Strong Fathers, Stronger Families Healthy Marriage and Responsible Fatherhood Program Evaluation

Study Protocol

Clinicaltrials.gov ID: NCT06907719

8/2/2023

PROGRAM BACKGROUND

1. PROGRAM SUMMARY

Please provide a brief summary of your grant project including the needs to be addressed, the services provided, and the population served.

The Strong Fathers, Stronger Families-Midsouth (SFSF-Midsouth) FIRE Project conducted by the Structured Employment Economic Development Corporation (Seedco) builds upon Seedco's regional capacity and track record accumulated since 2004 and adapts ten years of experience operating an ACF-funded Responsible Fatherhood Program in New York City to meet the needs of fathers in the Memphis, TN metropolitan region.

Sustained long term employment of parents is one of the key driving factors affecting child well-being. Fatherhood programs may not have the lasting effects program planners and policy makers expect to see, as participants who have successfully completed a program and started a job often do not maintain employment. This inability to sustain employment has a ripple effect across other components of fatherhood, including parenting or partnership relationships.

Needs: *Seedco's targeted geographic community for the proposed SFSF-Midsouth program is Shelby County and Tipton County in Tennessee and Crittenden County in Arkansas (the Greater Memphis Metropolitan region). This region is distinguished by high rates of poverty, concentrations of African American populations, and a largely urban center surrounding the Greater Memphis Metropolitan area. These communities are among the poorest in the region, with resources and opportunities further constrained by racial disparity. Participants served via this funding face a challenging economic climate and many face societal and emotional barriers. Seedco's needs analysis confirmed what the agency already knows from its experience serving many fathers, families, and local residents— that these individuals grapple with poverty, incarceration, crime, and single parenthood, or family instability. In short, this region needs and deserves a quality HMRF program.*

Services: *The SFSF-Midsouth Program will provide economic stability, healthy relationship, and parenting/fatherhood education via evidence-based curricula in combination with intensive case management to participants based on the results of a needs assessment completed at program enrollment.*

Population: The SFSF-Midsouth Program proposes to serve low-income fathers who face barriers to engagement with their children. These participants will be primarily young fathers, including biological, expectant, and adoptive fathers, stepfathers, and acknowledged father figures. Recruitment will focus on at-risk young fathers, low-income fathers, and active-duty military and veteran fathers living in Shelby County, TN, Tipton County, TN, and Crittenden County, AR. Specific numbers to be served are in the chart below:

PROGRAM PARTICIPATION TARGETS

Milestone	Year 1 4/1/21- 9/29/21	Year 2 9/30/21- 9/29/22	Year 3 9/30/22- 9/29/23	Year 4 9/30/23- 9/29/24	Year 5 9/30/24- 9/29/25	Total
Individuals Screened	225	450	450	450	450	2,025
Participants Enrolled	175	350	350	350	350	1,575
Participants who attend at least one primary workshop	175	350	350	350	350	1,575

Participants who attend at least 50% of primary workshops	165	330	330	330	330	1,485
Participants Graduating Healthy Relationship & Parenting Curricula (attend at least 90% of primary workshops)	158 (90%)	315 (90%)	315 (90%)	315 (90%)	315 (90%)	1,418
Participants who attend 100% of primary workshops	118	236	236	236	236	1062
Participants Placed in Jobs	105(60%)	210 (60%)	210 (60%)	210 (60%)	210 (60%)	945
Job Retention- 30 days	87 (50%)	175 (50%)	175 (50%)	175 (50%)	175 (50%)	787
Job Retention- 60 days	70 (40%)	140 (40%)	140 (40%)	140 (40%)	140 (40%)	630
Job Retention- 90 days	50	100	100	100	100	450
Job Retention- 180 days	40	80	80	80	80	360
Return Post-Graduation for Long-Term Case Management	87	175	175	175	175	787

Memorandum of changes to the Evaluation Study.

- SEEDCO Midsouth will aim to serve the same number of individuals in the descriptive study as in the RCT with a different estimated minimum effect size for the descriptive study. (Evaluation enrollment targets remain unchanged)
- The one-year local evaluation follow-up survey will no longer be collected and has been removed from the evaluation plan.
- The previously administered OLLE pre- and post-surveys will not be administered, as the measures needed to answer R1, R2, and R3 come from nFORM.

2. EVALUATION GOALS

Please briefly describe key goals of your evaluation and what you hope to learn below.

*The goals of the evaluation activities are to 1) Support the effective implementation of the SFSF- Midsouth FIRE Program with a rigorous Implementation Evaluation and a high-quality Continuous Quality Improvement (CQI) process, and 2) to conduct a rigorous Descriptive Study evaluation that answers the key research questions. **The research questions seek to understand if participants report significantly better parenting relationship behaviors, coparenting behaviors, and economic stability outcomes after program participation.***

3. EVALUATION ENROLLMENT

Please provide the expected start and end dates for program and evaluation enrollment using the tables below. For impact studies, please indicate expected start and end dates for each study group.

IMPLEMENTATION EVALUATION
Please leave blank if not conducting an implementation study.

	Program Enrollment	Study Enrollment
Start Date	4/1/2021	4/1/2021
End Date	3/31/2025	3/31/2025
Definition	Evaluating the extent to which the program is being implemented as intended, including program enrollment and retention outcomes.	Evaluating the extent to which the evaluation is being implemented as intended, including study enrollment, consent, and survey response rates.

DESCRIPTIVE EVALUATION
Please leave blank if not conducting a descriptive outcome evaluation.

	Program Enrollment	Study Enrollment
Start Date	4/1/2021	4/1/2021
End Date	3/31/2025	3/31/2025
Definition	*All participants across all grant years with no pilot program*	*All participants across all grant years with no pilot program*

4. EVALUATION TIMELINE

Please include a timeline for key activities of the evaluation below. Example of activities may include IRB submission, staff training, waves of data collection, analysis period, and report writing and submission.

Evaluation Activity	*Start Date*	*End Date*
Data collection (pre- and post-surveys) *Note: Prior to April 2021, SEEDCO was aiming to conduct an impact evaluation. Data collected during this time will still be used for the descriptive evaluation.*	4/1/2021	3/31/2025
Development and submission of Descriptive Evaluation Plan document	6/1/2023	7/30/2023
IRB Amendment Approval of descriptive study activity changes	7/24/2023	7/28/2023

Note: The original impact study, including a descriptive pilot period before randomization, was approved by the IRB in 2021 and was renewed annually in 2022 and 2023. The IRB approval indicated here is for an amendment describing the changes in study activities.		
Study Registration	7/28/2023	7/31/2023

* you may add rows by hitting the tab button, or right click and select insert row below

EVALUATION PLAN

1. RESEARCH QUESTIONS

1.1. OVERVIEW OF RESEARCH QUESTIONS

The primary overall research questions for this descriptive evaluation, which will be assessed utilizing pre- and post-surveys from nFORM, focus on program services and seeks to understand, "Is Strong Fathers, Stronger Families program participation associated with better participant outcomes?" This overall line of inquiry is operationalized by focusing on specific short-term outcomes to determine if parenting, co-parenting, and economic stability outcomes are improved after program participation.

No	Research Question	Implementation or Outcome?
I1	Are participants offered primary workshops and support services as intended (fidelity)?	Implementation
I2	How many primary workshops do participants attend (dosage), and how does this vary by workshop characteristics (e.g., timing and length of sessions) and participant characteristics (e.g., age, employment status, relationship status)?	Implementation
R1	Do SFSF-Midsouth participants experience significant increases in **Co-parenting Relationship** outcomes after program participation?	Primary Outcome
R2	Do SFSF-Midsouth participants experience significant increases in **Parenting Relationship** outcomes after program participation?	Primary Outcome
R3	Do SFSF-Midsouth participants experience significant increases in **economic stability** outcomes after program participation?	Primary Outcome

1.2. OUTCOME RESEARCH QUESTIONS

For each <u>outcome research question</u> listed above, whether a descriptive or impact design, summarize the inputs (e.g., program components, program supports, implementation features, etc.), target population (e.g., the population for which the effect will be estimated) and the outcomes (e.g., child well-being, father-child engagement, etc.) that will be examined to answer the research question(s). Comparisons for descriptive evaluations may reflect circumstances before the grant, pre-treatment, or pre-determined benchmark from other studies with similar interventions.

Research Question Number *Should correspond to the number indicated in Table 1.1 above*	Intervention *Program component or set of activities that the evaluation will test or examine*	Target Population *Population for which the effect of the treatment will be estimated*	Comparison *What the intervention will be compared to (e.g., pre-intervention for descriptive designs)*	Outcome *Changes that are expected to occur as a result of the intervention*	Confirmatory or Exploratory? *Confirmatory: those upon which conclusions will be drawn* *Exploratory: those that may provide additional suggestive evidence*
R1	SFSF primary workshop curricula (40 hours)	Low-income, minority, young fathers (and father figures) in the Greater Memphis area	Pre-intervention	Improved co-parent relationships	Confirmatory
R2	SFSF primary workshop curricula (40 hours)	Low-income, minority, young fathers (and father figures) in the Greater Memphis area	Pre-intervention	Improved p*arenting relationships*	Confirmatory
R3	SFSF primary workshop curricula	Low-income, minority, young fathers (and father figures) in the Greater Memphis area	Pre-intervention	Improved economic stability	Confirmatory

* you may add rows by hitting the tab button, or right click and select insert row below

2. BACKGROUND

For each outcome research question listed in 1.1, whether descriptive or impact design, briefly summarize the previous literature or existing research that informs the stated research question and how the evaluation will expand the evidence base. Explain why the research questions are of specific interest to the program and/or community. Only a short summary paragraph description is needed below. Additional documentation, such as a literature review, may be appended to this document.

Research Question	Existing Research	Contribution to the Evidence Base	Interest to the Program and/or Community
R1	Research with fathers in fatherhood programs has shown that co-parenting is a multidimensional construct with both positive and negative components, often made more challenging by the presence of new intimate relationships for co-parents. At the same time co-parenting programming has been shown to impact attitudes and beliefs about co-parents. One of the major areas of tension between co-parents is often financial support of the child.	This study has the potential to show how employment support services, combined with fatherhood programming, affects participant **co-parenting relationships**	Seedco has a strong interest in learning how to best provide services to fathers that improve co-parenting relationships.
R2	The research on father-child relationships in low-income and fragile families is limited and few have examined the impact when fathers live separately from their child and were not married at the time of birth. It has been shown that couple-oriented programs, such as those provided in fatherhood programs, can have an impact on father involvement.	This study has the potential to show how employment support services, combined with fatherhood programming, affects participant **parenting relationships.**	Seedco has a strong interest in learning how to best provide services to fathers that improve parenting relationships.
R3	Previous research has explored the potential impact of combining employment support services with fatherhood programming on participant economic stability. These services have been shown to help fathers acquire new skills, improve their resumes, and navigate the job market	This study has the potential to show how employment support services, combined with fatherhood programming, affects participant **economic stability.**	By addressing both employment and fatherhood-related challenges simultaneously, these integrated programs can offer comprehensive support and foster positive outcomes. Fathers participating in such programs are more likely to find stable employment,

	effectively. By increasing their employment opportunities, participants can secure stable jobs with better wages, benefits, and long-term prospects.		experience increased job satisfaction, and have higher earning potential. This, in turn, contributes to their economic stability* and the overall well-being of their families and communities.

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*Data on financial well-being and economic stability is collected via surveys administered to the participants. The Applicant Characteristics Survey (ACS) survey asks questions on employment status. Additionally, the enrollment tab on nFORM displays information on primary reasons for enrollment including to find a job. Similarly, in the client outcome tab, participants can be filtered based on varied employment status. nFORM Entrance and Exit survey also collect information on economic stability. These measures provide a sound understanding of the participant's rationale for joining the program as well as measuring how effective the program has been to improve participant's economic stability.

3. LOGIC MODEL

Clearly demonstrate how the research question(s) (and the related implementation features and/or participant outcomes) link to the proposed logic model and the theory of change for the program. You may append a copy of your logic model to this document.

See Appendix A for Theory of Change Logic Model

The appended logic model specifies a theory of change for delivering fatherhood curriculum and post-employment services to SFSF participants. Service delivery processes specified in the model are linked to the desired outcome. Model specification incorporates a descriptive study design to determine if participants report significantly improved primary outcomes after program participation.

Service delivery processes: Key aspects of service delivery processes in the theory of change—goals, inputs, activities, and outputs—articulate the experiences that are designed to solve specific problems for those who agree to participate in the SFSF Program. Solving each problem identifies three broad service delivery goals to maximize participation benefits for study groups as explained below:

*   **Goal 1** - **Deliver primary workshop hours and support services**: Program participants will receive the Blueprint and 24/7 Dad curricula, in combination with employment support services and case management through Seedco, but only after receiving an orientation about the SFSF and giving project staff informed consent to participate in study activities.
*   **Goal 2** - **Conduct Continuous Quality Improvement (CQI) to ensure full implementation of program**: Reports prepared and presented to the CQI Team by evaluators will use a series of performance indicators to track key outputs over time to identify any *primary or support SFSF services* delivered to program participants that might fall short of the intended amounts to be offered (i.e., fidelity standards) and received (i.e., dosage thresholds) by them. The CQI Team will then work with project staff to develop and implement performance interventions to address any outputs that need improvement to ensure the services offered to and received by participants meet the intended amounts by the end of each program year.
*   Desired Outcomes: Outcomes specified in the logic model theorize the primary outcomes that are desired for program participants after they receive primary workshop hours, case management support services, and employment support services.

4. HYPOTHESES

For each specified research question, state the hypothesized result(s) and briefly describe why these results are anticipated.

Research Question	Hypothesized Result
I1	Primary workshops, support services, and case management services were offered to all participants as needed, with fidelity to the program model.
I2	Participants received primary workshop hours (dosage) as intended, with 90% of enrollees receiving at least 90% of primary hours.
R1	Participants will experience better co-parenting relationships outcomes after program participation.
R2	Participants will experience better parenting relationships outcomes after program participation.
R3	Participants will experience better economic stability outcomes after program participation.

* you may add rows by hitting the tab button, or right click and select insert row below

5. RESEARCH DESIGN

For each research question, briefly describe why the research design proposed will answer each research question(s). State whether the proposed evaluation is a descriptive or impact evaluation and justify why the proposed research design is best suited to answer the research question(s).

Research Question	Design	Justification
I1	Assessment of fidelity to program model by tracking programmatic activities on nFORM.	Ensuring full program implementation to ensure that the intervention that is being measured is actually being delivered.
I2	Assessment of dosage by measuring the number of primary workshop hours received and exploration of	Ensuring sufficient dosage is being delivered to adequate number of participants and exploring what characteristics are associated with greater workshop participation.

	variation by workshop and participant characteristics	
R1	Pre to post outcome assessment of program participation for improved co-parenting relationships	Significant improvement in co-parenting relationship outcomes from pre to post estimates the maximum amount of benefit that can be attributed to Seedco services in the absence of a counterfactual.
R2	Pre to post outcome assessment of program participation for improved parenting relationships.	Significant improvement in parenting relationship outcomes from pre to post estimates the maximum amount of benefit that can be attributed to Seedco services in the absence of a counterfactual.
R3	Pre to post outcome assessment of program participation for improved economic stability.	Significant improvement in economic stability outcomes from pre to post estimates the maximum amount of benefit that can be attributed to Seedco services in the absence of a counterfactual.

* *you may add rows by hitting the tab button, or right click and select insert row below*

6. ONGOING GRANTEE AND LOCAL EVALUATOR COORDINATION

Describe how the grantee and local evaluator collaboratively worked together to identify the research question(s) and research design to ensure its feasibility and relevance. Describe how the grantee and local evaluator will continue to work together throughout the evaluation to proactively address unforeseen challenges as they arise and ensure the rigor and relevance of the evaluation and its findings. Describe how the grantee and local evaluator will coordinate dissemination efforts. Describe how these processes will occur while maintaining the independence of the evaluation.

Seedco and the local evaluator, Midwest Evaluation and Research (MER) began the process of collaboration prior to the release of the Funding Opportunity Announcement (FOA) for this project. This included multiple working meetings to discuss the project and the goals that Seedco had for the project, with a specific emphasis on what they had learned as a funded OFA grantee over the last two cohort cycles and what they would like to do differently. This included a discussion of enhancements to the program they believed would enhance participant outcomes, and the resource requirements of these enhancements. Several viable and relevant research question options were developed prior to the FOA and when the FOA was released the team had additional meetings to discuss the program that would be proposed to meet the goals and objectives of Seedco and OFA and how well the research question alternatives developed in advance worked with this program outline. Using this extended collaborative process, the research questions were designed that were most relevant and feasible.

The basis for ongoing coordination between Seedco and MER (the local evaluator) is regular communication, by way of recurring meetings and daily interactions with embedded staff.

Throughout the original proposal process, and during the evaluation planning phase, MER worked in consort with Seedco to design a study with research questions that are appropriate to the intervention. MER guides the process, given our experience designing and running evaluations, and Seedco provides expertise on their community, target population, and program/curricula specifics.

Recurring meetings will include a bi-weekly project CQI team meeting. Under the leadership of the Data Manager and Lead MER Evaluator, the CQI team reviews data from the nFORM and local evaluation systems to identify and mitigate implementation or data issues, and closely examine trends and accomplishments. This team includes Seedco organizational and project leadership, the MER Evaluation team, and front-line staff representatives (e.g., Facilitators, Case Managers).

In addition to CQI team meetings, overall project team meetings occur monthly (at a minimum), with project leaders across MER and Seedco in attendance, to ensure the partnership remains strong and that coordination across organizations is on track. This recurring, ongoing meeting structure is conducive to close coordination, ensuring that challenges can be quickly addressed, and promising strategies can be efficiently maximized.

One of the key components of this coordination effort is the Data Manager, employed with Seedco. The Data Manager functions to bridge the gap between organizations. They will interact with Seedco staff daily while completing their job duties and play a leadership role in the recurring meetings outlined above. See Section 8 below for more details about this role and others. Both the meetings and the roles outlined above will continue throughout the entire project period, providing opportunities to ensure the rigor and relevance of the evaluation and its findings, and to discuss and coordinate dissemination efforts (which will also be shared across MER and Seedco).

MER has experience operating prior evaluations using this described process. Clearly outlining roles and responsibilities maintains the independence of the evaluation. That is, the evaluation team helps identify and illuminate areas of concern or improvement (for the program and the evaluation), but the program staff have responsibility for implementing improvements and providing direct services to participants. In this way, Seedco and MER acknowledge our shared interest in and responsibility for a well-executed project and evaluation, but that MER is also an independent and external organization with a high level of integrity and is not responsible for nor invested in the specific outcomes of the program. This allows for close coordination without allowing for co-dependence, or for personal interests to influence evaluation findings.

7. LEAD STAFF

Define the roles of lead staff for the evaluation from both organizations below.

Name	Organization	Role in the Evaluation
Dr. Matthew Shepherd	Midwest Evaluation and Research	Principal Investigator
McKenna LeClear	Midwest Evaluation and Research	Senior Research Consultant
Dr. Saloni Sharma	Midwest Evaluation and Research	Evaluation Project Manager

Darrell K. Scott	Seedco	SFSF-Midsouth Program Director

* you may add rows by hitting the tab button, or right click and select insert row below

Articulate the experience, skills, and knowledge of the staff for the evaluation (including whether they have conducted similar studies in this field), as well as their ability to coordinate and support planning, implementation, and analysis related to a comprehensive evaluation plan.

Dr. Matthew Shepherd will serve as the Principal Investigator for this grant. As such, he has corporate responsibility for all evaluation activities. Dr. Shepherd has over 25 years' experience in program design and implementation, applied research, program evaluation, policy analysis, and evaluative technical assistance.

McKenna LeClear will serve as the Senior Research Consultant and provide oversight for HMRF evaluation activities as needed. Ms. LeClear has 5 years of evaluation research experience and oversees numerous other HMRF evaluations for MER.

Dr. Saloni Sharma will serve as the Evaluation Project Manager and will lead the effort to conduct a descriptive study and a Continuous Quality Improvement (CQI) process for the grant. Dr. Sharma has over 5 years of experience in Public Policy research prior to her time at MER.

Darrell K. Scott will serve as the SFSF Project Director and provide oversight to the Seedco Data Manager and Seedco Intake Specialist. He possesses the requisite managerial and analytic skills to successfully fill this position. The Data Manager and Seedco Intake Specialist will work closely with the evaluator and community partners on-site to complete data collection and management activities for the impact study <u>and</u> a Continuous Quality Improvement (CQI) process.

8. SAMPLE

8.1. TARGET POPULATION(S)

For each target population identified in Section 1.2, please describe the target population(s), and explicitly state whether the population(s) differs from those who will be broadly served by the grant. Describe how the target population will be identified. Explicitly state the unit of analysis (e.g., non-residential father, unmarried couple).

Description of Target Population	How is the population different from those who will be broadly served by the grant?	How will the target population be identified?	Unit of Analysis
Low-income, minority, young fathers (and father figures) in the Greater Memphis area	No difference, all program participants will be eligible to be study participants	The sample will be identified and recruited by the program staff. The project has identified multiple referral sources including: *HopeWorks* *A Step Ahead Foundation*	*Father*

		St. Andrew AME Church	
		Neighborhood Christian Center	
		Families Matter	
		The RISE Foundation	
		Children & Family Services	
		Maximus	
		Equus	
		Shelby County Community Services Agency	
		Tennessee Voices for Children	
		The Excel Center	
		Church Health Center	
		Christ Community Health Center	
		Cocaine Alcohol Awareness Program	
		Synergy	
		Dorothy Day House	

8.2. METHODS TO PROMOTE SUFFICIENT PROGRAM PARTICIPATION

Please describe methods to promote sufficient program participation in the table below.

What methods will you use to ensure sufficient sample is recruited, enrolls, and participates in the program?	Seedco will work with local referral partners and other CBOs to ensure that there are sufficient sample sizes, The CQI process will address issues regarding program recruitment and enrollment to ensure targets are met.
Who will be responsible for recruiting the evaluation sample?	The evaluation sample will not differ from the program population, in that all participants will be invited to participate in the evaluation. Enrollment into the evaluation will be conducted by the Data Manager who will conduct the informed consent process and proctor the baseline data collection efforts.

Please describe any incentives to be offered for program participation and/or completion and/or data collection and/or participation in the evaluation.	Evaluation Participation–No incentives will be used for the two data collections at baseline and post-test while participants are beginning or still engaged in service.

9. DATA COLLECTION

9.1. CONSTRUCTS AND MEASURES

Clearly articulate the constructs of interest, measures to evaluate those constructs, and specific data collection instruments. Provide any information on the reliability and validity of the data collection instruments. For standardized instruments, you may provide the citation for the instrument.

* you may add rows by hitting the tab button, or right click and select insert row below

Construct	Measure	Instrument	Reliability and Validity (if standardized instrument, you provide a citation for the instrument)
Program fidelity	Percent of enrolled participants who received each of the following: 1) primary workshops, 2) employment supports, 3) substantive service contacts, 4) referrals Number of substantive service contacts and referrals per participant	nFORM MIS	
Dosage	Number of primary workshop hours received, percent of target hours received Subgroup exploratory analysis of how dosage varies by workshop and participant characteristics	nFORM MIS	

Co-parenting Relationships	Composite measure that takes the average of 5 survey items related to positive co-parenting interactions with the mother of participant's youngest child (continuous, scale from 1-5 where 1 is strongly disagree and 5 is strongly agree) . Improvement will be measured by a participant's change score, calculated by subtracting their pre-program composite score from their post-program composite score.	nFORM Community-Based Fathers Survey (A13: d-h)	Reliability and validity will be assessed with a correlation matrix and factor analysis
Parenting Relationships	Daily hours spent with youngest child in past 30 days (change score from pre-program to post-program)

Frequency of reaching out to youngest child in past 30 days (change score from pre-program to post-program)

Composite measure that takes the average of 10-11 survey items related to positive parenting behaviors with youngest child (continuous, scale from 1-5 where 1 is Never, 2 is 1 to 2 days per month, 3 is 3 or 4 days per month, 4 is 2 or 3 days per week, and 5 is every day or almost every day) . Improvement will be measured by a participant's change score, calculated by subtracting their pre-program composite score from their post-program composite score. | nFORM Community-Based Fathers Survey (A2b, A2c, A5a-d: a-k) | Reliability and validity will be assessed with a correlation matrix and factor analysis |
| Economic Stability | Difficulty paying bills (categorical, scale from 1 to 4 where 1 is never and 4 is very often). Improvement will be measured by change score in participant's reported difficulty, calculated by subtracting their | nFORM Community-Based Fathers Survey B4, B3, B3a. | N/A (individual items will not be combined) |

	post-program value from their pre-program value.

Has savings account at end of program, among those who came into the program with no savings account

Has checking account at end of program, among those who came into the program with no checking account | | |

10.2 CONSENT

Describe how and when program applicants will be informed of the study and will have the option of agreeing (i.e., consenting to) or declining to participate in the study.

Because the planned evaluation involves human subjects, Seedco understands program implementation requires both IRB approval and participant informed consent. MER has an established relationship with Solutions IRB having secured more than 20 IRB approvals and renewals for evaluations it has conducts during the past five years. IRB clearance will be submitted for approval and obtained during the planning period.

To secure informed consent participants will attend an orientation / enrollment session (in person) where the Data Manager will describe the evaluation process, the risks and benefits of the project. Those people that wish to participate in the evaluation will complete an informed consent process and sign an informed consent document / form. All participants will receive a copy of the consent form with contact information for evaluation staff and how to contact the IRB if needed. Informed consent will take place prior to program enrollment and the collection of evaluation data.

9.2. METHODS OF DATA COLLECTION

If the evaluation will collect multiple waves of data, describe the timing of these waves below. When describing follow-up periods, specify whether the follow-up period will be post-baseline, post-random assignment, or post-program completion.

| Wave of Data Collection

(e.g., baseline, short-term follow-up, long-term follow-up)	Timing of Data Collection
Pre-Test (Wave 1)	Collected immediately following informed consent and study enrollment – during orientation session or first workshop

Post-Test (Wave 2)	Collected after the completion of core curriculum/primary workshop programing – during the last workshop session – approximately 8 weeks after enrollment/baseline

For each measure, describe how data will be collected detailing which data collection measures will be collected by which persons, and at what point in the programming or at what follow-up point.

Measure	Timing of Data Collection (baseline, wave of data collection)	Method of Data Collection	Who Is Responsible for Data Collection?	*Impact Evaluations Only:* **Will Methods or Collection Procedures Differ by Study Group?**	*Administrative Data Only:* **Will data access require data sharing agreement?**
nFORM Entrance Survey	Wave 1	Participant self-enters survey using online data collection platform	Data Manager will proctor data collection and assist participants as necessary		N/A
nFORM Exit Survey	Wave 2	Participant self-enters survey using online data collection platform	Data Manager will proctor data collection and assist participants as necessary		N/A

* you may add rows by hitting the tab button, or right click and select insert row below

9.3. ENSURING AND MONITORING DATA COLLECTION

Describe plans for training data collectors and for updating or retraining data collectors about procedures. Detail plans to regularly review data that have been submitted and to assess and swiftly address problems.

All program staff and evaluation staff will undergo a rigorous set of trainings to prepare for the evaluation. All staff receive an overview and introductory training to present the goals and objectives of the evaluation effort and its importance to the overall project. Next all staff receive training on human subjects protection and are required to pass a certification test on the subject matter. All staff will also receive a detailed training on the details of the descriptive evaluation including the evaluation tools, timing, and data collection processes.

In addition, the Data Manager and the primary local evaluation staff will undergo a rigorous training process to better understand the context of HMRF research, training on data collection procedures they will be responsible for, and training on the nFORM system and use of nFORM data in a CQI process. MER is creating networks of CQI Data Managers and Evaluation Project Managers across the 12 projects that we are evaluating so that all staff have access to experienced data managers and evaluation staff who have done this work previously.

Members of the CQI team will also receive specific training on the MER CQI process that has been developed prior to the launch of data collection or program services. As described elsewhere MER is assisting the program staff in implementing a robust CQI process that will focus on retention as one of the primary areas of program improvement and as such we are anticipating relatively modest levels of attrition for this data collection.

On a bi-weekly basis the local evaluation project lead will be responsible for downloading data from nFORM for processing and presentation to the CQI team for tracking and monitoring performance measurement outcomes (recruitment, enrollment, dosage, completion, referrals, etc.) so that near real time adjustments can be made to program implementation to ensure compliance with program goals and objectives.

As new staff come on board with projects or project staff turnover (or need refresher training), recorded training material can be shared and accessed with follow-up one on one training with the local evaluation project lead and/or the MER Line of Business Lead, as necessary.

10. IRB/PROTECTION OF HUMAN SUBJECTS

Please describe the process for protection of human subjects, and IRB review and approval of the proposed program and evaluation plans. Name the specific IRB to which you expect to apply.

Solutions IRB, a private commercial Association for the Accreditation of Human Research Protection Programs Inc. (AAHRPP) fully accredited Institutional Review Board, will ensure that this study is approved before any research activities take place. MER has had 14 research studies approved by Solutions IRB over the past four years, has completed over 15 annual check-in reports, and has submitted timely amendments when changes to studies needed to take effect.

All submissions are completed online, so turnaround for a new study approval is between 24 to 72 hours, though the full approval process can take approximately one to two weeks depending on the number of questions and requested revisions that the IRB makes. In the IRB

application submission, we will include descriptions of project staff, locations of study sites, the funding source, incentives, summary of activities, participant population, recruitment plans, risks and benefits, confidentiality of data, and the informed consent process along with all materials to be used in the study such as participant forms and surveys.

This revised descriptive study design will be submitted for IRB approval in late July 2023 in order to receive official approval by August 2023.

11. DATA

11.1. DATABASES

For each database used to enter data, please describe the database into which data will be entered (i.e., nFORM and/or other databases), including both performance measure data you plan to use in your local evaluation and any additional local evaluation data. Describe the process for data entry (i.e., who will enter the data into the database).

Database Name	Data Entered	Process for Data Entry
nFORM	Performance Measurement Data	Participant direct entry and staff direct entry (facilitator and case managers)

* you may add rows by hitting the tab button, or right click and select insert row below

11.2. DATA REPORTING AND TRANSFER

For each database provided in the table above, please indicate the ability to export individual-level reports to an Excel or comma-delimited format and whether identifying information is available for linking to data from other sources.

Database Name	Ability to Export Individual Reports?	What identifying information is available to facilitate linking to other data sources?
nFORM	Yes	nFORM client ID

* you may add rows by hitting the tab button, or right click and select insert row below

11.3. CURRENT SECURITY AND CONFIDENTIALITY STANDARDS

For each database provided in Section 11.1, please Indicate the ability to be able to encrypt data access during transit (for example, accessed through an HTTPS connection); be able to encrypt data at rest (that is, when not in transit), have in place a data backup and recovery plan; require all users to have logins and passwords to access the data they are authorized to view; and have current anti- virus software installed to detect and address malware, such as viruses and worms.

Database Name	Ability to encrypt data during transit?	Ability to encrypt at rest?	Data Backup and Recovery Plan?	Require all users to have logins and passwords?	Current Anti-Virus Software Installed?
nFORM	Yes	Yes	Yes	Yes	Yes

* you may add rows by hitting the tab button, or right click and select insert row below