HML IRB
RESEARCH & ETHICS

Research Ethics Protocols for the Protection of Human Subjects
EXPEDITED REVIEW

Project Title:	***Integrating Financial Capability into Employment Services (InFin)***
HML IRB Review ID#:	1013MEFA21
Initiating Official: Name & Organization	Sam Elkin. Principal Associate, MEF Associates sam.elkin@mefassociates.com
Principal Investigator: Degree(s), address, email	Mary Farrell, MPPM and Signe-Mary McKernan, PhD MEF Associates 1330 Braddock Pl, Suite 220 Alexandria, Virginia 22314
Other Key Personnel: Title, degree(s):	from MEF Associates: Sam Elkin, Principal Associate, MPP Valerie Benson, Senior Research Associate, MPP Riley Webster, Research Analyst, MPP Lorraine Perales, Research Analyst, MPP, MSW Eunice Yau, Research Assistant, BA from Urban Institute: Heather Hahn, Senior Fellow, PhD William J. Congdon, Principal Research Associate, PhD Mark Treskon, PhD

	Kassandra Martinchek, MPA
Primary study site(s): The location(s) of your subjects	United States
Duration of Study: & completion date	May 1, 2021 to January 31, 2024
Participation of Subjects: From – to dates	February 2022 to October 2022
Funding Source: Primary funder	Office of Planning, Research, and Evaluation (OPRE) at the US Department of Health and Human Services (HHS)

Billing: IRB approval cannot be provided without completing this section.	
Billing Information Please provide all billing information required by your organization, including PO or contract numbers we will need to invoice you.	
Billing Contact Please provide email address of invoice recipients.	

Date of IRB Request	15 October 2021
Date(s) IRB Comments Returned	None
Date Final Documents Received	15 October 2021
DATE OF IRB APPROVAL	18 October 2021

→ PROCESS: HML IRB will conduct a research ethics review of submitted materials and make comments below. We will then return this template for responses from researchers. Please reply in the right-side column, and we will issue a letter of approval or ask for further clarification.

	Ethics Review Board Criteria of Interest	IRB OK	Reviewer Comments or Requests for More Information
Section 1	***Research Risk*: Do submitted materials address potential risks of participation?**	**IRB use**	**Researchers: Please respond under IRB's red comments in another color**
1.1	Minimal Risk Only: Where the probability and magnitude of anticipated harm or discomfort is not greater than ordinarily encountered in daily life or during performance of routine physical or psychological exams or tests.	X	Please keep us informed of any subject protection protocol or research design changes that need to occur in adaptation to the COVID-19 pandemic in the sites of your study.
1.2	Research that may involve greater than minimal risk, but where risks are justified by anticipated benefits; where the relation of the anticipated benefits to risks is at least as favorable as available alternative approaches; and where the intervention or procedure is likely to yield generalizable knowledge.	X	
1.3	If there is potential for greater than minimal risk, are mitigating procedures described?	X	
1.4	Has (or will) approval for this study been obtained by any other research ethics committee or any other type of national or local entity? Urban Institute Institutional Review Board	X	
1.5	Comments, amendments, additions, or revisions	X	
Section 2	***Research Design:* Do submitted materials describe the proposed research?**		
2.1	Background and rationale	X	
2.2	Description of methodology	X	
2.3	Are all documents final versions?	X	

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2.4	Does study involve an intervention or treatment group?	X	
2.5	Does study involve a comparison or control group?	X	
2.6	Type of data collection: a. survey questionnaire……..…X b. subject interview……..……X c. key informant interview (KII)……..…….. d. focus group discussion (FGD)……..…X e. document review……..…… f. on-site observation……..……..…… g. case study……. h. secondary data analysis…..…… i. physical measurements ……. j. biological specimen ……..…….. k. other..……..…..……	X	
2.7	Number of Data Collections: a. one-time (no follow-up)……..……X b. two or more (follow-up) ……....X A subset of survey respondents may be included in more than one of the data collection activities (e.g., survey, interviews, and administrator FGD).	X	.
2.8	Sample size: Total *n* or approximate *n* = 163	X	
2.9	Are any subjects children (<18 years old)? None	NA	
2.10	Comments, amendments, additions, or revisions	X	
Section 3	***Recruitment:* Do submitted materials describe subjects and the recruitment process?**		
3.1	Subject identification: a. subjects' names are recorded with responses……X online surveys b. names recorded separate from responses…….…X phone interviews and remote FGDs c. no names are recorded ……..……	X	

	d. other personally identifiable information (PII) is recorded ……..X online surveys e. no PII is recorded ……..…… f. subjects are given a unique identifier.....X		
3.2	If name or any other PII is recorded, are procedures included for how this info will be kept separate from responses?	X	
3.3	Are sampling strategy & subject recruitment procedures adequately described?	X	
3.4	Do recruitment procedures show any indication of coercion, intimidation, compulsion, pressure, or force?	X	
3.5	If subjects are children, do materials adequately describe ages and why these ages are appropriate?	NA	
3.6	If subjects are children, are materials (e.g.: survey instruments, focus group topics, etc.) appropriate based upon age?	NA	
3.7	If subjects are children or other vulnerable groups, is recruitment done in a manner sensitive to potential vulnerabilities or weaknesses (real or perceived) subjects may have?	NA	
3.8	If subjects are paid, compensated, or provided a gift for participation, is the incentive described and justified as being non-coercive?	X	
3.9	If future contact with subjects is planned, does it provide for subject safety and data security through the research period and beyond?	X	
3.10	Comments, amendments, additions, or revisions	X	

Section 4	***Informed Consent:*** **IC is a negotiation whereby subjects are informed about the study and their rights, and they agree to participate voluntarily. IC must be sought from each subject or the subject's authorized representative confirming this process.**		
4.1	Type of Informed Consent: a. written & signed ……..…… b. written not signed ……..……X survey c. written & signed by authorized representative.…. d. verbal & signed or recorded……. e. verbal & signed by authorized representative…… f. verbal not signed……..……..……X interviews and FGDs g. active……. h. passive……. i. other …….	X	
4.2	Are written IC documents, using clear and simple wording, included?	X	
4.3	Are procedures for obtaining IC adequately described?	X	
4.4	Does IC include the purpose of the research presented in simple, age, education, and culturally appropriate local language?	X	
4.5	Does IC state that participation is voluntary, and subject may choose to not respond to any or all questions, or may withdraw without consequences?	X	
4.6	Does IC include a description of any risks or benefits to subjects?	X	
4.7	Does IC include a statement describing how confidentiality (or anonymity) of subjects and data will be maintained, and any limitations to confidentiality?	X	

4.8	Does IC include the expected duration of the subject's participation (hours/minutes)?	X	
4.9	Does IC provide identity and contact info of investigators?	X	
4.10	Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group?	X	
4.11	Where subjects differ by type (e.g.: age, sex, risk, status, etc.), are IC documents specific for each type?	X	
4.12	Where data collection differs by method (e.g.: survey, FGD, interview), do IC materials cover each method?	X	
4.13	For child subjects, is there provision for obtaining consent from parent, guardian, caregiver, or responsible person?	NA	
4.14	For child subjects, is their role in the study described adequately for them to provide written or verbal assent?	NA	
4.15	If IC is written, is a copy left with subjects or there is explanation for not doing so?	X	
4.16	Comments, amendments, additions, or revisions	X	
Section 5	***Subject Protections:*** **Do submitted materials clearly identify protection against risk?**		
5.1	Do materials describe the use of information collected?	X	
5.2	Are subjects given a clear indication of who will have access to their responses and in what form?	X	
5.3	If children or other vulnerable groups are subjects, do materials clearly describe special considerations or accommodations for their safety or protections?	NA	
5.4	If children or other vulnerable groups are subjects, have personnel had experience working with these groups? If not, what specialized instruction will they receive?	NA	
5.5	Have personnel collecting data from subjects had ethical training specific to the target group?	X	

5.6	Are personnel collecting data aware of ethical issues that may arise and their mitigation strategies?	X	
5.7	Comments, amendments, additions, or revisions	X	
Section 6	***Subject Risks:* Are risks reasonable in relation to any benefits to subjects and to the importance of knowledge that may be expected to result from the research?**		
6.1	Do study objectives show that risk is reasonable in relationship to expected gains?	X	
6.2	Does study deliver potential benefits to subjects through provision of information or services?	X	
6.3	In event of physical, psychological, social, or legal risk, do protocols describe and outline clear strategies to mitigate against these risks?	X	
6.4	If a subject discloses or is suspected to be at risk outside of the study, are procedures in place to address or report risk?	X	
6.5	Comments, amendments, additions, or revisions	X	
Section 7	***Data Protection:* Do data collection and storage protocols adequately ensure subject & data safety?**		
7.1	Are data collection tools appropriate and constructed to assure subject privacy, confidentiality, or anonymity?	X	
7.2	Do data collection procedures and environment ensure data security?	X	
7.3	Do procedures cover all data types (e.g., written, audio, video, observation), & are protections described for each type?	X	
7.4	Is chain of custody of data, from collection, transfer, analysis, de-identification, storage, to destruction, clearly described?	X	
7.5	Will a data set be created for storage, dissemination and/or use either publicly or restricted at the completion of this project? If yes, please describe the data set, where it	X	

	will be stored, with whom it will be shared, and its intended use.		
7.6	Is future contact with subjects, if any, planned in a way that ensures data security?	X	
7.7	Comments, amendments, additions, or revisions	X	

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