

**June 12, 2023**

**Ifaa Effectiveness Evaluation on Food Security and Nutrition**

**NCT05825716**

Clinicaltrials.gov NCT05825716

**JHSPH IRB Research Plan for New Data Collection***IRB Version: 11May2023*

*For new data collection, new data collection plus secondary data analysis, biospecimen repositories, and data coordinating center protocols.*

**DO NOT DELETE ANY QUESTIONS FROM THIS TEMPLATE**

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**PI Name: Shannon Doocy**
**Study Title: Ifaa Effectiveness**
**IRB No.: 23765**
**PI Version No. / Date: Version 4, June 12, 2023**


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**I. Aims of the Study:**

The Ifaa Project is a USAID-funded Resilience and Food Security Activity (RFSA) that is being implemented by Catholic Relief Services (CRS) and partners in the East Hararghe Zone of the Oromia Region in Ethiopia. Ifaa targets households that are participating in Productive Safety Net Programme (PSNP) which is a social protection program administered by the Government of Ethiopia that provides food and cash assistance to vulnerable households. The Ifaa Project will deliver multi-sectoral programming in 241 kebeles (sub-districts) in nine woredas (districts) of East Hararghe Zone, however, intervention packages vary by location. The proposed effectiveness evaluation will quantify the impacts of three different intervention packages in terms of key project indicators in the areas of household food security, diet, and child nutrition.

**II. Background and Rationale:**

Food insecurity and child undernutrition are persistent challenges in Ethiopia. In early 2023, over 22 million Ethiopians are food insecure as a result of drought, conflict and rising food prices and the situation is expected to worsen.<sup>i</sup> Prevalence of chronic malnutrition (stunting) is estimated at 37% and prevalence of acute malnutrition (wasting) is 7% among children less than five years of age. Only 14% of children have adequate dietary diversity and 11% meet the criteria for having a minimally acceptable diet.<sup>ii</sup>

Ethiopia's PSNP Programme, launched in 2005, aims to reduce food insecurity and vulnerability by providing economic opportunities and building resilience to crises through cash transfers, public works, and nutritional feeding programmes.<sup>iii</sup> The current 5<sup>th</sup> phase of PSNP targets approximately 8 million vulnerable households over five years, making it one of the largest social protection programs in sub-Saharan Africa. The PSNP program provides unconditional food or cash assistance for six months of the year in addition to public works employment that aims to build or enhance community assets.<sup>iv</sup> PSNP aims to enhance food consumption in the near-term while building and support household member's nutritional status by preventing asset depletion. Evaluations of the PSNP program have observed improvements in food security and asset protection at the household level, and at a community level, environmental improvements such as reduced deforestation.<sup>v</sup>

The overall goal of the Ifaa Project is improved food security of vulnerable households in targeted PSNP communities, contributing to a sustained reduction in rural poverty. To achieve this goal, Ifaa will provide additional multi-sectoral interventions to further benefit 60,000 PSNP households in Oromia region, which is Ethiopia's largest, most populous region and also one of its poorest. These interventions are aimed at strengthening and improving government services; agriculture and livelihood opportunities; health and nutrition; water and sanitation; gender and youth empowerment; and

natural resource management and environment. Ifaa has three different intervention packages which are presented in detail in **Table 1** (following page).

**Table 1: Ifaa Intervention Summary**

Ifaa Basic Intervention Package	Ifaa Enhanced Supplementary Interventions
PSNP Systems	
1) <b>Provision of food aid commodities</b> (wheat, oil, and pulse) per the PSNP transfer schedule for 3-6 months from January to June annually; 2) <b>Food System Taskforce (FSTF) capacity building</b> at woreda, kebele and community levels; and 3) <b>private sector engagement</b> for food transport.	Additional activities including: 1) establishment and training of <b>Community Technical Coordinating Forum (CTCF)</b> ; 2) <b>Case management capacity building</b> for FSTFs; and 3) <b>private sector construction</b> of infrastructure.
Health and Nutrition	
The primary <b>household level</b> intervention is ensuring health and nutrition linkages for Temporary Direct Support (TDS) clients. <b>Community level</b> interventions include 1) GoE basic health extension program; 2) GoE supportive supervision coaching; 3) GoE led community SBC sessions; and 4) capacity building for gov't and partners on Community Management of Acute Malnutrition (CMAM) Programming.	<b>Household level</b> interventions will include 1) the Care Group Model (CGM) approach; 2) home garden promotion; 3) the nutrition budget calculator; and 4) labor and time saving technologies. <b>Community level interventions</b> are 1) adolescent nutrition school clubs; 2) religious leader mobilization and training vulnerable groups; 3) audio toolkit against harmful traditional practices (HTPs); 4) enhanced SBC tools for health/nutrition promotion; 5) additional health extension programs; and 6) systems strengthening (woreda, kebele, community).
Water and Sanitation	
1) <b>Water infrastructure development</b> ; 2) <b>improved governance</b> via WASH committees; and 3) <b>water source monitoring</b> .	Supplemental WASH interventions including: 1) <b>CLTSH</b> -- Community Led Total Sanitation and Hygiene; 2) <b>WASH systems</b> assessments and strengthening; 3) Ensuring <b>water quality</b> and safety via routine monitoring; 4) <b>Private sector engagement</b> of WASH related businesses; <b>School WASH</b> Programs; and 5) <b>Market Based</b> Sanitation and Hygiene.
Natural Resource Management	
Integrated watershed management including 1) <b>Public works projects</b> (soil/water); 2) <b>community training</b> in planning and sustaining community assets; 3) Implementation of the <b>environment and social management framework (ESMF)</b> ; 4) <b>train gov't staff</b> on participatory watershed planning; and 5) <b>enhance participation of watershed committees</b> on community asset management.	Additional interventions include 1) Support to <b>watershed management committees to transit to watershed users' cooperatives</b> and 2) implement <b>Integrated Water Management Plus (IWM+)</b> with risk management and the <b>Water Benefits Calculator</b> .
Gender Youth and Social Development	
<b>Implementation and monitoring of PSNP Gender Targeting Provisions</b> whereby pregnant women, mothers of children <2yrs, and female headed households w/o able bodied labor are exempt from public works labor requirements; women work 50% as much time, have lighter tasks and child care is provided.	An Additional suite of interventions including: 1) <b>Community Conversations</b> for Adults and Youth to promote inclusivity; 2) <b>Male Engagement</b> training on positive gender norms; 3) <b>Gender Champions</b> —individual and couple volunteers to promote gender norms; 4) <b>Family Life Training</b> on strengthening joint-decision making for couples and service providers; 5) <b>Dignified Family Approach</b> trainings to promote peace and social cohesion; 6) <b>Functional Literacy Training</b> for women and youth in leadership; 6) <b>Leadership training</b> for women and youth in leadership positions; 7) <b>Youth Livelihoods Groups</b> and Volunteerism; 8) <b>Youth Employability and Entrepreneurial Training</b> ; 9) <b>School Gender Clubs</b> with curricula on life skills, gender equity, harmful traditional practices and leadership; and 10) <b>Youth Ambassadors</b> and Youth Led Community Conversations; 11) <b>GBV training</b> for

	community leaders and members; and 12) Establishment of <b>GBV committees</b> at kebele level and support to woreda level task forces.
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Livelihoods Interventions	
<b>Savings and Lending Groups (SILC Groups)</b> with 20-25 members. Groups meet (bi)weekly with monthly visits by Ifaa staff and serve as an entry point for livelihoods interventions. All SILC group members will receive 1) financial literacy training (as required by GoE, not delivered by CRS); and 2) support and training on business development and planning. All SILC group members receive at least one year of <b>follow up</b> and <b>linkages to public work interventions</b> . <i>Target: 30% of PSNP public works households.</i>	Additional resources provided to SILC Groups, including 1) Engagement of <b>Private Service Providers (PSPs)</b> to enable access to sustainable credit and larger loans; 2) <b>Financial Education</b> using an expanded 'Smart Skills' curriculum focusing on savings, smart borrowing and effective financial management; and 3) Life Skills Training for Youth (18-29).
<b>Livelihoods Pathways</b> including 1) On-Farm crop and livestock pathways ( <i>Target: 75% of SILC Group Members</i> ); 2) Off-Farm pathways for youth livelihoods diversification such as extension agents, value-add processing and production ( <i>Target: 20% of households</i> ); and 3) wage employment pathways for youth ( <i>Target: 5% of SILC Group Members</i> ). Each pathway has a detailed <b>technical training curriculum</b> delivered over a series of sessions; additional tailored <b>markets</b> and <b>business skills trainings</b> specific to each livelihood pathway.	Additional supports include: 1) <b>Seven Steps of Marketing Training</b> ( <i>Target: all on- and off-farm pathways</i> ); 2) <b>Climate Smart Agriculture</b> to reduce water needs and increase soil health and vegetation coverage ( <i>Target: 100% of On-Farm Pathway</i> ); 3) <b>Producers Groups and linkages</b> to markets/suppliers/buyers ( <i>Target: 20% of On-Farm Pathway</i> );
<b>Access to Finance</b> via formal financial linkages to service providers and capacity building for providers ( <i>Target: 70% of on- and off-farm pathway</i> )	Selected financial institutions will be provided with a <b>credit guarantee fund</b> and capacity building support to help facilitate loans. Private sector <b>value chain assessment and financing</b> [to address bottlenecks]. Additional <b>private sector engagement</b> (agro-dealers, SILC providers, animal health) and linkage facilitation.
<b>Livelihoods Transfers</b> of US\$300 for the poorest 30% of PSNP public works households.	<b>Youth Transfers</b> of \$250 for 20% of youth 18-29 (poorest and volunteer) participating in the on- and off-farm pathways.

A subset of kebeles (n=70) was randomly allocated to Ifaa Basic and Ifaa Enhanced Packages as part of a cross-RFSA learning activity (USAID is supporting to similar projects in other regions of Ethiopia) that is supported by the funder, USAID Bureau of Humanitarian Affairs. This effectiveness evaluation leverages this randomization to compare the two intervention packages. Additionally, 50% of kebeles were selected for livelihoods interventions, which occur in both Basic and Enhanced kebeles; livelihoods kebeles were selected based on criteria developed by CRS, but assignment to the enhanced vs basic package was random. Finally, approximately half of Ifaa Project kebeles are 'the free zone' where there is flexibility in intervention packages of the course of the project.<sup>1</sup> The distribution of the three Ifaa intervention packages that will compare in the proposed effectiveness evaluation is presented in **Table 2** below.

**Table 2: Ifaa Intervention Allocation by Administrative Area**

Woredas/Districts	Study Eligible Kebeles/Sub-Districts*		
	Ifaa Basic (n=25)	Ifaa Enhanced (n=34)	Ifaa Enhanced + Livelihoods (n=35)
Babile	Gemechu Ifa Jalale	Lekolo Shek husen Tofiq Tuluhoro	Erer guda Gambela Ibada gemechu Nejata gemechis
Chinaksan	Chelchale Kobobika	Biftuu Waree Gela	Amola Baduelemo

<sup>1</sup> These kebeles were not considered in the sampling frame because of the high risk of contamination.

	Migira	Kaleroga	Dawe kora
	Tiro gudoo Wachuhulet	Orda sost Tirosendare	Dembesele Kocher Merer Mudi dawwe
Deder	Burka Bereka Mumicha Nedi gelansedi	Gegewisa Haremfermekuni Huffe Kura dedar Lemen welteha	Burka Geba Cheka gemechu Chela Negeya Golu Oda kebena Welteha gudina
Fedis	Bareda Bedatu	Bid Borra Efitu dada Negaya bobasa Risiki	Ido Baaso Kerensa lencho Umer kule
Gursum	Ebsa Hariro Misira Saqabadii	Berite Gara wadaja Gefire guda Goro siyo Kebso Negeya	Awdal Day feres Harashi Kasa oromiya Oda oromiya
Jarso	Aneno mite Burka mete Debub debelo	Amen Epa jalela Gidiya licha Oda muda	Afgug Chala Gara abdula
Melka Belo	Fule negeya Haka mulisi Tokuma bilisumu	Bifitu negeya Daba kenisa Mulisa hakwa Tokuman kane	Chefe Jeneta Dire Qufa Welikituma bilusuma
Midega Tola	Ibiro musa Terkafeta	Kerensa Mukura	Bilisuma Biyo waraba Lencha Roba

\*Excludes free zone kebeles (where intervention packages may change) and Ifaa Basic+Livelihoods kebeles; \*\*one kebele excluded as a potential study location due to access concerns

As the Ifaa consortium learning partner, JHSPH has been requested to design an effectiveness evaluation of the different intervention packages to compare their outcomes in terms of key project indicators. The effectiveness evaluation will be independently designed and managed by JHSPH with the engagement of a private data collection firm.

### III. Study Design:

#### A. Study Design Overview

This study will leverage randomization of the Ifaa Basic and Enhanced Interventions and partial coverage of livelihoods interventions to **compare the outcomes of three different intervention packages** as illustrated in Figure 1. As part of the cross-learning activity, 70 Kebeles will have enhanced interventions (including nutrition interventions such as Care Groups<sup>2</sup> and

<sup>2</sup> Care Groups, is a group of 10-15 volunteer, community health educators who regularly meet together with CRS project staff for training and supervision. Each of these volunteers then go out at least monthly to do health promotion with a small cohort of mothers of young children. Each volunteer is selected by the mothers she serves and is responsible for regularly visiting a relatively-fixed group of 10-15 of her neighbors each month, sharing what she has learned and facilitating behavior change at the household level.

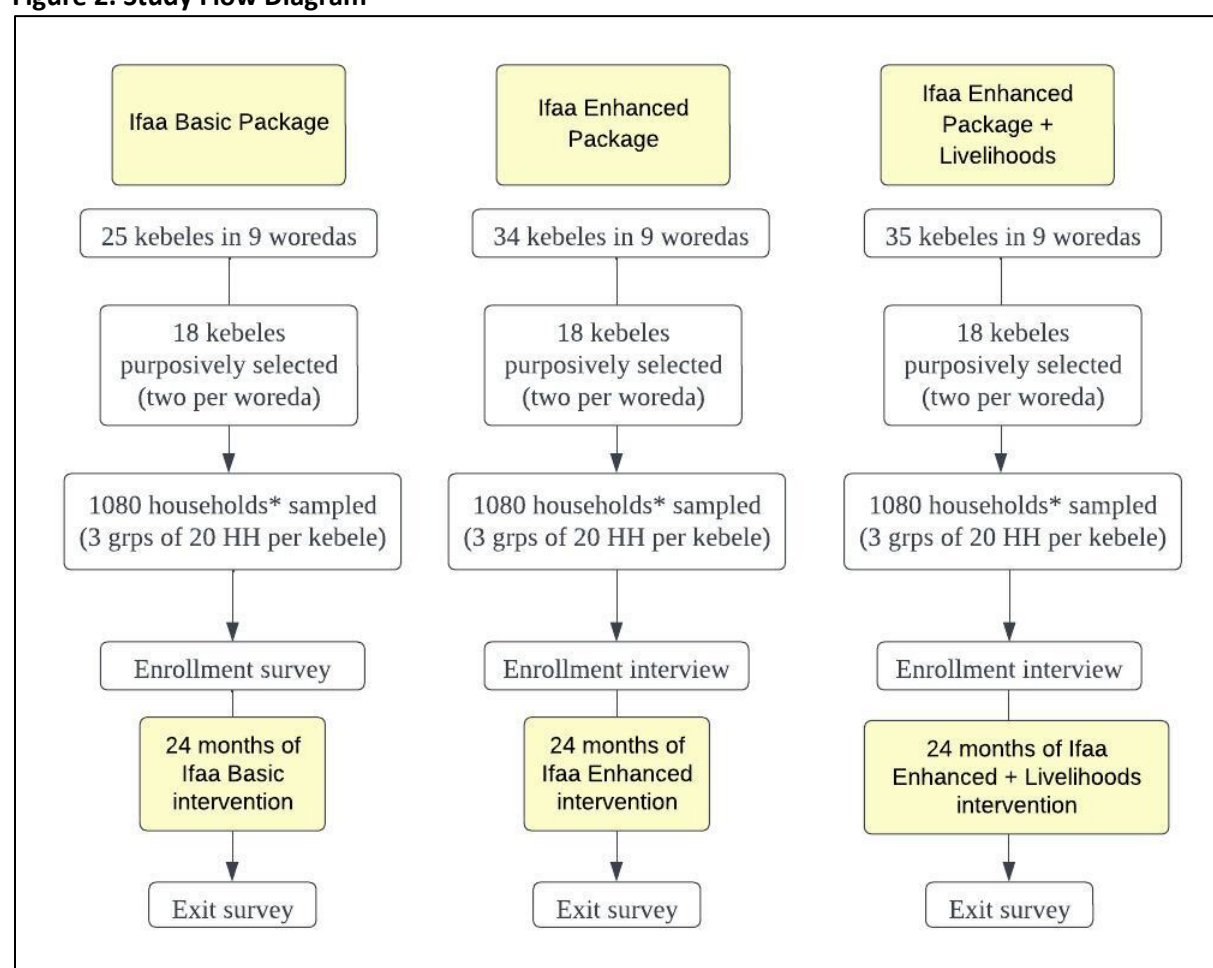
CCFLS<sup>3</sup>), and of these 50% (n=35) will have enhanced livelihoods interventions (package varies by location) while half will not have livelihoods programming; a total of 50 Kebeles will have the only “basic” intervention package, and of these 50% (n=25) will randomly have the basic livelihoods intervention. Restricting the study to Kebeles that underwent randomization has methodological benefits as compared to a quasi-experimental design that would be required if the study was expanded to other project areas. An overview of the study flow is presented in **Figure 2**.

**Figure 1. Ifaa Interventions and Study Groups**

	Ifaa Livelihoods Programming	
	Yes	No
Ifaa Basic Intervention Package	not a study arm	X
Ifaa Enhanced Intervention Package	X	X

As noted in Figure 1, the study includes three of the possible four Ifaa intervention combinations. Characterizing the impact of livelihoods programming without the Ifaa enhanced intervention was not considered a priority.

**Figure 2. Study Flow Diagram**



A longitudinal cohort design will be used to compare the effectiveness of three Ifaa intervention packages among PSNP beneficiaries: 1) the Ifaa basic package; 2) enhanced package without livelihoods; and 3) enhanced package with livelihoods. Under this approach, the enrolled households will have either a pregnant woman or children <36 months of age. Households will be followed over a two-year period, with the baseline and endline survey conducted at a similar time

<sup>3</sup> Community led complementary feeding sessions (CCFLS) is a six month program targeted at children at risk of acute malnutrition or recently discharged from a malnutrition treatment program. It includes caregiver training on child feeding practices and growth monitoring and is a six month intervention, with intensive services/training in the first month and follow up monitoring.

period in the calendar year to avoid seasonal changes in food security. The magnitude of change in key indicators over time will be assessed for each group; if needed, adjusted models will be used to account for baseline differences between groups. Outcome measures of focus are aligned with Ifaa indicators and include measures of household food consumption and child diet. To ensure adequate geographic coverage, a **stratified sampling design** will be used as follows:

- (1) **Kebele Selection.** Two kebeles per intervention arm will be purposively selected in each of the nine woredas with the aims of 1) of maximizing geographic similarity in terms of agro-ecological zone (lowland, midland, highland) and remoteness; and 2) ensuring sufficiently large beneficiary population is available for sampling purposes. In the case of smaller kebeles where it appears unfeasible to attain three clusters, the sample may be distributed across additional kebeles within the woreda.<sup>4</sup>
- (2) **Cluster Selection.** Within each kebele, the three largest communities and/or population concentrations from within each kebele will be selected as cluster start locations. This approach was identified to account for inclusion criteria, notably that households must have a pregnant woman or a child <36 months of age, which reduces the number of households that are eligible for study participation.<sup>5</sup> Once start locations have been identified, all beneficiary lists will be verified, and households that meet inclusion criteria will be enumerated. This process will occur immediately prior to the start up of data collection in the kebele. If fewer than 20 eligible households are identified in the community, enumeration will continue in adjacent communities until the target sample size is identified.
- (3) **Household Selection.** Data collection will begin within several days of the household enumeration exercise. Households will be sampled from the lists of beneficiaries that are verified as meeting inclusion criteria. In some cases, this may be exhaustive (e.g. in kebeles with small populations where adjacent communities needed to be visited to identify the target number of households). In larger kebeles or communities where the number of eligible households exceeds the target sample, a systematic list-based sampling approach (i.e. every  $n^{\text{th}}$  household) will be used. Replacement sampling will be used until the target number of households in each location are enrolled.

## B. Sample Size

The primary outcome measure for the evaluation is improvement in household food security. To align the evaluation with project aims, key project indicators are used as study outcome measures. These include: 1) At the household level, **Poor or Borderline Food Consumption Score (FCS)**; and 2) at the individual level, change in **minimum dietary diversity among children <5 years**. Sample size calculations are presented in **Table 3** (following page) and are based on both primary and secondary outcome measures for within-group change over time using available data from the Ifaa baseline along with Ifaa targets for change. Assumptions included the following: 1) power ( $1-\beta$ ) of 80% and significance of  $\alpha=0.05$ ; 2) a design effect of 1.5 to take into account differences across Kebeles; and 3) expected absolute change in proportion of primary/secondary outcome; and 4) loss to follow up rate of 20% over the study period. Based on initial sample size projections, a minimum sample size of 915-1,070 households per group and 2,745-3,210 is required which is sufficient to detect differences  $\geq 8\%$  between groups for both the primary and secondary outcome measures.

We are proposing a planned sample size of 1,080 per group or 3,240 households total. Given challenges in field coordination across multiple teams and delays in data quality monitoring reviews, it is possible that several additional households could be enrolled in a kebele. To ensure that the approved sample size is not inadvertently exceeded due to communication challenges we are requesting approval for a **maximum sample of 3,500 households**.

**Table 3: Sample Size Calculations**

	Baseline Value	Magnitude of Change	Sample Size per Group	Total Sample Size
	34% in Oromiya (WFP, 2021)	-8%	915	2745

<sup>4</sup> The number of beneficiary households per kebele ranges from approximately 75 to 650; given inclusion criteria it is unlikely that smaller kebeles will have 60 eligible households, in which case cluster(s) will be assigned in additional kebeles in the woreda.

<sup>5</sup> In the baseline survey, the average number of children <5 years in PSNP households was 0.83 and 14% of the population was <5 years of age. Based on this we estimate that 15-25% of Ifaa beneficiary households will meet study inclusion criteria.

Poor or borderline household food consumption (FCS)		-10%	609	1827
		-12%	402	1206
	48% in E Hararghe (UMN, 2020)	-8%	1070	3210
		-10%*	674	2022
		-12%	481	1443
Minimum dietary diversity among children <5 years	19.5% in Oromya (2019 DHS)	+8%	785	2355
		+10%	533	1599
		+12%	366	1098

\*denotes Ifaa change target

- C. *Does your study meet the NIH definition of “clinical trial”: “A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes”?*

Per the JHSPH IRB’s determination, this study meets the definition of a clinical trial.

#### IV. Participants:

##### A. Inclusion Criteria:

- Households are PSNP clients
- Households are Ifaa Project beneficiaries that are planned participants in: 1) SILC groups (Ifaa Basic); 2) SILC Groups AND Care Groups (Ifaa and Enhanced); or 3) SILC groups AND Care Groups AND a Livelihoods Pathway.
- Households have a pregnant woman OR at least one child <36 months of age
- Households have an adult member that is capable of giving informed consent and completing an interview

##### B. Exclusion Criteria:

- Child headed households (all members age 17yrs or less)
- Individuals not mentally able to give informed consent and complete an interview

#### V. Study Procedures:

##### A. Recruitment Process:

1. *Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and their qualifications.*

The JHU team will receive the list of PSNP households/Ifaa beneficiary households living in the sampled Ifaa Kebeles from CRS Ethiopia team. Trained enumerators will conduct a verification exercise and visit households on the list to confirm eligibility. After the verification exercise, a second visit will be made to selected households where enumerators will explain the study purpose, households will have the opportunity to ask questions, and oral consent will be obtained. Any adult household member will be eligible to participate, however, preference will be given to caretakers of young children/pregnant women followed by household heads.

2. *Address any privacy issues associated with recruitment.*

The recruitment procedure is expected not to put the potential study populations at risk. The study topic is not sensitive in the population and PSNP and Ifaa beneficiary status is already known among communities.

##### B. Consent Process:

1. *Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening.*



*a. Who will obtain informed consent, and their qualifications:*

A private Ethiopian data collection firm will be contracted to conduct the two household surveys. The data collection firm will use experienced interviewers. Prior to data collection, interviewers will be trained on the consent process and the data collection tool; training will co-led by a JHU research team member.

*b. How, where, and when the consent discussion(s) will occur:*

The consent discussion will occur at the beginning of the home visit for the enrollment interview. The enumerator will identify a quiet and private place in or near the household so that privacy can be maintained and interruptions avoided. The enumerator will read the consent statement aloud to prospective participants. They will have an opportunity to ask questions and discuss participation with the interviewer prior to consenting to participate.

*c. The process for determining whether a potential participant meets eligibility criteria. If you will collect personally identifiable information for screening purposes, collect only data needed for this purpose and explain what will happen to the data for individuals who are not eligible:*

As described above, Ifaa beneficiary lists will be used will be used for recruitment. Households on the list will be reviewed by Ifaa staff, government extension workers and/or enumerators prior to the start of data collection to determine if households are eligible, and if eligibility is unknown household visits will be conducted to verify eligibility.

*d. Whether you will obtain a signature from the participant or will use an oral consent process:*

Oral consent will be used due to high levels of illiteracy.

*e. Whether you will obtain a legally authorized representative's signature for adults lacking capacity:*

We do not plan to enroll individuals lacking capacity.

*f. If children are included in the study, if and how you will obtain assent from them:*

We will obtain anthropometric measurements on children that are <5 years of age at baseline and endline. Mid-upper arm circumference, weight and height will be collected. Child assent will not be obtained because of the young ages; instead consent of a parent or adult household member will be requested.

*g. If children are included in the study, how you will obtain permission for them to participate from their parent, legal guardian, or other legal authority (if child is in foster care or under government supervision). If any of the children are "wards of the state", additional regulatory requirements will apply:*

During the consent procedure, the enumerator will inform the anthropometric measurement of a child and will get permission from his/her mother.

*h. If you are seeking a waiver of informed consent or assent, the justification for this request:*

No, we will not have any waiver of informed consent for this study.

*i. Whether you will include a witness to the consent process and why:*

No, we will not have a witness to the consent process; this is not common practice in this setting.

*j. If the language is unwritten, explain how you will communicate accurate information to potential participants and whether you will use props or audio materials:*

Not applicable, the language is written.

2. Identify the countries where the research will take place, and the languages that will be used for the consent process.

Country	Consent Document(s) (Adult Consent, Parental Permission, Youth Assent, etc.)	Languages
Ethiopia	Adult Consent, parental permission	Afan Oromo

**C. Study Implementation:**

1. *Describe the procedures that participants will undergo. If complex, insert a table below to help the reviewer navigate.*

Following the consent process, the enumerator will use a tablet to conduct the baseline survey. The enumerator will secure a quiet place within or nearby the participant's residence to ensure privacy. The enumerator will read each question in the tablet to the study participant and record their answer to the tablet. The enumerator will provide explanation if study participants are not able to understand a question. The same procedure will be used for the endline survey. When the interview is over, the enumerator will request to take anthropometric measurements (weight, height, arm circumference) for all children <5 years of age.

The study households will be visited at two time points prior to intervention start up and again after 24 months of intervention exposure to ensure data is collected during the same season. The location of each household will be recorded with GPS and a hand-drawing map to ensure feasibility of follow up. A structured questionnaire will be used to collect data at both the household and individual child level, with data collected for all children <5 years of age in the household. The baseline and endline questionnaire will include the same content, with the exception of a module that will be added (in a future modification) to characterize Ifaa intervention participation and satisfaction. Questionnaire content will include background information on primary care taker (e.g. literacy, age, pregnancy status) and household characteristics (e.g. size, residence location) and household food security measures including [Food Consumption Score](#), [Household Hunger Scale](#), and [Coping Strategies Index](#). For children, individual level information to be collected includes child background information (e.g. age, sex); [Infant and Young Child Feeding Indicators](#); and anthropometric measurements (weight, height/length, arm circumference).

2. *Describe the number and type of study visits and/or contacts between the study team and the participant, how long they will last, and where/how they will take place.*

Each study participant will have three contacts by enumerators, two at baseline including one to determine eligibility and one to complete the interview (May 2023) and one at final evaluation (May 2025). All study visits will be made at the participant's residence. The survey will take 40 to 50 minutes and each interaction is anticipated to be one hour or less.

2. *Describe the expected duration of the study from the perspective of the individual participant and duration overall.*

From the participant's perspective, the overall study duration will be two years. The baseline survey and consent process will take less than one hour and the same process will be repeated at the endline survey.

3. *Provide a brief data analysis plan and a description of variables to be derived.*

The outcome variables of focus at the household level will be measures of food security, including 1) [Food Consumption Score](#), 2) [Household Hunger Scale](#), and 3) [Coping Strategies Index](#). At the individual level, outcome variables of focus will include 1) [Infant and Young Child Feeding Indicators](#) (in particular achievement of minimum dietary diversity); and 2) prevalence of stunting and wasting, in accordance with the [World Health Organization Child Growth Standards](#). Background information on individual (e.g. literacy, age, pregnancy status) and household characteristics (e.g. size, residence location) will also be collected so that these can be controlled for or used for disaggregation in data analysis. All outcomes will be analyzed as continuous variables and as categorical variables based on pre-determined thresholds.

A descriptive analysis of household sociodemographic characteristics and outcome measures will be performed. Continuous variables will be presented as mean (SD) and categorical variables as n (%). ANOVA tests will be conducted for baseline characteristics and primary and secondary outcomes to examine the comparability between the three and intervention groups; individual/household characteristics with significant differences between groups at baseline will be controlled for in models that estimate the effect of the interventions.

The program effect on expected primary outcome measures will be estimated using mixed-effect linear regression analysis for continuous outcomes and Generalized Estimation Equation (GEE) model for binary outcomes. In the mixed-effects models, the random effect component included indicators to control for clustering at school levels. The fixed component included the intervention group (intervention vs. control), time and an interaction term for group and time. The GEE models will be used to examine binary outcomes with longitudinal data from both enrollment and endline. These models will estimate the change in a binary outcome among members of a given intervention group from enrollment to endline, compared to the change in the same outcome in the control. The GEE models also included an interaction term between the intervention group and time (baseline/endline).

5. **Answer the following if they are relevant to your study design:**

- A. *If the study has different arms, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the assignment.*

The selected sites will be purposively allocated to 1) the Ifaa basic package (comparison); 2) basic package + care groups (intervention 1); and 3) basic package + care groups + livelihoods (intervention 2) by CRS and other implementation partners in ifaa project. The JHU research team is not engaged to the assigning interventions.

*Sections B thru F are not relevant.*

## VI. Data Custody, Management, Security, and Confidentiality Protections:

### 1. Data Sources: Identify the source(s) of data.

☒ Participant/Parent-Guardian/Legally Authorized Representative

☐ JHM Medical Records (from Epic)

**Note for JHM Data Users Only:** Please complete the **Data Trust Risk Tiers Calculator** available on the Applications and Forms page on the JHSPH IRB website: [<https://tinyurl.com/2p96md3s>] and upload a copy of the documents to the "Miscellaneous- Other" section of your PHIRST application.

In addition, review the **Data Protection Attestation for Research and/or Healthcare Operations** at: [<https://tinyurl.com/yszfkuur>] and certify your attestation of compliance to those requirements.

☐ I certify my attestation of compliance to JHM Data Protection Requirements

☐ Non-JHM Medical Records

☐ Outside Data Provider (CMS, National Death Index, Insurance Co., etc.)

☐ Other Existing Records (please specify):

| |

### 2. Data Content: Will you collect, use, and/or record personal identifiers about study participants for any purpose? Please look at the list of identifiers in Question 3 to help answer this question. **Note: Limited Data Sets (including dates, ages, and zip codes) are considered to be "identifiable".**

☒ Yes: Continue with Question 3

☐ No: Skip to Question 6

**3. Data Identification:** Identify the Personally Identifiable Information (PII)/Protected Health Information (PHI) you will access/collect by checking the box(es) below for “Recruitment” and “Study Data” needs.

Recruitment	Study Data	PII/PHI to be Accessed/Collected
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Name, signature, initials or other identifiable code
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Geographic identifier (address, GPS location, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	Dates (birth, death, clinical service, discharge, etc.)
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Contact information (phone number, email address, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	Identification numbers (SSN, driver’s license, passport, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	Health records identifiers (medical record #, insurance plan, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	Text of clinical record notes
<input type="checkbox"/>	<input type="checkbox"/>	Device identifiers (implants, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	Internet identifiers (IP address, social media accounts, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	Biometric identifiers (fingerprints, retinal scan, voice print, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	Audio Recordings
<input type="checkbox"/>	<input type="checkbox"/>	Video or full-face photographic images
<input type="checkbox"/>	<input type="checkbox"/>	Genomic / Genetic data
<input type="checkbox"/>	<input type="checkbox"/>	Other identifiers ( <i>list here</i> ):

**4. Identifiers:** If you have checked any of the boxes above, how will you protect personal identifiers?

- ☒ Will delete all identifiers (explain **when** you will delete identifiers):  
All unique identifiers will be deleted after endline data collection is completed.
- ☐ Will separate identifiers from analytic data and will store the link/code. Please explain where you will store the link/code:
- ☐ Will use a method to make it harder to connect the data with the study participant (jiggering date, use other methods to obfuscate, etc.).

**5. Data Transit Plans and Protections:** Identifiable data may transfer, sometimes with multiple steps, from mechanisms for collection to storage. For example, participants may complete a web-based survey, which is then downloaded to a storage platform. Briefly identify these steps and the protections for each step (including encryption used at each step).

- ☐ Will delete all identifiers prior to transfer.
- ☐ Will separate identifiers from analytic data and will store the link/code prior to transfer. *Please explain where you will store link/code:*
- ☒ Other (*please specify*): Data will be collected in an online survey platform using tablets and will be transferred from devices to a secure online server either immediately after the interview or at the end of the day (depending on cell phone coverage). We do not anticipate deleting or separating identifiers during data collection to help facilitate coordination of data collection and data quality monitoring.

**6. Device(s) used for data collection:** Identify the computing device(s) being used for identifiable data receipt/collection. Check all that apply.

We understand that resources in low resource countries may require use of systems that are not pre-approved. The following are examples of platforms/storage solutions that are **not pre-approved to store identifiable information** and require a risk assessment from JHSPH Data Security. Do not hesitate to contact [[jhsph\\_cybersecurity@jhu.edu](mailto:jhsph_cybersecurity@jhu.edu)] for an assessment.

- JHU Independent Departmental Servers

- Local Computer owned by JH
- Other computers or devices owned/managed by study team members and used for other than secure web access
- USB/Portable data storage device
- Other solutions not managed by IT@JH, e.g., commercial cloud storage (Box, Dropbox, iCloud, personal OneDrive, Google Drive, Amazon storage, etc.)

☐ Provided or managed by JHSPH IT

☒ Study-provided, and not managed by JHSPH IT. These must include the following protective controls:

- Data encrypted while “at rest” (on a storage device)
- Security patches and updates are routinely or automatically applied
- Devices have access controls so that:
  - o Each person accessing the device is uniquely identified (username)
  - o Passwords are sufficiently strong to prevent compromise
  - o All access is logged and recorded
  - o Unauthorized access is prevented
- Approved access list is reviewed periodically for correctness

☐ Other (please specify): | |

#### 7. Data Collection: Describe the format of data received/collected. Check all that apply.

- ☐ Paper/Hard Copy (must be secured in transit and placed in a secure cabinet/room)
- ☐ Audio recording
- ☐ Video recording
- ☐ Received directly by research team member and entered into file/database
- ☐ Mobile or Web App (custom developed). Review [\[guidance\]](#) and provide attestation of compliance
- ☐ Mobile or Web App (purchased). Specify product and version: | |
- ☒ Online survey. Specify mechanism/platform: www.kobotoolbox.org
- ☐ 3rd party collector (please specify): | |
- ☐ Existing data shared with JHSPH by data provider via electronic access/transfer
- ☐ Duplicate and backup copies will be secured with same rigor as original data
- ☐ Other (please specify): | |

#### 8. Devices/Platforms used for Analysis, Storage, Processing: Identify where the identifiable or de-identified data will be analyzed/stored. Check all that apply.

- ☒ Pre-approved storage and analysis platforms managed by JH/JHSPH for which security and risk mitigation measures are known.

*Identify pre-approved storage platform(s) being used:*

##### **JHM Preferred:**

☐ JH SAFE Desktop ☐ JH PMAP

##### **Other Approved Platforms:**

☒ JH One Drive/JHSPH OneDrive ☐ JH IT-Managed Network Storage ☐ JHM/JHSPH Qualtrics

☐ JHSPH HPCC ☐ JHSPH SharePoint ☐ JHSPH Shares ☐ JHU REDCap

☐ MARCC-Secure Environment

☒ Platform(s) not managed by JH/JHSPH, not pre-approved, and require a risk assessment review from JHSPH Data Security.

- Describe the not pre-approved platform(s) you plan to use: It is possible we may need to store data on separate commercial storage site so that it also can be accessed by colleagues in the field (often use JH OneDrive is not feasible due to poor connection and login issues with partners. If this is required, we will likely use the DropBox Platform because the Health Systems Program maintains a license and the study team is already using it.
- Describe the technologies you intend to use (software, hardware, connectivity) with a focus on the measures taken to secure collected data along the continuum of data collection, storage, transmittal and access: We plan to use Kobo Toolbox for data collection and transmission to a secure online server. Data is encrypted and this is an accepted platform used on widespread basis by our partner organizations.

**9. Access to Data and Access Controls:** How will you ensure that only authorized individuals can access the data? What access controls will you put into place to ensure that only authorized individuals may access and use the data. (For example, OneDrive [[guidance](#)] illustrates how to share files with “people you specify”. [[JHSPH Shares](#)] addresses providing permissions to individual people.) Check all that apply. Note: If you need assistance implementing secure access controls, contact [[jhsph\\_cybersecurity@jhu.edu](mailto:jhsph_cybersecurity@jhu.edu)]

- ☒ Will provide access to data in accordance with OneDrive/JHSPH-Shares guidance posted on JHU IT websites
- ☐ Will use secure access controls to limit access to individual-level data
- ☐ Will use secure access controls to provide other researchers controlled access only to aggregated study data

**10. Data Sharing:** Clarify if data are to be shared externally with third parties, including sponsors and other investigators, and whether only aggregated data will be shared, or if you will share individual-level data. Describe sharing and protection plans for that sharing, including the proposed use of data agreements.

Consider the following:

- *Information about your data sharing in the consent forms*
- *Information about data sharing laws in the country where data will be collected, and if they limit sharing, how you will comply with those limitations?*
- *Whether data will be shared in aggregate only, or individual level data*
- *Whether you plan to make the data publicly available, and in what form.*

- ☐ Will not share data with outside investigators
- ☒ Will make publicly available
- ☐ Will share with restrictions/controls
- ☐ Will share aggregated data only
- ☒ Will share individual-level data without identifiers
- ☐ Will deposit data into an existing data repository for future research. *Please explain.* | |
- ☐ Future research use and data sharing will have limited purposes. *Please explain.* | |

- ☒ Other sharing information: We believe that data must be made publicly available because this work is funded by USAID. Additionally, many open access journals require that de-identified data sets be published. We plan to publish deidentified data on [Humanitarian Data Exchange](#) at the end of the study.

**11. Duration and Destruction:** Explain how long data will be retained and the plan for eventual return, deidentification or destruction of data, including moving data to an archive.

We anticipate maintaining identifiable data for approximately 25-30 months, during study data collection and data verification/cleaning. After data cleaning is completed, all unique identifiers will be removed from the data and only a copy of de-identified data will be maintained. If GPS coordinates are maintained, a central cluster coordinate will be used instead of specific household locations.

**A. Certificate of Confidentiality:**

*All NIH studies include Certificate of Confidentiality (C of C) protections with the grant; the consent form must include the C of C language provided in our template. Other funders may obtain C of C protections through NIH. [<https://grants.nih.gov/policy/humansubjects/coc.htm>]*

Does the study have Certificate of Confidentiality protections? Yes ☐ No ☒

**VII. Risks of the Study:**

- A. *Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. Include risks beyond individuals to include the study population as a group and community risks. Ensure that the risks described in the consent documents are consistent with the risks outlined in the research plan.*

We do not anticipate any physical, psychological, emotional, social, legal, economic or breach of confidentiality risks to the study participants. The data being collected is not sensitive. The primary inconvenience for participants is time spent to participate in the study which is anticipated to be no more than two hours over the two year study period.

- B. *Describe steps you will take to mitigate or minimize each of the risks described above. Include a description of your efforts to arrange for care or referral for participants who may need it.*

The JHU research team will ensure the data collection team receives training in privacy and confidentiality using content developed based on guidance from the JHSPH IRB. It is anticipated that data collectors will not have access to interview data after it has been transmitted from tablets and that only a small number of study teams will maintain access to the data, thereby reducing risk of breach of confidentiality.

- C. *Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing “x” test/assessment, or dispensing “y” drug, how often do you expect an “anticipated” adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?*

Data will be collected two times, 24 months apart and involves only an interview and anthropometric measurement. We do not anticipate a significant chance of harm.

- D. *Describe the research burden for participants, including time, inconvenience, invasion of privacy in the home, out of pocket costs, etc.*

We expect each round of data collection to require less than one hour for participants. There will be no out of pocket costs. Data will be collected at or near the respondent’s home. The participant and interviewer will mutually agree on a private location, such that data collection can occur outside the home if invasion of privacy is a concern.

- E. *Describe how participant privacy, and if relevant – family privacy - will be protected during data collection if sensitive questions are included in interviews, or if study visits occur in the home setting.*

The survey questionnaire will not include culturally and individually sensitive questions. The enumerator will secure a quiet place in or near the residence of each study participant to ensure privacy, and to ensure distancing from other family members and neighborhoods. The majority of information collected is focused on the household; individual information that is collected will be focused on care giver reports of child diet which is not sensitive.

- F. *Levels of COVID-19 community transmission will vary considerably by geography and over time, and therefore, the responses to the pandemic may also vary. The risk of COVID-19 to study staff and participants from in-person research activities can be mitigated by appropriate study procedures. If you are conducting in-person research activities, please indicate the protections you plan to implement at your research site(s):*

- ☐ Not applicable
- ☐ COVID testing of staff
- ☐ COVID testing of study participants
- ☐ Indoor masking/wearing PPE
- ☐ Social distancing for indoor activities
- ☒ Symptom screening of staff
- ☐ Symptom screening of study participants
- ☐ Vaccination of research team members
- ☒ Other procedures/comments: we follow Ethiopian COVID guidelines

### **VIII. Direct Personal and Social Benefits:**

- A. *Describe any potential direct benefits the study offers to participants (“payment” for participation is not a direct personal benefit).*

All study participants benefit from the Ifaa project, however, there are no direct benefits to participating in this evaluation.

- B. *Describe potential societal benefits likely to derive from the research, including value of knowledge learned.*

Findings from this study will contribute to an understanding of multi-sectoral development programming in Ethiopia. Knowledge learned will be applied by CRS in future programming and USAID in future funding calls for similar resilience programs.

### **IX. Payment or Token of Appreciation:**

- A. *Do you plan to provide a non-monetary token of appreciation (food, soap, tea, chlorine tablets, etc.) to study participants? If no payment is provided, the JHSPH IRB strongly encourages providing such tokens. If yes, please describe below.*

We do not plan to provide non-monetary tokens of appreciation due to the fact that households are receiving Ifaa benefits.

- B. *If you plan to provide a monetary payment, describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not “payment,” and if the study will reimburse, explain.*

We do not plan to provide monetary payment due to the fact that households are receiving Ifaa benefits.



C. *Include the possible total remuneration and any consequences for not completing all phases of the research.*

Not applicable

**X. Study Management:**

**A. Oversight Plan:**

1. *Describe how the study will be implemented. List all parties, including collaborators and subcontractors, who will be “engaged” in the human subjects research project and their roles .*

The research will be led by a team from Johns Hopkins University (JHU) Department of International Health including Shannon Doocy, Yunhee Kang, and Seifu Tadesse. Dr. Doocy will serve as the PI, Dr. Kang will lead on data quality monitoring and analysis, and Mr. Seifu Tadesse, who is based in Ethiopia, will be responsible for training, data collection oversight and serve as the primary liaison between CRS and the data collection firm. The data collection firm will be jointly selected by CRS and JHU from a CRS list of pre-approved companies that have performed similar work for CRS previously. The data collection firm will be responsible for hiring enumerators which will have direct contact with study participants.

Prior to and during each phase of data collection, the team will have regular calls to ensure adequate coordination and progress; in addition regular data quality monitoring and email correspondence will be used as a means of communication during data collection. Following the training of survey teams, quantitative baseline data collection will be conducted at the participants' households using Tablets/smartphones on the Kobo data platform. The baseline survey planning and logistics, and participant recruitment and data collection is planned to occur in May 2023. Following the two years of Ifaa intervention, JHU endline data collection will occur in May 2025, and will follow a similar process as baseline.

A training protocol will be designed by the JHU study team which will be delivered over a several day period to data collectors prior to each round of data collection. The training will be led by Seifu Tadesse and supervisors from the local data collection firm. The training elements will include an overview of the study rationale, objectives, protocol, review of the quantitative tool, interviewing techniques, field survey procedures, field organization, quality control measures and IRB protocols, to ensure safety, confidentiality, and consent procedures. Training will include content based on the JHSPH IRB Field Guide and also be specifically tailored to the questionnaire content. As part of the training, a field test will be conducted to give enumerators the opportunity to practice the consent process and interviews; following the field test modifications may be made to further tailor the questionnaire to the context (during the baseline survey only).

At each round of data collection, enumerators will be directly supervised by a team leader with experience conducting surveys. Data collection will be co-supervised by the data collection firm (using their usual practices) with additional on-the-ground support from Mr. Seifu Tadesse along with remote data quality monitoring managed by Dr. Kang.

2. *What are the qualifications of study personnel implementing the project?*

Dr. Doocy (PI) is internationally recognized for conducting research to improve international humanitarian response. She has twenty years of experience working in partnership with humanitarian agencies in the areas of health systems and health service delivery, food security, nutrition and cash transfers. Dr. Doocy has conducted research and evaluations in a diverse range of humanitarian settings, including natural disasters and conflict, in Asia, Africa, the Middle East, Europe and Latin America. She has worked with numerous UN agencies including UNHCR, WFP, WHO, UNICEF and UNFPA in addition to various NGOs, governments, universities and international organizations. Her research and professional practice work centers on informing ongoing humanitarian health programs and responses, with the longer-term objective of expanding the evidence base to improve humanitarian policy and practice. Dr. Doocy has over 100 peer-reviewed articles on humanitarian emergencies and response and is involved in numerous humanitarian health committees and advisory groups. In addition to research and practice, Dr. Doocy teaches and administers academic programs in health systems and humanitarian health and has expertise in training and capacity development of global health professionals.

Yunhee Kang (Co-PI, data manager/analyst), Ph.D. is Assistant Scientist at the Department of International Health at the Johns Hopkins. She earned a Ph.D. degree in international nutrition from the Johns Hopkins School of Public Health. Her research interests include maternal and child health and nutrition, dietary assessment, food security and livelihoods, and impact and process evaluations of nutrition-sensitive programs. With more than 13 years of experience in field operations, she led or supported effectiveness/impact evaluation studies of large-scale, community-based health and nutrition projects in low-income settings. She conducted numerous population-based epidemiological research studies related to undernutrition/overnutrition, dietary quality, food security, food system, and the impact of COVID-19 on income change and livelihoods in collaboration with UN agencies and international NGOs.

Seifu Tadesse (Co-PI, responsible for data collection oversight), BA, MPH, is Mr. Seifu Tadesse is international research and M&E experts with more than 15 years' experience in Africa. He worked as Research Technical Managers, Research Team Leader, Principal Investigator (PI), and Qualitative and Quantitative researcher. He has concrete professional experience in research designing and implementation, prepare research qualitative and quantitative tools and research guidelines and organize and facilitate research capacity building training, provided routine technical support in data quality assurance. He involved in preparing research sampling framework, prepare research proposal, and involved in qualitative and quantitative data collection, data analysis and prepare report. Seifu has involved in research of multi-sectorial programs such as socio economic, livelihood, health, and education program studies and evaluations. He involved in the research and evaluations funded by World Bank, DFID, USAID, EU, Irish Aid, Canada CIDA. Also worked with WFP, UNICEF, INGO, and Government organizations in Ethiopia and other African Countries such as Zambia, Cameroon, Mali, and Lesotho. Seifu holds Master in Monitoring and Evaluation, Bachelor of Arts with Honors in Development Studies; and a Bachelor of Art in Business Management.

3. *How will non-professional personnel (data collectors) involved with the data collection and analysis be trained in human subjects research ethical protections? (Use the JHSPH Ethics Field Training Guide available on the JHSPH IRB website. If the study is a clinical trial, consider using the JHSPH Good Clinical Practice (GCP) For Social and Behavioral Research Field Guide).*

Data collectors will be trained on basic principles and protocols of human subjects research, using information from the JHSPH Ethics field training guide.

4. *If the JHSPH PI is responsible for data collection and will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team.*

The JHU PI and Co-Is will have oversight over the data collection process. As the data will be collected through an online platform, JHU will have full access to the data entry and management platform. JHU team member Mr. Seifu Tadesse is based in Ethiopia and will be responsible for interviewer training and management of the data collection process. Mr. Tadesse and Dr. Doocy have calls several times a week and regularly communicate via email. Dr. Doocy does not have site visits planned explicitly for this study, however, she regularly travels to Ethiopia for the Ifaa Project with her travel scheduled planned around maximizing the utility of visits across multiple ongoing Ifaa studies.

## **B. Protocol Compliance and Recordkeeping:**

*Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation (for assistance, contact: [\[housecalls@jhu.edu\]](mailto:housecalls@jhu.edu)).*

*Please provide information about study oversight to ensure compliance with IRB approval and regulatory and institutional requirements. If the study team does not follow study procedure, what is your plan for reporting protocol non-compliance?*

Any reported breach of data protocols and non-compliance with IRB will be immediately addressed by the JHU research team and corrected or the individual study team member removed from the study.

**C. Safety Monitoring:**

1. Describe how participant safety will be monitored as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role and what is that person's specific charge?

N/A

2. If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following:
  - a. The DSMB membership, affiliation and expertise.

N/A

- b. The charge or charter to the DSMB.

N/A

- c. Plans for providing DSMB reports to the IRB.

N/A

3. Describe plans for interim analysis and stopping rules, if any.

N/A

**D. Reporting Unanticipated Problems/Adverse Events (AEs) to the IRB (all studies must complete this section):**

**NOTE:** The IRB does not require PROMPT reporting of all AEs, only those that are unanticipated, pose risk of harm to participants or others, and are related to the study. Anticipated AEs may be reported with the Continuing Review/Progress Report.

Describe your plan for reporting to the JHSPH IRB, local IRBs, and (if applicable) to the sponsor. Include your plan for government-mandated reporting of child abuse or illegal activity.

The data teams will be trained on the JHU human subjects research guidelines, confidentiality, safety and protection. They will also receive training on appropriate child protection guidelines required by CRS Ethiopia.

**E. Other IRBs/Ethics Review Boards:**

If other IRBs will review the research, provide the name of each IRB/ethics review board and its Federal Wide Assurance number, if it has one (available on [OHRP's Website](#)). **For federally funded studies, subrecipients MUST have a Federal Wide Assurance (FWA) number from the OHRP. The IRB overseeing the subrecipient should be registered with the OHRP. The JHSPH IRB will not have oversight responsibility for international subrecipients, and generally will not oversee data collection at external U.S. institutions Please contact the [JHSPH IRB Office](#) with questions.**

Non-JHSPH IRB/REC	FWA Number
Oromia Regional Administration (local authority)	18852
Ethiopia Public Health Association	19561

**F. "Engaged" in Human Subjects Research:**

For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.

Insert collaborator names and FWA numbers, if available. Note who will be “engaged” in human subjects research by filling in the following table:

	JHSPH	Local Data Collection Firm	CRS
For federally funded studies, collaborators’ FWA	00000287		00027851
Primary Grant/Contract Recipient			X
Grant/Contract Subrecipient	X	X	
Hiring Data Collectors		X	X
Training Data Collectors	X	X	
Obtaining Informed Consent and/or Identifiable Data		X	
Accessing/Analyzing Identifiable Data	X		
Overseeing storage, access and use of biospecimens	N/A	N/A	N/A

**COMPLETE THE FOLLOWING SECTIONS WHEN RELEVANT TO YOUR STUDY: none are relevant**

## REFERENCES

- <sup>i</sup> <https://reports.unocha.org/en/country/ethiopia/card/1THC27CGy6/>
- <sup>ii</sup> Ethiopian Public Health Institute (EPHI) [Ethiopia] and ICF. 2021. Ethiopia Mini Demographic and Health Survey 2019: Final Report. Rockville, Maryland, USA: EPHI and ICF.
- <sup>iii</sup> [Capacity4dev | Connecting the Development Community \(europa.eu\)](#)
- <sup>iv</sup> Berhane G, Hoddinott J, and Kumar, N. (2017). The impact of Ethiopia’s Productive Safety Net Programme on the nutritional status of children: 2008–2012. ESSP Working Paper 99. Washington, D.C. and Addis Ababa: International Food Policy Research Institute (IFPRI) and Ethiopian Development Research Institute (EDRI). <http://ebrary.ifpri.org/cdm/ref/collection/p15738coll2/id/131051>
- <sup>v</sup> Berhane, G, Hoddinott J, Kumar N, et al. (2011) ‘Evaluation of Ethiopia’s Food Security Program: Documenting Progress in the Implementation of the Productive Safety Nets Programme and the Household Asset Building Programme’. Mimeo, Washington, D.C: International Food Policy Research Institute.