

# Columbia University Human Subjects Protocol Data Sheet

## General Information

**Protocol:** AAAP6855(M00Y03)      **Protocol Status:** Approved  
**Effective Date:** 02/02/2017      **Expiration Date:** 02/01/2018  
**Originating Department Code:** PFH Pop and Fam Health Rsch (8214402)  
**Principal Investigator:** Stark, Lindsay (Is2302)  
**From what Columbia campus does this research originate:** Medical Center  
**Title:** Creating Opportunities through Mentoring, Parental involvement and Safe Spaces (COMPASS)Ethiopia  
**Protocol Version #:**      **Abbreviated Title:** COMPASS Ethiopia  
**Was this protocol previously assigned a number by an IRB:** Yes  
**Previous Columbia IRB#:** AAAP6855      **Previous External IRB#:**

**Is the purpose of this submission to obtain a "Not Human Subjects Research" determination?**

No

## IRB Expedited Determination

**7. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodology.**

## Renewal Information

**Enrollment status:**

Closed to further enrollment: remaining research activities are limited to data analysis only

**Provide any additional information necessary to explain the study status:**

**Since the last renewal:**

**Have there been any changes in the relevant literature that would affect the study design or procedures?**

No

**Have there been any interim findings associated with this study?**

No

**Have there been any publications resulting from this study?**

No

**Have any participants been enrolled using the Short Form process?**

No

**Is there a Data Monitoring Committee (DMC), Data Safety Monitoring Board (DSMB), or other monitoring entity for this study?**

No

**Is an annual Progress Report required by the funding organization or coordinating center for this study?**

No

**Does this submission include a modification?**

Yes

**Provide a description of, and explanation for, all changes being proposed in this submission:**

January 30, 2017

Dear IRB Committee,

In tandem with our renewal of RASCAL IRB Protocol IRB-AAAP685, we are making a personnel modification with this submission. Yasmine Anwar (UNI: yja2105) will be added to the protocol as she will be assisting with research and data analysis.

We thank the board for their valuable time, and are available to respond to any pending questions or concerns.

Sincerely,  
Dr. Lindsay Stark  
Principal Investigator

**Indicate which sections of the Rascal submission are affected by the proposed modification. Each marked section must be revised as part of this submission:**

- |  |   |
|--|---|
| <input type="checkbox"/> General Information                         | <input type="checkbox"/> Exempt and Expedited                                 |
| <input type="checkbox"/> Attributes                                  | <input checked="" type="checkbox"/> Personnel                                 |
| <input type="checkbox"/> Funding                                     | <input type="checkbox"/> Background   |
| <input type="checkbox"/> Research Aims and Abstracts                 | <input type="checkbox"/> Procedures   |
| <input type="checkbox"/> Locations                                   | <input type="checkbox"/> Subjects   |
| <input type="checkbox"/> Data Security and Privacy                   | <input type="checkbox"/> Risks/Benefits/Monitoring                            |
| <input type="checkbox"/> Informed Consent/Recruitment                | <input type="checkbox"/> Attachments (including Rascal-generated attachments) |
| <input type="checkbox"/> No revisions to submission content required |   |

**Has the consent form been revised in this submission?**

No

**Does this submission include a report of a protocol violation?**

No

<b>Attributes</b>
-------------------

**Special review type: Check all that apply or check "None of the Above" box.**

- Review for 45 CFR 46.118 Determination (involvement of human subjects is anticipated but is not yet defined)  
 Funding review for Administrative IRB approval (such as for Center or Training Grants)  
 None of the above

---

**IRB of record information: Will a Columbia IRB be the IRB that is responsible for providing review, approval, and oversight for this study?**

Yes

**Select the most appropriate response:**

**Columbia will be the IRB of record for the study procedures conducted by Columbia researchers (Note: this response will apply to most submissions).**

---

**Is this research part of a multicenter study?**

No

---

**Please indicate if any of the following University resources are utilized:**

- Cancer Center Clinical Protocol Data Management Compliance Core (CPDM)
- CTSA-Irving Institute Clinical Research Resource (CRR)
- CTSA- Irving Institute Columbia Community Partnership for Health (CCPH)
- None of the above

**Background**

**Abbreviated Submission:**

The IRB has an abbreviated submission process for multicenter studies supported by industry or NIH cooperative groups (e.g., ACTG, HVTN, NCI oncology group studies, etc.), and other studies that have a complete stand-alone protocol. The process requires completion of all Rascal fields that provide information regarding local implementation of the study. However, entering study information into all of the relevant Rascal fields is not required, as the Columbia IRBs will rely on the attached stand-alone (e.g., sponsor's) protocol for review of the overall objectives.

If you select the Abbreviated Submission checkbox and a section is not covered by the attached stand-alone protocol, you will need to go back and provide this information in your submission.

---

**Study Purpose and Rationale:**

Provide pertinent background description with references that are related to the need to conduct this study. If this is a clinical trial, the background should include both preclinical and clinical data. Be brief and to the point.

- Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

Much attention has been devoted in recent years to the welfare of adolescent girls in humanitarian settings. Given the multitude of adversities adolescent girls face in emergency settings during their transition from childhood to adulthood, the large number of interventions targeted to this group is warranted, but few of these interventions have been rigorously evaluated to date. Thus, while an extensive literature review of published primary articles, published secondary literature reviews, and grey-literature reports identified 190 references to interventions among girls aimed at health outcomes in low- and middle-income countries (LMICs), only 49 of those citations described an evaluation of the program. Of those 49 studies, only 27 allocated the intervention randomly, primarily using a cluster randomization approach. Only one of these studies focused on a refugee population and it did not produce girl-specific results (Hallman et al, 2013). Of the 250 million people worldwide affected by natural and human-crafted disasters<sup>[1]</sup>, more than 50% of these are children under the age of 18. These humanitarian emergencies result in exposure to violence, family separation, splintering of community solidarity, shattered social trust, and inability to create an adequate livelihood. Patriarchal societies often lack protections for girls' and women's rights to social and economic equality, and as such, adolescent girls in complex emergencies may face increased risk to their safety and wellbeing, with little access to resources that promote resilience. A country surrounded by conflict on all sides, Ethiopia has been a common destination for refugees fleeing Sudan, South Sudan, Uganda, Eritrea, and Somalia. The International Rescue Committee's (IRC) assessments have identified that adolescent girls in Ethiopian refugee settings are often disadvantaged in development opportunities, which limits their safety, confidence and overall wellbeing. To promote the productive development and empowerment of girls, it is important to target interventions that build resilience and self-esteem,

and reduce risks related to early marriage, early pregnancy, exploitation and abuse. There is precedence in sub-Saharan Africa and other parts of the world for surveying adolescent girls on these topics because, for many girls, this is the stage at which marriage and/or sexual activity begins (which is generally a cultural marker of adulthood). For example, South Sudan has the ninth highest rate of child marriage in the world: UNICEF estimates that 9% of South Sudanese girls are married before age 15, and 52% before age 18[2]. Even in countries with much lower rates of school drop-out, teen sexual activity and fertility, this age group has been effectively interviewed. Among others, the UNICEF/CDC Violence Against Children Surveys (VACS) successfully asked 13-14-year-olds detailed questions about experience with sexual and other types of violence in Swaziland, Kenya, Tanzania, Zimbabwe and Haiti. Surveys are underway in Viet Nam, the Philippines, Malaysia, Cambodia and Indonesia, and planned in Zambia, Nigeria, Uganda and Rwanda. As further evidence for targeting this age group, Hallman et al found that the majority of interventions with a demonstrated effect on health status and behaviors of adolescent girls included those under the age of 14[3]. The International Rescue Committee (IRC) and Columbia University have a unique opportunity to address current evidence gaps in adolescent programming in humanitarian settings through the development of a rigorous evaluation of a DFID-funded program: COMPASS (Creating Opportunities through Mentoring, Parental involvement and Safe Spaces). It is envisioned that evidence gathered from this study will help define effective and supportive responses for adolescent girls in humanitarian contexts where they are largely invisible and under-served. This study will examine the impact of the COMPASS program in three refugee camps in Ethiopia. This intervention was designed by the International Rescue Committee (IRC) to address the needs of refugees living in Ethiopia before they reach the critical age of marriage and 'adulthood'. The research program will test the core approaches that IRC believes can help girls to reach their full potential – to be healthy, happy, productive, and thus contributing members of their communities. The program is focused on interventions that engage adolescent girls, those who are influential in their lives, service providers and other stakeholders, with the ultimate goal of co-creating environments in which girls are valued and protected. The central focus is establishing community-supported, girl-oriented 'safe spaces,' which have been defined as areas or places in the community in which girls can come and gather among themselves. In addition to working with adolescent girls, the program will invest in partners, families, service providers and others who are influential in girls' lives through outreach, discussion groups and training. The IRC program includes many of the features proven to be effective in other studies– a comprehensive social and economic program for adolescent girls with a multi-level approach that combines the characteristics of the most effective programs in the 2013 girls' health program review[4]. This will ensure that the environment supports girls' healthy development, safety and well-being. The study will examine the impact of the adolescent girls' program. The study will seek to determine whether the structured intervention with girls and their parents has an impact on outcomes that improve girls' safety and well-being. Research will focus on unpacking the components of the program in order to determine which components or combination of components have the most impact. This research will include a mix of qualitative and quantitative approaches to establish a foundation for good programming that supports adolescent girls' safe and healthy transition into adulthood. The IRC program includes many of the features proven to be effective in other studies– a comprehensive social program for adolescent girls with a multi-level approach that combines the characteristics of the most effective programs in the 2013 girls' health program review[5]. This will ensure that the environment supports girls' healthy development, safety and well-being.

research questions address gaps in existing evidence and best practice, and emphasize the importance of understanding not only whether the program is effective, but also how, why and under what conditions the program works. The IRC is the primary grant recipient for this study, and will own the data collected. The IRC will be responsible for hiring the local research team in country and overseeing data collection. Columbia University has received a sub-award from the IRC to provide technical support to the study. Columbia researchers will lead on the development of the study design and study instruments, the in-country training, data analysis and dissemination of results through peer-review publications.

---

[1] CPWG, *Funding for Child Protection in Emergencies*, film, 2011.

[2] UNICEF, *State of the World's Children*, 2013

[3] Hallman K, Stoner M, Chau M, Melnikas A. A review of control-comparison interventions on girls and health in low and middle-income countries. *The Girl Effect*, 29 March 2013.

[4] Hallman K, Stoner M, Chau M, Melnikas A. A review of control-comparison interventions on girls and health in low and middle-income countries. *The Girl Effect*, 29 March 2013.

[5] Hallman K, Stoner M, Chau M, Melnikas A. A review of control-comparison interventions on girls and health in low and middle-income countries. *The Girl Effect*, 29 March 2013.

---

#### Study Design:

**Describe the methodology that will be used in this study, covering such factors as retrospective vs. prospective data collection, interventional vs. non-interventional, randomized vs. non-randomized, observational, experimental, ethnography, etc.**

[ ] Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

An experimental design will be used to evaluate the impact of the safe space program for girls. In addition, qualitative research will address additional questions of acceptability, processes of change and best practice. The study design will employ a two group wait-list cluster randomized controlled trial where girls will be invited to participate in the COMPASS program, assigned to groups of approximately 20 for the purposes of the program, complete a pre-test baseline assessment, and will then be randomized by group to the intervention or control condition. In order to meet the sample size of 940 girls in the study (see below for power calculation), 44 groups of approximately 20 girls who are 13-19 and who speak one of the languages included in the study (Sudanese Arabic, Funj/Berta, Maban, Regarig and Engesena Quickly) will be selected to participate in the baseline assessment. All girls will be pre-tested at the same time. Girls in the treatment group will receive the intervention immediately after the initial pre-test/baseline assessment, which includes life skills education, access to mentors in safe spaces, and a structured parenting intervention for girls' caregivers. Then, after the treatment group has completed the intervention (at 12-months post-intervention initiation), both groups will take the post-test. The wait-list control group will receive the intervention only after completing the post-test. Through this approach, all girls receive the intervention whether they are randomized into the treatment or wait-list control group (although at different times), thus addressing ethical concerns of withholding the program from some study participants. This experimental design controls for threats to internal validity so that the change in outcomes between treatment and control are

attributable to the program and not the threats of history or maturation.

---

**Statistical Procedures:**

**Provide sufficient details so that the adequacy of the statistical procedures can be evaluated including power calculations to justify the number of participants to be enrolled into the study. Definitions of subject terms such as enrolled and accrued as used for Rascal submissions can be found in the Subjects section.**

Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

A sample size of at least 704 completed interviews is required to achieve an estimated Cohen's effect size of  $d = 0.3$  in the treatment group, compared to the control group. We believe this effect size estimate is conservative, but realistic. Our calculation assumes a power of 80%, alpha at the 5% level of significance and a design effect of 2.0. We will recruit a sample size of at least 940 girls (470 girls from the intervention blocks and 470 girls from the wait-list control blocks) to account for an anticipated 10% refusal at study onset and 25% attrition over a 12-month period.

---

**Exempt and Expedited**

**Is the purpose of this submission to obtain an exemption determination, in accordance with 45CFR46.101(b):**

No

---

**Is the purpose of this submission to seek expedited review , as per the federal categories referenced in 45CFR46.110?**

Yes

**Is the risk of harm to which subjects will be exposed as a result of this research no more than minimal?**

Yes

**Select the category or categories of research into which study procedures fall.**

Category 1 - Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

PLEASE NOTE: If blood is collected through an existing catheter, you do not qualify for expedited review under this category.

Category 3 - Prospective collection of biological specimens for research purposes by noninvasive means. Examples include: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of

exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

[ ] Category 4 - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

[ ] Category 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). PLEASE NOTE: If extra tissue is being taken during a routine clinical procedure (i.e. additional tissue that is not being taken for diagnostic purposes), you do not qualify for expedited review under this category.

[ ] Category 6 - Collection of data from voice, video, digital, or image recordings made for research purposes.

[x] Category 7 - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

**Do all procedures fall into one or more of the categories listed above?**

Y

**NOTE: This project appears to be eligible for expedited review.**

**Funding**

**Is there any external funding or support that is applied for or awarded, or are you the recipient of a gift, for this project?**

Yes

Award Type	Funding Source Name	Name of awarding agency	Status	Award # or Application Date	Federal/State/Local Government Direct or Subcontract	What is the award covering?	Rascal PT Number
Foundation/Private	Department For International Development					Entire Protocol	PT-AABL3711

Award Type	Funding Source Name	Name of awarding agency	Status	Award # or Application Date	Federal/State/Local Government Direct or Subcontract	What is the award covering?	Rascal PT Number
	(DfID) United Kingdom						

### Locations

Location Type	Facility Name	Domestic or International	Geographic Location	Local IRB Ethics Approval	Local Site Approval
Offsite	Sherkole, Bambasi, and Tongo refugee camps	International	Benishangul-Gumuz Region, Ethiopia	Yes	No, approval is not required
Columbia/CUMC	60Haven				

### Personnel

UNI	Name	Role	Department	Edit/View	Obtaining Informed Consent
ls2302	Stark, Lindsay	Principal Investigator	PFH HDPFH (821400X)	Edit	N
amw2239	Williams, Anaise	Other Engaged Personnel	PFH HDPFH (821400X)	View	Y
<b>Roles and Experience:</b> Graduate student assisting in qualitative data collection and analysis.					
av2016	Villadiego, Alejandra	Non-Engaged Personnel	PFH HDPFH (821400X)	Edit	N
<b>Roles and Experience:</b> Administration					
gy2153	Yu, Gary	Other Engaged Personnel	PFH HDPFH (821400X)	Edit	N
<b>Roles and Experience:</b> Biostatistician, working on quantitative analysis					
ijs2120	Seff, Ilana	Other Engaged Personnel	PFH HDPFH (821400X)	Edit	N
<b>Roles and Experience:</b> Graduate assistant providing assistance with research, data analysis, and general project support.					
kka2115	Asghar, Khudejha	Coordinator	PFH HDPFH (821400X)	Edit	Y
mam172	Munoz-Laboy, Miguel	Other Engaged Personnel	SMS Sociomedical Science (821500X)	View	N
<b>Roles and Experience:</b> Experienced qualitative researcher assisting in data analysis and report writing.					
mm4064	MacFarlane, Matthew	Other Engaged Personnel	PFH HDPFH (821400X)	Edit	N
<b>Roles and Experience:</b> Project Officer providing assistance with research, data analysis, and general project support.					
ms2778	Sommer, Marni	Investigator	SMS Sociomedical Science (821500X)	Edit	N
<b>Roles and Experience:</b> Experienced co-Investigator with substantial qualitative research experience, to lead qualitative study design and analysis.					



UNI	Name	Role	Department	Edit/View	Obtaining Informed Consent
tnc2115	Charles, Thana-Ashley	Other Engaged Personnel	MDM MSPH Admin (820100X)	Edit	N
<b>Roles and Experience:</b> MPH student assisting in research analysis					
yja2105	Anwar, Yasmine	Other Engaged Personnel	MDM MSPH Admin (820100X)	View	N
<b>Roles and Experience:</b> Graduate student assisting with data analysis					
ym2547	Mayevskaya, Yana	Other Engaged Personnel	PFH HDPFH (821400X)	View	Y
<b>Roles and Experience:</b> Graduate student assisting in qualitative data collection and analysis.					
znl2001	Lu, Zhi Ning	Non-Engaged Personnel	PFH HDPFH (821400X)	Edit	N
<b>Roles and Experience:</b> Administration and support in data analysis					

Training and COI										
The PI must ensure that each individual that is added as personnel has met the training requirements for this study ( <a href="http://www.cumc.columbia.edu/dept/irb/education/index.html">http://www.cumc.columbia.edu/dept/irb/education/index.html</a> ). For help identifying which research compliance trainings you may be required to take, visit the <a href="#">Research Compliance Training Finder</a> .										
UNI	Name	COI	HIPAA	HSP (CITI)	Research with Minors (CITI)	FDA-Regulated Research (CITI)	S-I	CRC	Good Clinical Practice (GCP)	Genetic Research Consent
ls2302	Stark, Lindsay	10/04/2016	03/07/2011	12/30/2015	12/30/2015					
amw2239	Williams, Anaise	12/05/2016	09/13/2016	11/15/2015	11/15/2015					
av2016	Villadiego, Alejandra	09/23/2016	06/10/2004	03/23/2015	03/23/2015					
gy2153	Yu, Gary	09/02/2016	03/18/2009	11/16/2015	11/16/2015	11/16/2015				
ijs2120	Seff, Ilana	09/21/2016	09/10/2016	09/12/2016	09/12/2016					
kka2115	Asghar, Khudejha	12/03/2016	03/22/2016	03/22/2016	03/22/2016			10/16/2015		
mam172	Munoz-Laboy, Miguel	10/18/2016	08/13/2004	12/04/2015	12/04/2015					
mm4064	MacFarlane, Matthew	10/12/2016	09/21/2011	10/17/2015	10/16/2015					
ms2778	Sommer, Marni	10/07/2016	03/18/2006	11/01/2016	11/01/2016					
tnc2115	Charles, Thana-Ashley	05/11/2016	03/05/2015	05/18/2015	05/18/2015	05/18/2015				
yja2105	Anwar, Yasmine	01/30/2017	01/30/2017	01/01/2016	01/01/2016					
ym2547	Mayevskaya, Yana	03/24/2016	03/24/2016	03/24/2016	03/24/2016					
znl2001	Lu, Zhi Ning	11/02/2016	09/11/2014	09/20/2014	09/20/2014					

**Departmental Approvers**

Electronic Signature: Lindsay Stark (821400X) - Principal Investigator Date: 01/31/2017

Electronic Signature: Yasmine Anwar (820100X) - Other Engaged Personnel Date: 01/31/2017

**Privacy & Data Security**

**Indicate the methods by which data/research records will be maintained or stored (select all that apply):**

- Hardcopy (i.e., paper)
- Electronic

**Where will the data be stored?**

- Y
- On a System
  - On an Endpoint

**Identify what type of endpoint will be used (select all that apply):**

- Desktop Computer
- Laptop Computer
- Mobile Device
- Other

**Does this study involve the receipt or collection of Sensitive Data?**

Yes

**If any Sensitive Data is lost or stolen as part of your research protocol, you must inform both the IRB and the appropriate IT Security Office (CUMC IT Security if at CUMC; CUIT if at any other University campus).**

**What type of Sensitive Data will be obtained or collected? Select all that apply:**

- Personally Identifiable Information (PII), including Social Security Numbers (SSN)

**Will Social Security Numbers (SSNs) be collected for any purpose?**

- No
- Protected Health Information (PHI), including a Limited Data Set (LDS)

**If any PHI is lost or stolen, you must inform both the IRB and the Office of HIPAA Compliance.**

**Indicate plans for secure storage of electronic sensitive data: check all that apply**

- Sensitive data will not be stored in electronic format
- Sensitive data will be stored on a multi-user system
- Sensitive data will be stored on an encrypted endpoint

**By Selecting an Endpoint Device and approving this protocol for submission to the IRB, the PI is attesting that the device and any removable media that may be used have been or will be registered and/or will be maintained in compliance with the University's Information Security Charter and all related policies. It is important that this information is updated, during the course of the study, as new devices are added.**

**Provide a description of how the confidentiality of study data will be ensured, addressing concerns or protections that specifically relate to the data storage elements identified above (e.g. hard copy, electronic, system, and/or endpoint):**

IRC staff supervising the fieldwork will explain to adolescent girls, caregivers, service providers, and other stakeholders that all information will be confidential. Quantitative interviews, in-depth interviews, focus group discussions and participatory activities will take place in a private area where they will not be overheard. IRC staff will request that stakeholders who are not participating remain out of earshot during the research process (including quantitative interviews, in-depth interviews, focus group discussions and participatory activities). The data collector will be instructed to re-assess privacy several times during the interview, discussion or activity. If privacy is compromised at any point during the interview, the data collector will pause or switch to a “dummy” questionnaire (or relevant equivalent activity, depending on the method) and return to the real interview only after privacy has been reestablished.

If privacy cannot be re-established, the data collector will reschedule the interview for another time. In the case of ACASI, the girl will wear headphones to further ensure privacy.

Training of data collectors will involve substantial focus on human subjects research, including the need to strictly adhere to confidentiality, both in quantitative and qualitative research activities. In qualitative research, data collectors will take hand written notes, which will then be typed up immediately after an interview or participatory activity. Hand written notes will be destroyed, and typed notes will be stored on a password protected computer, with only research staff allowed access to the data. Where qualitative data has been recorded via audio tapes, tapes will be kept confidential from the time of recording and will be locked when not in use. Tapes will be destroyed after the transcription and translation process is complete. When the de-identified data files are transferred to Columbia University, they will be stored on password-protected and encrypted devices according to Columbia University's data security policies.

**Is there or will there be a Certificate of Confidentiality (CoC) for this research?**

No

---

**Provide a description of the protections in place to safeguard participants' privacy while information is being collected:**

For the quantitative portion of the study, interview data will be collected using the ACASI system and will be uploaded to an external server between once per day and once per week, depending on feasibility of existing internet connections. Data files are anonymized and indexed by subject code, and once data is uploaded to the external server, it is no longer available on the device itself. This form of data transfer reduces the possibility that confidential information will be leaked beyond the intended research staff in the event that study devices are lost or stolen. Information linking the subject name to subject code will be kept at IRC country or regional headquarters to enable linkage of post-program assessments, and only de-identified information may be stored on the Columbia University premises, on encrypted laptops and desktops. As the IRC owns the data, the confidentiality of study data will follow the IRC's policies in the field.

---

**Procedures**

**Is this project a clinical trial?**

Yes

**Is this project a clinical trial that requires registration with [www.clinicaltrials.gov](http://www.clinicaltrials.gov)?**

Yes

**Has this study been registered with [www.clinicaltrials.gov](http://www.clinicaltrials.gov)?**

Yes

Please provide the registration number:

NCT02506543

Is this project associated with, or an extension of, an existing Rascal protocol?

Yes

Existing Rascal protocol #:

AAAO6612

Do study procedures involve any of the following?

Analysis of existing data and/or prospective record review

No

Audio and/or video recording of research subjects

Yes

Behavioral Intervention?

Yes

Biological specimens (collection or use of)

No

Cancer-related research

No

Drugs or Biologics

No

Future use of data and/or specimens

No

Genetic research

No

Human embryos or human embryonic stem cells

No

Imaging procedures or radiation

No

Medical Devices

No

Surgical procedures that would not otherwise be conducted or are beyond standard of care

No

Will any of the following qualitative research methods be used?

Survey/interview/questionnaire

Yes

NOTE: You must attach a PDF version of the survey(s)/interview(s)/questionnaire(s) to this protocol prior to submission.

Systematic observation of public or group behavior

No

Program evaluation

Yes

Will any of the following tests or evaluations be used?

Cognitive testing

No

Educational testing

No

Non-invasive physical measurements

No

Taste testing

No

**Is there an external protocol that describes ALL procedures in this study?**

Yes

[x] Check here if all procedures being conducted by Columbia researchers are detailed in the stand-alone protocol, or provide a detailed description of which procedures are being conducted by Columbia researchers.

## Recruitment And Consent

### Recruitment:

#### **Describe how participants will be recruited:**

For the quantitative portion of the study, all eligible girls and their caregiver will be recruited into the study following program enrollment. Girls will be formed into program groups based on geographic proximity, language, and age. Groups will be randomly assigned to either the program intervention group or the control group following baseline data collection.

For the qualitative portion of the study, adolescent girls and caregivers will be purposively selected for participation in focus groups or participatory activities. After the research team has consulted with local colleagues, program social workers and key informants of the community to generate a sample of adolescent girls and caregivers that captures a diversity of experiences and socio-demographic characteristics, caregivers will be approached by data collectors, who will explain the study and ask for the caregivers' consent for the adolescent girl to participate, as well as their consent to participate themselves. Following this, the selected adolescent girl will be asked to assent.

#### **Select all methods by which participants will be recruited:**

- Study does not involve recruitment procedures
- Person to Person
- Radio
- Newspapers
- Direct Mail
- Website
- Email
- Television
- Telephone
- Flyer/Handout
- Newsletter/Magazine/Journal
- ResearchMatch
- CUMC RecruitMe

---

### Informed Consent Process:

#### **Informed Consent Process, Waiver or Exemption: Select all that apply**

Informed consent with written documentation will be obtained from the research participant or appropriate representative.

Informed consent will be obtained but a waiver of written documentation of consent (i.e., agreement to participate in the research without a signature on a consent document) is requested.

If applicable, remember to attach the Information Sheet that will be provided/mailed to those subjects who agree to participate. If permission will be obtained over the phone, attach the Verbal Consent Script to be used to introduce the study to potential participants

**Waiver of written documentation of consent is applicable to:**

A portion of the study or subject population

**Identify the portion of the study (e.g., online survey, telephone interview, screening procedures) or subject population where a waiver of documentation of consent applies:**

Questionnaires (quantitative) and focus group discussions with caregivers and adolescent girls.

**Waiver of documentation of consent applies to:**

Adult participants

Parent providing permission for a child's involvement

**If minors will be involved, be sure to select 'Yes' in the Special Populations section in response to "Will children/minors be enrolled" on the Subjects Page and complete the Child Involvement Page. Procedures for obtaining assent (or permission) from minors is also addressed on that page**

Legally Authorized Representatives (LARs)

**Select the applicable basis for the waiver request: This study qualifies for a waiver of Written Documentation of Consent as per 45CFR46.117(c) as the following criteria are met in this study**

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

The primary risk is that participant may feel some discomfort with survey content. Girls will respond to sensitive questions using the Audio Computer-Assisted Self-Interview tablet (ACASI tablet) to protect confidentiality.

**Describe how participants' consent will be obtained and whether an information sheet will be used:**

Informed consent or assent will be obtained at the beginning of the study (prior to data collection) by trained

individual research staff using tablets with audio-recorded versions of the forms submitted with this request for IRB

approval. Where prospective subjects are under 18 years of age and unmarried, informed consent is required from

parents or guardians prior to approaching the minor for her assent. Girls who are under 18 and who marry during the

course of the study, and are therefore married at the time of endline assessment, would no longer be in the care of their

parents, and are thus considered emancipated minors with the ability to directly consent on their own.

The decision to administer consent via ACASI is due to the fact that participants in the camps speak non-written

languages, and there are very few literate women in the camps who would be available to be hired and trained to

consent girls. Given the nature of the study, the team felt it was not appropriate to recruit literate males to administer consent in these oral languages. After careful consideration, it was deemed most appropriate to proceed with an audio recording of the consent information. Literate male translators in the camp would translate the English content into Funj/Berta, Maban, Regarig and Engesena Quickly. A (likely non-literate) female would work alongside the male to record the translated version (given the belief that a female voice would be more appropriate). Different literate males would witness and certify that the translations in each language are accurate. Trained female IRC research staff members who speak one of the oral languages of this study, but who are likely illiterate, would play this recording individually to every girl and caregiver requiring consent/assent. These research staff would provide introductions, play the recording, be trained to answer questions about the study and the protocol, and would ensure the consenting procedures followed study protocol procedures. Consent or assent will be obtained verbally, and staff will complete a paper version of the form. Since the purpose of the intervention is to build knowledge, skills, and attitudes that promote self-empowerment, there will be a need to trace particular participants over time. Consent to trace participants who may change locations or move from one refugee camp to another has therefore been incorporated into the form. It will be emphasized that participating or not participating in the survey is purely voluntary and will have no effect on their access to the benefits of existing or future programs. Prospective subjects and their parents/guardians will also be told that they are free to withdraw from the study at any time and to refuse to answer some or all of the questions. Prospective subjects and their parents/guardians will also be assured that the utmost efforts will be made to ensure confidentiality of responses. Adolescent girls may feel compelled to consent to the study in spite of the use of standard informed consent procedures. Particularly in humanitarian settings where girls are struggling to meet their basic needs for safety, food, shelter and clothing, power differentials between the girls and both the IRC and Columbia University researchers may result in inadvertent coercion to participate in the study. The IRC and Columbia University will carefully analyze the context-specific factors that may result in participant coercion and discuss strategies for ensuring genuine informed consent. Some of the measures that may be used include:

- Build on existing staff experience with informed consent procedures in other projects.
- Intensive staff training on the importance of informed consent/assent and procedures to minimize potential coercion.

Such procedures may include careful explanation and repetition of the nature of voluntary consent (e.g., participation

in the study will not affect access to services, subjects are free to refuse to answer any questions or to withdraw from the study at any time). Participants will also be given time to consider their decision.

- Careful phrasing and translation of the consent forms, and options to use oral or written versions, to ensure maximum comprehension by non-literate participants.
- Multiple opportunities for participants to ask questions throughout the informed consent process and subsequent data collection. We will develop a list of responses to frequently asked questions that participants may raise to help guide data collectors.
- Clear process for withdrawing from the study, and clear phrasing and translation of the consent forms to ensure that participants are aware of the process.

A waiver of some or all elements of informed consent (45 CFR 46.116) is requested.

Planned Emergency Research with an exception from informed consent as per 21 CFR 50.24.

Informed consent is not required; this is exempt research.

---

### Subject Language

Enrollment of non-English speaking subjects is expected.

#### Languages anticipated:

**Other: Engesena Quickly, Funj, Maban, Regarig (Sudanese languages)**

**As you plan on enrolling non-English speaking subjects, administrative IRB approval of the translated documents (e.g., consent, recruitment materials, questionnaires) in the above selected languages are required. Please see the IRB's policy on the Enrollment of Non-English Speaking Subjects in Research for further details**

**(<http://www.cumc.columbia.edu/dept/irb/policies/documents/Nonenglishspeakingsubjects.Revised.FINALDRAFT.111909.website.doc>).**

---

### Capacity to Provide Consent:

**Do you anticipate using surrogate consent or is research being done in a population where capacity to consent may be questionable?**

No

---

## Research Aims & Abstracts

### Research Question(s)/Hypothesis(es):

This study will examine the impact of the COMPASS program in three refugee camps in Ethiopia. This intervention was designed by the International Rescue Committee (IRC) to address the needs



of refugees living in Ethiopia before they reach the critical age of marriage and 'adulthood'. The research program will test the core approaches that IRC believes can help girls to reach their full potential – to be healthy, happy, productive, and thus contributing members of their communities. The program is focused on interventions that engage adolescent girls, those who are influential in their lives, service providers and other stakeholders, with the ultimate goal of co-creating environments in which girls are valued and protected. The central focus is establishing community-supported, girl-oriented 'safe spaces,' which have been defined as areas or places in the community in which girls can come and gather among themselves. In addition to working with adolescent girls, the program will invest in partners, families, service providers and others who are influential in girls' lives through outreach, discussion groups and training. The IRC program includes many of the features proven to be effective in other studies– a comprehensive social and economic program for adolescent girls with a multi-level approach that combines the characteristics of the most effective programs in the 2013 girls' health program review. This will ensure that the environment supports girls' healthy development, safety and well-being.

---

#### **Scientific Abstract:**

The study design will employ a two group wait-list cluster randomized controlled trial where girls will be invited to participate in the COMPASS program, assigned to groups of approximately 20 for the purposes of the program, complete a pre-test baseline assessment, and will then be randomized by group to the intervention or control condition. In order to meet the sample size of 940 girls in the study, 44 groups of approximately 20 girls who are 10-19, unmarried, and who speak one of the languages included in the study (Sudanese Arabic, Funj/Berta, Maban, Regarig and Engesena Quickly) will be selected to participate in the baseline assessment. All girls will be pre-tested at the same time. Girls in the treatment group will receive the intervention immediately after the initial pre-test/baseline assessment, which includes life skills education, access to mentors in safe spaces, and a structured parenting intervention for girls' caregivers. Then, after the treatment group has completed the intervention (at 12-months post-intervention initiation), both groups will take the post-test. The wait-list control group will receive the intervention only after completing the post-test. Through this approach, all girls receive the intervention whether they are randomized into the treatment or wait-list control group (although at different times), thus addressing ethical concerns of withholding the program from some study participants. This experimental design controls for threats to internal validity so that the change in outcomes between treatment and control are attributable to the program and not the threats of history or maturation.

---

#### **Lay Abstract:**

The International Rescue Committee (IRC) and Columbia University have a unique opportunity to address current evidence gaps in adolescent programming in humanitarian settings through the development of a rigorous evaluation of a DFID-funded program: COMPASS (Creating Opportunities through Mentoring, Parental involvement and Safe Spaces). It is envisioned that evidence gathered from this study will help define effective and supportive responses for adolescent girls in humanitarian contexts where they are largely invisible and under-served. This study will examine the impact of the COMPASS program in three refugee camps in Ethiopia. This intervention was designed by the International Rescue Committee (IRC) to address the needs of refugees living in Ethiopia before they reach the critical age of marriage and 'adulthood'. The research program will test the core approaches that IRC believes can help girls to reach their full



potential – to be healthy, happy, productive, and thus contributing members of their communities. The program is focused on interventions that engage adolescent girls, those who are influential in their lives, service providers and other stakeholders, with the ultimate goal of co-creating environments in which girls are valued and protected. The central focus is establishing community-supported, girl-oriented ‘safe spaces,’ which have been defined as areas or places in the community in which girls can come and gather among themselves. In addition to working with adolescent girls, the program will invest in partners, families, service providers and others who are influential in girls’ lives through outreach, discussion groups and training. The IRC program includes many of the features proven to be effective in other studies– a comprehensive social and economic program for adolescent girls with a multi-level approach that combines the characteristics of the most effective programs in the 2013 girls’ health program review . This will ensure that the environment supports girls’ healthy development, safety and well-being. The study will examine the relative impact of the parenting initiative in addition to the program for adolescent girls. The study will seek to determine whether the structured intervention with girls’ parents has an added impact on girls’ safety and well-being. Research will focus on unpacking the components of the program in order to determine which components or combination of components has the most impact. This research will include a mix of qualitative and quantitative approaches to establish a foundation for good programming that supports adolescent girls’ safe and healthy transition into adulthood.

## Risks, Benefits & Monitoring

### Abbreviated Submission:

The IRB has an abbreviated submission process for multicenter studies supported by industry or NIH cooperative groups (e.g., ACTG, HVTN, NCI oncology group studies, etc.), and other studies that have a complete stand-alone protocol. The process requires completion of all Rascal fields that provide information regarding local implementation of the study. However, entering study information into all of the relevant Rascal fields is not required, as the Columbia IRBs will rely on the attached stand-alone (e.g., sponsor's) protocol for review of the overall objectives. .

If you select the Abbreviated Submission checkbox and a section is not covered by the attached stand-alone protocol, you will need to go back and provide this information in your submission.

---

### Potential Risks:

Provide information regarding all risks to participants that are directly related to participation in this protocol, including any potential for a breach of confidentiality. Risks associated with any of the items described in the Procedures section of this submission should be outlined here if they are not captured in a stand-alone protocol. Risks of procedures that individuals would be exposed to regardless of whether they choose to participate in this research need not be detailed in this section, unless evaluation of those risks is the focus of this research. When applicable, the likelihood of certain risks should be explained and data on risks that have been encountered in past studies should be provided.

Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

A primary concern in conducting research with adolescent girls is ensuring their safety. In order to minimize risks to participant safety, the IRC and Columbia University will implement the following

measures recommended by the WHO for collecting sensitive data:- Conduct intensive staff training on the importance of ensuring privacy, confidentiality and safety of participants, and the negative repercussions that may ensue if these are breached.- Have staff sign confidentiality agreements as part of their employment contract where possible and stipulate that breaches of confidentiality will result in immediate termination.- Develop and train staff on protocols for reporting and responding to breaches of confidentiality. Ensure that staff can report such breaches safely and confidentially without threat of repercussion.- Ensure that participant interviews are conducted in complete privacy. Train staff to switch to “dummy” questionnaires containing non-sensitive items in case of interruption.- Ensure that efforts to engage community leaders and obtain their support of the study do not reveal details about sensitive topics to be addressed through the course of data collection. *Conflict sensitivity and do no harm*We will ensure that communication and feedback mechanisms are in place to immediately flag areas where study procedures (e.g. participant sampling and recruitment strategies) may inadvertently exacerbate local tensions or conflict. We will also carefully evaluate the appropriateness of incentives to ensure that the introduction of incentives does not have negative consequences (e.g. create conflict or tensions in the community). *Participant distress*The IRC and Columbia researchers will ensure that staff are carefully selected and properly trained for minimizing and mitigating the risk of distress to participants. Sections of the interview that contain sensitive questions will be introduced with normalizing statements to make the participant feel that whatever answer she gives will not be considered “wrong”, surprising or judged in a negative way by the interviewer. Use of ACASI techniques will also minimize and mitigate risk of distress due to the anonymous nature of these approaches. Participants may still experience psychological distress during the course of data collection. The respondents will be informed before and during the interview that if they are uncomfortable answering any question, they can skip them or they can stop the interview at any time. Interviewers will be trained to identify girls in distress and stop interviews accordingly if a girl seems unable to continue. A debriefing will take place at the end of the interview by experienced interviewers who are trained to look for signs that may indicate a need for clinical intervention. The interviewer will acknowledge to the girl that there have been some sensitive questions and provide information about obtaining professional assistance. The girl will be informed of avenues of confidential support available locally.

---

#### **Potential Benefits:**

**Provide information regarding any anticipated benefits of participating in this research. There should be a rational description of why such benefits are expected based on current knowledge. If there is unlikely to be direct benefit to participants/subjects, describe benefits to society. Please note that elements of participation such as compensation, access to medical care, receiving study results, etc. are not considered benefits of research participation.**

Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

The study is designed to evaluate the impact of the IRC program: COMPASS (Creating Opportunities through Mentoring, Parental Involvement and Safe Spaces). The program is intended to improve girls’ self-esteem, self-empowerment, safety, and well-being. If the program is found to be effective, it may be scaled up throughout other settings in Ethiopia and elsewhere, thus benefiting large numbers of girls and communities.

**Alternatives:**

If this research involves an intervention that presents greater than minimal risk to participants, describe available alternative interventions and provide data to support their efficacy and/or availability. Note, participants always have the option not to participate in research.

Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

N/A. Research only presents minimal risk.

---

**Data and Safety Monitoring:**

Describe how data and safety will be monitored locally and, if this is a multi-center study, how data and safety will be monitored across sites as well.

Abbreviated Submission - This information is included in an attached stand-alone protocol. Proceed to the next question

Quantitative interview data will be collected using the ACASI system and will be uploaded to an external server between once per day and once per week, depending on feasibility of existing internet connections. Data files are anonymized and indexed by subject code, and once data is uploaded to the external server, it is no longer available on the device itself. This form of data transfer reduces the possibility that confidential information will be leaked beyond the intended research staff in the event that study devices are lost or stolen. Information linking the subject name to subject code will be kept at IRC country or regional headquarters to enable linkage of post-program assessments, and only de-identified information may be stored on the Columbia University premises. As stated above, in qualitative research, data collectors will take hand written notes, which will then be typed up immediately after an interview or participatory activity. Hand written notes will be destroyed, and typed notes will be stored on a password protected computer, with only research staff allowed access to the data. Where qualitative data has been recorded via audio tapes, tapes will be kept confidential from the time of recording and will be locked when not in use. Tapes will be destroyed after the transcription and translation process is complete. The databases at Columbia University used to store the de-identified information will be password protected. The computers are encrypted. Evaluations will be done periodically throughout study to ensure that no harm is being done to participants. Any adverse occurrences will be reported immediately to the PI.

<b>Subjects</b>
-----------------

Unless otherwise noted, the information entered in this section should reflect the number of subjects enrolled or accrued under the purview of Columbia researchers, whether at Columbia or elsewhere.

**Target enrollment:**

1,070

**Number enrolled to date:**

1,014

**Number enrolled since the last renewal or, if this is the first renewal, since the initial approval:**

27

**Number anticipated to be enrolled in the next approval period:**

0

**Does this study involve screening/assessment procedures to determine subject eligibility?**

IRB-AAAP6855

No

**Of the number of subjects enrolled, or the number accrued for interventional studies with a screening process:**

**How many remain on the study?**

0

**How many are off study?**

1,016

**How many completed the study?**

907

**Have any withdrawn of their own initiative?**

Yes

**How many?**

3

**Please explain:**

Out of the 3 refusals, two of them are direct refusal from the girls and the remaining one is parental refusal.

**Have any been removed by PI?**

Yes

**How many?**

41

**Please explain:**

Due to confusion over registration lists, 34 girls from the control group were mistakenly invited to participate in the intervention. These participants have been removed from the study. An additional 7 are reported to have permanently left the study catchment area, and data collection at endline would not be feasible with these 7 participants.

**Have any been lost to follow-up?**

Yes

**How many?**

65

**Please explain:**

These include 32 girls who migrated permanently; 24 who migrated temporarily (i.e. to visit their families and relatives in other camps during the summer during school closure); 4 girls who dropped; 1 girl with mental illness; and 4 girls whose situation is not known.

**Have any died while on study?**

No

**Have any subject complaints been received?**

No

**Is this a multi-center study?**

No

**Does this study have one or more components that apply to a subset of the overall study population (e.g. Phase 1/2, sub-studies)?**

Yes

Name/Procedure	Target enrollment	Enrolled to date	Enrollment Status
Qualitative activities with adolescent girls	165	120	Closed to further enrollment: remaining research activities are limited to data analysis only
<b>Addition Information:</b> This population is a sub-set of the girls who completed the quantitative survey. Consent has already been obtained. Target numbers are slightly higher than anticipated enrollment in anticipation of a 25% refusal rate.			

Name/Procedure	Target enrollment	Enrolled to date	Enrollment Status
Qualitative activities with caregivers	130	95	Closed to further enrollment: remaining research activities are limited to data analysis only
	<b>Addition Information:</b> Target numbers are slightly higher than anticipated enrollment in anticipation of a 25% refusal rate.		
Quantitative Survey	940	919	Closed to further enrollment: remaining research activities are limited to data analysis only
	<b>Addition Information:</b> All girls were enrolled at baseline. A subset of this population will complete qualitative activities.		

**Of the number enrolled, or the number accrued for interventional studies with a screening process, indicate:**

**Population Gender**

Females 92%	Males 8%	Non Specific 0%
----------------	-------------	--------------------

**Population Age**

0-7 0%	8-17 87%	18-65 13%	>65 0%	Non Specific 0%
-----------	-------------	--------------	-----------	--------------------

**Population Race**

American Indian/Alaskan Native 0%	Asian 0%	Native Hawaiian or Other Pacific Islander 0%	Black or African American 0%	White 0%	More than One Race 0%	Non-Specific 100%
--------------------------------------	-------------	---	---------------------------------	-------------	--------------------------	----------------------

**Population Ethnicity**

Hispanic or Latino 0%	Not Hispanic or Latino 100%	Non-Specific 0%
--------------------------	--------------------------------	--------------------

**Vulnerable Populations as per 45 CFR 46:**

**Will children/minors be enrolled**

Yes

**Note that upon "Save", you will see a link to the required "Child Involvement" page in the left side navigation menu. You must complete this page prior to submission.**

**Will pregnant women/fetuses/neonates be targeted for enrollment?**

No

**Will prisoners be targeted for enrollment?**

No

**Other Vulnerable Populations:**

- Individuals lacking capacity to provide consent
- CU/NYPH Employees/Residents/Fellows/Interns/Students
- Economically disadvantaged
- Educationally disadvantaged
- Non-English speaking

**Please ensure that your plan to enroll subjects in their primary language is described on the Informed Consent page.**

- Other Vulnerable populations

[ ]None of the Populations listed above will be targeted for Enrollment

**Subject Population Justification:**

Much attention has been devoted in recent years to the welfare of adolescent girls in humanitarian settings. Given the multitude of adversities adolescent girls face in emergency settings during their transition from childhood to adulthood, the large number of interventions targeted to this group is warranted, but few of these interventions have been rigorously evaluated to date.

The study will involve a sample size of 940 girls between the ages of 13-19 (470 girls in the intervention and 470 in the control arm of the study), to be selected from Sherkole, Bambasi, and Tongo refugee camps in the Benishangul-Gumuz region-state of Ethiopia. The total sample of adolescent girls participating in qualitative methodologies is 165. The total sample of caregivers participating in qualitative methodologies is 130. The target samples for qualitative activities consider a 25% refusal rate.

**Does this study involve compensation or reimbursement to subjects?**

No

**Child Involvement**

**RISK/BENEFIT DETERMINATION**

Please refer to the Columbia University IRB policy on research involving children for further information.

(Available on the IRB websites: CUMC IRB or Morningside/LDEO IRB.)

**'Minimal risk' means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**

**Select the option below that best describes your study.**

No more than Minimal Risk (45 CFR 46.404/21 CFR 50.51; i.e., 'Section 404')

**Explain how the risks of the research are minimal. 'Minimal Risk' means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**

A primary concern in conducting research with adolescent girls is ensuring their safety. In order to minimize risks to participant safety, the IRC and Columbia University will implement the following measures recommended by the WHO for collecting sensitive data:

- Conduct intensive staff training on the importance of ensuring privacy, confidentiality and safety of participants, and the negative repercussions that may ensue if these are breached.
- Have staff sign confidentiality agreements as part of their employment contract where possible and stipulate that breaches of confidentiality will result in immediate termination.
- Develop and train staff on protocols for reporting and responding to breaches of confidentiality. Ensure that staff can report such breaches safely and confidentially without threat of repercussion.
- Ensure that participant interviews are conducted in complete privacy. Train staff to switch to “dummy” questionnaires containing non-sensitive items in case of interruption.

Printed On: 05/19/2015 at 09:40 page 10 of 12

- Ensure that efforts to engage community leaders and obtain their support of the study do not reveal details about sensitive topics to be addressed through the course of data collection.

Conflict sensitivity and do no harm

We will ensure that communication and feedback mechanisms are in place to immediately flag areas where study

procedures (e.g. participant sampling and recruitment strategies) may inadvertently exacerbate local tensions or conflict. We will also carefully evaluate the appropriateness of incentives to ensure that the introduction of incentives does not have negative consequences (e.g. create conflict or tensions in the community).

#### Participant distress

The IRC and Columbia researchers will ensure that staff are carefully selected and properly trained for minimizing and mitigating the risk of distress to participants. Sections of the interview that contain sensitive questions will be introduced with normalizing statements to make the participant feel that whatever answer she gives will not be considered “wrong”, surprising or judged in a negative way by the interviewer. Use of ACASI techniques will also minimize and mitigate risk of distress due to the anonymous nature of these approaches.

Participants may still experience psychological distress during the course of data collection. The respondents will be informed before and during the interview that if they are uncomfortable answering any question, they can skip them or they can stop the interview at any time. Interviewers will be trained to identify girls in distress and stop interviews accordingly if a girl seems unable to continue.

A debriefing will take place at the end of the interview by experienced interviewers who are trained to look for signs that may indicate a need for clinical intervention. The interviewer will acknowledge to the girl that there have been some sensitive questions and provide information about obtaining professional assistance. The girl will be informed of avenues of confidential support available locally.

## WARDS AND FOSTER CHILDREN

**If 'Section 406' or 'Section 407' research was indicated, the inclusion of wards or foster children requires additional information and, if the research will be conducted in New York City (NYC), approval from the NYC Administration for Children's Services (ACS). Please select the appropriate option below.**

This research has not been categorized as 45 CFR 46.406 ('Section 406') or 45 CFR 46.407 ('Section 407').

## ASSENT OF SUBJECTS

**Assent of the child is required except in limited circumstances. The first step in determining whether assent is required and/or appropriate is to assess whether the children who will participate in the study will be capable of providing assent. The next step is to determine, for children who are capable of providing assent, whether assent will be obtained or should be waived.**

**Indicate whether the children who will be enrolled in this study will generally be capable of providing assent.**

Some or all are expected to be capable of providing assent.

**Please explain why some or all of the children are expected to be capable of providing assent, and if applicable, why some may not be capable.**

Adolescent girls may feel compelled to consent to the study in spite of the use of standard informed consent procedures. Particularly in humanitarian settings where girls are struggling to meet their basic needs for safety, food, shelter and clothing, power differentials between the girls and both the IRC and Columbia University researchers may result in inadvertent coercion to participate in the study. The IRC and Columbia University will carefully analyze the context-specific factors that may result in participant coercion and discuss strategies for ensuring genuine informed consent. Some of the measures that may be used include:

- Build on existing staff experience with informed consent procedures in other projects.
- Intensive staff training on the importance of informed consent/assent and procedures to minimize potential coercion. Such procedures may include careful explanation and repetition of the nature of voluntary consent (e.g., participation in the study will not affect access to services, subjects are free to refuse to answer any questions or to withdraw from the study at any time). Participants will also be given time to consider their decision.
- Careful phrasing and translation of the consent forms, and options to use oral or written versions, to ensure maximum



comprehension by non-literate participants.

- Multiple opportunities for participants to ask questions throughout the informed consent process and subsequent data collection. We will develop a list of responses to frequently asked questions that participants may raise to help guide data collectors.
- Clear process for withdrawing from the study, and clear phrasing and translation of the consent forms to ensure that participants are aware of the process.

**For the children who are capable of providing assent, indicate whether you propose to obtain assent or to request a waiver of the requirement to obtain assent.**

Assent will be obtained from children who are capable of providing voluntary and informed agreement to participate.

**Describe the process that will be used (e.g., with or without parents present, whether models, diagrams, or other aids will be used).**

Informed consent or assent will be obtained at the beginning of the study (prior to data collection) by trained individual research staff using tablets with audio-recorded versions of the forms submitted with this request for IRB approval. Where prospective subjects are under 18 years of age and unmarried, informed consent is required from parents or guardians prior to approaching the minor for her assent. Girls who are under 18 and married at enrollment, would no longer be in the care of their parents, and are thus considered emancipated minors with the ability to directly consent on their own.

The decision to administer consent using audio-recorded translations of the written English consent forms is due to the fact that participants in the camps speak non-written languages, so written translations cannot be obtained, and there are very few literate women in the camps who would be available to be hired and trained to consent girls. Given the nature of the study, the team felt it was not appropriate to recruit literate males to administer consent in these oral languages. After careful consideration, it was deemed most appropriate to proceed with an audio recording of the consent information. Literate male translators in the camp would translate the English content into Funj/Berta, Maban, Regarig and Engesena Quickly. A (likely non-literate) female would work alongside the male to record the translated version (given the belief that a female voice would be more appropriate). Different literate males would witness and certify that the translations in each language are accurate. Trained female IRC research staff members who speak one of the oral languages of this study, but who are likely illiterate, would play this recording individually to every girl and caregiver requiring consent/assent. These research staff would provide introductions, play the recording, be trained to answer questions about the study and the protocol, and would ensure the consenting procedures followed study protocol procedures. Since participants have low literacy and will listen to the consent in a non-written language, participants will not be asked to provide written documentation of their consent (such as a thumbprint or signature). To document consent, research staff will ask caregivers and girls verbally for consent, and mark responses on paper tracking forms.

Since the purpose of the intervention is to build knowledge, skills, and attitudes that promote self-empowerment, there will be a need to trace particular participants over time. Consent to trace participants who may change locations or move from one refugee camp to another has therefore been incorporated into the form.

It will be emphasized that participating or not participating in the survey is purely voluntary and will have no effect on their access to the benefits of existing or future programs. Prospective subjects and their parents/guardians will also be told that they are free to withdraw from the study at any time and to refuse to answer some or all of the questions. Prospective subjects and their parents/guardians will also be assured that the utmost efforts will be made to ensure confidentiality of responses.

The decision to administer consent via using audio-recorded translations of the written English consent forms is due to the fact that participants in the camps speak non-written languages, so written translations cannot be obtained, and there are very few literate women in the camps who would be available to be hired and trained for

consent girls. Given the nature of the study, the team felt it was not appropriate to recruit literate males to administer consent in these oral languages. After careful consideration, it was deemed most appropriate to proceed with an audio recording of the consent information. Literate male translators in the camp would translate the English content into Funj/Berta, Maban, Regarig and Engesena Quickly. A (likely non-literate) female would work alongside the male to record the translated version (given the belief that a female voice would be more appropriate). Different literate males would witness and certify that the translations in each language are accurate. Trained female IRC research staff members who speak one of the oral languages of this study, but who are likely illiterate, would play this recording individually to every girl and caregiver requiring consent/assent. These research staff would provide introductions, play the recording, be trained to answer questions about the study and the protocol, and would ensure the consenting procedures followed study protocol procedures. Since participants have low literacy and will listen to the consent in a non-written language, Consent or assent will be obtained participants will not be asked to provide written documentation of their consent (such as a thumbprint or signature). To document consent, research staff will ask caregivers and girls verbally for consent, and mark responses on by signature or thumbprint on the paper version of the formpaper tracking forms.

Since the purpose of the intervention is to build knowledge, skills, and attitudes that promote self-empowerment, there will be a need to trace particular participants over time. Consent to trace participants who may change locations or move from one refugee camp to another has therefore been incorporated into the form.

Informed consent or assent will be obtained at the beginning of the study (prior to data collection) by trained individual research staff using tablets with audio-recorded versions of the forms submitted with this request for IRB approval. Where prospective subjects are under 18 years of age and unmarried, informed consent is required from parents or guardians prior to approaching the minor for her assent. Girls who are under 18 and married at enrollment , would no longer be in the care of their parents, and are thus considered emancipated minors with the ability to directly consent on their own.

The decision to administer consent using audio-recorded translations of the written English consent forms is due to the fact that participants in the camps speak non-written languages, so written translations cannot be obtained, and there are very few literate women in the camps who would be available to be hired and trained to consent girls. Given the nature of the study, the team felt it was not appropriate to recruit literate males to administer consent in these oral languages. After careful consideration, it was deemed most appropriate to proceed with an audio recording of the consent information. Literate male translators in the camp would translate the English content into Funj/Berta, Maban, Regarig and Engesena Quickly. A (likely non-literate) female would work alongside the male to record the translated version (given the belief that a female voice would be more appropriate). Different literate males would witness and certify that the translations in each language are accurate. Trained female IRC research staff members who speak one of the oral languages of this study, but who are likely illiterate, would play this recording individually to every girl and caregiver requiring consent/assent. These research staff would provide introductions, play the recording, be trained to answer questions about the study and the protocol, and would ensure the consenting procedures followed study protocol procedures. Since participants have low literacy and will listen to the consent in a non-written language, participants will not be asked to provide written documentation of their consent (such as a thumbprint or signature). To document consent, research staff will ask caregivers and girls verbally for consent, and mark responses on paper tracking forms.

**Describe how assent will be documented (e.g., signed assent form, verbal assent with documentation of process in the research record).**

Verbal assent with documentation of the process in research records will be used.

## PARENT/GUARDIAN PERMISSION

Permission of parents/guardians of the children is required except in limited circumstances. Permission from IRB

IRB-AAAP6855

Page 26 of 28

Approved for  
use until: 02/01/2018



one parent/guardian is acceptable for research categorized as Section 404 or Section 405 unless waiver of informed consent is approved or the IRB determines that permission from both parents is warranted.

Select the parental permission option that applies to your study, and provide the rationale for your response if justification is requested. For most studies, one selection is appropriate, however, if more than one option applies, select all that apply.

The permission of one parent/guardian will be obtained.

The permission of both parents/guardians will be obtained. - THIS IS REQUIRED IF YOU HAVE CATEGORIZED YOUR RESEARCH AS 45 CFR 46.406 OR 45 CFR 46.407

No parental permission will be obtained because each of the following waiver criteria for waiving parental permission apply (45 CFR 46.408(c)):

No parental permission will be obtained because the involvement of children in this research meets the criteria for a complete waiver of consent (45 CFR 46.116(d)), which is requested in the "Recruitment and Informed Consent" section.

## Documents

Archived	Document Identifier	Document Type	File Name	Active	Stamped	Date Attached	CreatedBy
No	Certification of Translation_ signatures	Certificate of Translation	Certification of Translation_ signatures.pdf	Y		06/30/2015	Alejandra Villadiego (av2016)
No	Columbia University - Final signed PA 2014 12 16	Funding/Grant Application/Subcontract	Columbia University - Final signed PA 2014 12 16.pdf	Y		06/30/2015	Alejandra Villadiego (av2016)
No	In-Country Approval	Local IRB/Ethics/Site Approval	COMPASS MOU with ARRA 22 October 2014.pdf	Y		05/18/2015	Alejandra Villadiego (av2016)
No	Baseline Focus Group Discussion with Caregivers-2.6.15	Other	Baseline Focus Group Discussion with Caregivers-2.6.15.pdf	Y		05/18/2015	Alejandra Villadiego (av2016)
No	Baseline Participatory Mapping Activity-2.6.15	Other	Baseline Participatory Mapping Activity-2.6.15.pdf	Y		05/18/2015	Alejandra Villadiego (av2016)
No	MiguelMunozLaboy_citicompletionreport2	Other	citiCompletionReport1382795-2.pdf	Y		11/16/2015	Khudejha Asghar (kka2115)
No	MiguelMunozLaboy_citiCompletionReport1	Other	citiCompletionReport1382795.pdf	Y		11/16/2015	Khudejha Asghar (kka2115)
No	Cover_Letter_Ethiopia	Other	Cover_Letter_Ethiopia.pdf	Y		05/18/2015	Alejandra Villadiego (av2016)
No	Debrief Script	Other	Debrief Script.pdf	Y		06/30/2015	Alejandra Villadiego (av2016)
No	ETH Baseline Report draft 26 Feb 2016	Other	ETH Baseline Report draft 26 Feb 2016.docx	Y		03/31/2016	Khudejha Asghar (kka2115)
No	MiguelMunozLaboy_citicompletioncertificate	Other	MunozLaboyOffice.pdf	Y		11/16/2015	Khudejha Asghar (kka2115)
No	Study Withdrawal Form	Other	Study Withdrawal Form.pdf	Y		05/18/2015	Alejandra Villadiego (av2016)
No	Subaward_SOW	Other	Subaward_SOW.pdf	Y		05/18/2015	Alejandra Villadiego (av2016)
No	Third_Party_witness_Exemption_Request	Other	Third_Party_witness_Exemption_Request.pdf	Y		05/18/2015	Alejandra Villadiego (av2016)

Archived	Document Identifier	Document Type	File Name	Active	Stamped	Date Attached	CreatedBy
No	IRB Protocol ETH 6.7.16 clean	Standalone/Sponsor's Protocol	IRB Protocol ETH 6.7.16 clean.pdf	Y		06/13/2016	Khudejha Asghar (kka2115)
No	IRB Protocol ETH 6.7.16 trackchanges	Standalone/Sponsor's Protocol (tracked)	IRB Protocol ETH 6.7.16 trackchanges.docx	N		06/13/2016	Khudejha Asghar (kka2115)
No	GS ETH Final_endline_31 may16 clean	Study Material/Instrument	GS ETH Final_endline_31 may16 clean.pdf	Y		05/31/2016	Khudejha Asghar (kka2115)
No	InDepthInterview Caregivers June 3 2016	Study Material/Instrument	InDepthInterview Caregivers June 3 2016.pdf	Y		06/03/2016	Khudejha Asghar (kka2115)
No	InDepthInterview Girls June 2 2016	Study Material/Instrument	InDepthInterview Girls June 2 2016.pdf	Y		06/03/2016	Khudejha Asghar (kka2115)
No	Qual_Group Activity_ETH_Girls June.01.16	Study Material/Instrument	Qual_Group Activity_ETH_Girls June.01.16.pdf	Y		06/03/2016	Khudejha Asghar (kka2115)
No	GS ETH Final_endline_31 may16 trackchanges	Study Material/Instrument (tracked)	GS ETH Final_endline_31 may16 trackchanges.docx	Y		05/31/2016	Khudejha Asghar (kka2115)