Columbia University Human Subjects Protocol Data Sheet

General Information

Protocol:	AAAO6612(M01Y03)	**Protocol Status:**	Approved
Effective Date:	04/14/2017	**Expiration Date:**	02/20/2018
Originating Department Code:		PFH Pop and Fam Health Rsch (8214402)	
Principal Investigator:		Stark, Lindsay (ls2302)	
From what Columbia campus does this research originate:		Medical Center	
Title:	Creating Opportunities through Mentoring, Parental involvement and Safe Spaces (COMPASS)		
Protocol Version #:		**Abbreviated Title:**	COMPASS
Was this protocol previously assigned a number by an IRB:		Yes	
Previous Columbia IRB#:	AAAO6612	**Previous External IRB#:**	

Is the purpose of this submission to obtain a "Not Human Subjects Research" determination?
No

IRB Expedited Determination

10. Minor change in previously approved research during the period (of one year or less) for which approval is authorized.

Modification 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:
Baseline and endline data collection is complete, and analysis is ongoing.
Modification Summary: Provide a description of, and explanation for, all changes being proposed in this submission:
April 14, 2017

Dear IRB Committee,

Please accept with this letter the submission of our renewal and modification of our materials related to RASCAL IRB Protocol IRB-AAAO6612.

Jaime Morrisson (jwm2154) has been added to this IRB protocol, since she will be involved in data analysis and report-writing.

Additional responses to correspondence from the IRB are below:

1. As per CUMC policy all study personnel are required to complete the HIPAA training certification before they are approved to participate in the conduct of a research project. Study team member, Jaime Morrison, is required to

complete HIPAA training as per CUMC policy. The required research exam can be accessed through the RASCAL website, www.rascal.columbia.edu, Training Center, and HIPAA exam TC0019.
Jaime Morrison has completed the HIPAA training, and confirmed with the IRB that her certificate was acceptable. Her training certificate is attached to this submission.

2. 'Subjects' section: It is noted that you have revised the section to indicate that 1,654 subjects are off study. Please revise the number of subjects enrolled to date to 1,654.
The number of enrolled subjects has been updated to 1,654, which includes both 1,633 enrolled and 20 which were removed from the study.

3. It is noted you've attached a protocol dated 1.8.2016. Please advise whether the protocol has been revised and/or the purpose of attaching the protocol with this submission.
The standalone protocol has not been changed, but it seems that it may have been mistakenly archived during the last modification. We have re-attached it, as was requested by the Rascal system, during this modification.

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

Sincerely,

Lindsay Stark
Principal Investigator

Does this submission include a report of a protocol violation?

No

If a Protocol Violation is unanticipated, at least possibly related to the research, and involves risks to subjects or others, it should be reported to the IRB within one week (5 business days) as an Unanticipated Problem (UP) in Rascal. For more information please review the IRB Policy on Deviations and Violations: http://www.cumc.columbia.edu/dept/irb/policies/documents/ProtocolDeviationandViolationOct292013finalclean.pdf

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

[ ]General Information
[ ]Attributes
[ ]Funding
[ ]Research Aims and Abstracts
[ ]Locations
[ ]Data Security and Privacy
[ ]Informed Consent/Recruitment
[ ]No revisions to submission content required
[ ]Exempt and Expedited
[x]Personnel
[ ]Background
[ ]Procedures
[x]Subjects
[ ]Risks/Benefits/Monitoring
[x]Attachments (including Rascal-generated attachments)

Has the consent form been revised in this submission?

No

Does this modification include only administrative changes?

No

Attributes

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)
[x]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)
[x] 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.

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

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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.

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

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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.

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

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
Federal/State/Local Government	Department For International Development (DfID) United Kingdom	Department for International Development	Awarded/Received	40080602	Subcontract Recipient: International Rescue Committee	Entire Protocol	PT-AABM5890

Locations

Location Type	Facility Name	Domestic or International	Geographic Location	Local IRB Ethics Approval	Local Site Approval
Offsite	International Rescue Committee designated spaces	International	South Kivu, Democratic Republic of the	No, approval is not required	No, approval is not required

Location Type	Facility Name	Domestic or International	Geographic Location	Local IRB Ethics Approval	Local Site Approval
			Congo		
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)	Edit	N
	Roles and Experience: Graduate assistant providing assistance with research, data analysis, and general project support.				
av2016	Villadiego, Alejandra	Non-Engaged Personnel	PFH HDPFH (821400X)	Edit	N
	Roles and Experience: Program Coordinator who oversees administrative processes				
gy2153	Yu, Gary	Other Engaged Personnel	PFH HDPFH (821400X)	View	N
	Roles and Experience: Experienced statistician assisting in quantitative data analysis and report-writing.				
ijs2120	Seff, Ilana	Other Engaged Personnel	PFH HDPFH (821400X)	Edit	N
	Roles and Experience: Roles And Experience: Graduate assistant providing assistance with research, data analysis, and general project support.				
jwm2154	Morrison, Jaime	Other Engaged Personnel	GEU SFS Student Stipends (2550206)	View	N
	Roles and Experience: Graduate student assisting with data analysis and report-writing.				
kka2115	Asghar, Khudejha	Coordinator	PFH HDPFH (821400X)	Edit	N
	Roles and Experience: Project Officer providing assistance in research and analysis				
mam172	Munoz-Laboy, Miguel	Other Engaged Personnel	SMS Sociomedical Science (821500X)	Edit	N
	Roles and Experience: Experienced qualitative researcher assisting in data analysis and report-writing.				
mm4064	MacFarlane, Matthew	Other Engaged Personnel	PFH HDPFH (821400X)	Edit	N
	Roles and Experience: Project Officer providing assistance with research, data analysis, and general project support.				
ms2778	Sommer, Marni	Investigator	SMS Sociomedical Science (821500X)	Edit	N
	Roles and Experience: Investigator leading qualitative design and analysis				
tnc2115	Charles, Thana-Ashley	Other Engaged Personnel	MDM MSPH Admin (820100X)	View	N
	Roles and Experience: Graduate student assisting in qualitative data analysis and report-writing				
ym2547	Mayevskaya, Yana	Other Engaged Personnel	PFH HDPFH (821400X)	Edit	N
	Roles and Experience: Graduate student assisting in data analysis				
znl2001	Lu, Zhi Ning	Non-Engaged Personnel	PFH HDPFH (821400X)	Edit	N
	Roles and Experience: Assisting in project support and quantitative 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 (http://www.cumc.columbia.edu/dept/irb/education/index.html). For help identifying which research compliance trainings you may be required to take, visit the Research Compliance Training Finder.

UNI	Name	COI	HIPAA	HSP (CITI)	Research with Minors (CITI)	FDA-Regulated Research (CITI)	S-I	CRC	Good Clinical Practice (GCP)	GCP - Third-party tracking	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						
jwm2154	Morrison, Jaime	04/11/2017		04/26/2016	04/26/2016						
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					
ym2547	Mayevskaya, Yana	02/03/2017	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: Jaime Morrison (2550206) - Other Engaged Personnel Date: 04/12/2017

Electronic Signature: Lindsay Stark (821400X) - Principal Investigator Date: 04/14/2017

Privacy & Data Security

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

[ ]Hardcopy (i.e., paper)

[x]Electronic

Where will the data be stored?

Y

[ ]On a System

[x]On an Endpoint

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

[x]Desktop Computer

[x]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:

[x]Personally Identifiable Information (PII), including Social Security Numbers (SSN)

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

No

[x]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

[x]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

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 re-established. 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 or CAPI 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. As the IRC owns the data, the confidentiality of study data will follow the IRC's policies in the field. Columbia is responsible for study design and data analysis of de-identified data. IRC will de-identify the dataset before sending it to Columbia University. The IRC Research, Monitoring and Evaluation Manager is responsible for data de-identification. Only de-identified information may be stored on the Columbia University premises, on encrypted laptops and desktops.

Procedures

Is this project a clinical trial?
Yes

Is this project a clinical trial that requires registration with www.clinicaltrials.gov?
Yes

Has this study been registered with www.clinicaltrials.gov?
Yes

Please provide the registration number:
NCT02384642

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

Existing Rascal protocol #:
AAAP6855

Do study procedures involve any of the following?

Analysis of existing data and/or prospective record review
Yes

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.

Analysis of Existing Data and/or Prospective Record Review

Indicate whether the data that will be collected or utilized for the proposed study are in existence as of the current IRB submission date.

All of the data are in existence

Provide the date range of the existing data, documents, or records (e.g., medical charts, school records, census data)

Beginning Date: 05/25/2015
End Date: 12/01/2016

Note that end dates beyond the initial IRB Protocol submission date or future requests for a date parameter extension beyond the provided end date may require informed consent and HIPAA Authorization to be obtained from subjects.

Data will be obtained from (select all that apply):

[ ] Columbia and/or NYP (e.g., departmental databases/systems, patient charts, Eclipsys, WebCIS, administrative/billing records, etc.)

[x] Outside Columbia and/or NYP:

Identify the source:
As the IRC owns the data, the confidentiality of study data will follow the IRC's policies in the field. Only de-identified information may be stored on the Columbia University premises.

Based on the types of data to be obtained from outside source(s), additional documentation/authorization, such as Data Use or Business Associate Agreements, may be necessary.

Will a member of the research team be abstracting data directly from source documents?

No

If any existing data was obtained from a prior research study, was any member of the current research team involved (e.g., obtained consent, performed study procedures, conducted data analysis) in the project or procedures that collected and/or used identifiable information?

N/A

Indicate the manner in which the existing data and/or the records to be reviewed prospectively will be collected or received:
(Select all that apply. At least one must be selected.)

[ ] Contains direct identifiers (e.g., name, MRN, date of birth)
[ ] Coded and the research team has the key and can link the data to direct identifiers
[ ] Coded and the research team does not have access to the key to link data to direct identifiers
[x] Prior to the receipt of the data by the research team submitting this protocol, the identifiers will be removed and no link will remain.

Specify who will remove the identifiers:

IRC will de-identify the dataset before sending it to Columbia University. The IRC Research, Monitoring and Evaluation Manager is responsible for data de-identification.

[ ] The information was originally or will be collected without identifiers

If data are collected or received at any point in time with direct identifiers or linked to identifiers, then the data are considered to be identifiable, and the requirements for Informed Consent (or a waiver, if applicable) and HIPAA Authorization (or a waiver, if applicable) apply. The necessary information will need to be included in the respective sections of the submission.

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 at the time of program enrollment. Girls will be formed into program groups based on geographic proximity. Groups will be randomly assigned to either the program plus caregiver intervention group or the control group (see below).

For the qualitative portion of the study, adolescent girls and caregivers will be purposively selected for participation in in-depth interviews, focus groups or participatory activities. After the research team has consulted with local colleagues, program social workers and elders 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
[x] 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

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

Documentation of informed consent is applicable to:
The study in its entirety

Identify the portion of the study (e.g., prospective portion, focus groups, substudy 2) or subject population for which documentation of consent will be obtained::

Documentation of participation will be obtained from::

[x] Adult participants
[x] Parent providing permission for a child's involvement
[ ] Legally Authorized Representatives (LARs)

Describe how participants' written consent will be obtained:
Informed consent or assent will be obtained at the beginning of the study (prior to data collection) by trained individual researchers who use 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 get married 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 submitted consent forms are in English, since it is essential to have IRB-approved forms before having them translated. However, nearly all the subjects speak little or no English. The informed consent or assent forms will be translated carefully into Swahili and Mashi, which are the dominant language of respondents and the translated forms will then be resubmitted for final IRB approval. The accuracy of the translation will be checked by UN-caliber translators who also have a sound understanding of local, rural idioms. The translated version will be field tested by a member of the research team, working with experts in the local languages (including young people), to ensure that the translated documents convey the intended meanings and can be well understood by people in the camps.

Because the literacy rates are very low in communities, it is not appropriate to ask prospective subjects or their parents/guardians to read the informed consent or assent forms. The researcher will seek to obtain informed consent in Swahili and Mashi by reading the form out loud. Consent or assent will then be obtained by signature or thumbprint.

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.

Data collectors will explain 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.

Informed consent is not required for exempt research but is recommended for such research when there will be interaction with research participants for the purpose of the research.

[ ] 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.

[ ] 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:

French

Other: Swahili, Mashi

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):

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 outcomes 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.

Scientific 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. 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. The study design will employ a two–arm randomized controlled trial where girls will be randomized to receive a basic package of services, which includes life skills education and access to mentors in safe spaces, or the basic package plus a structured parenting intervention for girls' caregivers. An experimental design will be used to evaluate the relative impact of the parenting initiative in addition to the safe space program for girls. In addition, qualitative research will address questions of acceptability, processes of change and best practice. Groups in North and South Kivu will be randomized so that every group is randomly designated as a group that will either roll out the core intervention or the intervention plus caregiver component. Groups that do not receive the parental intervention during the study, will receive the intervention when the study is complete to reduce communal jealousies. The study will examine the relative impact of the parenting initiative in addition to the program for adolescent girls and seek to determine whether the structured intervention with girls' parents has an added impact on girls' safety and well-being.

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. In the DRC, the COMPASS program will involve a structured intervention for girls between the ages of 10-14 that is intended to 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 safe. The program is centered on establishing or supporting community-supported safe spaces for girls where they can come and gather among themselves and participate in a structured life-skills curriculum. In addition to the safe spaces for girls, the COMPASS project will also implement structured activities for the parents and caregivers of participants. 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.

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

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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.

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

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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.

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

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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, on encrypted laptops and desktops.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.

Subjects

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:

1,829

Number enrolled to date:

1,654

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

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	215	202	Closed to further enrollment: remaining research activities are limited to data analysis only
	Addition Information: 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. Interviews have been completed.		
Qualitative activities with caregivers	202	165	Closed to further enrollment: remaining research activities are limited to data analysis only
	Addition Information: This population is a sub-set of the caregivers who completed the quantitative survey. Consent will be obtained for their participation in the endline in-depth interviews. Target numbers are slightly higher than anticipated enrollment in anticipation of a 25% refusal rate. Interviews have been completed.		
Quantitative survey	1,829	1,633	Closed to further enrollment: study-related procedures ongoing
	Addition Information: All girls and caregivers were enrolled at baseline. A subset of this population will complete qualitative activities		

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

[x]Economically disadvantaged

[x]Educationally disadvantaged

[x]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 program evaluation will have inclusion criteria that reflect the target audience for the intervention. Adolescent girls ages 10-14 who give informed consent will be interviewed from the sites participating in the project (14 in South Kivu). While the program targets unmarried girls, girls may not reveal their marital status due to laws against underage marriage in DRC, and exclusion from the program may exacerbate vulnerability to legal repercussions. Thus, girls who are both married and unmarried at the time of the baseline assessment will be included in the study, along with their primary caregiver.

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.

• 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.

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.

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 researchers who use 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 get married 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 submitted consent forms are in English, since it is essential to have IRB-approved forms before having them translated. However, nearly all the subjects speak little or no English. The informed consent or assent forms will be translated carefully into Swahili and Mashi, which are the dominant language of respondents and the translated forms will then be resubmitted for final IRB approval. The accuracy of the translation will be checked by UN-caliber translators who also have a sound understanding of local, rural idioms. The translated version will be field tested by a member of the research team, working with experts in the local languages (including young people), to ensure that the translated documents convey the intended meanings and can be well understood by people in the camps.

Because the literacy rates are very low in communities, it is not appropriate to ask prospective subjects or their parents/guardians to read the informed consent or assent forms. The researcher will seek to obtain informed consent in Swahili and Mashi by reading the form out loud. Consent or assent will then be obtained by signature or thumbprint.

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.

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

Because the literacy rates are very low in communities, it is not appropriate to ask prospective subjects or their parents/guardians to read the informed consent or assent forms. The researcher will seek to obtain informed consent in Swahili and Mashi by reading the form out loud. Consent or assent will then be obtained by signature or thumbprint.

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.

Data collectors will explain 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.

PARENT/GUARDIAN PERMISSION

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

[x] 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.

Attached HIPAA Forms

Number	Type	Title	Status
AAAL2900	G	DRC Form G	Approve

Documents

Archived	Document Identifier	Document Type	File Name	Active	Stamped	Date Attached	CreatedBy
No	Adolescent Girls' Assent French	Assent Form	150422 Baseline - Informed Consent - Adolescent Girls' Assent_FRENCH.pdf	N		04/22/2015	Alejandra Villadiego (av2016)
No	Adolescent Girls' Assent Mashi	Assent Form	150422 Baseline - Informed Consent - Adolescent Girls' Assent_Mashi.pdf	N		04/22/2015	Alejandra Villadiego (av2016)
No	Adolescent Girls' Assent Swahili	Assent Form	150422 Baseline - Informed Consent - Adolescent Girls' Assent_SWAHILI.pdf	N		04/22/2015	Alejandra Villadiego (av2016)
No	Adolescent Consent	Assent Form	Informed_Consent_Form_for_Adolescent_10-14_02.18.15.pdf	N		02/19/2015	Alejandra Villadiego (av2016)
No	Letter of Translation Certification 07.01.2016	Certificate of Translation	Letter of Translation Certification 07.01.2016.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Parent Guardians Self Consent_French	Consent Form/Addendum	150422 Baseline - Informed Consent - Parent Guardians Self Consent_FRENCH.pdf	N		04/22/2015	Alejandra Villadiego (av2016)
No	Parent Guardians Self Consent Mashi	Consent Form/Addendum	150422 Baseline - Informed Consent - Parent Guardians Self Consent_Mashi.pdf	N		04/22/2015	Alejandra Villadiego (av2016)
No	150422 Baseline - Informed Consent - Parent Guardians Self C	Consent Form/Addendum	150422 Baseline - Informed Consent - Parent Guardians Self Consent_SWAHILI.pdf	N		04/22/2015	Alejandra Villadiego (av2016)
No	Baseline - Informed Consent - Parent-Guardian for Ado	Consent Form/Addendum	150422 Baseline - Informed Consent - Parent-Guardian for Adolescent Participation_FRENCH.pdf	N		04/22/2015	Alejandra Villadiego (av2016)
No	Baseline - Informed Consent - Parent-Guardian for Ado	Consent Form/Addendum	150422 Baseline - Informed Consent - Parent-Guardian for Adolescent Participation_Mashi.pdf	N		04/22/2015	Alejandra Villadiego (av2016)
No	Baseline - Informed Consent - Parent-Guardian for Ado	Consent Form/Addendum	150422 Baseline - Informed Consent - Parent-Guardian for Adolescent Participation_SWAHILI.pdf	N		04/22/2015	Alejandra Villadiego (av2016)

Archived	Document Identifier	Document Type	File Name	Active	Stamped	Date Attached	CreatedBy
No	Caregiver Consent	Consent Form/Addendum	Caregiver_Informed_Consent_Form_for_Adolescent_Participation_10-14_02.18.15.pdf	N		02/19/2015	Alejandra Villadiego (av2016)
No	Parent_Guardian Consent	Consent Form/Addendum	Informed_Consent_Form_for_Parent_Guardian_02.19.15.pdf	N		02/19/2015	Alejandra Villadiego (av2016)
No	Subaward_SOW	Funding/Grant Application/Subcontract	Subaward_SOW.pdf	Y		11/25/2014	Alejandra Villadiego (av2016)
No	Endline - Warm-up activity guide French	Other	07.01.2016 Girls Warm Up Activity French Translation.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - Warm-up activity guide Mashi	Other	07.01.2016 Girls Warm Up Activity Mashi Translation.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - Warm-up activity guide Swahili	Other	07.01.2016 Girls Warm Up Activity Swahili Translation.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Internal Baseline Report	Other	DRC Baseline Report_Final Draft.pdf	Y		01/06/2017	Matthew MacFarlane (mm4064)
No	JaimeMorrisonHIPAA Privacy TrainingCertificate	Other	JaimeMorrisonHIPAA Privacy TrainingCertificate.pdf	Y		04/14/2017	Khudejha Asghar (kka2115)
No	Journal Article	Other	JournalArticle.DRC.ACASI.pdf	Y		01/06/2017	Matthew MacFarlane (mm4064)
No	IRB Protocol DRC 1.8.16 clean	Standalone/Sponsor's Protocol	IRB Protocol DRC 1.8.16 clean.pdf	Y		04/12/2017	Khudejha Asghar (kka2115)
No	Endline - Girls IDI guide English	Study Material/Instrument	InDepthInterview Girls June 2 2016.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - Girls IDI guide French	Translated Study Material	07.01.2016 Girls IDIs French Translation.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - Girls IDI guide Mashi	Translated Study Material	07.01.2016 Girls IDIs Mashi Translation.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - Girls IDI guide Swahili	Translated Study Material	07.01.2016 Girls IDIs Swahili Translation.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - CG IDI guide French	Translated Study Material	07.01.2016 ParentCaregiver IDIs French Translation.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - CG IDI guide Mashi	Translated Study Material	07.01.2016 ParentCaregiver IDIs Mashi Translation.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - CG IDI guide Swahili	Translated Study Material	07.01.2016 ParentCaregiver IDIs Swahili Translation.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - Girls 1012YO French	Translated Study Material	2016.07.01 Outil Quantative DRC Girls1012YO_French clean version.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - Girls survey French	Translated Study Material	2016.07.01 Outil Quantative DRC Girls_French clean version.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - Girls 1012YO Mashi	Translated Study Material	2016.07.01 Outil quantitatif DRC GIRLS1012YO_Mashi clean version.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)

Archived	Document Identifier	Document Type	File Name	Active	Stamped	Date Attached	CreatedBy
No	Endline - Girls 1012YO Swahili	Translated Study Material	2016.07.01 Outil quantitatif DRC GIRLS1012YO_Swahili clean version.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - Girls survey Mashi	Translated Study Material	2016.07.01 Outil quantitatif DRC GIRLS_Mashi clean version.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - Girls survey Swahili	Translated Study Material	2016.07.01 Outil quantitatif DRC GIRLS_Swahili clean version.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - CG survey French	Translated Study Material	2016.07.04 Caregiver Quant Survey French Translation.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - CG survey Mashi	Translated Study Material	2016.07.04 Caregiver Quant Survey Mashi translation.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)
No	Endline - CG survey Swahili	Translated Study Material	2016.07.04 Caregiver Quant Survey Swahili translation.pdf	N		07/05/2016	Zhi Ning Lu (znl2001)