly aggregate data from staff at the Oakland pilot site that describes the volume and types of community-based interventions they conduct within the community during their work shifts (e.g., the time of day their shift took place, the number of community-level conversations staff have during their work shifts, the number of times they de-escalated a situation during their shift, the number of times they called 9-1-1). No individual data will be collected and it will not require data collection from human subjects.

Publicly available data

- If available, we will collect publicly available data for jurisdictions served by the C.R.I.S.E.S. pilots in order to assess: the change in volume of emergency response by law enforcement in relevant geography (pre-pilot vs. post); the estimated cost of law enforcement response and other costs associated with traditional crisis response (on a per-incident basis); the change in the number of voluntary vs. involuntary (e.g., 5150) placements in crisis stabilization facilities in relevant geography (pre-pilot vs. post); and the change in suicide rates (pre-pilot vs. post).

EVALUATION TIMELINE

The timeline for the overall evaluation is as follows:

- Design of evaluation is finalized: May 2025 (initial CPHS approval); August 2025 (first IRB amendment)
- Pilots submit service delivery data to CDSS, which is then shared with the evaluation team for research purposes: July 2025-June 2026 (CPHS approval received in May 2025)
- Pilots offer client satisfaction surveys to clients during follow-ups and clients complete surveys: July 2025-June 2026 (CPHS approval received in May 2025)
- Following CPHS approval: Social Finance conducts interviews with clients: August 2025-June 2026
- Social Finance implements study procedures detailed above: May 2025-October 2026
- Pilots conclude service delivery under this program: February 2027
- Evaluation report published: Mid-2027

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.

Attachment 4 - Client Consent Form and Satisfaction Survey.docx	Consent Form
Attachment 4B - Client Consent Form and Satisfaction Survey Spanish_June 2025 Submission.docx	Consent Form
Attachment 5 - Interview Participant Consent and Questions_June 2025 Submission.docx	Consent Form
Attachment 2 - Service Delivery Data Collection Template_June 2025 Revision.xlsx	List of Variables

Attachment 1 - Research Questions and Data.docx

Other
Documents

Attachment 3 - Client Satisfaction Recruitment Templates
English_Spanish_June 2025 Revision.docx

Recruitment

Attachment 6 - Interview Recruitment Template_June 2025
Submission.docx

Recruitment

Deleted Attachments: 5 (Most Recent: Attachment 5 - Interview Participant
Consent and Questions June 2025 Submission.docx on
06/27/2025 7:14 PM ET)

RECORDING

Will audio or video recording occur?

Yes

Describe how the recordings will be maintained during and upon completion of the project. Describe what will become of the recordings after use (e.g., shown at scientific meetings, erased, etc.).

Interview recordings and transcripts will be securely stored in a password-protected Microsoft Teams account. Access to recordings will be limited to three authorized staff members (one of the study's Principal Investigators and two additional research staff). As described in section 3i of Study Procedures, interview transcripts from Teams will be downloaded to a password-protected SharePoint site and subsequently uploaded to Dovetail for analysis purposes. Interview coding data from Dovetail will also be downloaded onto a password-protected SharePoint site for analysis purposes. Dovetail utilizes multiple data security techniques to ensure that third party data is stored securely, such as regular data backups and recovery tests, encryption of all data at rest and in transit, static code analysis and third-party vulnerability scanning, and many other cloud security techniques. Upon completion of the study, all data with PID will be deleted.

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.

CDSS: Department of Social Services

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.

SERVICE DELIVERY DATA

Over the course of evaluation implementation, we will review service delivery data pilots submit to CDSS. We expect these individuals will represent diverse characteristics. Because we do not know how many individuals will request and receive alternative crisis response services, we do not know how many records will be generated from service delivery data.

CLIENT SATISFACTION SURVEY DATA

In addition, we expect to engage individuals who received services through the C.R.I.S.E.S. program via a web-based client satisfaction survey. As described in the STUDY PROCEDURES section, the individuals we engage will include individuals who:

1. Interact with C.R.I.S.E.S. services and receive a follow-up from the pilot.

This group includes:

(i) Individuals in crisis who receive services from crisis responders
(ii) Individuals who called for crisis response services (for themselves or someone else)

(iii) Bystanders who are on scene, including friends, family and other community members who are present at the time of the crisis response.

2. Agree to be contacted to fill out the survey

3. Do not fall into any of the following exclusion criteria:

(i) Are currently in crisis or have particularly sensitive needs, (e.g., an individual who is experiencing signs of severe emotional distress during the follow up call such as uncontrollable crying, panic attacks or expressing thoughts of self-harm will not be asked to take survey). These clients require immediate and ongoing support.

(ii) Made the crisis response team feel unsafe during the original crisis response (if the response team recorded whether they felt safe)

(iii) Are under the age of 18.

These individuals will provide feedback on their experiences with C.R.I.S.E.S. pilots. Because we do not know exactly how many individuals will receive crisis response services, or how many will consent to fill out the survey through the survey link provided to them by pilots, we do not know how many individuals will be involved in the client satisfaction portion of this study or the breakdown of the various groups represented.

We expect that this group will include individuals 18 and older, representing various gender identities, sexual orientations, and racial/ethnic identities within the communities served by the pilot program. These characteristics will vary by pilots' service areas across California: City of Oakland, Marin

County, Sacramento County, and Santa Cruz County.

INTERVIEW DATA

The evaluation team will aim to interview 24 individuals who received crisis response services. These individuals represent a subset of those who completed client satisfaction surveys, so the population of interviewees will have all of the characteristics of survey respondents described above. As described in Study Procedures – Client Interviews – Recruitment and Participant Selection, interviewees are those who completed a client satisfaction survey, agreed to be contacted for an interview, were selected by the evaluation team to participate in an interview (with selection occurring on a monthly basis) and completed an informed consent form. Recruitment language and questions and scripts for these interviews can be found in Attachment 5 and 6.

RATIONALE

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

AB-118 enacted the Community Response Initiative to Strengthen Emergency Systems Act, or the C.R.I.S.E.S. Act, for purposes of creating, implementing, and evaluating the C.R.I.S.E.S. Grant Pilot Program.

Social Finance is studying the requested groups in order to answer the study's key research questions.

Using service delivery data collected by pilots, we will answer research question (2) "How effective was the implementation process?", and in particular, the following sub-questions:

- (i) What was the number of clients served?
- (ii) How timely were emergency responses?
- (iii) Did clients receive referrals to additional services?

By surveying and interviewing clients, we will be able to answer the following research questions:

- (1) Were individuals satisfied with the services they received from community-based crisis response programs, especially members of populations disproportionately impacted by law enforcement emergency response?
- (2) How effective was the implementation process (i.e., did the program achieve its intended results)?

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.)?

Modify to include surveys in Spanish option

07/24/2025 • Jonni Johnson, PhD • *Not Internal*

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

SERVICE DELIVERY

There is no recruitment process for service delivery data, which sites are collecting and submitting to CDSS in accordance with AB-118.

CLIENT SATISFACTION SURVEYS

The recruitment procedures for the client satisfaction survey are as follows:

1. A pilot staff member follows up via telephone or in person with an individual who has requested crisis services.
2. During the follow-up interaction, the staff member provides routine follow-up services and then offers the individual the option to fill out a survey. Spanish speaking staff who serve Spanish speaking clients will offer the option to fill out a survey in Spanish, using the script included in the client satisfaction recruitment templates.
3. If the individual agrees to complete the survey, the pilot will share the survey link with the client via text or email within 24 hours of follow-up interactions. A Spanish language version of the invitation with survey link may be provided to a Spanish speaking client.
4. Clients who click on the link will be directed to an informed consent form and survey questions hosted on Qualtrics.
5. When clients go to the link they will be provided with an informed consent form. They complete and sign the form prior to beginning the survey.
6. Clients will complete the survey.

Only clients who received crisis response services and a follow-up call or visit will be offered the survey. There will be no public flyers or open recruitment processes for the survey. Pilots will use the verbal script provided in Attachment 3 to ask clients to take a survey about their experiences with alternative crisis response services. The survey will remain open until the end date for pilot service delivery under the C.R.I.S.E.S. grant (June 30, 2026) at which time the evaluation team will analyze the data for the final evaluation report.

Surveys will be conducted in English. When an individual is successfully

contacted at follow-up, they will be asked to complete the survey once.

INTERVIEWS

The Recruitment procedures for client interviews are as follows:

Social Finance will engage consenting interview participants from the C.R.I.S.E.S. Pilot Program through a structured interview process. The evaluation team will aim to interview approximately 24 individuals who received crisis response services (approximately 6 from each pilot) with recruitment focused on clients who submit satisfaction survey responses between July 2025 and June 2026 and indicate their willingness to participate in a follow-up interview.

To select interviewees, at the end of each month, the evaluation team at Social Finance will review that month's surveys to determine how many clients at each pilot site have agreed to be contacted for interviews. We anticipate a relatively low response rate based on prior research, such as the Urban Institute's evaluation of Denver's STAR Program. If more than one client per pilot site agrees to an interview within a month, Social Finance will randomly select one individual to contact, reaching out through the respondent's preferred method (email or text). The initial message will state that participation is optional and responses are confidential, explain compensation, and provide guidance for consent and scheduling, including a link to the informed consent form and a request for interview availability to facilitate scheduling (see Attachments 5 and 6). If there is no response, Social Finance will follow up within seven days by the same method. If there is still no response to the follow-up message after an additional seven days, and there are additional clients who agreed to an interview within that month, we will randomly select another individual to reach out to. This process will continue until six interviews have been conducted at each pilot site. (See Study Procedures for a more detailed description of how the sample is formed.)

Attach copies of all recruitment materials.

Attachment 3 - Client Satisfaction Recruitment Templates English_Spanish_June 2025 Revision.docx	Recruitment Materials
Attachment 6 - Interview Recruitment Template_June 2025 Submission.docx	Recruitment Materials

Deleted Attachments: 1 (Most Recent: Attachment 3 - Client Satisfaction Recruitment Templates English_Spanish_June 2025 Revision.docx on 06/27/2025 7:17 PM ET)

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.

This study has exclusion criteria: The survey and interviews will not be offered to individuals if they:

- (i) Are currently in crisis or have particularly sensitive needs, (e.g., an individual who is experiencing signs of severe emotional distress during the follow up call such as uncontrollable crying, panic attacks or expressing thoughts of self-harm will not be asked to take the survey and therefore will be excluded from consideration for interviews). These clients require immediate and ongoing support.
- (ii) Made the crisis response team feel unsafe during the original crisis response (if the response team recorded whether they felt safe)
- (iii) Are under the age of 18.
- (iv) Prefer a language other than English (for interviews). This amendment includes a Spanish-language client satisfaction survey and survey recruitment language, but the evaluation team will not offer an option for Spanish-language interviews.

The evaluation team has trained pilot sites to apply these exclusion criteria. However, if the evaluation team inadvertently collects information from any minors over the course of recruitment, we will destroy the data.

More broadly, the populations we seek to engage are likely to have vulnerable characteristics. Since our study will seek to survey and interview individuals who have received services through alternative crisis response, subjects may include those who have experienced mental health crises, psychiatric hospitalizations, challenges with substance use, and/or have lived experience with police-based or alternative emergency response. While this study will not specifically prioritize economically or educationally disadvantaged persons or impaired decision-making abilities, it is also possible that individuals filling out surveys and participating in interviews will possess those characteristics.

Prior to participating in the survey, clients must fill out an informed consent form that makes clear participation is entirely voluntary, explains that clients can stop answering questions at any time, and provides guidance on who to contact if respondents experience distress during survey completion or interview participation. This amendment proposes a similar consent process for interviews; clients must complete an informed consent form prior to the interview, and the research team conducting the interview will also verbally

re-iterate at the beginning of the interview that participation is voluntary, confirm they still want to participate in the interview, remind the participant that they can skip any questions they do not wish to answer, and they can stop the interview at any time without penalty. See Attachments 5 & 6 for the interview consent form and recruitment language.

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.

CLIENT SATISFACTION SURVEYS

For client satisfaction surveys, Social Finance will conduct an incentive lottery, which awards a \$25 incentive to one respondent selected at random from every 10 surveys that are submitted, to be distributed via phone number or email address. All survey responses submitted, for which respondents agreed to enter the incentive lottery, will be eligible for the lottery. The number of questions respondents answer will not impact their eligibility for the lottery.

At every 10 surveys submitted, Social Finance will randomly select one survey and issue a gift card to the respondent. The research team will select a recipient by using a random number generator to assign a random number every 10 surveys submitted, sorting the responses by the random number, and selecting the smallest random number. To disburse the incentives, Social Finance plans to use a vendor such as Tremendous that allows recipients to select their preferred delivery mode (either a virtual or physical pre-paid debit card) and can issue incentives using either a phone number or email address.

INTERVIEWS

Clients participating in interviews will receive a \$55 gift card as compensation for their time (45-minute interview on Microsoft Teams). Compensation will be provided following the interview via text or email through the payment site Tremendous.

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.

The consent procedure should be as long as the participant needs to consider disclosing details about a traumatic event to researchers. See comment above about possibly sending consent and questions earlier to reduce distress during interview for participants.

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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 study will take place over a two-year period and will be completed in two separate parts. Phase One: Study Design began in August 2024 and concludes in August 2025 with approval of this amendment for client interviews. Phase Two: Evaluation Implementation and Report Creation has begun (following CPHS' May 2025 approval of protocols for service delivery data collection and client satisfaction survey administration) and will conclude by October 2026.

Between Phase One and Phase Two of the evaluation, C.R.I.S.E.S. pilots will be designing their pilots, delivering services, and collecting data about service delivery operations. However, Social Finance will not access any data submitted by pilots until after receiving IRB approval.

We expect each survey will take each respondent approximately 20 minutes to complete (5 minutes for the completion of the consent form, and 15 minutes for the survey questions).

We expect each client interviews will take approximately 50 minutes of each interviewee's time (5 minutes to complete the interview consent form and scheduling details, and 45 minutes for the interview with the evaluation team).

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.

The primary risks to participants include psychological risks, loss of data security and associated loss of confidentiality.

1. Psychological risks

Since our study will seek to survey and interview individuals who have received services through alternative crisis response, subjects will likely include those who have experienced mental health crises, psychiatric hospitalizations, challenges with substance abuse, and/or have lived experience with police-based or alternative emergency response. Discussing their experiences with alternative crisis response services may lead participants to recount traumatic experiences and possibly feel uncomfortable or upset.

Social Finance will prioritize the interviewee's safety and well-being throughout the survey and interview process by applying a trauma-informed approach. To mitigate these risks, the interviewer will remind participants at the beginning of the interview, and again as needed, that participation is entirely voluntary and that they can skip any questions or stop the interview at any time without penalty. The survey and interview guide only include questions that are necessary to collect data that will help the evaluation team answer our research questions. Additionally, members of the evaluation team who conduct interviews will first undergo training on trauma-informed interviewing techniques, including how to recognize signs of trauma and avoid actions that could re-traumatize the individual. The training would be provided by an organization such as JT Consulting (www.consulting-jt.com), which has previously trained Social Finance staff members on trauma-informed approaches to engaging community members. JT Consulting specializes in training organizations to apply a trauma-informed lens when responding to and supporting individuals impacted by interpersonal or community violence.

If participants express a need for additional support, the interviewer will provide the 24/7 Suicide and Crisis Lifeline (9-8-8) as an additional resource. No physical, legal, or financial risks are anticipated. All data collected will be de-identified in analysis and reporting to mitigate any risk related to participant confidentiality.

2. Loss of data security and associated loss of confidentiality

This may be a risk if data that is collected through the project is not secured appropriately. This risk is very low due to data security efforts we are taking to secure PID, which include storing survey responses and interview data in

password-protected locations that are only accessible to three Social Finance staff members, and ensuring that service delivery data collected by pilots does not contain any PID or HIPAA identifiers. Additional information on data security is provided in more detail below.

AUDIO/VIDEO RECORDING RISKS

State if audio/video taking could increase potential risk to subject's confidentiality.

See note above about removing information disclosed in the interview prior to uploading to Dovetail. It may be needed to remove the specifics (e.g., dates, medical diagnoses specifics, places of service) and replace with generic terms if Dovetail can otherwise perform the analysis without these details.

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We do not anticipate increased risks for audio/video recordings as we will seek to maintain the confidentiality and security of these recordings.

We may see an interview participant's first and last name, as well as their face, when they come on screen. Before we record, we will ask them for permission to record, request that they change their display name on Teams to just their first name, and ask them to go off camera so that we capture only an audio recording. We will not record an interview without these conditions being met.

As described elsewhere in this application, interview recordings and transcripts will be securely stored in a password-protected Microsoft Teams account. Interview transcripts from Teams will be downloaded to a password-protected SharePoint site and subsequently uploaded to Dovetail for analysis purposes. Interview coding data from Dovetail will also be downloaded onto a password-protected SharePoint site for analysis purposes. For all data types, access to data will be limited to three authorized staff members (one of the study's Principal Investigators and two additional research staff). Upon completion of the study, all data with PID will be deleted.

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.

It is possible that individuals responding to the client satisfaction survey or engaging in interviews may experience psychological discomfort or distress. In the consent language in Attachment 4, we refer individuals filling out the survey who experience distress or need urgent help to 9-8-8, the 24/7 Suicide and Crisis Lifeline. 9-8-8 is a key resource that crisis response pilots already use to encourage the communities they are serving to seek help for mental health crises and is able to refer individuals to relevant local services.

INTERNATIONAL RESEARCH

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

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

No

LESS RISKY METHODS

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

While we believe this study is already a minimal risk study, we could opt to do this research without interacting with human subjects at all (for instance, by only reviewing publicly available data and service delivery data collected by pilots, and foregoing surveys to gather feedback on services). While such an approach could further eliminate risk, it would not allow the project to answer its research questions, which require capturing nuanced, firsthand accounts of individuals' experiences with alternative crisis response programs. Understanding the impact and effectiveness of these programs requires collecting feedback from individuals who have received services, including those who may have experienced mental health crises or substance use challenges.

Survey responses and feedback from client interviews will provide valuable data on the personal, social, and systemic factors that influence the outcomes of alternative crisis response programs. This information is critical for providing a comprehensive assessment of how the program operates, its effects on individuals' well-being, and how programs like these can be improved.

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.

This project will benefit society as a whole by collecting data on the impact and lessons learned from pilots. To the extent that non-police crisis response is implemented more widely throughout California, learnings from pilot implementers and the individuals they are serving will provide valuable guidance to the state and local government entities and implementing partners looking to scale these initiatives. Potential outcomes of pilot implementation (e.g. cost savings through decreased use of emergency services, increased community trust in crisis response services, and/or reduction in law enforcement response to behavioral crises) could benefit the surrounding communities where the pilots reside, and influence policy decisions relating to emergency response.

Individuals who are willing to participate in this study may benefit directly by providing feedback on crisis response services that could continue to serve their communities following the conclusion of these pilots. By completing a client satisfaction survey and/or participating in an interview to share their experiences with the services they received, they may influence the future delivery of alternative crisis response services that more effectively address the needs of community members and reduce reliance on traditional law enforcement. In addition, their perspectives will be amplified through their inclusion in a state-mandated evaluation report that will discuss how community-based crisis response can be replicated and scaled. Their opinions could ultimately influence services and systems that may impact them.

JUSTIFICATION OF RISKS

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

While the study acknowledges the potential psychological risks for participants, these risks are mitigated through a trauma-informed approach. By carefully crafting survey questions that are essential to answering the study's research questions (with input from community stakeholders who have lived experience with emergency response), and allowing participants to opt out of any questions, the study minimizes potential discomfort or distress and treats participants with care, professionalism and respect.

To address confidentiality risks in surveys and interviews, the survey and interview consent forms address the confidentiality of data records by explaining to participants that Social Finance will keep the information they share private and in a secure location. In addition, participants' names and other personal information that could be used to identify individuals will only be collected for the purpose of compensating participants and conducting interview outreach. The information never be used in any report, nor will it be shared with anybody outside of Social Finance. For the survey, while respondents need to provide their first name and a phone number or email address if they wish to participate in a random gift card drawing, they may choose not to provide this information and can participate anonymously. For interviews, respondents must provide contact information in order to receive scheduling details for the interview, but they can also choose not to participate.

Juxtaposed with relatively modest risks, there are clear direct and indirect benefits for those who choose to participate in this study. By sharing their experiences through a survey, participants will have the opportunity to influence the future design and delivery of alternative crisis response services in their communities, ensuring these services better meet the needs of those they serve. Their perspectives will also be amplified through inclusion in a state-mandated, public-facing evaluation report.

The evaluation report will guide state and local government entities in scaling initiatives that have the potential to improve community well-being, foster trust in crisis response services, and reduce reliance on law enforcement for behavioral crises. The potential outcomes, including cost savings from reduced use of emergency services, increased public trust, and more effective crisis intervention, could have transformative effects on communities across California.

Administrative 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
Finger, voice print or other bio-metric identifier

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.

As part of CDSS' agreement with Social Finance, Social Finance has committed to training employees in the handling of PID to preserve information security and privacy. (The agreement refers to "Confidential, Sensitive, and/or Personal Information", or CSP. As described above, Social Finance may access a limited amount of PID – first names, email addresses, and phone numbers. We will also collect audio recordings of individuals who participate in recorded interviews (we will ask interviewees to turn off their camera prior to starting the recording). This falls under the definition of Personal Information. We will instruct all research staff who have access to PID not to download any PID or transfer any PID outside of Social Finance's secured SharePoint, Qualtrics, Teams, or Dovetail accounts. Additionally, by the time Social Finance begins collecting data for the evaluation, all members of the research team will have completed the Human Research Protection Training provided by the U.S. Department of Health and Human Services. Research team members who interview clients will undergo training on trauma-informed interviewing, as described in Study Procedures.

Under the agreement with CDSS, Social Finance has committed to instruct all employees with access to PID regarding:

1. The confidential nature of the information;
2. The civil and criminal sanctions against unauthorized access, use, or disclosure found in the California Civil Code Section 1798.55, Penal Code Section 502 and other state and federal laws;
3. CDSS procedures for reporting actual or suspected information security incidents in Paragraph V - Information Security Incidents and/or Breaches of our contract with CDSS; and
4. That unauthorized access, use, or disclosure of CDSS PID is grounds for immediate termination of this Agreement with CDSS and Social Finance

STAFF VETTING PROCEDURES

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

There are several layers of staff vetting protections in place for all Social Finance employees with access to data associated with this project:

1. In accordance with Social Finance's agreement with CDSS to conduct this research, before a member of Social Finance's workforce may access CDSS CSP, Social Finance has committed to conducting a thorough background check of that worker and evaluate the results to assure that there is no indication that the worker may present a risk to CDSS information technology systems and/or CDSS data. Social Finance retains each workforce member's background check documentation for a period of three (3) years following Agreement termination.
2. All are required to have completed Human Research Protection Training provided by the U.S. Department of Health and Human Services before data collection begins at Social Finance.
3. All are briefed on the data requirements of our contract with CDSS and this IRB proposal.

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.

CRISES_Act_IRB_Evaluation_Request_legalupadte11.27.23.pdf

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.

Can you speak to limitations of Dovetail using transcripts for own purposes? Has SF limited this use?

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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.

Social Finance will ensure that data will not be reused or provided to any unauthorized person or entity in the following ways:

In accordance with Social Finance's agreement with CDSS:

1. Training procedures will include instructions for Social Finance employees regarding the consequences of unauthorized access, use, or disclosure of PID.
2. All systems processing and/or storing CDSS PID have a routine procedure in place to review system logs for unauthorized access.
3. Upon expiration or termination of the Agreement between Social Finance and CDSS, or upon a date mutually agreed upon by the Parties following expiration or termination, Social Finance shall return or destroy the CDSS PID.

In addition, any CDSS PID Social Finance collects in connection with this project will reside on secure SharePoint, Qualtrics, Teams, and Dovetail accounts, with limited access granted to three Social Finance staff members working on this project who need access to deliver on the scope of work. Social Finance will limit PID data collected to that which is necessary for the evaluation. Social Finance will instruct pilots participating in this evaluation not to submit any other PID for this project.

CONFIDENTIALITY OF PUBLISHED DATA

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

We will not publish any PID collected through this project. Additionally, we will avoid publishing combinations of identifiers (e.g., gender, race, age, etc.) that could possibly identify specific individuals if the sample size is less than 11.

In accordance with Social Finance's contract with CDSS, we will de-identify the report pursuant to the CalHHS Data De-Identification Guidelines and the CDSS Data De-Identification Reference Guide to ensure the information in the report cannot be used to identify any of the individuals in the report.

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?

Social Finance will request only the minimum necessary data to answer the research questions outlined above. During the evaluation design phase, Social Finance engaged extensively with CDSS, pilots, and community stakeholders to narrow down and refine the list of data in line with research goals. This project will not access any data from pilots that is recorded earlier than the date of study approval by the IRB (spring 2025) or later than October 31, 2026 (the due date of our final report).

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.

Yes. Any CDSS PID Social Finance collects in connection with this project will reside on a secure SharePoint, Qualtrics, Teams, and Dovetail accounts, with limited access granted to three Social Finance staff members on this evaluation team who need access to deliver on the scope of work. Data on the site is only accessible by authorized personnel via a Microsoft username and password that uses multi-factor authentication.

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.

In accordance with Social Finance's contract with CDSS, we will de-identify the report pursuant to the CalHHS Data De-Identification Guidelines and the CDSS Data De-Identification Reference Guide to ensure the information in the report cannot be used to identify any of the individuals in the report. For example, Social Finance will not publish any information that could be used to identify an individual and which is based on small quantities of data (i.e., results involving fewer than 11 individuals). To the extent that we collect data from any groups representing fewer than 11 individuals, we will combine those groups with others before making any characterizations about those aggregate counts. Prior to publishing a final report, we will review the counts of any data disclosed to ensure that summary data follows this principle.

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*

CRISES IRB Data Security Letter 2024-12-18_docusign.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.

No

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?

See comment above about uploaded transcripts that may contain other information (e.g., medical diagnoses) that may be uploaded to Dovetail unless SF is redacting this information.

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data will be de-identified

Explain what identifiers will be removed and how.

Certain identifiable fields from the survey (such as name, email, phone number) will be stripped from the analysis file and stored separately and securely during data analysis. This limits access and exposure to sensitive information for only those times where it is necessary (such as conducting incentive lotteries and distributing payments). The evaluation team will also strip any PID fields (such as name, email, and phone number) from all interview transcripts and notes prior to coding and analysis. It is possible that interview recordings generated during Microsoft Teams interviews may contain identifiable information; these will be stored only in the secure Microsoft Teams account.

Upon conclusion of the study, all survey and interview data, including transcripts and recordings, will be deleted.

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.

N/A – there will be no PID in paper form

FAXING

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

N/A – PID will not 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.

N/A – there will be no PID in paper form

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.

There will be no PID in paper form. The only PID in electronic form will be saved on secure SharePoint, Qualtrics, Teams, and Dovetail accounts, with limited access granted to three Social Finance staff members on this evaluation team who need access to deliver on the scope of work. Data on the site is only accessible by authorized personnel via a Microsoft username and password that uses multi-factor authentication. Social Finance staff will not download any PID for this project onto their personal laptop computers or portable electronic storage media.

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.

N/A – As noted earlier, there will be no PID in paper or electronic form that will be saved anywhere except secure SharePoint, Qualtrics, Teams, and Dovetail accounts, with limited access granted to three Social Finance staff members on this evaluation team who need access to deliver on the scope of work. Data on the site is only accessible by authorized personnel via a Microsoft username and password that uses multi-factor authentication.

SERVER SECURITY

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

There will be no PID in that will be saved anywhere except for secure SharePoint, Qualtrics, Teams, and Dovetail accounts, with limited access granted to three Social Finance staff members on this evaluation team who need access to deliver on the scope of work. Data on the site is only accessible by authorized personnel via a Microsoft username and password that uses multi-factor authentication.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

No information that could be used to identify an individual respondent will be used in any public report. Certain identifiable fields will be stripped from analysis files and stored separately and securely during data analysis. This limits access and exposure to sensitive information for only those times where it is necessary (such as conducting incentive lotteries and distributing payments). Upon conclusion of the study, the survey data will be deleted.

DISK STORAGE

State whether all disks with PID will be destroyed.

N/A – As noted earlier, there will be no PID in paper or electronic form that will be saved anywhere except a secure SharePoint, Qualtrics, Teams, and Dovetail accounts, with limited access granted to three Social Finance staff members on this evaluation team who need access to deliver on the scope of work. Data on the site is only accessible by authorized personnel via a Microsoft username and password that uses multi-factor authentication.

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 and passwords.

FIPS 140-2 COMPLIANCE: WORKSTATIONS

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

Yes. As noted in Social Finance's contract with CDSS, all Social Finance-owned or managed workstations, laptops, tablets, smart phones, and similar devices that process and/or store CDSS PID must be encrypted using a FIPS 140-2, until deprecated, certified algorithm which is 128 bit or higher, such as Advanced Encryption Standard (AES). The encryption solution must be full disk unless approved by the CDSS Information Security Office.

FIPS 140-2 COMPLIANCE: LAPTOPS

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

Yes. As noted in Social Finance's contract with CDSS, all Social Finance-owned or managed workstations, laptops, tablets, smart phones, and similar devices that process and/or store CDSS PID must be encrypted using a FIPS 140-2, until deprecated, certified algorithm which is 128 bit or higher, such as Advanced Encryption Standard (AES). The encryption solution must be full disk unless approved by the CDSS Information Security Office.

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.

N/A – As noted earlier, there will be no PID in paper or electronic form that will be saved anywhere except a secure SharePoint, Qualtrics, Teams, and Dovetail accounts, accessible only by authorized personnel via a Microsoft username and password that uses multi-factor authentication.

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.

Yes. As noted in Social Finance's contract with CDSS, to correct known security vulnerabilities, Social Finance shall install security patches and updates in a timely manner on all Social Finance-owned or managed workstations, laptops, tablets, smart phones, and similar devices that process and/or store CDSS PID as appropriate based on Social Finance's risk assessment of such patches and updates, the technical requirements of Social Finance's systems, and the vendor's written recommendations. If patches and updates cannot be applied in a timely manner due to hardware or software constraints, mitigating controls will be implemented based upon the results of a risk assessment.

PASSWORD CONTROLS

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

Yes. As noted in Social Finance's contract with CDSS, all users must be issued a unique username for accessing PID. Social Finance's password policy must be based on information security best practices for password length, complexity, and reuse.

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. Social Finance's contract with CDSS has the following provisions regarding electronic security controls:

2. System Security Controls

a. System Timeout. The system providing access to the CDSS PID must provide an automatic timeout, requiring re-authentication of the user session after no more than thirty (30) minutes of inactivity for applications, and fifteen (15) minutes of inactivity for desktops and laptops.

b. Warning Banners. All systems (servers, desktops, laptops, etc.) containing CDSS PID must display a warning banner at login stating that data is confidential, systems are logged, and system use is for business purposes only. Users must be directed to log off the system if they do not agree with these requirements.

c. System Logging. The system must maintain an automated audit trail which can identify the user or system process which initiates a request for CDSS PID, or which alters CDSS PID. The audit trail must be date and time stamped, must log both successful and failed accesses, must be read only, and must be restricted to authorized users. If CDSS PID is stored in a database, database logging functionality must be enabled. Audit trail data must be archived for at least one (1) year after occurrence.

d. Access Controls. The system must use role-based access controls for all user authentications, enforcing the principle of least privilege.

e. Transmission Encryption. All data transmissions of CDSS PID by Social Finance outside the secure internal network must be encrypted using a FIPS 140-2, until deprecated, certified algorithm, such as Advanced Encryption Standard (AES), with a 128bit key or higher. Encryption can be end to end at the network level, or the data files containing CDSS PID can be encrypted. This requirement pertains to any type of CDSS PID in motion such as website access, file transfer, and email.

f. Intrusion Detection. All systems involved in accessing, holding, transporting, and protecting CDSS PID that are accessible via the Internet must be protected by a comprehensive intrusion detection and prevention solution.

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.

As noted above, all data transmissions of CDSS PID by Social Finance outside the secure internal network must be encrypted using a FIPS 140-2, until deprecated, certified algorithm, such as Advanced Encryption Standard (AES), with a 128bit key or higher. Encryption can be end to end at the network level, or the data files containing CDSS PID can be encrypted. This requirement pertains to any type of CDSS PID in motion such as website access, file transfer, and email.

INTERNET ACCESSIBILITY

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

Yes. But it will only be accessible via a secure SharePoint, Qualtrics, Teams, and Dovetail accounts, with limited access granted to three Social Finance staff members on this evaluation team who need access to deliver on the scope of work. Data on the site is only accessible by authorized personnel via a Microsoft username and password that uses multi-factor authentication.

DISPOSING OF PID

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

Electronic PID will only be stored in secure SharePoint, Qualtrics, Teams, and Dovetail accounts with limited access managed via role-based access control (RBAC). At the conclusion of the project, all data with PID will be deleted from the environment, as well as any backup repositories or trash/recycling containers.

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 comments above regarding consent form timing and possibility of supplying the questions prior to the interview.

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See instructions and examples on CPHS website.

During routine follow up with clients, pilots will use the script provided in Attachment 3 to ask clients who received services if they would be willing to complete a client satisfaction survey to share more about their experiences with the program. If clients agree to have the survey sent to them via text or email, pilots will send a survey link to clients via text or email within 24 hours of follow-up conversations. A Spanish language version of the verbal invitation script and survey invitation text will be provided for clients who prefer Spanish. Social Finance will provide the Spanish language script to sites with Spanish language speaking staff who are equipped to communicate with Spanish speaking clients.

Individuals who receive the link to the client satisfaction survey via text or email will be asked to fill out a consent form before they are able to fill out the survey. The informed consent language included in Attachment 4 includes:

- A statement that the study is research/its purpose,
- Description of foreseeable risk/discomforts,
- Description of benefits
- Statement regarding confidentiality of the records,
- Statement regarding minimal risk for participant involvement,
- Explanation of whom to contact for questions about the research,
- Statement that participation is voluntary

A Spanish language version of the survey consent form will be provided for clients who prefer Spanish.

Once individuals have read through the consent language, they will optionally consent to the following (as 3 separate steps): 1) participating in the survey, 2) entering a lottery for a chance to receive a \$25 gift card after submitting the survey, for which they would provide their first name and email address or phone number in order to receive an incentive payment; 3) agreeing to be contacted for a 1:1 interview in the future to learn more about their experiences with the program, for which they would provide their first name and email address or phone number in order to be contacted.

Individuals who agree to be contacted for a 1:1 interview to gather more feedback about the program will be sent a message over text or email (outlined in Attachment 6) with instructions to complete an online informed consent form for the interview which can be found in Attachment 5. Social Finance will not contact anyone for interviews until or unless the IRB has approved our proposed plan to do so.

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.

Attachment 4 - Client Consent Form and Satisfaction Survey.docx	Consent Form
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Attachment 4B - Client Consent Form and Satisfaction Survey Spanish_June 2025 Submission.docx	Consent Form
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Attachment 5 - Interview Participant Consent and Questions_June 2025 Submission.docx	Consent Form
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TRANSLATED DOCUMENTS

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

Attachment 4B - Client Consent Form and Satisfaction Survey Spanish_June 2025 Submission.docx	Consent Form
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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.

Fried_Resume & Credentials pg3.docx	Translator Curriculum Vitae
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HIPAA Determination

HIPAA INSTRUCTIONS

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

COVERED ENTITY

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

No

HEALTHCARE PROVISIONS

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

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

Yes

HIPAA WAIVER

Are you requesting a waiver or alteration of HIPAA authorization?

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.

Yes

Provide a detailed description of the protected health information (including databases and variable names) to be utilized, and the HIPAA covered entity for which a waiver or alteration of authorization is required.

As described in Study Procedures, pilots are required by statute to collect service delivery data and report it to CDSS. No personally identifiable data (PID) or HIPAA variables will be reported as part of pilots' quarterly service delivery data submissions to CDSS, which are also shared with Social Finance for purposes of the research. However, to compile data for the service delivery data submissions, some of the pilot sites will obtain the data from records that are covered by HIPAA. Social Finance will require a waiver to access this data for the evaluation, which is stored on CDSS' secure data collection platform as described in Electronic Safeguards. The service delivery data variables are outlined in the data collection template in Attachment 2. The variable names include:

- Quarter of call
- Time of call
- Who placed the call
- Call origin
- Screening: Mental health-related call
- Screening: Drug or alcohol related call
- Screening: Safety threats indicated by caller
- Screening: Abuse
- Time of arrival on scene
- Time of departure from scene
- Called for police or medical backup
- Psychiatric hospitalization
- Transport location
- Other service provided
- Responder safety
- Client refused service
- Crisis resolved on scene
- Referral to 9-1-1
- Referral to ER / hospital
- Referral to mental health treatment
- Referral to substance use treatment
- Referral to housing support
- Referral to workforce support
- Referral to other support
- Follow-up event

- Follow-up format

If pilot sites are not already collecting certain data elements as part of their programs, they may omit those fields when submitting the data to CDSS; the data elements in the template are recommended but not required fields.

Below is a description of pilot-specific data sources that each pilot site has informed us they will draw from to compile the service delivery data reports to submit to CDSS. Three sites are obtaining the data from HIPAA-protected sources. (The Social Finance evaluation team is not involved in pilot sites' service delivery data collection processes. The evaluation team will only access the completed data reports submitted to CDSS to support the evaluation.)

Marin County: Marin County's CBO partner, the Marin County Cooperation Team, is still establishing its data collection protocols. To manage its HIPAA-covered data, Marin County will either use a third-party Electronic Health Record (EHR) system, such as SmartCare or Epic, or develop an internal HIPAA-compliant reporting and filing system.

Santa Cruz County: Santa Cruz County's CBO partner, Family Services Agency of the Central Coast, tracks crisis response data for each call using an Excel data collection workbook. This data is uploaded onto AVATAR EHR, where records are stored in compliance with HIPAA standards.

Sacramento County: The Sacramento County Department of Health (BHS), in partnership with CBO partner Bay Area Community Services, Inc, uses a HIPAA-compliant electronic health care system called Smartcare. This system stores details about the mobile crisis request, response, and intervention (when applicable), including follow-up care.

City of Oakland: Since Oakland's CBO partner, Family Bridges, does not provide direct services as a health care provider, they have informed us they will not be collecting HIPAA-covered data. Family Bridges collects dispatch-related data through the Trek Medics Beacon Platform (used for dispatch data collection), and crisis responders collect data through Microsoft 365.

Provide a description of why the research cannot practicably be conducted without the waiver or alteration.

If Social Finance did not receive a HIPAA waiver, Social Finance would have to ask pilot sites to collect HIPAA authorizations from individuals at the time of crisis, which is not feasible for the following reasons:

1. **Client Distress and Vulnerability:** Individuals experiencing a crisis are often in a state of distress and vulnerability. Requesting consent to share HIPAA data in such moments can exacerbate their emotional and psychological state, potentially causing further harm. It is inappropriate to burden them with consent procedures during these critical times.

2. **Pilot Capacity:** Clients have unique crisis response service delivery models and data collection approaches that Social Finance seeks to avoid disrupting. If Social Finance were to request an authorization process as part of

C.R.I.S.E.S. response services, it would create an additional requirement for crisis responders to manage, when they have limited resources to operate the program and are focused on meeting clients' needs.

Provide a rationale for why the research could not practicably be conducted without access to and use of the protected health information.

The research conducted under the CDSS C.R.I.S.E.S. Pilot Program is aimed at evaluating the effectiveness of crisis intervention services provided to individuals in distress. To conduct a thorough evaluation and answer the research questions of this evaluation, it is crucial to have access to detailed and accurate data about the individuals served and the services provided to them, as outlined in Attachment 2 (template outlining service delivery data elements). Multiple pilots store this information in HIPAA-compliant systems.

Provide a detailed account of the plans and measures that will be in place to protect identifiers from improper use and disclosures.

Pilots will not submit any identifiers in their service delivery data submissions to CDSS. No identifiers are included in the sample template, and Social Finance will instruct pilots to exclude any identifiers from the submissions.

For the client satisfaction survey, the names, phone numbers, and/or email addresses collected by Social Finance will only be provided by the respondent in the survey hosted on Microsoft Forms. We will ensure that electronic PID will only be stored in Qualtrics and Social Finance's Microsoft cloud environment on our SharePoint site with limited access managed via role-based access control (RBAC). At the conclusion of the project, all data with PID will be deleted from the environment, as well as any backup repositories or trash/recycling containers. There is no health or research justification for retaining the identifiers.

For the interviews, conversations will be recorded via Microsoft Teams. Interviewees must turn their video off prior to the recording. Recordings will only include the individual's first name and an audio recording of the conversation which may include any personal details individuals choose to share during the interview. All recordings and transcripts will be securely stored on Social Finance's Microsoft Teams cloud environment, as well as Dovetail, with limited access managed via role-based access control (RBAC). At the conclusion of the project, all data with PID will be deleted from the environment, as well as any backup repositories or trash/recycling containers. There is no health or research justification for retaining the identifiers.

In addition, Social Finance will maintain the administrative and physical safeguards detailed in this application to maintain data security over the course of the project.

Provide a detailed description of the plans to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a health or research justification for retaining the identifiers or if such retention is otherwise required by law, include that rationale in your response.

Pilots will not submit any identifiers in their service delivery data submissions

to CDSS. No identifiers are included in the sample template, and Social Finance will instruct pilots to exclude any identifiers from the submissions.

For the client satisfaction survey and interviews, the PID collected by Social Finance will be deleted at the conclusion of the project, as well as any backup repositories or trash/recycling containers. There is no health or research justification for retaining the identifiers.

In addition, Social Finance will maintain the administrative and physical safeguards detailed in this application to maintain data security over the course of the study.

Amendment Changes

List the pages and questions that have been changed.

The following sections have been modified in the IRB application to account for additions and modifications to study procedures. The proposed addition of interview protocols is largely responsible for the majority of additional context added to the original response in these fields.

I. Project Information

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

PROJECT TYPE DETAILS: Indicate which, if any, apply to this research. Check all that apply.

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.

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.

II. Project Details

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.

RECORDINGS: Will audio or video recording occur? / Describe how the recordings will be maintained during and upon completion of the project. Describe what will become of the recordings after use (e.g., shown at scientific meetings, erased, etc.).

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.

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

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.)?

SCREENING: Will subjects be screened prior to entry into the research?

COMPENSATION: Will subjects be compensated 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.

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.

AUDIO/VIDEO RECORDING RISKS: State if audio/video taking could increase

potential risk to subject's confidentiality.

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 are provided, state that clearly.

LESS RISKY METHODS: Describe any less risky methods and why they are not being used.

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.

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

Administrative Safeguards

HIPPA IDENTIFIERS

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.

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.

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.

Physical Safeguards

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

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.

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.

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

STORING IDENTIFIERS: Indicate whether identifiers will be stored separately from analysis data.

DISK STORAGE: State whether all disks with PID will be destroyed.

Electronic Safeguards

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.

INTERNET ACCESSIBILITY: Note if PID in an electronic form will 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.

Informed Consent Procedures
INFORMED CONSENT PROCEDURES
CONSENT FORMS

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

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

HIPAA Determination

HIPAA WAIVER

Provide a detailed description of the protected health information (including databases and variable names) to be utilized, and the HIPAA covered entity for which a waiver or alteration of authorization is required.

Provide a detailed account of the plans and measures that will be in place to protect identifiers from improper use and disclosures.

Provide a detailed description of the plans to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a health or research justification for retaining the identifiers or if such retention is otherwise required by law, include that rationale in your response.

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

See comment above about incomplete interviews/researchers' plan for completing 6 full interviews or 6 interviews (per site) only regardless of completion status.

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Yes

Attach a copy of your project budget here

C.R.I.S.E.S. Budget for IRB 06.26.25_June 2025
Revision.xlsx

Project
Budget

Deleted Attachments: 1 (Most Recent: C.R.I.S.E.S. Budget for IRB 06.26.25_June 2025 Revision.xlsx on 06/27/2025 7:46 PM ET)

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

Social Finance CRISES IRB Cover Letter 2025-06-30
Signed.pdf

Cover
Letter

Deleted Attachments: 1 (Most Recent: Social Finance CRISES IRB Cover Letter 2025-06-30 Signed.pdf on 06/30/2025 3:16 PM ET)

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

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