



Date: Thursday, August 11, 2016 11:20:06 AM

Print Close

ID: IRB13-1481

View: 1.1 Study Identification

**1.1 Study Identification**

This is the first step in your IRB Application. As you complete this application, you will automatically be guided to the appropriate forms needed to complete your submission. *Please note that you will see only those sections which apply to your submission based on the information you provide.*

- \* Full Study Title:**  
Evaluating Child Protective Effects of Economic Strengthening and Child Rights Interventions among Ultra-poor Families in Burkina Faso
- \* Short Study Title: (Limit to 25 characters. This short title will appear with the IRB number for tracking within AURA)**  
Children in Burkina Faso
- \* Principal Investigator:**  
Leyla Ismayilova
- Will the Principal Investigator be obtaining consent?**  
 Yes  No

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View: 1.2 Study Personnel

**1.2 Study Personnel**

- Primary Contact:**  
Leyla Ismayilova
- Will the Primary Contact be obtaining consent?**  
 Yes  No
- Co-Investigators:**

Last Name	First Name	Dept	Profile	Disclosure Date	Management Plan Date
<a href="#">View</a> Karimli	Leyla	SSA	<a href="#">Leyla Karimli's Profile</a>		
- Other Study Personnel:**

Last Name	First Name	Dept	Profile	Disclosure Date	Management Plan Date
<a href="#">View</a> Blum	Austin	Student	<a href="#">Austin Blum's Profile</a>		
<a href="#">View</a> Gaveras	Eleni	SSA	<a href="#">Eleni Gaveras's Profile</a>		
- Is this study supported by a regulatory support group?**

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View: 1.3 Research Team Summary

**1.3 Research Team Summary**

Validate that researchers previously selected appear. If not, return to View 1.2 and add/edit.

**1. Principal Investigator:**

Last Name	First Name	Dept	Profile	Consenting Subjects	Human Subjects Training Completed	Other Human Subjects Training Completed	Disclosure Date	Management Plan Date
Ismayilova	Leyla	SSA	<a href="#">Leyla Ismayilova - Profile</a>	No	2/25/2013		7/1/2016	

**2. Primary Contact:**

Last Name	First Name	Dept	Profile	Consenting Subjects	Human Subjects Training Completed	Other Human Subjects Training Completed	Disclosure Date	Management Plan Date
Ismayilova	Leyla	SSA	Leyla Ismayilova - Profile	No	2/25/2013		7/1/2016	

**3. Co-Investigators:**

Last Name	First Name	Dept	Profile	Consenting Subjects	Human Subjects Training Completed	Other Human Subjects Training Completed	Disclosure Date	Management Plan Date
Karimli	Leyla	SSA	Leyla Karimli's Profile	no				

**4. Other Study Personnel:**

Last Name	First Name	Dept	Profile	Consenting Subjects	Human Subjects Training Completed	Other Human Subjects Training Completed	Disclosure Date	Management Plan Date
Blum	Austin	Student	Austin Blum's Profile	no	2/7/2015	8/14/2014		
Gaveras	Eleni	SSA	Eleni Gaveras's Profile	no		11/25/2014		

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View: 1.4 Funding Sources

**1.4 Funding Sources****1. \* Funding Source: (Please check all that apply)**

Externally Funded/Supported

**2. If Internally funded, please choose from the following:**

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View: 1.4.1 External Funding Information

**1.4.1 External Funding Information**

You indicated that this as an externally funded study. Please provide the following information about all external funders of this study. *Please note that all external funding sources MUST be routed through URA. If your funding source is not listed, please contact the IRB office.*

**1. \* Primary Funding Source:**

AURA Grants Funding Proposal (select below)

FP056931-01-PR

**2. Additional funding sources for study related expenses (study interventions, study drug/device provided at no cost, etc.)**

ID Name PI Last Name PI First Name Sponsor Prime Grantee Status Submission Deadline  
There are no items to display

**3. Please list any other additional funding sources.****4. If this study involves an umbrella grant, please clarify which part(s) of the umbrella grant will**

**be associated with this specific protocol.**

This protocol is associated with specific activities to be carried out by the University of Chicago research team. These activities include:

- Developing and adapting the instrument for data collection;
- Pilot testing of data collection tools;
- Collecting baseline data;
- Analyzing and reporting the baseline data;
- Collecting a 12-month follow-up data;
- Analyzing the results, and publishing in peer-reviewed articles;

Field activities in Burkina Faso, including participant recruitment, informed consent, data collection and intervention delivery, will be implemented by

- 1) Trickle Up, a partner organization with field offices in New York and Burkina Faso, and
- 2) Aide aux Enfants et aux Familles Démunies (ADEFAD), local partner of TrickleUp in Burkina Faso.

Additionally, the project will involve Women's Refugee Commission (WRC). The commission, another partner on this project, is a part of the International Rescue Committee (IRC) and is a member of the Child Protection in Crisis Learning (CPC). CPC, hosted by Columbia University Mailman School of Public Health, is a global network of humanitarian agencies and academic partners working to improve the protection of children in crisis-affected settings. Through the CPC network, WRC will assist with dissemination of study findings. Based on UChicago IRB submission, WRC will also assist with obtaining local IRB approval through the Child Protection in Crisis Burkina Faso Program Learning Group (PLG).

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View: 1.5 Study Locations

**1.5 Study Locations****1. Select UChicago locations where this study will be conducted:**

Location Name

There are no items to display

**2. If "UChicago (Other)" was chosen, please specify the UChicago location.****3. \* Is this a multi-site study? (If there are multiple sites conducting this study, please answer "Yes" whether or not the UChicago is the lead site)**
 Yes  No
**4. \* Are the UChicago researchers conducting this study or any portion of the study at a non-UChicago site (in the United States)?**
 Yes  No
**5. \* Are the UChicago researchers conducting this study or any portion of the study at an international site (outside the United States)?**
 Yes  No

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View: 1.5.3 International Sites

**1.5.3 International Sites**

You indicated that this study is being conducted at an international site and being overseen by the UChicago PI. Please provide the following information about the site(s) being overseen by the UChicago PI.

**1. \* Please specify the international sites where this research is being conducted and overseen by the UChicago PI:**

	Name of Site	Street Address	City:	Country	Type of Site	Local Review	Ethics Board Name	FWA #	Contact Info
<a href="#">View</a>	TrickleUp	14 BP 179	Ouagadougou	Burkina Faso	Households	Not Applicable	National Committee of Ethics,		(Name) Rachel Nanema (Title) Program Manager, TrickleUp-Burkina Faso (Phone number) 226-

Quartier  
Ouaga  
2000,  
Secteur  
15 sis  
rue 15-  
947

Burkina  
Faso

5037-4563 (Email)  
rnanema@trickleupbf.org

**2. Please attach Ethics or IRB Committee Review Document(s) for each site listed.**

Name

There are no items to display

**3. If there is no local ethics committee or IRB review of this study), please provide additional information for all that apply.**

We will seek the local IRB approval from the National Committee of Ethics in Burkina Faso following the initial review at the SSA UChicago.

**4. Specify your familiarity with and/or knowledge of the local research context.**

This study will be implemented in partnership with two local partners in Burkina Faso: TrickleUp and ADEFAD (Aide aux Enfants et aux Familles Démunies). The economic empowerment intervention will be administered by TrickleUp - an organization involved in reduction of extreme poverty in Burkina Faso since 2004. Drawing on 30 years of global experience, the Trickle Up program in Burkina Faso entails economic strengthening interventions to "graduate" ultrapoor women and their households out of extreme poverty. ADEFAD specifically focuses on children protective issues in poor families and will be responsible for the delivery of child protection intervention.

Through a community participatory approach, the communities themselves identify households living in extreme poverty. Within each of these households, a woman is identified to further participate in the program. Approximately 25-30 women form a village-level savings group receiving training on income-generating activities along with a non-repayable grant of 50,000 CFA. TrickleUp program supports these groups over a period of 3 years.

TrickleUp and ADEFAD have been partnering since 2008, serving over 1,000 families in Burkina Faso. At the national level, TrickleUp is an active member of the Child Protection in Crisis (CPC) Burkina Faso Program Learning Group (PLG), which includes local and national NGOs, CBOs, the University of Ouagadougou and government ministries.

In addition, during the development/preparation phase (first 3 months) jointly with TrickleUp, we will convene a Community Collaborative Board consisting of local experts in the field of child protection to review language, conceptual equivalence and culturally appropriateness of measurement instruments, recruitment strategies and data collection methods. Representatives of the Child Protection in Crisis (CPC) Burkina Faso Program Learning Group (PLG) and local consultants from the University of Ouagadougou will be also involved in the study.

**5. Specify how data will be taken out of the country, including the procedures in place to protect confidentiality.**

All hard copies of questionnaires and consent forms will be stored in locked cabinets in the TrickleUp office in Burkina Faso. Hard copies of questionnaires will not be taken out of the country. Instead, data will be entered into Excel or SPSS file in TrickleUp office in Burkina Faso.

After completing the informed consent process, participants will be assigned a unique identifier that they will use to store baseline and follow-up data. Therefore, all data will be masked for personally identifiable information and the dataset will contain no identifying information. This will protect from breach of confidentiality when sharing dataset between the field office in Burkina Faso and the research team at University of Chicago. Any software file transmitted over the Internet (e.g., for backup purposes) will be encrypted using a 128-bit AES algorithm prior to transfer.

All software files with identifying information (e.g. contact info) will be located on password and firewall protected computers. The list of participants containing link between identifying information and code numbers will be password-locked. Only the TrickleUp Country Representative (Alexice Tô), and the Principal Investigator (Leyla Ismayilova) will have access to this file. This list will be destroyed at the completion of the study. Analysis and reporting will be done only with combined data; no individually identifiable information will be published.

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View: 2.1 Research Categories

## 2.1 Research Categories

### 1. \* What type of IRB review are you requesting?

- Full Board Review (at convened meeting)**
- Expedited Review
- Exempt Determination
- Not Human Subjects Research Determination
- Unsure/Do Not Know

### 2. Required Additional Reviews

Dependent upon your research activities, consideration of this research may be required by other UChicago Committees. Please consider the research categories below and seek approval from the designated Committee if needed.

**Please select any applicable committees below. (Check all that apply)**

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None of these committees are required to the review this study

### 3. If "Other," please indicate the name(s) of applicable committee(s).

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View: 2.2 Purpose

## 2.2 Purpose

### 1. \* What is the primary activity of the study? (Please check **ONE**)

Administration of survey(s), interviewing, conducting focus groups, observational research, psychological testing, or similar activities

### 2. \* Please provide a brief, non-technical (lay) language description of the purpose of the research, including the research question.

The study aims at building the evidence base around the role of household economic strengthening and child rights sensitization intervention in improving protection outcomes for children, both as a means to better protect vulnerable children from violence and exploitation in Burkina Faso, and as part of a global effort to:

- Inform national Child Protection systems;
- Create program guidance tools for practitioners; and,
- Ensure that the protection of children is not an afterthought of anti-poverty interventions, but rather a central concern in all responses.

The specific objectives of this evaluation study are:

1. To test the effect of the household economic intervention developed by TU on child protection outcomes (labor-related family separation, child labor, including child exploitation and involvement in hazardous work, violence against children, and child marriage);
2. To test the additive effect of a child protection sensitization component on child protection outcomes compared to the economic intervention alone; and,

Specific research questions are:

1. Compared to families in the wait-list control arm, to what extent do ultra-poor households assigned to Trickle Up economic strengthening intervention for female caregivers demonstrate better protection outcomes for household children (family separation, children per household working, studying at madrassas, married by age of 17, exposure to violence including the worst forms of child labor) at 12 follow-up periods?
2. Compared to families in the wait-list control arm and families receiving the economic intervention alone,

to what extent do households that receive combined Trickle up and child protection sensitization intervention demonstrate better child protection outcomes at 12-month follow-ups?

3. What are the caregiver-level factors (economic well-being, women's empowerment, caregiver's well-being, normative beliefs about child abuse, etc.) that mediate changes in the child protective outcomes and contribute to reducing protection risks for children?

**3. Please provide an explanation of how this study will contribute to existing knowledge. Please include relevant citations of previous studies that provide a justification for this study. If the relevant citations are in the attached protocol document, please only provide a reference to the applicable section(s) and/or page numbers.**

A 2012 survey found that 1.25 million (or 37.8%) of children ages 5-14 in Burkina Faso are working to augment the incomes of their families, or because their families are too poor to support them. Each year, in the Nord and Sahel Regions bordering Mali, after the dry season and just before the new planting season begins, school attendance tends to plummet because rates of hunger increase, and children are subject to a variety of child protection risks related to their poor household economic status. However, for the poorest households, these risks are not just cyclical but are year-round. They include:

- Child labor under hazardous conditions and labor-related family separation due to work in gold mines, cotton fields, or plantations in the Ivory Coast or in the South of Burkina Faso, involving physical deprivation and violence;
- Adolescent girls being sent away to work as maids in Ouagadougou and other towns, facing risks of sexual exploitation and abuse; and,
- Boys being sent to madrassas (religious schools), where they are made to do unpaid and/or hazardous work including begging in the street, and are subject to physical abuse.

Many end up in the Worst Forms of Child Labor, a category of violence defined by the UN as including practices similar to slavery, debt bondage and serfdom, and forced or compulsory labor and hazardous work.

With the ongoing food and nutrition crisis in the Sahel Desert, the situation has recently worsened in some areas of Burkina Faso. Children living in ultra-poor households in Burkina Faso—those who are among the poorest of the extreme poor—are particularly vulnerable to the above forms of violence that accompany family separation; however, they also face risks of violence and deprivation at home, including hazardous labor, forced and early marriage, and transactional sex.

Although poverty is widely accepted as the primary driver of family separation worldwide, the impact of economic interventions on children's welfare is rarely assessed. A methodical search of literature in 2011 found few examples of economic strengthening programs that had been rigorously evaluated for their outcomes on the protection and well-being of children in beneficiary households. This is particularly the case regarding ultra-poor households, whose children tend to be most vulnerable due to their economically and socially marginal situations, and who are generally left out by economic initiatives.

Furthermore, while the stabilization and strengthening of household economies is believed to be necessary for enhancing child protection, not enough is known about whether economic strengthening alone is sufficient to bring about significant child protection outcomes.

This study will test the assumptions underlying hypotheses that household economic strengthening improves child protection, while also revealing dynamics about how and why such changes do or do not take place. This will have direct implications for the design of economic empowerment programs in the field. These implications include, but are not limited to, the potential added value of integrating measures to directly promote child protection.

The study also aims to test whether the addition of a low-cost child rights and child protection sensitization intervention can deepen any protective effects on children that may result from the economic intervention, thus also helping to determine whether economic strengthening interventions alone are sufficient to significantly improve child protection outcomes.

**4. \* In non-technical language, describe the tasks/tests or procedures subjects will be asked to complete or undergo.**

**Explain step by step what subjects will be asked to do; be sure to distinguish those tasks which are experimental from those which are not being done specifically for research-purposes, as**

**applicable.**

**If subjects are not actively participating in the research (for example, this is a leftover sample collection protocol, chart review, or secondary data analysis), describe what will be done with samples and/or data as well as how they will be obtained.**

This study employs a 3-arm cluster randomized control design to evaluate the effect of economic empowerment intervention and the additive effect of child rights sensitization on child protection.

Eligible households, consisting of female caregivers and their children, will be recruited from ultrapoor communities in Nord Region, Burkina Faso, where Trickle Up operates. Twelve comparable villages will be selected based on similar characteristics (population size, geography, distance from an urban center, and socio-economic status of residents). Villages will be randomly assigned to three study arms (4 villages per arm).

The study will recruit female caregivers and all their eligible children from total of 360 households in the selected villages (30 households per village / 120 households per study arm). Participants (female caregivers and their children age 10-16 who live in the household) will be randomly assigned to the wait-list control arm, treatment arm 1 (Trickle Up arm, economic empowerment only), or treatment arm 2 (Trickle Up Plus arm, economic empowerment plus child protection sensitization). To minimize cross-arm contamination, randomization will be conducted at the village level and eligible participants from the same village will be assigned to the same condition. All participants will participate in two assessments: baseline and a 12-month follow-up.

#### I. Trickle Up Economic Strengthening Intervention (Trickle Up arm)

The economic empowerment intervention was designed by the implementing partner - Trickle Up - to respond to disparities particular to gender and age, as well as the needs of a particularly disadvantaged economic class, the ultra-poor, which includes disproportionate numbers of women and their dependent children. The intervention is based on proposition that when women have greater income, they are more likely than men to use their resources on household needs, including for feeding, clothing and educating their children. Therefore, the intervention involves directly female adults within the household, and includes the following:

- 1) Savings group formation and training in a locally-adapted, low-risk, informal form of micro-finance recognized for its sustainability and its ability to reach those who lack access to formal financial services. With approximately 25-30 participants each, savings groups provide participants with a safe place to save, access to credit, and the opportunity to build social capital. Savings groups help participants smooth incomes during times of vulnerability, and provide the foundation for building financial self-reliance. They also serve as a platform for additional training and educational interventions.
- 2) Household livelihood planning and training. These are regular group meetings and one-on-one mentoring are aimed at increasing participants' understanding of how to leverage and manage resources. The training curriculum is custom-designed for populations with limited or no literacy and numeracy skills and is designed around basic business concepts, goal setting, and future planning.
- 3) Seed capital grants to assist in micro-business start-up (e.g. vending, animal husbandry). These are conditional seed capital grant of approximately \$100 (50,000 CFA franc) to help kick-start a new or ongoing livelihood activity for people who are too poor to take on the risk of a micro-loan.
- 4) Bi-weekly to monthly one-on-one mentoring/coaching on livelihood development conducted by field workers.

The economic empowerment intervention will be administered by Trickle Up.

#### II. Sensitization on Child Protection from Violence and Exploitation (Trickle Up Plus arm)

The combined economic and child rights sensitization arm will also include a sensitization component on beliefs and knowledge related to protection of children from violence and exploitation.

The child protection sensitization intervention is specifically designed to address a list of issues, including (a) low enrollment and retention rates in school, particularly among girls; (b) labor migration at an early age, with mostly boys being sent to mining sites, and mostly girls being sent to towns to work as domestic maids; (c) early and forced marriage of girls; and (d) cultural attitudes and expectations around gender

that underlie girls' vulnerability to violence. Sensitization will include a female caregiver involved in the study, a child(ren) involved in the study, and a male head of the household. Sensitization will cover the following information:

- The dangers of sending children away from home for work (in mining sites, or to other towns to work as domestic servants) or to serve as Talibés (children enrolled in madrasas, where they are known to be subject to hazardous unpaid work and corporal punishment);
- The negative consequences of early and forced marriage;
- The importance of school enrollment, attendance and performance for girls, including the opportunity cost of domestic chores; and,
- Cultural attitudes and expectations around gender that underlie girls' vulnerability to violence.

The sensitization component will be implemented by Trickle Up's local partner, ADEFAD (Aide aux Enfants et aux Familles Démunies - Burkina Faso), which has 10 years of experience in child protection sensitization work in Burkina Faso.

Although the current evaluation covers baseline and post-intervention assessment for a period of 12 months, participants will receive intervention for up to three years, which is the program cycle of TrickleUp.

### III. Wait-list condition (Control Arm)

Eligible households randomly assigned to the control condition will be put on the wait list. In line with ethical research practice, participants assigned to the wait-list condition will receive the Trickle Up intervention upon completion of the evaluation phase.

**5. \* Is this a resubmission of a previously approved study that has been terminated or has expired?**

- Yes  No

**6. If yes to question 5., what is the previous IRB number? Please also provide a brief description of**

- 1. (1) the preliminary results of the project, if any;**
- 2. (2) any complaints about the research from subjects;**
- 3. (3) any new information regarding the risks to subjects (such as literature search results or new publications) received since cessation of approval;**
- 4. (4) all unanticipated problems that occurred at the UChicago;**
- 5. (5) whether any research was conducted during the lapse in approval; AND**
- 6. (6) the reason the study is being resubmitted.**

**7. Is another site requesting that the UChicago be the IRB of Record?**

- Yes  No

**8. Are you requesting that an outside IRB (not UChicago) be the IRB of record for this study?**

- Yes  No

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View: 2.2.2 Additional Activities (Methods & Procedures II)

## 2.2.2 Additional Activities (Methods & Procedures II)

You indicated that the primary activity of the study is the administration of survey(s), interviewing, conducting focus groups, observational research, etc. If this study does NOT include any of research procedures listed below, please return to section 2.2 question 1. and select an alternate primary purpose.

Please provide the following information about this study.

**1. \* What research procedures does the study involve? (Please check all that apply, including the main purpose and any other procedures that may occur on the study.)**

Surveys/Questionnaires

**ID:** IRB13-1481

View: 5.0 Methods &amp; Procedures II

Please select continue to proceed to the next view for pertinent questions regarding the methods that are associated with your study.

If your study does not involve any of the methodologies in this section you will skip ahead to the next section

**ID:** IRB13-1481

View: 5.1 Surveys &amp; Questionnaires

## 5.1 Surveys/Questionnaires

You have indicated that this research will involve the use of surveys or questionnaires.

**1. \* Please provide the names of all surveys/questionnaires to be used in this study and/or a description of any that are not formally named (e.g. study specific questionnaires).**

To explore the research questions posed by this study, we will develop two instruments (Caregiver Instrument and Child Instrument), adapting items from the following standard questionnaires:

Child Survey:

- Child's Labour Questions from ILO/International Labour Organization SIMPOC Survey
- Food Security Questions from the Household Hunger Scale (HHS, 2011)
- Rosenberg Self-Esteem Scale (Rosenberg, 1965)
- Center for Epidemiological Studies Depression Scale for Children /CES-DC (Weissman MM, Orvaschel H, Padian N. 1980)
- Parental Social Support for Adolescents /PSSA (Aneshensel & Sucoff, 1996)
- Child Abuse Screening Tool - Children's Version (ICAST-CH) (International Society for the Prevention of Child Abuse and Neglect/ISPCAN. Runyan, et al., 2009)
- Revised Child Impact of Events Scale (Perrin, Meiser-Stedman, & Smith, 2005)

Caregiver Survey:

- GAD (Generalized Anxiety Disorder)-7 Anxiety (Spitzer et al, 2006)
- Patient Health Questionnaire (PHQ-9) (Kroenke & Spitzer, 2002)
- Positive Relationship with Parents – Parent Survey (Child Trends for the Flourishing Children Project)
- Child Discipline (Adapted from UNICEF's Multiple Indicators Survey / MICS4)
- Women's Empowerment and Domestic Violence questions from the DHS Women's Status Module (2012)

**2. \* Are all surveys/questionnaires to be administered standard?**

Yes  No

**3. If no, please list the non-standard questionnaires and list any prior use(s) of those questionnaires.**

Some of the items in the instruments to be designed for this study will be adapted from the non-standard survey conducted by TrickleUp. This survey aims at assessing families' household's economic well-being and livelihood development and includes the following:

- Questions about labor-related family separation, involvement in child labor;
- Diversification of income sources; food security; savings behavior and access to and usage of credit; household assets (both productive and consumer); housing; economic activity and income of both women participants and the broader household (taking into account often polygamous families with multiple sub-units); consumption patterns and coping mechanisms in times of need;
- Investment in children's basic needs, including education;
- Questions about women's role and participation within the household and community.

In addition, administrative data from savings groups (e.g., attendance, savings amounts) will be sought in order to provide independent estimates of key economic variables.

**4. \* Please clarify how often subjects will be asked to complete surveys/questionnaires and the approximate length of time that each questionnaire will take.**

Questionnaires, translated in French and Moore (French is an official language in Burkina Faso, and Moore is one of the principal local languages spoken by approximately 40% of population), will be administered by trained Research Assistants. Data will be collected at two points: at baseline, and a 12-month follow-up. Caregiver Instrument and Child Instrument will be administered separately by trained research

assistants at participant's home.

The same instruments will be administered to participants at a 12-month follow-up.

Caregiver Instrument will be administered for 60 minutes with female caregivers (a wife or any other adult female nominated by the male head of the household for participation in the study). Child Instrument will be administered for 45-60 minutes with the child age 10-16 living at home.

Although the grant proposes three assessments (baseline, six-month post-intervention and one-year follow-up), due to the budget constraints, the number of assessments was reduced to two. All participants will participate in two assessments: baseline and a 12-month follow-up.

## 5. Please attach any surveys or questionnaires or related documents.

Name

Child Survey - ENGLISH

Child Survey - FRENCH

Mother Survey - ENGLISH

Mother Survey - FRENCH

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View: 6.0 Methods & Procedures III

Please select continue to proceed to the next view for pertinent questions regarding the methods that are associated with your study.

If your study does not involve any of the methodologies in this section you will skip ahead to the next section.

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View: 7.1 Study Population

## 7.1 Study Population

1. **\* Select the population(s) that will be enrolled from the list of vulnerable populations below. (Please check all that apply)**  
Healthy Children (under the age of 18)
2. **Please select any additional populations that will be enrolled in this study. (Please check all that apply)**  
Healthy Adult Volunteers  
Non-English Speakers  
International Subjects
3. **\* Describe any populations to be excluded from the research. Research should involve equitable selection of subjects; researchers should not select subjects on the basis of discriminatory criteria. Selection criteria that excludes individuals based on age, gender, language or racial or ethnic group requires a clear, scientific rationale for the exclusion.**  
Subject Exclusion Criteria  
Participants will be excluded from participation in the study if the child or the parent is assessed to have a cognitive impairment that would interfere with their ability to provide informed consent. As a part of the informed consent process, conducted through a French-speaking research assistant, potential participants will be asked to state their understanding of areas addressed during the informed consent discussion including (1) the nature and extent of participation in the study; (2) risks involved with participation; and (3) the potential benefits of participation in the study. If a participant is unable to respond to any of the three items, this child/female caregiver pair will be excluded from the study.
4. **\* Please provide the number of subjects to be enrolled (this is the expected number of subjects needed to complete all study procedures).**  
720
5. **\* Please specify the exact age range to be enrolled. For example, 0-6 months, 18 and up, 18-24 yrs, etc.**  
10-16 year old children and adult female caregivers (18 and up).
6. **If applicable, please provide more information regarding multiple study groups and the total number of subjects needed for each group. (e.g. 100 healthy children and 100 children with**

**autism or chart review of 100 subjects and prospective enrollment of 100 subjects)**

She study will recruit participants from 360 households (120 household per arm).

The number of subjects to be enrolled is 360 female caregivers and all their eligible children (potentially, the study will recruit at least 360 children ages 10-16)."

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View: 7.1.1 Healthy Children (Minors)

**7.1.1 Healthy Children**

You have indicated that this research will involve healthy children. Please provide information about the healthy children that are subjects in this study.

1. **\* Please justify the risks to healthy children participating in the project.**  
The risks to healthy children participating in the project are not greater than those ordinarily encountered in daily life in their communities.
2. **\* In the PI's opinion, what is the level of risk to the subject?**  
No greater than minimal risk to the subject (45 CFR 46.404)
3. **\* Who are you proposing to obtain parental permission from?**  
One parent
4. **\* Will assent from children be obtained?**  
Obtaining assent
5. **If applicable, will consent be obtained when child subjects turn 18?**  
 Yes  No

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View: 7.9 Non-English Speakers

**7.9 Non-English Speakers**

You indicated that this study involves non-English speaking subjects.

1. **\* Please describe the non-English speaking population(s) to be enrolled.**

*Please attach the associated translated consent document(s) in the Consent Procedures section, along with certification of translation. Please ensure that any translated surveys, advertisements or other documents are attached in the appropriate sections of this form.*

The study will be conducted in Burkina Faso among female caregivers and children ages 10-16 living in the household. Official language in Burkina Faso is French. However, 28.7% of adult population ages 15 and above are illiterate.

Around 40% of population also speaks Moore - one of the principal local languages in Burkina Faso. Moore is spoken by prevailing majority of people in the Northern part of Burkina Faso - an area covered by this study.

All instruments and consent forms will be translated into Moore and French (French is an official language in Burkina Faso, and Moore, and back translated into English. The TrickleUp Country Representative in Burkina Faso is multilingual (Moore, English, and French). The staff in TrickleUp and ADEFAD implementing the treatment all speak Moore and French. The study will hire Moore- and French-speaking Research Assistants for data collection purposes (i.e. to administer surveys and enter data). The Co-Investigator, Dr. Karimli, is also fluent in French and will review translated study materials.

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View: 8.1 Recruitment and Screening

**8.1 Recruitment & Screening**

1. **\* Will any member of the UChicago research team be approaching potential participants for involvement in this study and/or will the UChicago researchers be recruiting with advertisements?**  
 Yes  No
2. **If no, briefly explain why not.**

The study will be conducted in Burkina Faso and no UChicago employees will be involved in recruitment of study participants.

Interaction with human subjects (screening, recruitment, and enrollment of participants in the study; data collection) will be conducted by TrickleUp in Burkina Faso and its partner organization - ADEFAD (Aide aux Enfants et aux Familles Démunies); and the study will seek local IRB approval from the National Committee of Ethics in Burkina Faso.

No other partners (including Women's Refugee Commission (WRC), Burkina Faso Program Learning Group (PLG) and local consultants (from the University of Ouagadougou), or other representatives of the Child Protection in Crisis (CPC)) will be involved in either interaction with research participants or reviewing the identifiable data.

No U Chicago employees (including PI Leyla Ismayilova and Co-Investigator Leyla Karimli) will be involved in screening, recruitment, enrollment of study participants, or actual collection of data. The study Co-I (Leyla Karimli) will have no access to identifiable data.

The PI or Co-I will be involved only in the study design, training of local staff, data analysis and interpretation and overall supervision of all field activities. The PI or Co-I will not be involved in recruitment and will not be approaching any potential participants for involvement in the study.

The question 8.1.1 was answered 'Yes' in order to provide information about the recruitment process.

The screening and recruitment of participants will be implemented by partner organizations operating in the field, i.e. TrickleUp and ADEFAD (Aide aux Enfants et aux Familles Démunies). This evaluation study will use the same recruitment and selection procedures employed by Trickle Up to enroll participants in its economic intervention programme. This process is designed to identify and engage the most impoverished and vulnerable households in the community. However, for this evaluation we will modify the verification process to only select women with children ages 10+ years.

As a part of the recruitment process, Trickle Up's local implementing partner ADEFAD conducts a Participatory Wealth Ranking (PWR) exercise. The PWR, facilitated by ADEFAD, is conducted within the community and by the community members. Resulting from this exercise is the list of locally defined poverty criteria.

These poverty criteria are, then, used to screen and select the poorest households within the community.

Once the poorest households are selected, the TrickleUp staff visits the households and verifies the household's poverty level (against the poverty criteria defined through PWR exercise).

The communication between the TrickleUp and the household involves the male head of the household. If the household is assessed as being ultra-poor, the TrickleUp staff seeks consent from a male head of the household for his wife to be offered an opportunity to engage in economic empowerment program activities.

If family is polygamous, TrickleUp works with whichever woman has been nominated by the male head of the household. However, if during the household-level verification, a significant disparity in the living conditions of the wives is noted, the field agent will attempt to persuade the husband to allow them to work with the most "least advantaged" wife.

The recruitment will continue until the full sample size (360 households) is reached.

**ID:** IRB13-1481

**View:** 8.1.1 Recruitment

### 8.1.1 Recruitment

You indicated that this study will be recruiting subjects for this study. Provide the following information about how you will identify and recruit subjects for this study.

1. **\* How will you identify or screen potential subjects to recruit/include in this study? (Check all that apply)**  
 Directly Approaching Subjects  
 Other
2. **Describe details of recruitment method where applicable, including names of relevant publications, websites, etc.. If "Other," please describe the recruitment method.** (For example,

if you indicate "Newspaper," please provide the name of the newspaper.)

The process of recruiting and enrolling participants for this study consists of three main steps that have been implemented by the Trickle Up and ADEFAD in the past to recruit program participants.

#### 1) Selection of Villages

First, the Trickle Up, together with its local implementing partner ADEFAD, identifies villages with the poorest yield for their crops and highest level of poverty (according to the regional, province and commune level, as well as according to information provided by local authorities). Once these villages are identified, ADEFAD conducts a Participatory Wealth Ranking exercise where community members develop locally defined poverty criteria for the community. Usually, up to 75% of community members participate in this exercise. This process is a part of community-based participatory poverty assessment used by TrickleUp for its program planning, and no consent or assent forms will be obtained at this step.

#### 2) Selection of Households

Second, using the locally defined poverty criteria mentioned above, TrickleUp and ADEFAD select ultra-poor households, and holds visits in these households with the male head of the household. During this visit, the staff representative of TrickleUp and ADEFAD assess the household's economic conditions and verify whether it falls into the "ultra-poor" category as defined by locally developed poverty criteria. We will use this visit for recruiting and screening participants. Consent form is obtained at this step from male head of the household.

#### 3) Selection of Individual Participants

Third, once the screening is completed, two additional consent forms will be obtained at this step: a consent of an adult female caregiver and an assent of a child participant. A female caregiver, nominated by the male head of the household, will be offered information about the study. The information will be provided by trained RAs and will describe project purposes, procedures, risks and financial incentives for participation. If an adult female #1 (in the list of women nominated by the male head of the household) refuses to participate, the data collector/recruiter will then approach an adult female #2, and so on. Interested female caregivers and their eligible children will receive the same recruitment information about the study as male heads of households.

#### Inclusion Criteria

Households that meet the following eligibility criteria will be invited to participate in the study:

- 1) Household meets locally defined poverty criteria (classified as an ultra-poor household);
- 2) Household has at least one child ages 10-16;
- 3) Male head of household provides permission for his wife and child to participate in the study;
- 4) Eligible child and female caregiver/parent can commit to study participation.

Eligible and consenting female caregivers and children will be enrolled in the study.

### 3. \* Please specify who will make initial contact with the potential subject.

The trained TrickleUp staff conducting the household-level poverty assessment described above will make initial contact with the potential subject.

Alexice Tô, the TrickleUp Country Representative in Burkina Faso, and trained data collectors/research assistants will be responsible for recruitment, screening and obtaining informed consent from participants.

### 4. Please attach all recruitment documents.

Name

[View](#) Description of participant recruitment process by TrickleUp

[View](#) Examples of locally defined poverty criteria utilized by TrickleUp to recruit the households into the program

[View](#) Screening instrument (in French) utilized by TrickleUp to recruit participants into the program.

ID: IRB13-1481

[View](#): 9.1 Compensation

## 9.1 Compensation

### 1. \* Will subjects be paid or otherwise compensated for participation in the study?

Yes  No

ID: IRB13-1481

[View](#): 9.1.1 Compensation Details

## 9.1.1 Compensation Details

You indicated that this study involves compensation. Provide the following information about the compensation used in this study.

**1. \* How much will subjects be compensated (total and prorated amounts)?**

All participants will be compensated (non-monetarily) for their participation in baseline and follow-up assessments. Participants will not be compensated for their participation in interventions.

However, participants assigned to one of two intervention arms will also receive Seed Capital Grants in the amount of 50,000 CFA franc (approximately \$100) as a part of Trickle Up Economic Strengthening Program to assist in micro-business start-up (e.g. vending, animal husbandry).

If desired, wait-list control participants will receive the same Trickle Up intervention and benefits upon completion of the evaluation phase.

**2. \* What type of compensation will subjects receive (e.g. monetary, course credit, gifts, gift card)?**

Per suggestion of community leaders and CCB Board members, community meal will be organized once all the interviews are finalized in the community, and participants will receive compensation in the form of a meal.

**3. \* When will subjects receive the compensation (e.g. after each study visit, at the end of the study, etc.)?**

Subjects will receive the compensation upon completion of the interview: once at baseline, and another time at a 12-month follow-up.

**4. If payment will not be prorated, provide a justification as to why not.**

Participants will receive non-monetary incentives and, therefore, they will not be prorated.

ID: IRB13-1481

View: 10.1 Risk Assessment

## 10.1 Risk Assessment

*Risks can include deception, punishment, use of drugs, covert and/or participant observation, induction of mental and/or physical stress, procedures which could physically harm the subject, materials and behaviors commonly regarded as socially unacceptable within the setting of research, procedures that might be regarded as an invasion of privacy, possible/probable disclosure of information that could be harmful to the subject (e.g., child abuse, criminal behavior, political repression, immigration status, HIV status, employment status, sexual orientation, etc.)*

**1. Will the research include any of the following items? (check all that apply)**

Procedures that might be regarded as an invasion of privacy  
Possible disclosure of information that could be harmful to the subject

**2. \* Please describe the risks associated with the study. Include consideration of physical, psychological, financial, social, legal and other factors. Please include any non-physical risks (risks to employment, loss of confidentiality, etc.). For studies that involve a drug or device, if data is available, estimate expected frequency, degree of severity, and potential reversibility, including any potential late effects.**

The primary risk for this study is that participants may feel uncomfortable when answering personal questions (e.g. history of violence, normative beliefs about family-level aggression, child's exposure to sex work or sexual violence) that may cause psychological discomfort and/or distress for participants.

Another risk for the study participants is loss of confidentiality. The field staff will be trained to deal with these issues in accordance with the measures described below.

There may be other risks, which are not known at this time. The steps taken to address these risks are described below, and will be discussed with participants during the informed consent process.

**3. \* Please describe the precautions that will be taken to minimize risks/harms, including rescue provisions, if applicable. Where appropriate, discuss provisions for ensuring necessary professional intervention in the event of a distressed subject.**

To address the risk of psychological discomfort indicated above:

Any participant (child or adult) who feels discomfort about the interview and who does not wish to participate or chooses to terminate participation will be allowed to do so at any time, and for any reason.

They will still be compensated for their participation in that interview. If one part of the child-adult pair is no longer in study, both will be terminated from further participation.

To address the risk of loss of confidentiality:

At the beginning of each interview, participants (both children and adults) will be reminded that all information shared by them will remain confidential. They will also be reminded that their information will not be shared with their family members, community members, or public officials. By signing the consent and assent forms, participants agree not to talk about private information outside of the interview. The dataset will contain no names, addresses, or any information that can identify the participants.

**4. Please describe the process that will be followed if a subject discloses or it has been found that there is intent to harm themselves or others.**

During the informed consent and assent procedure, all study participants will be informed that any information shared by them will remain confidential and will not be shared with anyone. Exceptions, however, will be made in cases when participants are at a risk of immediate harm to themselves or others. All research staff in contact with study participants will be trained to immediately inform PI of any such concern.

If a child expresses suicidal ideation requiring immediate clinical attention, the staff will notify local authorities (i.e. local representative of the Ministry of Social Action and National Solidarity). When necessary, staff will ensure that the child is admitted to the nearest hospital emergency room for psychiatric evaluation, and follow the guidance of mental health professionals in subsequently supporting affected children and their parents.

To report possible cases of child abuse, the following procedures will be followed:

- 1) The field agent from ADEFAD, informed within 24 hours, visits the family members to collect more detailed information;
- 2) The ADEFAD field agent, then, informs the head of "Child Protection" services within the local (Yatenga district) division of the Ministry of Social Action and National Solidarity;
- 3) Upon assessment, the local division of the Ministry works together with ADEFAD and other partners to handle the case.
  - If case is assessed as "not serious", ADEFAD will conduct series of sensitization activities with family members.
  - If case is assessed as "serious", traditional community management system will be employed to involve local traditional community authorities.
  - If case is assessed as "very serious", the local division of the Ministry will initiate legal procedures with the support from relevant authorities (health, security, law enforcement) and child protection agencies (local NGO, service providers). The Ministry will ensure the adequate care for the child (medical treatment, psychological support, rehabilitation, and reintegration). A plan of care will be determined by the agent of Ministry of Social Action on a case-by-case basis. The local division of the Ministry of Social Action and National Solidarity has experience of working with partner organizations (such as AMMIE (Association providing moral, material, and intellectual support to child development), ABBEJB) based in Ouahigouya.

**5. \* Risks: Please provide an explanation as to why the identified risks are reasonable. Risks may be justified in relation to the anticipated benefit to subjects and/or in relation to the importance of that knowledge that may reasonably be expected to result from the research.**

Risks are justified in relation to the anticipated benefits to subjects.

Collecting information about child protective outcomes in ultra-poor communities will be essential for evaluating economic strengthening and child rights interventions that targets local needs and culture. This evaluation study will contribute to understanding of the role of economic strengthening and child rights sensitization to reduce risk of violence among extremely poor children, and should contribute to informing future policy debates and guidelines at the national and regional level. Lessons learned from the evaluation will be valuable for informing the design of the TrickleUp program in Mali. If proven to be efficacious, the CPC Learning Network's Program Learning Group in Burkina Faso will disseminate the

findings in Burkina Faso and in the West African sub-region and ensure the study's policy uptake in-country.

ID: IRB13-1481

View: 10.2 Data Confidentiality

## 10.2 Data Confidentiality

**1. \* How will data be recorded? (check all that apply)**

Coded (Data will be linked to subjects via encrypted codes)

**2. \* Where will the research data be stored? Please specify the physical location and how it will be secured to protect confidentiality. (e.g., password-protected computer, locked office, locked files, etc.). In addition, please specify the individual responsible for ensuring data confidentiality (please include name and contact information).**

TrickleUp Country Representative, Alexice Tô, supervised by Drs. Ismayilova (PI) and Karimli (Co-I), will be responsible for daily management of data, ensuring that all study staff adhere to human subjects guidelines and ensuring data confidentiality.

All hard copies of data will be stored in locked cabinets in TrickleUp office in Burkina Faso. Only the TrickleUp Country Representative and Project Manager will have access to these cabinets. Completed questionnaires, consent forms, and the file with linking data will be kept separately.

All study data will be masked for personally identifiable information. After completing the informed consent process, participants will be assigned a unique identifier. The list of study identification numbers with names will be destroyed at the completion of the study.

Only PI and project staff will have access to the study data. Computer files will be encrypted and stored in password and firewall protected computers. Analysis and reporting will be done only with combined data; no individually identifiable information will be published. Issues of participant confidentiality will be monitored closely during the field research activities, data collection, and process measurement. The dataset will contain no information identifying participants.

The staff is responsible for immediately notifying the PI and Co-Investigator on any breaches of protocol, breakdowns in the consent process, violations of confidentiality of the data, complaints by participants or any serious problems or adverse events.

**3. \* Please indicate how long the data will be kept.**

As per APA guidelines, we will keep data for the period of 7 years after the contact with research participants.

**4. Who, other than the specified study team, will have access to the study records or data? Specify their name, role, and affiliation.**

No one outside of the specified study team will have access to the study records or data.

If access to dataset is requested, we will use the procedures described below:

Once all of the data have been de-identified, cleaned, and validated, and main findings have been published, the Investigators expect to share data with the scientific community.

Datasets will be made available to any individual who makes a direct request to the PI and indicates the data will be used for the purposes of research (per CFR Title 45 Part 46: "Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.>").

The investigators will follow a data sharing agreement that specifies the following conditions be met before data are shared:

- A formal research question is specified a priori;
- Names, affiliations, and roles of any other individuals who will access the shared data;
- The deliverable(s)—e.g., manuscript, conference presentation—are specified a priori;
- Proper credit and attribution—e.g., authorship, co-authorship, and order—for each deliverable are

specified a priori;

- A statement indicating an understanding that the data can not be further shared with any additional individual(s) or parties without the PI's permission;
- IRB approval for use of the data (or documentation that IRB has determined the research is exempt);

Shared data will be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. Data will be shared in electronic format native to the software used by the Investigators; requestors are expected to handle converting electronic formats (though the Investigators will consider converting to tab-delimited text format if possible). Upon completion of the deliverable(s), the requestor will be instructed to destroy all copies of the data. If deliverables have not been produced yet, the agreement to share data will be revisited annually to decide to continue sharing or terminate the sharing agreement. If the Investigators determine that the sharing agreement should be terminated, the requestor will be instructed to destroy all copies of the data.

**ID:** IRB13-1481      **View:** 10.2.1 Data Confidentiality (Coded or Identified Data)

### 10.2.1 Data Confidentiality

You indicated that this study involves use of coded or identifiable data. Provide the following information about the identifiable or coded data used in this study.

- \* If coded or identified data will be released to individuals outside of the study team, please indicate the provisions that will be taken to ensure that the transmission of the data will maintain confidentiality. Please also indicate how subjects will be informed that data may be shared. If coded or identified data will not be released to individuals outside of the study team, please state that below.**

The coded or identified data will not be released to individuals outside of the study team.

Only the PI and the investigative team will have access to the coded data. The electronic version of the assessment data, with no identifying information, will be encrypted and electronically transferred to the US-based research team using password protected files via email. No other individuals outside of the investigative team will have access to the data.

- \* Describe what will happen to the data or data set when the study is completed. Please indicate your plans for the destruction of identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs, if applicable.**

After the completion of the study, all digital files with identifying information will be destroyed.

- \* Will a Certificate of Confidentiality be obtained for this study?**

Yes  No

- If available, please attach the Certificate of Confidentiality.**

Name

There are no items to display

**ID:** IRB13-1481      **View:** 11.1 Data Safety & Monitoring Plan

### 11.1 Data Safety & Monitoring Plan

- \* Choose the ONE choice below that most accurately reflects the plan for data and safety monitoring for this study.**

The study will be monitored by the study investigator(s).

- Please provide a description of the reporting mechanism for reporting unanticipated problems and periodic safety information to the IRB, and, if applicable, to the study sponsor and/or the FDA.**

Members of the research team will monitor adverse events that could affect participant safety. Although the proposed intervention program is unlikely to cause harm, should an adverse event occur, we will report it immediately to University of Chicago's Institutional Review Board (IRB) and National Council of Ethics in Burkina Faso.

**3. How often will adverse events and safety information be analyzed?**

Oversight and Review of Adverse Events:

Every two months through the main phase of the trial, the investigative team will review all adverse event data to date to determine if systematic trends exist among adverse event data to warrant changes to study protocols and procedures. Any proposed changes will be reviewed with staff at the study site, and, if needed, an external consultant (e.g., other senior investigators conducting research on violence against children). Approval for changes in study protocol or materials will then be obtained from the respective IRBs.

The investigative team will also conduct systematic analyses of adverse event data (e.g., associations among frequency, type, severity of adverse events; participant characteristics; and operational aspects of research such as time-point) to inform future studies as well as recognize that such activities represent a potentially under-researched area of inquiry and scientific endeavor unto itself.

**4. Are there any plans to perform an interim efficacy analysis?**

Yes  No

**5. If yes, please describe. If no, please detail why not.****6. Describe how frequently the independent monitor(s) or DSMB will meet and/or review study data, if applicable.**

The study will not convene a formal Data and Safety Monitoring Board (DSMB). However, the Community Collaborative Board (CCB) will review the research protocol for any major concern prior to implementation. During the trial, the CCB will review cumulative study data to evaluate safety, study conduct, and scientific validity and integrity of the trial. Once a study is implemented, the CCB will convene as often as necessary, but at least once in 6 months, to examine the accumulated safety and enrollment data, review study progress, and discuss other factors (internal or external to the study) that might impact continuation of the study as designed. In case of AEs and SAEs, the Board will discuss overall study safety and develop recommendations.

ID: IRB13-1481

View: 13.1 Benefits

**13.1 Benefits****1. \* Please describe any potential for direct benefits to participants in this study. If none, state that here and in the consent form.****Compensation should not be described as a benefit.**

Households where poverty was the predominant reason for sending children away for work or religious schools are likely to benefit the most from the economic strengthening intervention. With greater income and assets resulting from the intervention, increased investment in children's basic needs is expected to result in reduced child labor, reduced child exposure to exploitation and violence, and improved education outcomes, which has its own violence-mitigation benefits for children.

Households with greater numbers of children are likely to see the benefits diffused somewhat, either through having to divide the increased allocation to children among a greater number, and/or because the caregiver's time will be more constrained with childcare duties relative to beneficiaries with fewer children.

The child protection sensitization component may be particularly beneficial to caregivers with little or no exposure to information about children's rights and effects of violence on children.

After completing the 12-month follow up, control group participants will also have the opportunity to receive the intervention, if desired.

**2. Please describe any potential benefits to society.**

With few existing economic strengthening programs based on rigorous evaluation results, this evaluation study holds the potential of generating significant research, program and policy impact for children involved in child labor and exposed to violence.

This study will generate potential impact by entailing rigorous evaluation of previous untested assumptions regarding the effect of economic empowerment on child protective outcomes.

While extreme poverty is a major contributor to violence toward and exploitation of children, households living in ultra-poverty are not normally reached by economic strengthening programs due to their social marginalization and other limitations. With support from CGAP and the Ford Foundation, TrickleUp and nine other institutions piloted a cluster of micro-economic interventions designed specifically for people living in ultra-poverty across eight countries. This methodology is now being rolled out by TrickleUp in Burkina Faso. However, this model has never been tested for its impact on family separation and the protection outcomes of household children, the subject of the proposed evaluation.

The research priority is firmly rooted in major global policy processes including the United States government's all-agency Action Plan on Children in Adversity 2012-2017, which prioritizes coordinated, multi-faceted action to "eliminate barriers to care and support" for children, promote permanent family care and minimize risks of family separation. The Action Plan acknowledges that this "may involve increasing their income-generation potential," because "[h]ousehold poverty and the cost of education can be significant factors in a parent's decision to place a child in institutional care [and] exploitive labor situations..." The Action Plan also calls for support in building the evidence upon which to base effective economic strengthening programs.

ID: IRB13-1481

View: 13.2 Alternatives / Options

## 13.2 Alternatives/Options

- \* Please describe the alternatives to participation in this study. If there are no alternatives, please state that participation is voluntary and the alternative is not to participate. For intervention studies, please describe appropriate alternative clinical procedures or courses of treatment available to subjects.**

Participants have the alternative to choose not to participate in the study, or to terminate their participation at any point during the study or follow-up period.

If either adult or child participant refuses to participate in the study at the assessment (interview) stage, either at baseline or at a 12-month follow-up, they are still offered an economic empowerment intervention by TrickleUp and its partners. This is contained in the Consent and Assent forms, and will be explained to participants during the informed consent and informed assent procedures.

- If this is a clinical trial, please explain the standard of care for subjects if they do not participate in the study. If the trial were not in existence, what course of action would the PI recommend for patients who will be approached for study participation?**

ID: IRB13-1481

View: 14.1 HIPAA

## 14.1 HIPAA

- \* Will the study view, access, share, collect, use, or analyze health information that is individually identifiable?**

Yes  No

ID: IRB13-1481

View: 15.1 Costs

## 15.1 Costs

- \* Are there any costs associated with the study (that the subject will be responsible for or will be billed to someone else)? This includes costs to subjects, costs to subject's insurance, or costs to the research account.**

Yes  No

ID: IRB13-1481

View: 16.1 Informed Consent Determination

## 16.1 Informed Consent Determination

- \* Please indicate the type(s) of consent that will be involved in this study (Check all that apply).**

Written Consent Form      Signed consent will be sought from the subject or the subject's legally authorized representative.

ID: IRB13-1481

View: 16.2 Process of Consent

## 16.2 Process of Consent

**1. \* Please describe procedures to obtain consent, including how, when and where consent will be discussed and documentation obtained. Be specific regarding when consent will be obtained (e.g. "immediately before beginning study procedures" or "two days before study procedures will start").**

As indicated earlier, the process of recruiting and enrolling participants for this study consists of three main steps:

1) The first step entails identifying poor villages and establishing the locally defined poverty criteria. No consent or assent forms will be obtained at this step.

2) The second step entails recruitment and screening of participants from ultra-poor households, using the locally defined poverty criteria.

Informed consent will be obtained at this step from male head of the household.

3) Finally, two additional consent forms will be obtained at this step: a consent of an adult female caregiver, and an assent of a child participant. Children will complete an assent form, separately from their female caregivers.

In all instances of obtaining a participant's consent and assent, the consent and assent forms will be thoroughly explained and the Trickle up staff obtaining a consent and assent will solicit and answer any questions from the participant.

If, at the screening stage, a male head of the household refuses to provide his consent, no one from this household will be enrolled in the study. A female caregiver, nominated by the male head of the household, will be offered to participate in the study. If a female caregiver refuses to participate in the study, she will not be enrolled in the study as well. If her eligible child refuses to participate in the study, the child will not be enrolled in the study.

If child refuses to participate, the household will still remain in the study, and questions regarding the child will be asked from the adult female. If, however, adult female refuses to participate, the household will not remain in the study.

If caregivers do not want to participate, the household will not be enrolled in the study, which implies the household will not receive any intervention program, but only for the period of evaluation (i.e. 12 months). Once evaluation is completed (i.e. after 12 months), the household can benefit from the intervention, along with households from the control group.

**2. \* How will you determine whether the subject understands the study? Throughout the course of the study, how will you continue to ensure the subject understands the study?**

As part of the informed consent process, conducted through a Trickle Up staff member, potential participants will be asked to state their understanding of areas addressed during the informed consent discussion including (1) the nature and extent of participation in the study; (2) risks involved with participation; (3) the potential benefits of participation in the study. If a participant is unable to respond to any of the three items, this child/female caregiver pair will be excluded from the study.

Given the high illiteracy level among the potential participants (only 29% of adult population ages 15 and above are literate), an informed consent/assent process will involve a witness who can read and write. Depending on the household, the witness can be an educated member of the household, an educated relative living outside of the household, or an educated community member. To avoid the possible coercion, the witness will be someone trusted and nominated by the potential participant.

Also, given a high illiteracy level among the potential participants, a signature in the form of finger paints will be accepted.

ID: IRB13-1481

View: 16.6 Children (Assent)

## 16.6 Children (Assent)

You indicated that this study involves the use of assent. Provide the following information about obtaining assent from children.

**1. \* Please specify from which children assent will be obtained, as well as how the assent of the children will be obtained and documented. Please be sure to include a signature line for the "Assent of Child" on the written consent form (if applicable).**

Children (ages 10-16 living in the household) will complete an informed assent form, separately from their

parents, to avoid possible coercion. The assent form will be read and explained to the child, and at the end of each section, the staff member obtaining the assent, will solicit and answer any questions from the child. If a child refuses to participate in the study, she/he will not be enrolled in the study. If any of the parents refuse to participate in the study, no one from this household (including any of the children living in the household) will be enrolled in the study.

ID: IRB13-1481

View: 16.7 Non-English Speaking Participants

## 16.7 Non-English Speaking Participants

You indicated that this study involves non-English speaking subjects. Provide the following information about how non-English speaking subjects will be informed of the study.

**1. \* Describe the process of how you will explain the study and ensure that the non-English speaking subjects understand the study and their participation in research.**

Trained French-speaking and Moore-speaking research assistants will administer assent and parental consent and conduct screening to determine eligibility. All consent and assent forms will be available in French and in Moore.

**2. \* Please indicate the method of translation**

Translated Consent Form

**3. If the research will primarily include subjects who speak a language other than English, the informed consent documents should be translated into that language. Please indicate the language(s) and method of translation.**

All study participants will be non-English speakers. All materials (i.e. consent and assent forms, questionnaires) will be translated into French and Moore and back-translated into English by a professional translator in Burkina Faso, and then reviewed by French speaking Co-Investigator, multilingual (French, Moore, English) TrickleUp Evaluation Coordinator and other French-speaking and Moore-speaking members of the study team.

**4. \* Please indicate whether or not an interpreter will be used. If so, how will you guarantee that the interpreter will maintain confidentiality of subjects? For whom does the interpreter work and how will the interpreter be recruited for the study?**

Qualified translators will be used to translate the written forms from English into French and Moore, and back translate to English.

The intervention is implemented by the TrickleUp country team in Burkina Faso and their local partners based in Burkina Faso. All the staff members in TrickleUp team in Burkina Faso and their local partners are fluent in both French and Moore. No interpreters will be used for this process.

Recruitment and enrollment of participants, as well as assessment (at baseline and 12-month follow-up) will be conducted by the trained staff and research assistants who speak both French and Moore. No interpreters will be used for these processes.

**5. \* Please indicate who will be responsible for updating subjects of study progress or any changes, collecting complaints, etc. during the course of the study.**

Dr. Karimli, the Co-Investigator and Alexice Tô, the TrickleUp Country Representative will be responsible for overseeing the field activities in Burkina Faso. Alexice Tô will also be responsible for the daily management and communication with study participants. The process will be supervised by Dr. Ismayilova, the PI.

Team of TrickleUp and ADEFAD, fluent both in French and Moore, will be in daily contact with the study participants through the process of administering the intervention.

**6. If you are conducting research outside the United States, please indicate subjects' native language and literacy level.**

The study will be implemented in Burkina Faso. It is a low-income country, where French is an official language, and only 28.7% of total adult population ages 15 and above are literate. Among the female adult population ages 15 and above, only 21.6% are literate. Moore is one of the principal local languages spoken by about 40% of the population.

ID: IRB13-1481

View: 16.8 Consent/Assent Documents

## 16.8 Consent/Assent Documents

**1. Attach consent forms, assent forms, short forms/summary documents, oral consent scripts, translated consent forms or information sheets.**

Name

[CHILD ASSENT - English](#)

[CHILD ASSENT - French](#)

[CHILD ASSENT - Moore](#)

[Formulaire d'accord de l'ENFANT 2"ok".pdf](#)

[Formulaire de Consentement Femme -révisé 21 mai \(1\).pdf](#)

[Formulaire de Consentement FEMME'2'ok".pdf](#)

[Formulaire de consentement HOMME'2 'ok".pdf](#)

[HUSBAND CONSENT - English](#)

[HUSBAND CONSENT - French](#)

[HUSBAND CONSENT - Moore](#)

[MOTHER CONSENT - English](#)

[MOTHER CONSENT - French](#)

[MOTHER CONSENT - Moore](#)

**ID:** IRB13-1481

View: 17.1 Additional Supporting Documents

### 17.1 Additional Supporting Documents

**1.** Please upload the study protocol document here:

Name

[Grant Proposal](#)

[Local \(Burkina Faso\) IRB Approval-English](#)

[Local \(Burkina Faso\) IRB Approval-French](#)

[Response to IRB-BF-Feb26-2014.docx](#)

[Response to IRB-BF-June25-2014](#)

**2.** Use this space to attach any additional supporting documents. Please be clear and concise in the "Title" field when attaching a document, so the IRB can readily identify documents.

***PLEASE NOTE: Do NOT attach documents here that are requested throughout the SmartForm, including Informed Consent Forms, Advertisements, Questionnaires, Surveys, etc. Use the "Jump To" menu above to navigate to the appropriate section to ensure that all documents are attached in the proper sections.***

Name	Type of Document
<a href="#">View Leyla Karimli_Human Subjects Protection SBR with minors(0.01)</a>	Other

**ID:** IRB13-1481

View: 19.1 Final Page

### 19.1 Final Page

You have completed your IRB submission form. However, the study **has not yet been submitted to the IRB for review.**

#### Next Steps:

#### In order to complete your submission:

1. Click the "Hide/Show Errors" button in the header above to show any questions that need to be answered before submitting to the IRB. Ensure that all required questions have been answered.

#### Submit to the IRB:

2. Exit the Form (click Finish below) to navigate to the Study Workspace
3. Only the study PI can submit to the IRB. If you are the PI, Click the "Submit to IRB" Activity in the study workspace. If you are NOT the PI, then select "Submit to PI for Endorsement" to notify the PI that the study is ready to submit.

The study State (in the upper left corner of the submission workspace) will show "IRB Assignment" when the study is successfully submitted to the IRB.

ID: IRB13-1481

[View: Co-Investigator Edit View](#)

## 1.2a Co-Investigators

- \* Co-Investigator:**  
[Leyla Karimli](#)
- Will Co-Investigator be obtaining consent?**  
 Yes  No

ID: IRB13-1481

[View: Co-Investigator Edit View](#)

## 1.2a Co-Investigators

- \* Co-Investigator:**  
[Austin Blum](#)
- Will Co-Investigator be obtaining consent?**  
 Yes  No

ID: IRB13-1481

[View: Co-Investigator Edit View](#)

## 1.2a Co-Investigators

- \* Co-Investigator:**  
[Eleni Gaveras](#)
- Will Co-Investigator be obtaining consent?**  
 Yes  No

ID: IRB13-1481

[View: 1.5.3a International Sites](#)

## 1.5.3a International Sites

- Name of Site:**  
TrickleUp
- Street Address:**  
14 BP 179 Ouaga 14, Quartier Ouaga 2000, Secteur 15 sis rue 15-947
- \* City:**  
Ouagadougou
- \* Country:**  
Burkina Faso
- Type of Site (e.g., school, lab, office, private home, or public space):**  
Households
- Local ethics committee or IRB review of this study:**  
[Not Applicable](#)
- Name of Ethics or IRB Committee Review Board:**  
National Committee of Ethics, Burkina Faso
- FWA Number for site (if applicable):**
- Contact information from Site. (Please include Name, Title, Phone Number, and Email)**  
(Name) Rachel Nanema  
(Title) Program Manager, TrickleUp-Burkina Faso

(Phone number) 226-5037-4563  
(Email) rmanema@trickleupbf.org