

## View xForm - Project Application v6

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

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**Data entry**

**New Submission Study Personnel**

## NEW CONTACT INSTRUCTIONS

February 2025 cycle. \_\_\_\_\_ Was Tabled to the April Cycle.  
\_\_\_\_\_ HSC Project \_\_\_\_\_

A DSL from Social Finance is attached.

A LOS from CDSS is attached.

01/06/2025 • Sussan Atifeh • Internal

### Summary:

Researchers from Social Finance have submitted this application to request approval for a project involved with human subjects' contacts. The California Department of Social Services (CDSS) Office of Equity is working with a nonprofit called Social Finance to evaluate a pilot program called the C.R.I.S.E.S. Act Grant Pilot Program. This program aims to reduce the reliance on police for crisis situations that don't involve fires or medical emergencies.

This project involves data collection from various sources, including:

- Programmatic data: Collected by pilot sites during client intake, crisis response, and follow-ups. This data will be shared with the evaluation team at Social Finance.
- Interviews and focus groups: Conducted with clients who received crisis response services, their family members, community stakeholders, grantee and CBO staff members, and other partners.

- No request for state data.
- Project is funded by CDSS.

01/07/2025 • Sussan Atifeh • Internal

Dear Researchers: Please check all pages of the application (scroll down to see the entire page), address the comment(s), and resubmit the application.

Thanks,

01/07/2025 • Sussan Atifeh • *Not* Internal • Resolved

*If personnel are not found by their email address while trying to complete the*

following questions, you can add them in the system with the link below. Click on the "New Contact Form" and complete it. Within a few minutes of completing the form, you will receive an email notifying you of the availability of the new contact. You should then be able to add them in the subsequent questions.

New Contact Form

## PRINCIPAL INVESTIGATOR (PI)

**Enter the Principal Investigator's email address.**

for PI's institution, please select Social Finance - Boston from the dropdown menu.

01/06/2025 • Sussan Atifeh • Not Internal • Resolved

Catherine Dun Rappaport, MPP

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

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

Social Finance - Boston

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

Boston

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

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

Massachusetts

**Attach a copy of the PI's Curriculum Vitae.**

Dun Rappaport\_Resume.docx PI Curriculum Vitae

Deleted Attachments: 1 (Most Recent: Dun Rappaport\_Resume.pdf on 01/03/2025 2:47 AM ET)

## CO-PRINCIPAL INVESTIGATOR (CO-PI)

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

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

Alina Xu, MBA/MPA

**Email:** axu@socialfinance.org

**Business:** (510) 449-8961

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

Xu\_Resume.docx Co-PI Curriculum Vitae

## ADMINISTRATIVE CONTACT

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

Matthew La Rocque, MPP

**Email:** mlarocque@socialfinance.org

**Business:** (310) 923-2482

## RESPONSIBLE OFFICIAL (RO)

**Enter the RO's email address.**

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

Jake Segal, BA

**Email:** jsegal@socialfinance.org

**Business:** (978) 621-4025

## OTHER RESEARCH STAFF

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

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

Matthew La Rocque, MPP

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

Sarah Osborn, BA

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

Amber Ivey, JD / MPA

**Email:** aivey@socialfinance.org **Business:** (757) 971-8622

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

False

## 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

## PROJECT SITE

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

Social Finance

## STUDY PROCEDURES

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

Do you need access to any state data for conducting this study? If yes, please select "Data Registry."

If no, disregard this comment. Thanks.

01/07/2025 • Sussan Atifeh • Not Internal • Resolved

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  
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.**

Projects cannot begin before they have been reviewed. The earliest possible start date is always the date of the next public meeting at which the project will be heard. Please select 2/7/2025 or a date following this date within a few weeks. thanks.

01/06/2025 • Sussan Atifeh • Not Internal • Resolved

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

04/04/2025



**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.**

It seems that the first part of the purpose is incomplete?

03/23/2025 • Laura Lund, MA • *Not Internal*

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).

Social Finance’s study will focus on CDSS’s C.R.I.S.E.S. pilot program. It 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 answer these research questions by collecting and 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

## **MAJOR RESEARCH QUESTION**

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

The following research questions were defined at the outset of this work and 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)? Effective measures will vary based on available data and specific pilot interventions. Examples include:
  - 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?

## 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**

Are there any research staff from CDSS who interact directly with participants (as in interviews or focus groups)? Please clarify in this section.

01/07/2025 • Sussan Atifeh • *Not Internal* • Resolved

[Not applicable] The informed consenting process for 2 pilots (missing)/client satisfaction/Stakeholder interviews/Family member contact is lacking as currently described with respect to Title 45 CFR 46. The consent documents should have: a statement that the study is research/its purpose, description of foreseeable risk/discomforts, description of benefits, possible alternative procedures (if applicable), 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 (not just permission to skip a question). Participants should also be permitted to read/review language to consider versus hearing a statement and avoid coercion/have sufficient time to review and ask questions. Additionally, they should be given a copy for their records unless a waiver of written consent is being requested. Given the study description, I do not see reasoning for the potential request for a written consent waiver.

If in the Client satisfaction it is explained that their names will not be shared, then how would the follow up interview/focus group be conducted? This conflicts with the interview procedures that ask them to disclose their names and locations as well as how/reasons involved in the program.

You outlined that the client satisfaction may "elicit strong emotions or memories related to trauma" - what is the plan to mitigate or respond to such risk? What support is provided to participants if they experience distress during/after the study?

For client satisfaction: "pilots may make modifications to the response formats to align with programming in their site." and "Pilots can adjust these questions based on the client's experience and context, and each pilot's specific goals and program design." - We cannot approve materials that may change without explicit options of how they would change.

For client satisfaction, the format of in person conversation, call, text, and survey form are all listed as modalities for collecting this information. Scripts for each of these need to be submitted.

01/24/2025 • Jonni Johnson, PhD • *Not Internal*

[Not Applicable] You mention in the Attachment 3 informed consent and questionnaires document that interviews will take place in-person, but this is not described in the procedure. Do you intend to conduct in-person (versus virtual) interviews?

For the specific interview and focus group questions, you indicate that some questions are subject to change based on program design. Only approved materials can be used. If you anticipate that e.g., Sacramento versus Oakland questions will vary then please submit specific questions that will be used at each pilot site to be evaluated in all languages that are intended to be included.

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

I made similar comments throughout the application for sections that included these statements -- but outlining specifically here for the research team: We cannot approve materials that are not presented in the application. Places where you indicate "Examples include" or members will be from this group but not limited to is not sufficient. Approval is limited to inclusion in this protocol. If any change is to be made to research question, study personnel access to data, change in procedure, modified consent method, then an amendment will need to be submitted for approval to the board.

[Not Applicable] Elsewhere you mention that consent and possibly interviews will be conducted in different languages other than English. These copies will need to be submitted for

approval as well.

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

For client satisfaction, you indicate that conversations will not be record, but anonymized data collected will be shared. Please elaborate what is meant by data will be anonymized. Will the customer satisfaction data be shared at the individual (record) level or will pilot sites only share data that has been aggregated in some way? You mention that you plan to make the interviews representative of the geographic/demographic of area, will this not require the sharing of data in some way? If individual level data, please provide a list of the specific data fields that will be shared with the research team by the pilot sites. If data will be aggregated, please provide the specific data fields that will be shared and the plan for aggregation. Please provide the specific questions that will be asked. How are people recruited for these surveys? Is everyone served by the pilot site asked to participate? Are exclusion criteria applied? If so, why?

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

[Not Applicable] It would be helpful to clearly articulate as in the compensation section the number of participants as well as information on who they are, how many are being recruited, if and how that recruitment is targeted, and how the subjects will be recruited. Only email scripts in English are included, but you also indicate that there will be phone calls and text messages -- and possibly other languages. You also indicate that the materials may vary between pilot sites. All of these variations need to be included for approval.

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

[Not Applicable for specifics but - Updated comment by Ms. Lund regarding this] Regarding the family member participation: Please provide the script that you will use to ask individuals to provide the name of a family member to participate in the study. Where is this information then kept electronically?

It is important that the language used for all consents is not coercive and does not make the subject uncomfortable if they refuse. If you are only going to ask for 6 family members how

will you choose which participants to ask to share this information with you? The consent language should let participants know that this is something you will ask for, why you are asking, what you will ask, and how you will use the information. If it is the case that family members may not know that the subject accessed services there should be a caveat in the consent that by contacting family members you cannot ensure the confidentiality of some of the subject's private information.

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

[Not Applicable] A pre-test group is mentioned (i.e.,  $n = 2$ ). Since the researchers plan to test the questions on representatives of the vulnerable population this pre-test should be handled as a pilot test in the participating subjects are appropriately consented prior to administration of the interviews.

How are these pre-test subjects selected? This should be described in the procedures. The final version of the interview instrument for this pilot test as well as any recruitment materials should be included in the protocol. If after conducting the pre-test interviews it is determined that the procedure should be modified then an amendment will need to be submitted to CPHS for approval.

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

There is a reference in a couple of places in the protocol to receiving 'other' data from the pilot sites beyond what has been listed in the protocol and encouraged to share any other data they like with you. Only the data fields approved in the protocol may be shared by the pilot sites with the research team for the purposes of this study. Pilot sites may not share, and the research project cannot incorporate, additional data that has not been reviewed and approved by the IRB.

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

[Not Applicable] There are concerns with the project procedures Attachment 4 including:  
Information provided by the client to the agency for the purpose of receiving services cannot be used for research unless that person gives consent or there is statutory

authority to use the information without the individual's consent or a waiver of consent is obtained. If the source of the information falls under HIPAA, a HIPAA authorization or waiver will be necessary. Several of the sources cited (e.g., notes from mental health professionals or first responders) would seem to be protected by HIPAA.

In Table 3—how is the unique identifier created? Is there a crosswalk with the personally identifying information about subjects linked to the unique identifier? Who has access to this file, what's in it, where is it stored?

Table 3—There is a field identified as 'call location', but specific information about the contents of this field is not provided. This field should be the largest geographic unit that would provide meaningful data to meet your research goals. You should describe how you will ensure that the pilot sites do not send you specific addresses of subjects even if they collect those for program purposes.

Table 3—You state 'ideally' the pilot sites will not share PID with you. No justification has been provided for needing any PID for this study. Please describe the procedures you will put in place to ensure that no PID is shared with you by pilot sites and what you will do if PID is received in error.

Table 3—Why do you need zip code?

Table 3—you propose to collect information on whether individuals received psychiatric hospitalization. This is highly sensitive information. Please describe how you will ensure that this information is not associated with any information that could directly or indirectly identify an individual.

Is the information from the intake forms, responder notes, etc. only for individuals who have consented to participate in this study? If not, how many individuals will be included?

Do some of the responders providing information/notes have a duty of confidentiality under the law? If so, is it not a violation of this duty to share the information with the research team without the specific consent of the participant and a HIPAA waiver where appropriate?



--Table 4—If the client satisfaction survey is a source of data for this research then the survey must be submitted for approval. The protocol mentions that different sites may use different instruments/questions—all instruments and questions must be submitted for approval. Local pilot sites may have the option of omitting some questions (optional questions should be noted in the final version of submitted materials) but they may not change the wording.

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

[Not Applicable] It appears that you plan to record interview sessions that occur over Zoom but not those that occur in person. Why? Why is recording necessary? What will you do with the recordings?

[Not Applicable] Will interview questions be collected over text/email/phone?

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

I am still not clear on the eligibility criteria for inclusion in the client satisfaction survey arm of this study. Who is eligible to be recruited/how is eligibility defined? What are the inclusion/exclusion criteria?

03/23/2025 • Laura Lund, MA • *Not Internal*

Researchers state:c. Social Finance will develop protocols for collecting, anonymizing and ensuring the quality of data collected from sites, and establish procedures that safeguard data, as described further throughout the Study Procedures section.

Please describe your plans for 'anonymizing' the data. I could not find a description of this process anywhere. De-identification and anonymizing are not synonymous.

03/23/2025 • Laura Lund, MA • *Not Internal*

Researchers state: 2. Collect pilot-specific data on program design, staffing, and operations, including data on:

a. Pilot design processes: Summary of pilot design decision making process, including brief descriptions of community

engagement activities (i.e., the types of people and organizations engaged, the numbers engaged, the methods of engagement, and general insights gleaned from those engagements)

b. Team structure: Composition and roles of the team implementing the crisis response pilot (including whether the actual team structure matches the original proposal in the original grant agreement)

c. Team demographics: Summary of client-facing crisis response team demographics at an aggregate level, including race/ethnicity and gender identity

d. 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.

e. Training summaries: Summaries of any training that the client-facing crisis response team received.

This part of the study is not subject to human subjects review. It appears from this description that data are being collected at the program level and not the individual level, and that the data about demographics, etc., refers to team members and not program participants, and will be provided descriptively in the aggregate. Summary descriptions of program services do not require IRB approval as no human subjects are involved.

I would strongly urge that this application be revised to include only those aspects of the research that require IRB approval. As written this application is difficult to follow because of the multiple arms of the study and the lack of adequate specificity in some important areas. It would be much easier for reviewers to follow if the unnecessary complexity of study components that do not require IRB review was removed.

03/23/2025 • Laura Lund, MA • *Not Internal*

Researchers state: 3. Collect service delivery data from pilots.

a. 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.

b. Service delivery data collection: Pilots will provide data on delivery of crisis response services at a quarterly cadence, at the individual level, using anonymized unique identifiers (see Attachment 1 outlining the purpose of the unique identifiers and how they will be created). Data on service delivery includes data collected by pilots in the course of delivering crisis response services, including during client intake, crisis response, and follow-ups with clients. Specific data fields to be collected 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 (see Attachment 2 for more detail on what we propose to collect, and Attachment 3 for our service delivery data collection template). Because we do not know exactly how many individuals will request and receive alternative crisis response services, we do not know exactly how many records will be generated from service delivery data. However, no personally identifiable data (PID) or HIPAA fields will be collected as part of these quarterly data submissions, thereby enabling pilots to honor their duty of confidentiality to the individuals they are serving.

I am concerned about the researcher's statement regarding duty of confidentiality. Duty of confidentiality extends beyond PID or HIPAA identifiers. If an individual's record is subject to HIPAA none of the information in the protected record may be used for research without the knowledge and consent of the individual (via a HIPAA authorization) or unless there is a HIPAA waiver. In reviewing the planned service data collection tool, the key question would be whether this information is obtained from/abstracted from confidential records that are subject to HIPAA. Please state the specific source of this information (data collected by pilots is very vague) and whether it is covered by HIPAA (mental health records and medical records are covered as well as some other types of

encounter data for mental health/medical services). If this information is obtained from a source covered by HIPAA, researchers will need to request a HIPAA authorization from the individuals whose data is being used or request a HIPAA waiver for this study.

03/23/2025 • Laura Lund, MA • *Not Internal*

Researchers state: 4. Ensure quality data on service delivery by training pilots on data collection, and by cleaning and conducting quality checks on data submitted.

a. To ensure that data is high quality and to mitigate bias, we will encourage pilots to do the following:

(i) Make consistent use of templates through which they can record, export, and submit service delivery data on a quarterly basis, such that the structure of the data (number of rows, number of columns, column names and categories) never changes.

(ii) Train their staff in data collection to ensure that staff recording data have a shared understanding of the tools and data categories.

(iii) Enter data directly into forms, spreadsheets, or other databases on phones, tablets, or PCs, soon after interacting with clients. If a responder waits hours or days after an interaction to input data, recollections of the response may not be as fresh and/or primary source notes from the event may be difficult to transcribe with accuracy. We will instruct pilots not to share any service delivery data with the evaluation team beyond the fields described in Attachment 2.

(iv) Clarify reasons for missing or incomplete data. If a response team is unable to collect a particular piece of data, it is preferable for the team to enter explanatory information such as "RESPONDENT REFUSED" or "DID NOT ATTEMPT TO COLLECT" to explain why data is missing.

Please note, it is not sufficient to 'encourage' pilot sites to collect the data using approved methods (approved by the IRB, including forms, data fields, etc.) and to train pilot sites to use approved data collection methods. It is the responsibility of the PI of the study to ensure that the approved data collection methods and appropriate training are adhered to by all sites and to assure the IRB of this.

Researchrs state: c. As part of the data cleaning process, we 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; 3) communicate reminders to pilots to avoid including these fields in the future.

Thank you for having a plan in place in the event of an unintentional disclosure. Please also state how you will ensure that no PID or HIPAA fields will be included in the data submitted to you by the pilot sites. How will you train them, what safeguards will you put in place? This is not a minor issue. No PID should 'accidentally' be transmitted to you by sites. This would be a violation not only of the research protocol (and a reportable adverse event) but of individuals' privacy rights; it could potentially constitute a data breach of confidential PHI that would require disclosing to the affected individuals as well as be subject to possible fines or penalties under law.

03/23/2025 • Laura Lund, MA • *Not Internal*

Regarding the client satisfaction surveys (item 5)

Please describe the population of individuals eligible for recruitment into this arm of your study. During what time period?

03/23/2025 • Laura Lund, MA • *Not Internal*

If I understand correctly, the recruitment procedures for the satisfaction survey are:

1. a member of staff (who?) follows up via telephone or in person with an individual who has requested client services.
2. During that visit/phone call the member of staff provides routine follow up services and then offers the individual the option to fill out a survey.

You state: 2) Pilots will not offer the survey to those who are actively experiencing crisis, have particularly sensitive needs or who are under the age of 18 (additionally, the consent form asks individuals to affirm they are at least 18 before completing the survey).

Please provide examples of what you mean by 'experiencing crisis' and 'particularly sensitive needs'.

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 conversations.

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.

Is this correct?

03/23/2025 • Laura Lund, MA • *Not Internal*

There are equity issues with the proposed 'compensation lottery'. First, it is not compensation. Compensation is money (usually) that researchers pay participants to offset specific costs individuals incur a part of their participation in the research, such as parking fees or lost wages. In this case you are talking about providing an incentive or gift to participants for participating in the research. This is fine, but it must be equitable across all participants who are participating in the research. If everyone has an equal chance to 'win' the \$25 dollars this scheme would be fine, but if the number of individuals participating each month varies then the probability of winning will advantage those who participant in a month when fewer individuals participate compared to a month in which more individuals participate. So, individuals who participate in a month in which 20 people participate have a greater likelihood of receiving the incentive than those who participate in a month with 100 participants. If it is not

possible to find a way to provide an equitable incentive then no incentive should be offered.

03/23/2025 • Laura Lund, MA • *Not Internal*

Researchers state: b. Using site-level service delivery data collected by pilots, we will develop summary statistics reflecting the overall picture of how crisis response services were implemented across sites, while accounting for individual differences in service models across pilots.

Please describe this aspect of your study in more detail. What site level service delivery data are you referring to? Are these the data referenced in item 4? Please describe your planned 'summary statistics' and how these are related to the stated goals and research questions for your study.

03/23/2025 • Laura Lund, MA • *Not Internal*

In reviewing the plan for client satisfaction surveys and service delivery data it is not at all clear why researchers need to associate a unique client ID with either of these data sources. Why is it necessary to associate a unique ID with this information? From a data privacy perspective it would be much better to collect this information without any potentially identifying link to the individual. Unless there is a clear justification for collecting the information associated with a unique identifier please remove the unique ID from the data collection tool.

03/23/2025 • Laura Lund, MA • *Not Internal*

Does attachment 3 contain the same information as Table 3 in attachment 2?

03/24/2025 • Laura Lund, MA • *Not Internal*

Attachment 4 contains this statement:[If answer is yes, pilots collect a preferred phone number or email and send survey link to client's preferred form of contact within 24 hours. Phone numbers and email addresses should be stored electronically in a secure, password-protected location.]

How is the information about phone number/email captured at the time of collection? Is it entered into a paper form? Entered into an electronic database on site?

03/24/2025 • Laura Lund, MA • *Not Internal*

Attachment 4 contains this text: Survey invitation text for Grantees to send to participants by text message or email:

We would like to hear about your experiences with [PILOT PROGRAM NAME]'s crisis response services. Your feedback is important and will be used to improve our services.

If you're able, please click on the following link to take this optional, 15-minute survey and you'll have a chance to win a \$25 gift card: [SURVEY LINK]

Is this the text or email that individuals were told that they would receive within 24 hours? If so, it should contain information that lets them know that you are following up on the previous contact you made in which they expressed interest in participating in a survey (so they know who you are and how you got their text/email), that the link will take them to a consent form which they should read carefully and sign before proceeding to the survey, and provide them with the name of a person they can call or email if they have questions.

03/24/2025 • Laura Lund, MA • *Not Internal*

This statement should be removed from the consent form: If chosen for an interview, you will get \$55.

This application does not include any information about the follow up interview portion of this study. The IRB will need to review all materials related to the follow up interview to determine if a \$55 gift is appropriate. Until this has been approved you cannot tell participants that this is what they will receive.

03/24/2025 • Laura Lund, MA • *Not Internal*

The consent form contains this statement: As with any data collection, there is always a small risk that your information could be lost,

I am not sure what this means? The real concern is that someone else may become aware of the information.



\*Note to reviewers - the study proposal has been significantly revised. Many of the previous comments are no longer applicable. I have place [Not Applicable] at the beginning of the previous comments that no longer apply.

03/28/2025 • Jonni Johnson, PhD • Internal

Study procedures include the following:

1. Develop data collection approach, with an eye toward minimizing data collection burden, collecting meaningful information and focusing on collecting information that directly addresses the research questions.

a. Social Finance will determine what data on service delivery (from pilots) and individual-level data (from individuals who receive crisis response services) will be needed to address research questions. The evaluation team will ensure that targeted data is available and that it is not extractive or burdensome for pilots or individuals to provide targeted data.

b. Social Finance will right-size the work, ensuring that the individual-level client survey is concise and only collects the information needed for the study while offering respondents meaningful opportunities to provide information about their experiences; minimizing solicitation of information that could be triggering; and working closely with pilots to ensure that data collection on service delivery aligns closely with learning goals and data collection capacity.

c. Social Finance will develop protocols for collecting, anonymizing and ensuring the quality of data collected from sites, and establish procedures that safeguard data, as described further throughout the Study Procedures section.

d. For all of the above activities, the evaluation team will collaborate with pilots, CDSS, and members of CDSS' Stakeholder Workgroup, composed of individuals with lived experience related to law enforcement-based and/or alternative crisis response, who advise CDSS and pilots on goals, design, and evaluation of the pilot program. For example, the evaluation team will work closely with pilot staff and Stakeholder Workgroup members to assess whether the client survey captures key elements of feedback from clients that can inform future service delivery, while remaining concise and simple to interpret.

2. Collect pilot-specific data on program design, staffing, and operations, including data on:

a. Pilot design processes: Summary of pilot design decision making process, including brief descriptions of community engagement activities (i.e., the

types of people and organizations engaged, the numbers engaged, the methods of engagement, and general insights gleaned from those engagements)

b. Team structure: Composition and roles of the team implementing the crisis response pilot (including whether the actual team structure matches the original proposal in the original grant agreement)

c. Team demographics: Summary of client-facing crisis response team demographics at an aggregate level, including race/ethnicity and gender identity

d. 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.

e. Training summaries: Summaries of any training that the client-facing crisis response team received.

### 3. Collect service delivery data from pilots.

a. 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.

b. Service delivery data collection: Pilots will provide data on delivery of crisis response services at a quarterly cadence, at the individual level, using anonymized unique identifiers (see Attachment 1 outlining the purpose of the unique identifiers and how they will be created). Data on service delivery includes data collected by pilots in the course of delivering crisis response services, including during client intake, crisis response, and follow-ups with clients. Specific data fields to be collected 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 (see Attachment 2 for more detail on what we propose to collect, and Attachment 3 for our service delivery data collection template). Because we do not know exactly how many individuals will request and receive alternative crisis response services, we do not know exactly how many records will be generated from service delivery data. However, no personally identifiable data (PID) or HIPAA fields will be collected as part of these quarterly data submissions, thereby enabling pilots to honor their duty of confidentiality to the individuals they are serving.

### 4. Ensure quality data on service delivery by training pilots on data collection, and by cleaning and conducting quality checks on data submitted.

a. To ensure that data is high quality and to mitigate bias, we will encourage

pilots to do the following:

- (i) Make consistent use of templates through which they can record, export, and submit service delivery data on a quarterly basis, such that the structure of the data (number of rows, number of columns, column names and categories) never changes.
- (ii) Train their staff in data collection to ensure that staff recording data have a shared understanding of the tools and data categories.
- (iii) Enter data directly into forms, spreadsheets, or other databases on phones, tablets, or PCs, soon after interacting with clients. If a responder waits hours or days after an interaction to input data, recollections of the response may not be as fresh and/or primary source notes from the event may be difficult to transcribe with accuracy. We will instruct pilots not to share any service delivery data with the evaluation team beyond the fields described in Attachment 2.
- (iv) Clarify reasons for missing or incomplete data. If a response team is unable to collect a particular piece of data, it is preferable for the team to enter explanatory information such as "RESPONDENT REFUSED" or "DID NOT ATTEMPT TO COLLECT" to explain why data is missing.

b. To the extent there are differences in the structure and quality of service delivery data that pilots will share with the evaluation team each quarter, we will first harmonize and clean data submissions across pilots to maximize data quality. We will identify inconsistencies and gaps, follow up with sites about missing or incomplete data, and re-code or clarify data entries as needed, to prepare the data for analysis at the site level and across sites. As needed, Social Finance will work with pilots to troubleshoot data submission issues.

c. As part of the data cleaning process, we 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; 3) communicate reminders to pilots to avoid including these fields in the future.

5. Administer a client satisfaction survey to individuals who received crisis response services and follow-up calls from pilots.

a. 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. Names and contact information will only be used to issue survey compensation 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).

b. Context for administering client satisfaction surveys: As part of pilots'

crisis response service model, pilots will conduct follow-up phone calls or visits to individuals who requested crisis response services and, in some cases, those who interacted with crisis responders (even if they did not make the initial call). The purpose of follow-ups is to check in on individuals' well-being following the crisis response and provide any additional support. 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.

c. Survey invitations: At the end of the follow-up phone call or visit, the pilot staff member conducting the follow-up will invite the client to fill out an optional survey about their experiences with the crisis response services. When pilot staff members offer the survey to clients, they must state that the survey is optional, they can skip any question they do not want to answer, and not participating will not impact their access to services. Pilots will generally attempt to offer the survey to all clients, with a few exceptions. 1) It is possible that follow-up calls or visits to certain individuals will not be practical or appropriate (e.g., missing contact information, interactions in which responders did not feel safe), so those individuals will not be given an opportunity to complete a survey. 2) Pilots will not offer the survey to those who are actively experiencing crisis, have particularly sensitive needs or who are under the age of 18 (additionally, the consent form asks individuals to affirm they are at least 18 before completing the survey). If the client 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 conversations. Social Finance will provide a link to pilots to share with clients that includes an informed consent form and survey questions hosted on Qualtrics. (See Attachment 4 for the survey invitation script that pilots will use.)

d. Survey consent: Clients will access the survey link and 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 5 for consent form and survey questions). Clients will also be given the opportunity to consent to participate in a compensation lottery for survey respondents (more detail below) and consent to be contacted for a 1:1 follow-up interview. If they want to participate in the compensation 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 compensation lottery or to be contacted for follow-up, they are not asked to provide their name or contact information. Individuals who consent to be contacted for a 1:1 follow up interview may be contacted individually at a later date via the contact information they provide. At the time of the future interview, the evaluation team will obtain informed consent from the individual to participate in the interview. 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. Survey data will be stored on a secure server with password-protected access limited to one of the study's Principal Investigators and two additional research staff.

e. Survey completion: If the client consents to take the survey, they will then respond to survey questions. 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.

f. Compensation for time spent completing the survey: Social Finance will conduct a monthly compensation lottery, which awards a \$25 incentive to one respondent each month, to be distributed via phone number or email address (see details in the Compensation section).

6. Collect any publicly available data to help answer key research questions.

a. 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).

7. Analyze data to answer key research questions for the study's final report.

a. Ensuring data security and confidentiality during analysis: When analyzing survey data, PID fields (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 follow-up outreach for interviews). Upon conclusion of the study, the survey data will be deleted.

b. Using site-level service delivery data collected by pilots, we will develop summary statistics reflecting the overall picture of how crisis response services were implemented across sites, while accounting for individual differences in service models across pilots.

c. Using client satisfaction survey responses, we will analyze several dimensions of client feedback, including 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. We will adhere to CalHHS Data De-identification guidelines when analyzing and reporting data (i.e., we will not report on cell sizes smaller than 11).

d. We will analyze information on pilot operations provided by pilots (such as descriptions of pilot service models, description of community engagement activities, timelines, costs, staffing). Special attention will be paid in this analysis to determining the differences in pilot implementation across sites and the extent to which sites are implementing similar or different crisis response programs.

e. We will seek to analyze any publicly available data to understand broader jurisdiction-level trends in the metrics described in part (6) above, including changes in law enforcement emergency response volume. If no publicly available data is available, Social Finance will work with stakeholders to develop estimates, where possible. Since it will be difficult to attribute causal changes in any of these areas directly to individual pilots, we will exercise caution in characterizing any trends we identify.

## 8. Summarize and report evaluation results.

a. 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.

b. Survey data summaries: Social Finance will share quarterly survey data summaries 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. The evaluation team will then generate summaries of responses for each question and share with CDSS and pilots. Each pilot will only have access to results for their own survey; i.e., the Oakland pilot will only see summaries of survey results from Oakland crisis response clients. We will not share individual-level survey data with CDSS or pilots. We may share individual answers to free response questions submitted by survey respondents to support pilots with learning and improvement, if the feedback does not contain any PID, HIPAA identifiers, or other data (or combinations of data) that could conceivably be used to identify an individual. For example, if a survey 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 share that response with pilots or CDSS.

c. 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.

The timeline for the evaluation is as follows:

- Design of evaluation is finalized: April 2025
- Pilots begin collecting data: May 2025
- Pilots aim to conclude service delivery under this program: June 2026 (an extension is possible through August 2026)
- Social Finance implements study procedures detailed above: May 2025-October 2026
- Evaluation report published: October 2026

**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 2 - Research Questions and Data.docx	List of Variables
Attachment 3 - Service Delivery Data Collection Template.xlsx	Misc/Other
Attachment 1 - Unique ID Instructions.docx	Other Documents
Attachment 5 - Client Consent Form and Satisfaction Survey.docx	Protocol
Attachment 4 - Client Satisfaction Recruitment Templates.docx	Recruitment Materials

Deleted Attachments: 13 (Most Recent: Attachment 4 - Client Satisfaction Recruitment Templates.docx on 03/07/2025 5:53 PM ET)

## RECORDING

**Will audio or video recording occur?**

No

## **DECEPTION**

**Will deception be used in this study?**

No

## **CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CHHSA) DEPARTMENTS LIST**

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

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.**

[Not applicable with current submission] Please include the breakdown of each of the different groups here as you have outlined in the compensation section.

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

In some parts of the application you state that individuals may be included who called on behalf of someone else but who did not themselves receive services? Please clearly describe who is eligible to be included in this study.

03/24/2025 • Laura Lund, MA • *Not Internal*

Over the course of evaluation implementation, we expect to engage individuals who received services through the C.R.I.S.E.S. program via a web-based survey. 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.

## **RATIONALE**

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

We are studying the requested groups in order to answer our key research questions. By surveying clients, we will be able to understand the extent to which individuals were satisfied with the services they received from community-based crisis response programs, especially members of populations disproportionately impacted by law enforcement emergency response. Learnings from surveys will inform all our research questions; they will particularly shed light on the first two 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.)?**

[Not applicable] You indicate that emails, phone calls, and text messages will be used in English as well as other languages; however, only the email recruitment in English is provided for the Focus group and Clients. Please include all materials and all languages that you intend to use for all modalities to be evaluated.

Additionally, if you intend to conduct these interviews in groups, please remove the statement that everything you share will be anonymous because inherently they will be disclosing personal information in a group setting. Add that their disclosure of this information will take place in a group so that they understand the design of the study before agreeing to be contacted further.

Will additional attempts be made to persons if no contact is made after the first attempt? If so, please outline the plan/specific # of attempts for this contact in the procedure section.

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

[Not applicable] When potential participants respond to the recruitment email, what information are they given about the study and how to participate? Please provide the scripts that will be used.

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

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

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. Social Finance will provide a client satisfaction survey link to pilots, to share during follow-up calls or visits with clients who received services. Pilots will use the verbal script provided in Attachment 4 to ask clients to take a survey about their experiences with alternative crisis response services. 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. 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.

**Attach copies of all recruitment materials.**

Attachment 4 - Client Satisfaction Recruitment  
Templates.docx

Recruitment  
Materials

Deleted Attachments: 4 (Most Recent: Attachment 4 - Client Satisfaction Recruitment Templates.docx on 03/07/2025 5:54 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: Pilots should not offer the survey to clients during follow-up if: 1) based on the pilot staff member's assessment, the client was still in crisis, has particularly sensitive needs, or made responders feel unsafe, and it would not be appropriate to offer the survey; 2) if the client is under the age of 18 (note that the survey consent form will also ask respondents to affirm they are 18 or older). 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 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 will possess those characteristics.

The survey includes an informed consent form that makes clear participation is entirely voluntary, explains that clients can stop answering survey questions at any time, and provides guidance on who to contact if respondents experience distress during survey completion.

## COMPENSATION

### Will subjects be compensated for participating in the study?

[Not Applicable - refer to Ms. Lunds comment for modified description clarification]--Compensation—all participants should receive equitable compensation for participation in the study. You indicate the pilot sites may pay participants for their engagement -- It is not equitable if some participants receive a \$25 gift card and others receive only a chance to win a \$25 gift card for the same level of participation. You state that you will mail them the debit card—at what point will you collect name and address? Is this necessary? Is there a way to provide them with compensation without collecting their personal information?

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

Please see my comments above regarding the potentially inequitable nature of the planned lottery scheme. As proposed some individuals are more likely to receive the gift than others.

03/24/2025 • Laura Lund, MA • *Not Internal*

Agree with Ms. Lund comment - this approach is not equitable based on a monthly drawing. A more equitable approach would be 1 random drawing with replacement done at the end of the study, but please modify the approach or drop the compensation

03/28/2025 • Jonni Johnson, PhD • *Not Internal*

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.**

Social Finance will conduct a monthly compensation lottery, which awards a \$25 incentive to one respondent selected at random each month, to be distributed via phone number or email address. All survey responses submitted in each month, for which respondents agreed to enter the compensation lottery, will be eligible for the monthly lottery. The number of questions respondents answer will not impact their eligibility for the lottery.

At the end of each month, Social Finance will randomly select one survey and issue a gift card to the respondent. The research team will select a monthly compensation recipient by using a random number generator to assign a random number to all surveys submitted in that month, 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.

## 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.**

[Not applicable] Won't this time be dependent upon how many persons will be included in the focus group? Is it reasonable to expect that 6 persons will be able to answer 6 questions pertaining to sensitive materials in 45 minutes? Is it possible to have the interviews be individual for the persons/family members receiving the services?

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

*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 April 2025. Phase Two: Evaluation Implementation and Report Creation will begin following IRB approval in the spring of 2025 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 receive or access any data from 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).

## 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.

- Psychological risks may arise. Since our study will seek to survey 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.
  - o The study will mitigate these risks by prioritizing a trauma-informed approach to surveys, including asking only those questions that are necessary to collect data that helps the project answer its research questions, as well as prioritizing respondents' self-care (e.g., stressing via informed consent that all questions are optional to answer, ensuring respondents know they can stop answering questions at any time, and providing respondents information about who to contact if they experience distress).
- Loss of data security and associated loss of confidentiality may be a risk if data that is collected through the project is not secured appropriately.
  - o This risk is very low due to data security efforts we are taking to secure PID, which include storing survey responses on an encrypted folder on a SharePoint site that provides access 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.



## 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.**

[Not applicable] You plan to interview persons about distressing events - can community outreach/mental health support information be provided to participants in case mental or physical adverse events arise due to participation in your study?

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

It is possible that individuals responding to the client satisfaction survey may experience psychological discomfort or distress. In the consent language in Attachment 5, 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.**

[Not applicable with current procedure] Can interviews be conducted instead of focus groups for all clients and their families?

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

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 from these individuals will provide invaluable 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.**

Please remove the compensation for their time as a benefit for being enrolled in the study as well as clarify this in the consent form benefits section. This is an incentive, not a benefit.

02/02/2025 • Jonni Johnson, PhD • *Not Internal* • Resolved

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 may benefit directly by providing feedback on crisis response services that could continue to serve their communities following the conclusion of these pilots. By responding to the client satisfaction survey 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, the survey consent form addresses 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 never be used in any report, nor will it be shared with anybody outside of Social Finance. 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.

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

In your description of the procedures, you plan to collect and evaluate dates of services and zip codes of services. Please add these as HIPAA identifiers.

02/02/2025 • Jonni Johnson, PhD • Not Internal • Resolved

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

Name

Telephone numbers

Email address

## TRAINING PROCEDURES

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

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. This falls under the definition of Personal Information.) We will instruct all research staff who have access to PID -- which will be stored and accessed only on a secure SharePoint with limited access -- not to download any PID or transfer any PID outside of Social Finance's secured SharePoint. 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.

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.**

*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 site, with limited access granted to three Social Finance staff members working on this project and need access to deliver on the scope of work. Social Finance will limit PID data collected to that which is necessary for the evaluation, such as contact information (first names, email addresses, and phone numbers) for individuals who agree to participate in a compensation lottery for the client satisfaction survey, and for survey respondents who agree to be contacted for follow-up interviews. 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.**

Given that this is four pilot sites - it doesn't appear that any of the numbers will be large enough for publication. The majority of the numbers would need to be presented as a whole to comply for CalHHS Data De-identification guidelines (i.e., no cell size < 11).

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

Please add that you will be following CalHHS Data De-identification guidelines.

03/28/2025 • Jonni Johnson, PhD • *Not Internal*

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.

## 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 collect 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). Social Finance will not request or receive any data needed for the evaluation prior to approval of this application by CPHS or later than October 31, 2026. Social Finance will not request or receive any data needed for the evaluation prior to approval of this application by the Institutional Review Board.

## **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 site, 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.**

Please see note above regarding Cal-HHS standards for data redaction for cells < 11. It doesn't seem like any of the pilot sites could have the number reported since all are estimated to be 6.

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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

Deleted Attachments: 1 (Most Recent: 2024-12-18 CRISES IRB Data Security Letter.pdf on 01/07/2025 12:25 PM ET)

## 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.**

What are the physical records that are being collected and kept? Are these the responses collected from the pilots? Why are these to be retained after entered electronically?

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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?**

Modify section if lottery approach is dropped

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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 compensation lotteries and distributing payments). Upon conclusion of the study, the survey data 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 a secure SharePoint site, 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 a secure SharePoint site, 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.**

[Not Applicable with submission] You indicate that interview and focus groups data will be recorded and the first question asked pertains to people disclosing their names and locations as well as their specific interactions with the programs. How will this information be kept secure?

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There will be no PID in that will be saved anywhere except for a secure SharePoint site, 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 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 compensation 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 site, 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 site in the cloud, 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 site, 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 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.

## **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.**

[Not applicable with current submission] What will happen if participants agree to respond to your questions but not agree to be recorded? What will happen if one participant in focus group agrees to be recorded, but another one does not agree?

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

[Not applicable with current submission] Add consenting procedure for the pre-test (n = 2) persons and specific description of how informed consent will be documented for interviews, focus groups, and pre-test.

02/02/2025 • Jonni Johnson, PhD • *Not Internal*

*See instructions and examples on CPHS website.*

During routine follow up with clients, pilots will use the script provided in Attachment 4 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.

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 5 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

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 compensation; 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. At the time of the follow-up interview, the evaluation team would obtain informed consent from the individual to participate in the interview. As noted in the Study Procedures section, Social Finance will submit an amendment detailing proposed interview and interview consent procedures for IRB

approval at a later date. 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.**

This study is essentially requesting a waiver of written consent; however, it is not demonstrating why this is a need, especially given that a main recruitment method is to email participants. Why do participants not receive (e.g., via email) the consent copy in more detail to make an informed decision on whether to engage in the study or not?

No where in the consent is there mention of what to do, who to contact if experience distress during or after participation in the study. These will be very sensitive topics that you intend to interview persons on (in front of other strangers). They should be provided time and full disclosure of the potential for experiencing distress as well as resources provided to them for what to do/who to call if feels of distress arise during or after participation.

02/02/2025 • Jonni Johnson, PhD • Not Internal

*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 5 - Client Consent Form and Satisfaction Survey.docx

Consent Form

Deleted Attachments: 3 (Most Recent: Attachment 3. Stakeholder Interviews and Focus Groups Informed Consent and Questions.docx on 03/07/2025 5:32 PM ET)

## HIPAA Determination

## HIPAA INSTRUCTIONS

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

### COVERED ENTITY

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

No

### HEALTHCARE PROVISIONS

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

No

### OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

## Cover Letter and PI Signature for PI Submission

### BUDGET

Does this project have a budget?

Yes

**Attach a copy of your project budget here**

C.R.I.S.E.S. Budget for IRB 3.7.25 Resubmission.xlsx Project Budget

Deleted Attachments: 2 (Most Recent: C.R.I.S.E.S. Budget for IRB 1.23.25.xlsx on 03/07/2025 3:40 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 2025-03-07.docx.pdf

Cover  
Letter

Deleted Attachments: 1 (Most Recent: Social Finance CRISES IRB Cover Letter 2025-03-01.pdf on 03/07/2025 3:41 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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