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Assessment of a household play space intervention to reduce infant *Campylobacter* infection in Ethiopia: a randomised controlled feasibility trial

Baseline trial design document

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Ethiopian collaboration partners:

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1. Background

Globally, growth faltering (i.e. stunting) is the most prevalent form of undernutrition. Due to the relationship with infection, improved household WASH (water, sanitation and hygiene) was recently incorporated into the malnutrition framework as a primary barrier to pathogens. However, recent large and robust controlled trials including both WASH and nutrition (and combined) arms have failed to show a consistent effect on infant health.[1–3] It is hypothesised that this lack of effect is due to a substantial burden of contamination from animal faeces and related pathogenic bacteria.[4] Although in rural, subsistence livelihood contexts in low-income countries animals commonly share living quarters, animal faecal contamination remains a largely overlooked threat to infant health.[5] Risk is further increased by the normal age-related developmental behaviours which pertain specifically to infants, including crawling and regular hand-to-mouth activity which often results in the direct ingestion of animal faecal material and indirect ingestion from contaminated floor surface material and fomites.[6–8] As such, without considering the separation of both animal *and* human faeces from living environments, WASH interventions and programmes are unlikely to reduce pathogen exposure from all sources to the extent needed to improve infant health. This team is contributing to this very new and dynamic area of global health and development research.[9] A growing body of evidence shows certain animal husbandry practices results in high pathogen contamination in homes through multiple transmission pathways. Studies have tested for and reported high levels of pathogenic bacteria of animal origin in infant faeces, and has shown significant associations between both incidence and prevalence of these pathogens and malnutrition.[10] This includes recent research by this team which demonstrated significant associations between household poultry ownership, poultry and infant infection with pathogenic *Campylobacter* and infant stunting, wasting and diarrhoea.[11] Other research quantifies and qualifies the transmission pathways where infants are exposed to animal pathogens, typically through hand-to-mouth behaviours and crawling and exploratory play – also recently described by the team.[6]

Thus it is likely that reducing stunting in the most resource-poor areas will require a solution which more substantially blocks exposure to infants. Whilst the corralling or caging of livestock is a pragmatic solution, it has been found in formative research to be culturally unacceptable, mainly for economic reasons,[12,13] and may even increase infection-related symptomatic diarrhoea due to high faecal concentrations near the home environment.[13,14] In these studies, infants continued to enter and handle the poultry and experienced higher rates of Campylobacter-related diarrhoea than before animal separation.[14,15] Given that each

transmission pathway is closely linked to infant play and exploration, one proposed solution is the creation of an infant and young child play space[16]: a clean, safe environment in which babies and infants can freely play which avoids key faecal transmission routes.[12] The provision of a sanitary space in which crawling infants can be left to explore offers the opportunity to interrupt primary transmission routes, whilst providing an environment which is safe, practical and conducive to infant growth and development.[16] During our formative research in Ethiopia, we found that such a space was desirable: caretakers in focus group discussions expressed concern about the level of animal faeces where their child plays, which they understood to cause disease. Those who had been given a canvas mat, as part of an adapted TIPs (Trials for Improved Practices) method, unanimously suggested that a play area was of great value and a way to keep their child clean: 'he doesn't get dirty things in his mouth'. The area was easy to keep clean ('even if they urinate on the mat or defecate on the mat, we can clean it easily. We wash it and put it in the sun and then bring it back into the house') and of great benefit to the mothers who could continue with their activities if the infant was on the mat.

This trial is therefore designed as a feasibility study with a non-blinded, pilot, randomised baseline trial between Cranfield and People in Need in collaboration with Hawassa University. It proposes to assess the feasibility and fidelity of a household play space as a complex intervention to reduce infection in infants. Results will suggest the feasibility of scaling up the intervention into a full trial to test the effect on reducing pathogen infection in infants to improve growth and other health outcomes. To test this, the study will measure community adherence to appropriate use, competence of behavioural change methods and and estimates of an effect size for the potential of a play space to reduce infant infection.

Outcomes will contribute to a significant gap in the literature on the potential for an alternative, sustainable and practical household solutions to reduce infection in infants from pathogenic bacteria in contexts where the caging and corralling of livestock is deemed largely unacceptable.

2. Baseline trial aim

2.1 Baseline trial aims

The study address the following primary aims:

1. Evaluate the feasibility of a household play space as a complex public health intervention
2. Estimate an effect side of the play space intervention on the infection parameter. This will be done by using prevalence rates of Campylobacter in the general population versus any reduction found in the trial at 14 days and/or at 4 weeks Fidelity of the HPS intervention will be tested via assessing:

Secondary outcomes include:

1. Infant health outcomes, including growth data, diarrhoeal prevalence and infection prevalence at 3 time points and relationship to play space use
2. Hours spent using a play space each day
3. Determinants of use or the barriers preventing use
4. Acceptance of the play space and adherence to maintaining play space cleanliness

3. Household play space design: design for baseline trial

3.1 Household play space design method

The HPS was designed following a Trials by Improved Practice (TIPs) method which piloted 3 different prototypes. Using TIPs, program planners pre-tested the actual practices that a program would promote. The procedure consisted of a series of visits in which the interviewer and the participant analysed current practices; negotiated which new practice can be adopted and how; and following the trialling of the new practice, reflect on the barriers and motivations that prevent/enable the new practice to be fully adopted. The results are moved directly into program design.

The TIPs approach was implemented and assessed at the following stages:

- Household selection through direct observation
- Information, caretaker consent and play space allocation along with behaviour negotiation (N.B. this may occur at the same time as household selection)
- Visit 1: 5 days after the play space allocation
- Visit 2: 1 month after visit 1

The TIPs process also used the results of a User Centred Design workshop (with researchers, designers, parents and a psychologist) and prototype design suggestions from Cranfield Universities Centre for Creative Design (C4D).

Following the TIPs study, results were analysed and corroborated in order to determine the ‘best’ design from the 3 prototypes. Findings are detailed elsewhere. Subsequently, the final

design was determined and communicated to a manufacturer for the design and build of one prototype as the play space to be used in this trial. Details of the design and manufacture are as follows.

3.2 Household play space manufacture and design specifications

The 100 play spaces are currently in production with a local artisan who is working under an agreed design contract for production with People in Need. The prototype selected to be manufactured in bulk for the trial is that of 'best design' from the three trialled by TIPs. Design specifications are as follows:

- Bamboo structure (unvarnished)
- Floor plan: 1.20 x 1.20 metres
- Wall height: 70 cm from ground
- Flat bamboo panel 25 cm from the floor
- Space between slats: 4 cm
- 25 mm gap between the play space base and the ends and between the play space base and the sides
- The side of the wall and floor are detachable (foldable)
- Locking mechanism between two doors with simple hook and loop
- Mattress bottom (sponge) with cover (plastic canvas). Thickness: 4 cm
- Mattress size: 1.17 metres x 1.17 metres
- There should be a clear, bold mark on the inside wall of the play space at the top of the mattress to show the height of the mattress
- There should be no rough edges, or protruding parts, nails or pegs

3.3 Household play space design images

3.4 Household play space safety considerations

Using the prototype designs from the TIPs research, the same teams at Cranfield University and PiN further developed the design requirements of the HPS for the baseline trial. Safety requirements and standards align with both British Standards (BSOL) and International Standards (ISO) and are taken from ISO 7175-1:2019 Furniture -- Children's cots and folding cots for domestic use -- Part 1: Safety requirements, published January 2019. The justification for using BSOL is that many ISO standards have been adopted as British Standards. International and EU standards are written in the same way as national standards[17] and further the British Standards Institution enables the UK to participate in national, EU and international standards-making systems and for overseeing standards adopted in the UK.[17] Details of how the HPS was designed in line with these specifications and guidelines and checking adherence is detailed below. Furthermore, the ISO standard provides guidance on statements and warnings which should be issued in the local language. These are also detailed below.

3.4.1 Relevant ISO considerations for play space design

Table 1. Relevant ISO considerations for HPS design and testing (ISO 7175-1:2019)

ISO 7175-1 Furniture. Children's cots and folding cots for domestic use. Part 1: Safety requirements			
Safety aspect	**BSO safety recommendation**	**Reference section**	**Play space design consideration**
Flammability of materials	- The maximum rate spread of flame of textiles, coated textiles or plastic covering shall be 30 mm / s - There shall be no flash-effect	4.2.2	- Bamboo structure - Canvas floor covering
Edges and protruding parts	Edges and protruding parts accessible during normal use shall be rounded or chamfered and free of burrs and sharp edges	4.4.1.1	- Edges of walls - 25 cm panel from bottom
Assembly holes	There shall be no accessible holes between 7 mm diameter and 12 mm diameter, unless the depth is less than 10 mm	4.4.2.2	Top of corners and holes within the structure
Distance between cot base and sides and ends	It shall not be possible for the 25 mm cone to pass between the cot base and the sides, and between the cot base and the ends	4.4.2.3	Cot base and sides/ends
Distance between slats of the cot base	It shall not be possible for the 60 mm cone to pass between two adjacent slats of the cot base	4.4.2.5	Distance between slats in sides of cot
Head entrapment on the outside of the cot	completely bound openings on the outside (exterior) of the cot that allow passage of the small head probe, shall also allow the	4.4.3	Distance between slats in sides of cot

	large head probe to pass completely through the bound opening		
Sheer and squeeze points during use	There shall be no accessible shear and squeeze points which close to less than 18 mm	4.4.4.3	Squeeze points in door mechanism
Locking system	- Folding cots that fold towards the inside shall be equipped with at least two locking systems fulfilling the requirements of 4.4.6.2 - All other folding cots shall be equipped with a locking system fulfilling the requirements of 4.4.6.2 in order to prevent an unintentional folding	4.4.6.1	Locking and folding of the cot using a simple hook and loop
Strength of the cot base	No element of the cot base shall break, nor shall the cot base become dislodged and the function of the cot shall not be impaired	4.4.7.3	Cot base
Mattress base height	- With the mattress base in the lowest position, the minimum distance between the upper side of the mattress base and the upper edge of the cot side and end shall be at least 500 mm If the mattress is not an integral part of the cot: — the measurement shall be made from the mark of the maximum thickness of the mattress and the upper edge of the cot side and end; or — if the indication of the maximum thickness of the mattress is provided by a text, the measurement shall be made from the top surface of the cot base and the upper edge of the cot side and end, minus the maximum thickness of the mattress	4.4.8.2	Mattress height
Wall/side strength	The slats or sides and ends and corners shall neither break nor become detached. The function of the cot shall not be impaired	4.4.8.3	Walls
Mattress size	If a mattress is supplied with the cot, there shall be no gap more than 30 mm between the mattress and the sides ends in any position of the mattress	4.6	Mattress size

3.4.2 Other safety considerations noted by the field team

- The play space should not be placed near windows. Cords on drapes and blinds can strangle the baby (likely not relevant to most rural Ethiopian homes)
- The play space should not be placed near any naked flame or fire inside the home, even if the fire is controlled
- Never replace the mattress or padding in the play space, as it might not fit the playpen
- All padded parts should be checked regularly for tears; cover or repair all tears.

- The play space should not be used beyond the age of 2 years, when the infant can too easily climb out of the play space by themselves
- There should be no removable parts that the child can fit in their mouth
- The play space should not be varnished which would increase flammability

3.5 Providing instructions for household play space use

According to *BS ISO 7175-1 Furniture. Children's cots and folding cots for domestic use. Part 1: Safety requirements*, instructions shall be provided in the official language(s) of the country where the play space is distributed or sold. These instructions shall be headed “IMPORTANT, RETAIN FOR FUTURE REFERENCE: READ CAREFULLY” in letters not less than 5 mm high. The instructions for use must contain the following warnings, statements and markings as detailed in the sections below.

Note: These will be provided on laminated sheets in both Amharic and Sidamo to each household receiving a play space.

3.5.1 Instructions for use: warnings

The word WARNING can be given at the top of a list of warnings. The instructions for use shall include the following warnings:

a) Warning: Be aware of the risk of open fire and other sources of strong heat, such as electric bar fires, gas fires, etc. in the near vicinity of the cot

b) Warning: Do not use the cot if any part is broken, torn or missing and use only spare parts approved by the manufacturer

c) Warning: Do not leave anything in the cot or place the cot close to another product, which could provide a foothold or present a danger of suffocation or strangulation, e.g. strings, blind/curtain cords, etc.

d) Warning: Do not use more than one mattress in the cot.

3.5.2 Instructions for use: statements

The instructions for use shall include the following statements:

e) Statement that a cot is ready for use, only when the locking mechanisms are engaged and to check carefully that they are fully engaged before using the folding cot

g) When movable sides are provided, a statement that “if you leave the child unattended in the cot, always make sure that the movable side is closed”;

i) Assembly drawing, a list and description of all parts and tools required for assembly and a diagram of the bolts and other fastenings required

j) Thickness of the mattress shall be such that the internal height (surface of the mattress to the upper edge of the cot frame) is at least 500 mm in the lowest position of the cot base and at least 200 mm in the highest position of the cot base

k) A statement that the mark indicates the maximum thickness of mattress to be used with cot

l) The minimum size of the mattress to be used with the cot. The dimension shall take into account that there shall be no gap more than 30 mm between the mattress and the sides end ends in any position of the mattress

m) Statement that all assembly fittings should always be tightened properly and that fittings should be checked regularly and retightened as necessary

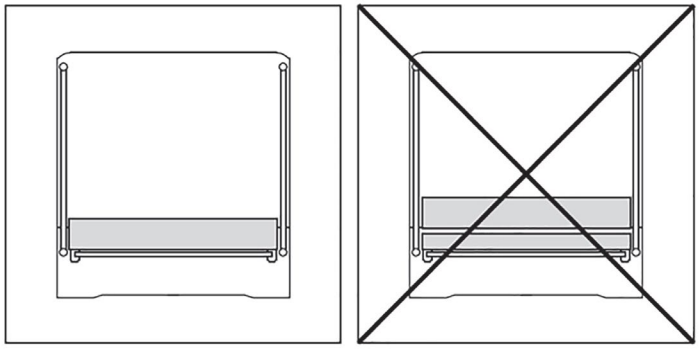
n) Instructions for washing/cleaning, when applicable

o) Statement to prevent injury from falls that when the child is able to climb out of the cot, the cot shall no longer be used for that child

p) The following warnings shall appear on the instruction for use of folding cots which the mattress is an integral part of the product through a mattress base.

“WARNING — Only use the mattress sold with this cot, do not add a second mattress on this one, suffocation hazards"

A pictogram may be added, however the pictogram will not replace the warning.



3.5.3 Instructions for use: marking

All cots for which a claim of conformity to *BS ISO 7175-1 Furniture. Children's cots and folding cots for domestic use. Part 1: Safety requirements* is made shall be permanently marked with the following information if the mattress is not an integral part of the cot:

a) Name, registered trade name or registered trade mark of either the manufacturer or distributor or retailer together with additional means of identifying the product

b) Reference to ISO (ISO 7175-1)

c) The maximum thickness of the mattress to be used; this can be in the form of text, a distinct mark on the cot at the correct height, e.g. a line, or by other means.

4. Baseline trial design and methods

4.1 Power and effect size

As the baseline trial is a pilot / feasibility study, there is no need to calculate the power of the study for the size of the intervention and control groups.

4.2 Sampling strategy

Total participants for the study will be 100 households across two study arms (intervention and control – detailed below). The sampling strategy will involve randomly assigning kebeles (villages) within PIN intervention areas to specific arms of the study. Within kebeles, the sampling frame will be created from health centre catchment areas. With the aid of the local health office and local Health Extension Workers, the team will list households with infants aged 10–18 months that comply with the eligibility/exclusion criteria. From this frame, infants will be randomly selected to build the sample. There will be no geographical overlap between the control and intervention arms.

4.3 Trial study participants

4.3.1 Study numbers and criteria

Total participants for the study will be 100 households across two study arms:

1. **Control:** No intervention (HPS will be provided at the end of the trial) **= 50**
2. **Intervention** with HPS (household will keep HPS at the end of the trial) **= 50**

Eligibility criteria:

- Infants aged 10−18 months at the start of the trial (proposed January 2020)
- Infants living in villages within PiN intervention areas (Sidama zone, SNNPR region)
- Households with free-roaming poultry OR cattle OR both
- Not involved in any other study

Exclusion criteria:

Pertaining to caregivers:

- Participating in other ongoing PIN studies

- Do not own domestic animals

Pertaining to infants:

- Outside the age range of 10-18 months at the trial start
- Participating in other ongoing PIN studies
- Known to have been low birth weight, pre-term or experienced other birth complications

4.4 Play space distribution and data collection plan

Play space distribution:

- Play spaces will be distributed via use of PiN's Toyota Hilux pick-up trucks, with 4 play spaces in the back. *(N.B. Depending on whether 2 or 3 cars are used this will dictate if 8-12 households can be visited a day)*

Data collection:

- On the day of play space distribution, households will have baseline measurements taken as per table 2 below
- Households will be visited 14 days later to collect data as per Table 2
- Households will be visited at endline (4 weeks from baseline) to collect data (Table 2)

Faecal sample collection:

- Households will be visited 24 hours prior to data collection visit and given a sterile sample collection bag with sterile spoon. Caretakers will collect a faecal sample of their infant and keep for collection during the data collection visit the following day *(N.B. use of the sterile bag and spoon for faecal sample collection was trialled during June fieldwork with good success)*

Control group:

- Play spaces will be given to the control group after the baseline trial has finished and with the same instructions for use as given to the intervention group at the trial start

The Gantt chart below shows how households might be visited at the initial visit, at 14 days into the trial and 1 month later at the endline visit. Visiting 10 households a day would require 2 fieldworkers who are able to visit different sites.

NB. As logistics are still in consideration during submission of ethics, it is possible the household visit plan may change to less or more households per day, depending on the availability of cars and data collectors. The exact start dates of the study may also shift. Thus the below chart serves only as an example of how data collection would occur.

JANUARY **Monday 27th**	**Tuesday 28th** • Finish preparation and communication with university staff • Print surveys and discuss questions for final changes • Finalise preparation details and discuss schedule	**Wednesday 29th** • Print laboratory protocols and record forms • Finalise changes to surveys and print all • Print all consent forms	**Thursday 30th** • Take consumables to laboratory (a.m.) • Train microbiology staff (a.m.) • Training for data collectors in Hawassa office • Finalise HH list and assign study numbers to HH	**Friday 31st** • Transport 25 play space to Kebele (A) • Transport 25 play space to Kebele (B) **TRIAL BEGINS** **Kebele A:** • Distribution bags households 1-5 **Kebele B:** • Distribution bags households 26-30
Monday 3rd **Kebele A:** • Collect households 1-5 • Distribute bags households 6-10 **Kebele B:** • Collect households 26-30 • Distribution bags households 31-35	**Tuesday 4th** **Kebele A:** • Collect households 6-10 • Distribution bags households 11-15 **Kebele B:** • Collect households 31-35 • Distribution bags households 36-40	**Wednesday 5th** **Kebele A:** • Collect households 11-15 • Distribution bags households 16-20 **Kebele B:** • Collect households 36-40 • Distribution bags households 41-45	**Thursday 6th** **Kebele A:** • Collect households 16-20 • Distribute bags households 21-25 **Kebele B:** • Collect households 41-45 Distribute bags 46-50	**Friday 7th** **Kebele A:** • Collect households 21-25 **Play space distribute** **Kebele B:** • Collect households 46-50 **Play space distribute** **Kebele C:** • Distribute bags households 51-55 **Kebele D:** • Distribute bags households 76-80
Monday 10th **Kebele C:** • Collect households 51-55 • Distribute bags households 56-60 **Kebele D** • Collect households 76-80 • Distribute bags households 81-85	**Tuesday 11th** **Kebele C:** • Collect households 56-60 • Distribute bags households 61-65 **Kebele D:** • Collect households 81-85 • Distribute bags households 86-90	**Wednesday 12th** **Kebele C:** • Collect households 61-65 • Distribute bags households 66-70 **Kebele D:** • Collect households 86-90 • Distribute bags households 91-95	**Thursday 13th** **Kebele C:** • Collect households 66-70 • Distribute bags households 71-75 **Kebele D:** • Collect households 91-95 • Distribute bags households 96-100	**Friday 14th** **Kebele A:** • Distribute bags households 1-5 **Kebele B:** • Distribute bags households 26-30 **Kebele C:** • Collect households 71-75 **Kebele D:** • Collect households 96-100

Monday 17th **Kebele A:** • Collect households 1-5 • Distribution bags households 6-10 **Kebele B:** • Collect households 26-30 • Distribution bags households 31-35	**Tuesday 18th** **Kebele A:** • Collect households 6-10 • Distribution bags households 11-15 **Kebele B:** • Collect households 31-35 • Distribution bags households 36-40	**Wednesday 19th** **Kebele A:** • Collect households 11-15 • Distribution bags households 16-20 **Kebele B:** • Collect households 36-40 • Distribution bags households 41-45	**Thursday 20th** **Kebele A:** • Collect households 16-20 • Distribute bags households 21-25 **Kebele B:** • Collect households 41-45 • Distribute bags 46-50	**Friday 21st** **Kebele A:** • Collect households 21-25 **Kebele B:** • Collect households 46-50 **Kebele C:** • Distribute bags households 51-55 **Kebele D:** • Distribute bags households 76-80
Monday 24th **Kebele C:** • Collect households 51-55 • Distribute bags households 56-60 **Kebele D** • Collect households 76-80 • Distribute bags households 81-85	**Tuesday 25th** **Kebele C:** • Collect households 56-60 • Distribute bags households 61-65 **Kebele D:** • Collect households 81-85 • Distribute bags households 86-90	**Wednesday 26th** **Kebele C:** • Collect households 61-65 • Distribute bags households 66-70 **Kebele D:** • Collect households 86-90 • Distribute bags households 91-95	**Thursday 27th** **Kebele C:** • Collect households 66-70 • Distribute bags households 71-75 **Kebele D:** • Collect households 91-95 • Distribute bags households 96-100	**Friday 28th** **Kebele A:** • Distribute bags households 1-5 **Kebele B:** • Distribute bags households 26-30 **Kebele C:** • Collect households 71-75 **Kebele D:** • Collect households 96-100
Monday 2nd **Kebele A:** • Collect households 1-5 • Distribution bags households 6-10 **Kebele B:** • Collect households 26-30 • Distribution bags households 31-35	**Tuesday 3rd** **Kebele A:** • Collect households 6-10 • Distribution bags households 11-15 **Kebele B:** • Collect households 31-35 • Distribution bags households 36-40	**Wednesday 4th** **Kebele A:** • Collect households 11-15 • Distribution bags households 16-20 **Kebele B:** • Collect households 36-40 • Distribution bags households 41-45	**Thursday 5th** **Kebele A:** • Collect households 16-20 • Distribute bags households 21-25 **Kebele B:** • Collect households 41-45 • Distribute bags households 46-50	**Friday 6th** **Kebele A:** • Collect households 21-25 **Kebele B:** • Collect households 46-50 **Kebele C:** • Distribute bags households 51-55 **Kebele D:** • Distribute bags households 76-80

Monday 9th	**Tuesday 10th**	**Wednesday 11th**	**Thursday 12th**	**Friday 13th**
Kebele C: • Collect households 51-55 • Distribute bags households 56-60 **Kebele D** • Collect households 76-80 • Distribute bags households 81-85	**Kebele C:** • Collect households 56-60 • Distribute bags households 61-65 **Kebele D:** • Collect households 81-85 • Distribute bags households 86-90	**Kebele C:** • Collect households 61-65 • Distribute bags households 66-70 **Kebele D:** • Collect households 86-90 • Distribute bags households 91-95	**Kebele C:** • Collect households 66-70 • Distribute bags households 71-75 **Kebele D:** • Collect households 91-95 • Distribute bags households 96-100	**Kebele C:** • Collect households 71-75 **Kebele D:** • Collect households 96-100 • **Distribute 25 play spaces to Kebele C** • **Distribute 25 play spaces to Kebele D** **TRIAL ENDS**
Monday 16th	**Tuesday 17th**	**Wednesday 18th**	**Thursday 19th**	**Friday 20th** **Sophie leaves**

Figure 1. Baseline trial data collection Gantt chart

5. Trial outcome measures and data collection time points

5.1 Trial outcome measures and time points

The table below details the various outcome measures and control variables and the time points at which at which data are collected during the trial. The sections below give further detail, and as appropriate surveys and procedures are included in the Appendix.

Table 2. Trial outcome variables and data collection time points

Outcome variable	Measure	Control group	Play space group	Baseline measure	14 day measure	1 month measure
Recruitment	Proportion of contacted houses who consented		x		x	x
Attrition	Loss to follow-up		x		x	x
Adherence	Non-use of HPS		x		x	x
	Appropriate use		x		x	x
	Appropriate cleaning		x		x	x
	Appropriate use and cleaning		x		x	x
Acceptability	Infant in HPS upon arrival		x		x	x
	Proportion of HPS use during daily activities		x		x	x
Control variable	**Measure**	**Control group**	**Play space group**	**Baseline measure**	**14 day measure**	**4 week measure**
Infant microbiology of stool sample for Campylobacter	Culture-based	x	x	x	x	x
Household demographics / SES	Survey	x	x	x		
Household WASH facilities and use	Survey	x	x	x		
Animal ownership and husbandry practices	Survey	x	x	x		
Infant diarrhoeal prevalence	Survey	x	x	x	x	x
Infant feeding practices and nutrition	• Minimum meal frequency • Individual dietary diversity score • Feeding of fresh or reheated foods	x	x	x	x	x

Breastfeeding practices	• Breastfeeding at 1 year • Breastfeeding definition (full, partial, none)	x	x	x	x	x
Infant anthropometry	• Height • Weight • MUAC	x	x	x	x	x

5.1.1 Infant health data: anthropometry and diarrhoea prevalence

Infant health status is assessed by asking questions on recent episodes of diarrhoea and from anthropometric measurement. This includes recumbent length and weight (to calculate length-for-age scores, weight-for-length and weight-for-age z-scores as per WHO growth standards) and mid-upper arm circumference (MUAC) to give a second measure of current weight status and wasting (low weight for length). Diarrhoea prevalence is assessed by caregiver report as occurrence over the last 7 days, where diarrhoea is defined as three or more loose stools over a 24-hour period, according to the WHO definition. Both the responses to diarrhoea prevalence and the data from anthropometry will be captured on Survey 1. This survey is shown in Appendix A.

5.1.2 Infection prevalence: infant faecal *Campylobacter* prevalence

Infant infection with *Campylobacter* is assessed at the three study time periods to assess change in infection prevalence throughout the trial and with use of the play space. Infection is assessed through collection and analysis of an infant faecal sample, whereby the isolation and growth of *Campylobacter* under microaerophilic conditions will allow for the determination of *Campylobacter* presence (and thus assumed infant infection) and abundance. Microbial testing will be performed at Hawassa University laboratory under the fieldwork collaboration agreement with those partners. Appendix B shows a brief flowchart for isolating *Campylobacter*.

5.1.3 Survey: Demographics, WASH, animal husbandry, nutrition and breastfeeding

Survey 1 captures data on household socioeconomic status, and demographics of infant sex and age and also assesses WASH facilities including latrine type and use, water source and storage, handwashing practices, animal ownership and husbandry practices, infant nutrition and infant health measures. Specifically it assesses possible routes of contamination from an unsafe water source and storage, improper faecal disposal or unimproved latrine use, from the presence (or non-presence) and use (or non-use) of a handwashing station and from the presence of livestock in domestic areas during the day and night.

This survey assesses feeding practices by incorporating surveys from PiN's IndiKit database of validated questionnaires (Appendix A). These include:

- Minimal Meal Frequency *(MMF; % of children 6–23 months of age who received solid, semi-solid or soft foods the minimum number of times or more the previous day/night)*
- Feeding of Fresh or Reheated Foods *(FFRF; % of mothers of children aged 6-23/59 months who during the previous day fed their children only foods that were freshly prepared or reheated to boiling point)*
- Individual Dietary Diversity Score *(IDDS; the average number of different food groups consumed by infants aged 10-18 months the previous day and night)*

These surveys give an indication of an individual's food security, as well as of the diet's micronutrient adequacy. The FFRF indicates a possible other route to *Campylobacter* infection if food not properly reheated is contaminated before serving (although food will not be sampled).
Breastfeeding practices are assessed by a combined use of:

- PiN's IndiKit survey on continued breastfeeding at 1 year *(% of children 12–15 months of age who received breast milk during the previous day or night)*
- Breastfeeding characterisation as Full, Partial or None *(full [exclusive or predominant, i.e., received only breast milk or breast milk with water or clear liquids], partial [received breast milk plus other milk or food] or none [is not breastfeeding])* as taken from Labbok M, Krasovec K (1990).

5.1.4 Adherence: HPS use and cleanliness

Based on the TIPs results from the prototype trial, behaviours to be studied are:

- Estimate of total daily hours of use
- The times at which caretakers/mothers of infants use the HPS and the responsibilities/activates which dictate use
- Mothers of infants adequately maintain a HPS. This is assessed via cleanliness spot check and presence of urine or faeces (human/animal) or animals in the HPS. This survey is shown in Appendix C.

5.1.5 Adherence: Barrier analysis

The TIPs approach used in the design of the HPS allowed for continued identification of the barriers the caregivers face in using the HPS. A week after the introduction of the play spaces a Barrier Analysis further understood the determinants to create effective future behaviour change strategies using PiN's Behaviour Change toolkit (http://www.behaviourchange.net/document/33-

behaviour-change-toolkit). (Appendix C). This barrier analysis will be used in this feasibility trial also to determine reasons for both use and non-use of the HPS. It will help to determine the fidelity of HPS use and potential to scale up the intervention into a full trial.

It may also help to determine:

- Are we targeting the right group 10-18 months?
- Are there other confounding factors that affect play space use? (E.g. livelihood patterns, women's use of time)?
- Is the community engagement protocol correct?
- Would this way of HPS distribution and working with HEWs for HPS introduction work for scaling up the HPS intervention into a full trial?

6. Trial data collection, processing and storage

6.1 Data types

The data to be collected by method and the types and file types are detailed in the table below. Observation notes in the form of long-hand note taking are unlikely to be collected given time restraints.

Table 3. Data types by method as collected during the baseline trial

Data collection method	Raw data	Data type	File type
Survey data	Documented answers	Word; numerical	.xlsx
Anthropometric data	Height, weight, mid-upper arm circumference	Numerical	.xlsx
Observation notes	Notes	Word	.docx
	Photographs	Photos	.jpg
Microbiological sample analysis	- Bacterial count data - Presence/absence	Numerical	.xlsx

6.2 Data storage

Data will be saved into a folder on a secure server at the PiN Hawassa office and subsequently transferred onto an external hard drive for transfer to Cranfield University where it will be analysed. All data will eventually be saved onto Dropbox as well as an external hard drive. The table below details the data processing and storage details for each of the data collection methods and file types.

Table 4. Data file types, processing and storage details for different data types.

Data collection method	Raw data	File type	Data processing and storage details
Survey data and anthropometry	Documented answers on form	.xlsx	• Transcribed into excel (using coding) and saved into excel for each interview • Saved on secure server and on external hard drive in labelled folder
Fieldwork/ observation notes	Notes	.docx	• Type any additional notes in English into a MS Word document with infant ID as identifier • Saved on secure server and on external hard drive in labelled folder
	Photographs	.jpg	• Photographs saved on secure server and on external hard drive in labelled folder
Microbiological sample analysis	Bacterial count data/numerical data	.xlsx	• Transcribed into excel (using coding) and saved into excel • Saved on secure server and on external hard drive in labelled folder

6.3 Standardised file naming conventions

Data will be saved accordingly:

1. Each data set (i.e. each household) will be saved into a folder with the household number (1-100)
2. Within each folder (1-100), data will be saved in one of three folders under the naming convention: 1A, 1B or 1C where and ‘A’, ‘B’ or ‘C’ stand for baseline, 14-day measure or endline measure respectively
3. Within each of the three folders, data will be saved under the naming convention: householdID(number)_date (dd/mm) where ‘date’ is the day that the data was collected and where where and ‘A’, ‘B’ or ‘C’ stand for baseline, 14-day measure or endline measure respectively

e.g. 1_120919_A

1_120919_B

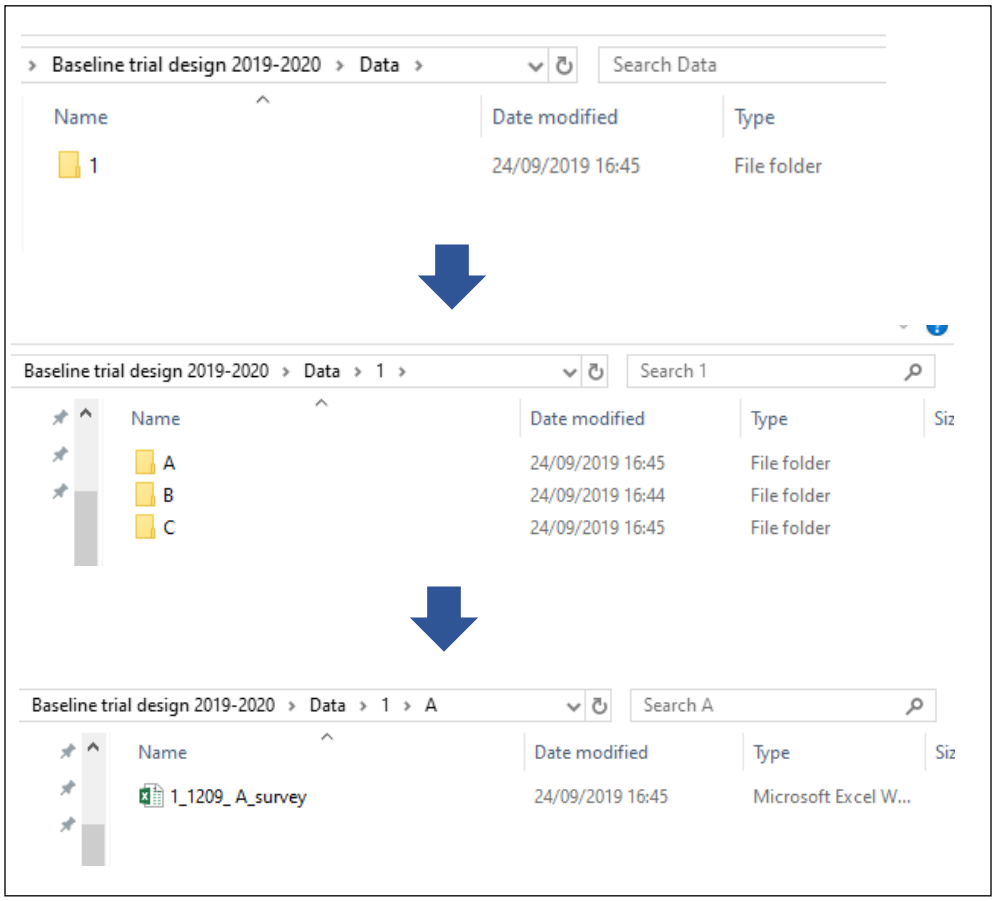
1_120919_C

And will contain files named accordingly:

- Survey data **(1_1209_A_survey)**
    - Including anthropometric data
- Fieldwork/observation notes **(1_1209_ A_notes)**
- Photographs **(1_1209_ A_photo_1)**
- Microbiological data
    - **(1_1209_ A_culture)**

An example of how this would appear saved is shown below in the figure.

Figure 2. Image representing example of saved data with file naming conventions



6.4 Data analysis plan

Survey data will be collected either on paper or using a tablet. Infants will already be anonymous before data is entered into Microsoft Excel but there will be no identifiable variables within the Excel datasheet.
Anthropometry and microbiology data will be numerical and also entered into Excel.
All data will be assessed using Microsoft Excel and SPSS Statistics (IBM, V22.0; USA) using standard tabulation, correlation and regression techniques. This will be further refined as the data types are gathered.

7. General ethical principles

The sections below detail ethical principles as relate to this research and in general, particularly working with infants and young children (IYC). The sections below incorporate guidelines which adhere to the *Guidelines for the ethical conduct of medical research involving children* as written by the Royal College of Paediatrics (RCP) and Child Health Ethics Advisory Committee.
See here for the full document:
https://www.rcpch.ac.uk/sites/default/files/page/ADC%202000_2.pdf
Advice and guidance is also sought from the *Ethics Guide: Medical research involving children* as written by the Medical Research Council (MRC).
See here for the full document:
https://mrc.ukri.org/documents/pdf/medical-research-involving-children/

The MRC is committed to the highest ethical standards in medical research. The fundamental principles underpinning research on human beings and information relating to them have been elaborated and refined in various national and international guidelines. These are as follows:

- Participants' interests must prevail over those of science and society, where there is conflict
- The research must have potential to generate scientific understanding that may be a basis for improvements in human health and wellbeing
- There must be an acceptable balance of risk and benefit for participants
- Researchers can only proceed if they have obtained voluntary informed consent from the participant to participate in research (special safeguards apply when this is not possible)

- An appropriate independent research ethics committee must review and approve the research proposal.

8. Ethical conduct working with infants and children

8.1 The benefit of research involving infants and young children (IYC)

Medical research involving IYC is an important means of promoting child health and wellbeing. Such research includes systematic investigation into normal childhood development and the aetiology of disease, as well as promoting health. Medical research involving IYC is important for the benefit of all IYC. It leads to innovations in healthcare that can substantially improve their health and quality of life. However, the benefits of medical research must outweigh potential risks which are assessed both prior and during fieldwork. The following document outlines further details of infants to take part in the fieldwork as well as an assessment of risk and researcher responsibility.

8.2 What data types from IYC are being collected in this fieldwork?

Data collected from IYC in this phase of fieldwork are laid out below. Specific details of each data type can be found in the protocol in the specified relevant section.

Table 5. Data types to be collected from infants during the trial

Fieldwork instrument	Data type	Relevant protocol section	Relevant Appendix
Survey	- Infant sex - Date of birth - Diarrhoea incidence	5.1.1 5.1.3	A
Anthropometry	- Weight (kg) - Height (cm) - MUAC (mid-upper arm circumference; cm)	5.1.1 5.1.3	A
Microbiological analysis	- Faecal sample (non-intrusive)	5.1.2	B

8.3 Assessing the risk when working with IYC

Assessment of potential harm included estimates of certain research aspects and considerations. The table below (adapted from RCP) details these aspects and details how they pertain (or not) to the trial to be carried out.

Table 6. Assessing the risks when working with IYC and how they pertain to the trial

Research aspect	Considerations	Implication for 2019 field research
Type of intervention	How invasive or intrusive is the research? (psychosocial research should be assessed as carefully as physical research)	Not invasive; minimally intrusive (minimal data requirements, observing infant in natural environment, minimal photography and collecting faecal sample via non-intrusive method). No treatment, intervention or medical care is administered.
Magnitude	How severe may the harms associated with research procedures be?	Not severe; N/A
Probability	How likely are the harms to occur?	Very unlikely
Timing	Might adverse effects be brief or long lasting, immediate or not evident until years later?	Very unlikely
Equity	1. Are a few infants/children drawn into too many projects simply because they are available? 2. Are researchers relying unduly on infants/children who already have many problems?	1. The formative research purposefully observes infants 6–18 months old. A random sampling frame should address issues of selection, however in the instance that there are not substantial numbers of infants in this age group, those that are available may be more heavily relied on to participate. These participants are volunteered by their caregiver who must consent with full information, and care is taken by the coordinating staff not to repeat recent surveys nor collect unnecessary data. Similarly, the researchers recognise that sometimes conducting no new research at all is the most appropriate response to concerns of over-research. 2. Random sampling methods should provide a sample varied demographically .Participants in this field of research are likely to experience multiple hardships in terms of poverty and need. These communities are vulnerable and sensitive to research – as such, care is taken to ensure the community is not over-researched and does not feel themselves exploited and that those researched do not feel the research impacts their social identities and relationships within their community.
Interim finding	If evidence of harm in giving or withholding certain treatment emerges during the trial, how will possible conflict between the interests of the infant/child subjects and of valid research be managed?	Unlikely to occur as there is likely no 'single' solution to the issue of stunting. Any results from other studies which are published during the formative research period may influence the intervention, only in that they may improve design to improve outcomes for the infant

8.4 Designating risk

The RCP ethics guidelines for IYC states:

'Risks may be estimated as minimal, low or high.

Minimal (the least possible) risk describes procedures such as questioning, observing, and measuring IYC, provided that procedures are carried out in a sensitive way, and that consent has been given. Procedures with minimal risk include collecting a single urine sample (but not by aspiration), or using blood from a sample that has been taken as part of treatment'.

This formative research thus appears as 'minimal risk' according to the RCP guidelines.

8.5 Ethical considerations and rationale for the inclusion of IYC in this study

Research involving IYC should only be carried out if it cannot feasibly be carried out on adults (MRC). Therefore the researcher needs to assess beforehand whether the same potential benefit could be derived from studies on adults, which involves asking the following questions:

- Is the disease specific to IYC, with no close analogy in adults? **Yes**
- Will the study increase understanding of the IYC development and/or wellbeing with the aim of improving IYC health? **Yes**
- Are the relevant pharmacokinetics of the treatment option being studied already known in adults? **N/A**
- Is it expected that the pharmacokinetics for IYC and adults will differ? **N/A**
- Is there a need to test this? **N/A**
- Is the adult-style therapy shown or believed to be unpalatable or difficult to administer to IYC? **N/A**
- Has the therapy previously been developed for adults and not tolerated by IYC? **N/A**
- Is the adult disease believed to have its origins in early life? **Yes**
- Will studies involving IYC shed light on the disease and its natural history and increase understanding of the possibilities of prevention? **Yes**

If the answer to any of these questions is yes, IYC may ethically be involved in this research, and may benefit from it.

9. Specific ethical principles pertaining to IYC

IYC require special protection because they are less likely than adults to be able to express their needs or defend their interests – they may not have the capacity to give consent.
The following principles guides all MRC-funded research involving IYC:

- Research should only include IYC where the relevant knowledge cannot by obtained by research in adults
- The purpose of the research is to obtain knowledge relevant to the health, wellbeing or healthcare needs of IYC
- Researchers can only involve competent IYC if they have obtained their caregiver's informed consent beforehand

- Researchers should involve parents/guardians in the decision to participate wherever possible, and in all cases where the IYC is not yet competent
- A caregiver's refusal to participate or continue in research should always be respected
- If an IYC becomes upset by a procedure, researchers must accept this as a valid refusal
- Researchers should attempt to avoid any pressures that might lead the IYC to volunteer for research or that might lead parents to volunteer their IYC, in the expectation of direct benefit (whether therapeutic or financial)
- Research involves partnership with the IYC and/or family, who should be kept informed and consent to separate stages of the project. Obtaining consent is a continuing process, rather than a one-off occurrence. IYC and their families are likely to appreciate some recognition of their role in this partnership, such as a certificate of participation
- Researchers must take account of the cumulative medical, emotional, social and psychological consequences of the infant involved in research. IYC with certain conditions may be exposed to a sequence of research projects. It is advisable to consider the risks of a particular research procedure in the context of the infant's overall involvement in projects by different researchers.

The RCP ethics committee also suggest the following:

1. All proposals involving medical research on IYC should be submitted to a research ethics committee.

10. Data security as pertains to IYC

Data security as it pertains to IYC is particularly important given breaches could propose a risk. From the outset the need to protect them is considered and systems and processes are designed with this in mind.

- During research in the field, observational notes will be transferred to a secure (password protected) external hard drive and onto secure servers at the office of PiN
- All data will be anonymised and encrypted as soon as it is saved according to the file naming conventions
- There will be no way in which text files, photos or data from the faecal sample can be linked to the participating infant: i.e. no personal or sensitive data will link the file to the data set and subsequently to the infant themselves

- The external hard drive will be stored in a locked cabinet for the duration of the time that the data is saved
- The data will be regularly and consistently checked that it has not been otherwise accessed
- Upon leaving Ethiopia the lead researcher will transport the data on an external hard drive and upon securing the data on Cranfield University server will ensure that the data is deleted from the servers of PiN so it is not held in more than one location
- There will be no direct access to data either on the hard drive or on the internal servers of PiN or Cranfield University than by the lead researcher and supervisory team (S Budge, A Parker, P Hutchings and C Garbutt)
- The research team will retain personal information collected online from an IYC for only as long as is necessary to fulfil the purpose for which it was collected, and delete the information using reasonable measures to protect against its unauthorised access or use
- The research team respect the confidentiality of any information that they may come into contact with and under no circumstances will such information be divulged or passed to any persons or organisation in any form unless such disclosure is discussed, agreed and authorised
- An individual's right to data erasure is particularly relevant if they gave their consent to data collection on behalf of their infant.

11. Statement of ethical responsibility

I, the PhD researcher:

- Recognise the vulnerability of the IYC in this context and have the experience of having worked in several developing settings with babies and infants prior to this PhD
- Will ensure to adhere to the above mentioned general and IYC-specific principles at all times during the fieldwork and will report any suspected issues or problems
- Will ensure that participants (caregivers of IYC) fully understand the project and understand the right of refusal and withdraw
- Will be sensitive to any possible discomfort and will remove that participant from the study
- Understand that participant willingness to participate is an on-going experience which is constantly assessed at each visit, and not something which is disregarded after consent is gained

- Confirm that the stated data collected on IYC (including survey, observational notes, photos and faecal samples) will be managed, analysed, stored and deleted in accordance with the research protocol

S Budge, 2019

12. Informed consent forms

The table below details the consent forms which apply to the study and the different data to be collected (where appropriate). These are translated into Amharic by the local field team and will be verbally translated into Sidamo during the consent process by aid of the principal fieldworker or data collector (hygiene promoter) and with the aid of the HEW local to the kebele. The family will also have experienced a prior 'sensitisation' meeting where the study has been explained, including the play space delivery, use, data to be collected and time points for data collection (without detailing specific days to avoid respondent bias). These forms can be viewed in the Appendix as detailed below.

Table 7. Consent forms and participant information sheets to be used in the trial

Consent form	Study aspect to which ethics document applies	Language	Relevant Appendix
Informed consent	Home visit	English	D
		Amharic	F
Informed consent	Faecal sample collection	English	E
		Amharic	F
Participant information sheet	'Sensitisation' prior and home visits	English	G
		Amharic	H

13. References

1. Null C, Stewart CP, Pickering AJ, et al. Effects of water quality, sanitation, handwashing, and nutritional interventions on diarrhoea and child growth in rural Kenya: A cluster-randomised controlled trial. Lancet Glob Heal. 2018;6(3):e316–e329.
2. Luby SP, Rahman M, Arnold BF, et al. Effects of water quality, sanitation, handwashing, and nutritional interventions on diarrhoea and child growth in rural Bangladesh: a cluster randomised controlled trial. Lancet Glob Heal. 2018;6(3):e302-e315.
3. Rogawski McQuade ET, Platts-Mills JA, Gratz J, et al. Impact of Water Quality, Sanitation, Handwashing, and Nutritional Interventions on Enteric Infections in Rural Zimbabwe: The Sanitation Hygiene Infant Nutrition Efficacy (SHINE) Trial. J Infect Dis. 2019;jiz179.
4. Pickering A, Null C, Winch P, Mangwadu G, Arnold B, Prendergast A. The WASH Benefits and SHINE trials: interpretation of WASH intervention effects on linear growth and diarrhoea. 2019;7(8):e1139-e1146.
5. Prendergast AJ, Gharpure R, Mor S, et al. Putting the “A” into WaSH: a call for integrated management of water, animals, sanitation, and hygiene. Lancet Planet Heal. 2019;3(8):e336-e337.
6. Budge S, Hutchings P, Parker A, et al. Do domestic animals contribute to bacterial contamination of infant transmission pathways? Formative evidence from rural Ethiopia. J Water Health. 2019.
7. Mattioli MCM, Davis J, Boehm AB. Hand-to-mouth contacts result in greater ingestion of feces than dietary water consumption in Tanzania: A quantitative fecal exposure assessment model. Environ Sci Technol. 2015;49(3):1912-1920.
8. Morita T, Perin J, Oldja L et al. Mouthing of Soil Contaminated Objects is Associated with Environmental Enteropathy in Young Children. Trop Med Int Heal. 2017;22(6):670–678.
9. Budge S, Parker AH, Hutchings PT, Garbutt C. Environmental enteric dysfunction and child stunting. Nutr Rev. 2019;77(4):240–253.
10. MAL-ED Network Investigators. Relationship between growth and illness, enteropathogens and dietary intakes in the first 2 years of life. BMJ Glob Heal. 2017;2:(e000370).
11. Budge S, Barnett M, Hutchings P, et al. Domestic poultry ownership is associated with infant Campylobacter spp. infection and malnutrition: formative evidence from Ethiopia. Press. 2019.
12. Ngure F, Reid B, Humphrey J, Mbuya M, Pelto G, Stoltzfus R. Water, sanitation, and hygiene (WASH), environmental enteropathy, nutrition, and early child development: Making the links. Ann N Y Acad Sci. 2014;1308(1):118–128.
13. Marquis G, Ventura G, Gilman R et al. Fecal contamination of shanty town toddlers in households with non-corralled poultry, Lima, Peru. Am J Public Heal. 1990;80(2):146–149.
14. Oberhelman R, Gilman R, Sheen P et al. An intervention-control study of corralling of free-ranging chickens to control Campylobacter infections among children in a Peruvian peri-urban shantytown. Am J Trop Med Hyg. 2006;74(6):1054–1059.
15. Harvey S, Winch P, Leontsini E et al. Domestic poultry-raising practices in a Peruvian shantytown: Implications for control of Campylobacter jejuni-associated diarrhea. Acta Trop. 2003;86(1):41–54.

16. Mbuya M, Tavengwa N, Stoltzfus R et al. Design of an intervention to minimize ingestion of fecal microbes by young children in Rural Zimbabwe. Clin Infect Dis. 2015;61(S7):S703–S709.
17. ISO. BS ISO Title: Draft BS ISO 7175-1:2019(en) Furniture. Children's cots and folding cots for domestic use. Part 1: Safety requirements. December 2017. European standards and the UK. Available online at: https://www.iso.org/obp/ui/#iso:std:iso:7175:-1:ed-2:v1:en. Accessed September 2019.

Appendix A – Survey 1: SES, WASH, animal husbandry, infant nutrition and infant health measures

SURVEY 1
SES, WASH, animal husbandry, infant nutrition and infant health measures

Household ID	Number:
Visit: **A: Baseline** **B: 14 day** **C: Endline**	Letter:
Date of interview:	
Time of interview:	

Infant details

Infant sex:	Male	Female	
Date of birth:	Month:		Don't know
	Year:		Don't know

A. Socioeconomic status

A1.	How many people are living in this household?	
A2.	What is the main source of income of your household?	Farming
		Livestock
		Pitty trading
		Bee keeping
		Land rent
		Small business
		Forest product
		Employee (Government, private, NGO)
		Daily labour
		Service
		Other
A3.	Do you, or any member of your household, have a formal means of saving money in cash form? For example an account with a bank or credit union?	Yes No

B. Latrine facilities

B1.	Where do you and your family members defecate?	Defecate in the open
		Pit latrine without slab
		Pit latrine with slab
		Use ventilated improved pit latrine
		Use flush or pour toilet (connected to a sewer system or septic tank)
		Use composting toilet
		Other (specify):
		No response
B2.	Can you please show me the latrine?	Latrine was shown
		Latrine was not shown *(skip next question)*
B3.	*For the data collector: Does the latrine show visible signs of being used?*	Latrine is likely used
		Latrine is likely not used

C. Water source, collection and storage

C1.	What is your household's main source of drinking water during this season?	Tube well or borehole
		Protected shallow well
		Harvested rainwater
		Piped water/public tap
		Protected spring
		Surface water source (river, stream, pond, puddles, unprotected spring)
		Unprotected/ open shallow well
		Cart with small tank/drum
		Tanker-truck
C2.	Who usually goes to this source to fetch the water for this household?	Mother
		Father
		A grandparent
		Female child (under 15 years old)
		Male child (under 15 years old)
C3.	Can you please show me where you store your drinking water?	Specific place shown
		No specific place shown *(skip next question)*
C4.	For data collector: *Are the water containers clean?*	Observation: Yes No

C5.	For data collector: *Do the water containers have narrow necks and / or protecting covers?*	Observation: Yes No
C6.	For data collector: *Does the container have a tap or narrow mouth for drawing the water?*	Observation: Yes No

D. Handwashing practices

D1.	Can you tell me where you and your family wash your hands? *(Check the place)*	No specific handwashing facility available
		Tippy-tap available
		Bucket with tap available
		Jug available
		Basin available
		Sink available
D2.	Is there water available?	Yes No
D3.	Do you have soap for washing your hands?	Yes No
D4.	Can you please show me where you wash your hands?	Area was shown
		Area was not shown *(skip next question)*
D5.	For data collector: *Does the area show signs of being used?*	If yes: Handwashing is likely
		If no: Handwashing is not likely

E. Animal husbandry and keeping practices

E1.	Do you raise any animals?	Yes	No
E2.	If yes, which?	Cattle	How many?
		Goats	How many?
		Donkey	How many?
		Sheep	How many?
		Chickens	How many?
		Other:	How many?
E3.	Where do the animals live during the day?	Outside, enclosed in an area	
		Outside, roaming free	
		Inside in the same room as the family	
		Inside in a separate room to the family	
		Other:	
E4.	Where do the animals sleep during the night?	Outside, enclosed in an area	
		Outside, roaming free	

		Inside in the same room as the family
		Inside in a separate room to the family
		Other:

F. Infant feeding practices

Individual Dietary Diversity Score

F1.	Did your infant eat or drink anything yesterday?	Yes No Don't know *If yes, proceed:*
F2.	**Can you please tell me exactly what your infant ate and drank…**	*(You must add details and ask the different ingredients below for each meal!)*
	… before breakfast?	
	… for breakfast?	
	… between breakfast and lunch?	
	… for lunch?	
	… between lunch and dinner?	
	… for dinner?	
	… after dinner?	
F3.	During the last day or night, did your infant eat any fruit, vegetables or snacks which you did not mention?	*If yes, record:*

Minimum Meal Frequency

F4.	Did you breastfeed your infant yesterday during the day or at night?	Yes No Don't know
F5.	Can you please count how many meals and snacks - including fruit - did your infant eat yesterday?	_ _ _ _ *(number of meals)* _ _ _ _ *(number of snacks)*

Feeding of Fresh or Reheated Foods

F6.	For **BREAKFAST**, did you prepare this meal:	Less than two hours before the child ate it
		More than two hours before the child ate it
F7.	Before you gave the food to your infant, did you reheat it or did you provide it as it was?	Reheated it
		Provided as it was
F8.	How much did you warm up the food? • Did you reheat it just a little bit so that the infant can eat it immediately? • Or did you reheat it to being very hot so you had to wait for it to cool down before giving it to the infant?	Reheated to being warm
		Reheated to being very hot
F9.	For **LUNCH**, did you prepare this meal:	Less than two hours before the child ate it
		More than two hours before the child ate it
F10.	Before you gave the food to your infant, did you reheat it or did you provide it as it was?	Reheated it
		Provided as it was
F11.	How much did you warm up the food?	Reheated to being warm
		Reheated to being very hot
F12.	For **DINNER** did you prepare this meal:	Less than two hours before the child ate it
		More than two hours before the child ate it
F13.	Before you gave the food to your infant, did you reheat it or did you provide it as it was?	Reheated it
		Provided as it was
F14.	How much did you warm up the food?	Reheated to being warm
		Reheated to being very hot
F15.	Did you feed your infant any **SNACKS** yesterday? If yes, did you reheat it or provide it as it was?	Reheated it
		Provided as it was
F16.	How much did you warm up the food?	Reheated to being warm
		Reheated to being very hot

Breastfeeding practices

F17.	Can you tell me about the age of your youngest children?	The youngest child: _ _ _ (age in months) Second youngest child: _ _ _ (age in months) *Cross the other answers if the respondent has one child only*
F18.	*For the infant in this study:* Yesterday, did you breastfeed this infant during the day or night?	Yes No Don't know
F19.	Do you give your infant any water or clear liquids?	Yes No
F20.	Do you give your infant any other types of milk or foods?	Yes No

G. Infant health

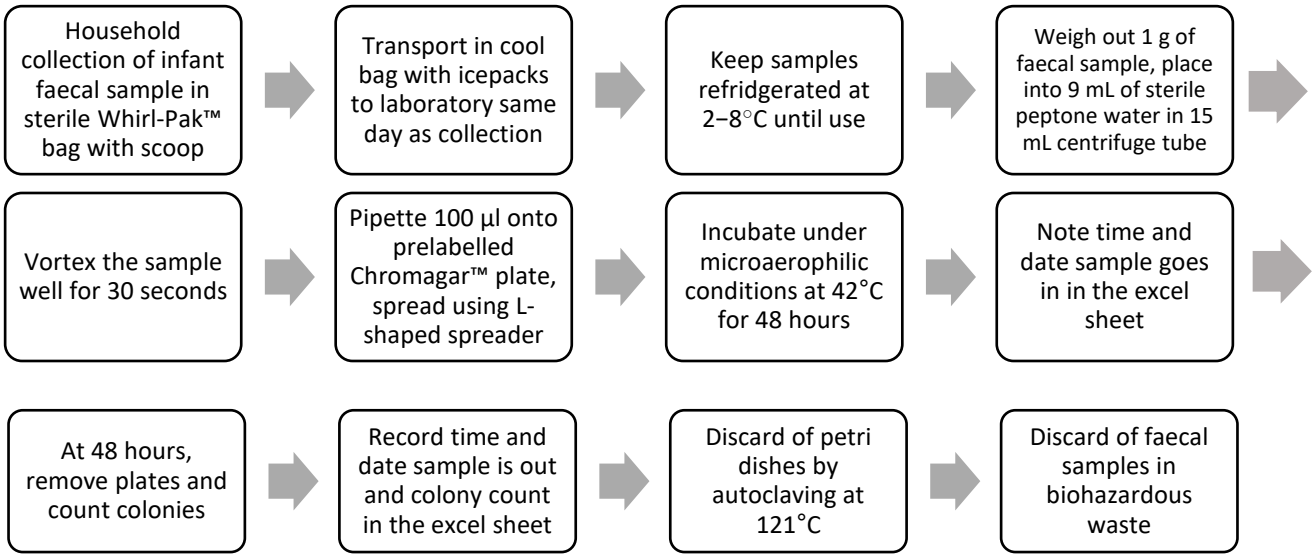
Diarrhoea incidence

G1.	In the last day, has your child had watery/loose stools?	Yes No Don't know	
G2.	How many days has this happened?	_ _ days	Don't know
G3.	Was your child sick (vomiting) at the same time as the diarrhoea?	Yes No Don't know	

Anthropometry

G4.	Infant length	**G5**.	Infant weight	**G6.**	Mid-upper arm circumference
_ _ _ _ (cm)		_ _ _ _ (kg)		_ _ _ _ (cm)	

Appendix B – Microbiology flow chart for *Campylobacter* culture



Appendix C – Survey 2: Play space use, maintenance and Barrier Analysis

SURVEY 2
Play space use and maintenance and Barrier Analysis

Household ID	Number:
Visit: **A: Baseline** **B: 14 day** **C: Endline**	Letter:
Date of interview:	
Time of interview:	

A. Play space use

A1.	Was the baby in the play space when you arrived?	Yes No
A2.	How long does the mother report using the play space each day?	_ _ _ hours
A3.	Who watches the infant when it is in the play space?	
A4.	If the mother takes the infant out of the play space, what are the reasons?	• • •

B. Play space and infant hygiene

B1.	Is the infant visibly dirty on their body and clothes?	Yes No
B2.	Does the infant have dirty hands and nails?	Yes No
B3.	Does the play space show signs of dirt on the mattress?	Yes No
B4.	Is there urine or faeces inside the play space?	Yes No
B5.	If yes, if the faeces human or animal?	Human Animal
B6.	Are there any animals around or inside the play space?	Yes No
B7.	If yes, which animals?	
B8.	Ask the mother if any animals go inside the play space	Yes No
B9.	If yes, which animals go inside?	

C. Play space time use

C1.		

D. Barrier Analysis

D1.	Do you think that you would use the play space for your infant whenever you can?	Yes No Don't know
D2.	What are the **advantages** of using the play space?	• • •
D3.	What are the **disadvantages** of using the play space?	• • •
D4.	What makes it **easy** for you to use the play space?	• • •
D5.	What makes it **difficult** for you to use the play space?	• • •
D6.	Who are the people who **approve** of you using the play space for your infant?	• • •
D7.	Who are the people who **disapprove** of you using the play space for your infant?	• • •
D8.	How difficult is it for you to use the play space for your infant every time you could use it?	• • •
D9.	How difficult is it to remember to use the play space for your infant every time you could use it?	• Very difficult • A bit difficult • Not difficult • Don't know/will not say
D10.	How likely do you think it is your infant will get diarrhoeal disease within the next month?	• Very likely • Quite likely • Not likely • Don't know/will not say
D11.	How serious would it be if your infant had a diarrhoeal disease?	• Very serious • Quite serious • Not serious • Don't know/will not say
D12.	How likely do you think it is your infant will get diarrhoeal disease if you used the play space whenever you could?	• Very likely • Quite likely • Not likely • Don't know/will not say

D13.	Do you think God approves of you using the play space?	Yes	No	Don't know
D14.	Are there any community rules which prevent you from using the play space? *If yes,* what are they?	Yes	No	Don't know
D15.	Are there any cultural rules that you know of against using the play space? *If yes,* what are they?	Yes	No	Don't know

For the data collector: Please write down any other comments or details from the caregiver about the place space	

Appendix D – Informed consent: Survey data (1 of 2)

INFORMED CONSENT FORM 1 of 2: Survey data

Title of the project:	Assessment of a household play space intervention to reduce infant *Campylobacter* infection in Ethiopia: a randomised controlled feasibility trial
Name of the researcher:	Sophie Budge
Researcher's contact details:	s.g.budge@cranfield.ac.uk; (+44)7472167267
Household number:	
Date:	

Part 1: Data collection and storage

1. I understand that the data will be used by Cranfield University for the purpose of research ONLY.
2. My household and infant has a participant number as shown above. The researcher(s) will record data against this number. Identifiers such as sex, age, and location will not be linked to my households or my infant
3. Data will remain completely anonymous
4. Data will be collected together and analysed using computer statistical software. Once the data has been analysed, it will be impossible to identify any individual household or infant.
5. Once the data has been analysed, all results will be securely stored on the People in Need and Cranfield University network and accessed only by authorised users in accordance with the UK Data Protection Act 2018 (DPA 2018).
6. Data will be securely deleted within a year of the end of the research.

Part 2

The following data will be collected during this visit. Survey data will be typed and saved as number and text files.

Survey data:

- Infant sex and age
- Latrine facilities and use
- Handwashing facilities and use
- Animal husbandry

- Infant feeding practices including breastfeeding
- Infant diarrhoea
- Anthropometric data from my infant, including height, weight and arm circumference

Part 3: Consent and participant withdrawal

1. I confirm that I have been informed about the aim and objectives of this research project and agree to participate.
2. I understand that the information that will be processed from the survey data and my infant growth data will be treated with the strictest confidence.
3. No names or identifiers will be used in any report, publication or presentation and ALL data will remain completely anonymous.
4. I understand that I am free to withdraw myself and/or my infant and any data from the study at any time by informing a member of the research team
5. Contact details have been provided. Samples that I have provided up until I withdraw my consent will be analysed.

I understand that the final analysis will be published in support of the research findings and will be anonymous. ☐

I am happy for this data to be published: Yes / No
(circle as appropriate)

I confirm that I fully understand the information provided on this form and therefore give my consent for MYSELF AND MY HOUSEHOLD to take part in this research.

Participant's name:			
Participant's signature or thumbprint:		**Date:**	
Researcher's name:			
Researcher's signature:		**Date:**	

I confirm that I fully understand the information provided on this form and therefore give my assent ON BEHALF OF MY INFANT to take part in this study

Participant's name:			
Participant's signature or thumbprint:		**Date:**	

Researcher's name:			
Researcher's signature:		**Date:**	

Appendix E – Informed consent: Faecal sample data (2 of 2)

INFORMED CONSENT FORM 2 of 2: Infant faecal samples

Title of the project:	Assessment of a household play space intervention to reduce infant *Campylobacter* infection in Ethiopia: a randomised controlled feasibility trial
Name of the researcher:	Sophie Budge
Researcher's contact details:	s.g.budge@cranfield.ac.uk; (+44)7472167267
Household number:	
Date:	

Part 1: Data collection and storage

1. I understand that the data will be used by Cranfield University for the purpose of research ONLY
2. My household and infant has a participant number as shown above. The researcher(s) will record data against this number. Identifiers such as sex, age, and location will not be linked to my households or my infant
3. Data will remain completely anonymous
4. Data will be collected together and analysed using computer statistical software. Once the data has been analysed, it will be impossible to identify any individual household or infant
5. Once the data has been analysed, all results will be securely stored on the People in Need and Cranfield University network and accessed only by authorised users in accordance with the UK Data Protection Act 2018 (DPA 2018)
6. Data will be securely deleted within a year of the end of the research

Part 2: Data types and processing

The following data types, other than previously specified, will be collected during this visit:

- **ONE faecal sample** from my infant at **THREE time points**

1. Faecal samples will be used for microbiological analysis using culture techniques ONLY
2. The samples will be disposed of safely once enough material is used for analysis
3. No material will be stored or transported
4. No human DNA material or enzymes are to be analysed at all
5. There will be no research into the health status, health disorders or the functioning of the human body
6. I understand the purpose of collecting my infant faeces is to solely look for the pathogen *Campylobacter* subspecies and will not provide me with any data on my infant's health or wellbeing

Part 3: Consent and participant withdrawal

1. I confirm that I have been informed about the aim and objectives of this research project and agree to participate
2. I understand that the collection of a faecal sample from my infant is totally safe and un-intrusive and will not harm me or my infant in any way
3. I understand that the information that will be processed from the faecal sample will be treated with the strictest confidence.
4. No names or identifiers will be used in any report, publication or presentation
5. ALL data will remain completely anonymous.
6. I understand that I am free to withdraw myself and/or my infant and any data from the study at any time by informing a member of the research team. Contact details have been provided
7. Samples which I have provided up until I withdraw my consent will be analysed

I understand that the final analysis will be published in support of the research findings and will be anonymous. ☐

I am happy for this data to be published: Yes / No
(circle as appropriate)

I confirm that I fully understand the information provided on this form and therefore give my assent ON BEHALF OF MY INFANT to take part in this study:

Participant's name:			
Participant's signature or thumbprint:		**Date:**	
Researcher's name:			
Researcher's signature:		**Date:**	

Appendix E – Informed consent: forms 1 and 2 (Amharic)

<u>በመረጃ ዕውቀት/ግንዛቤ ላይ የተመሰረተ</u>
<u>ፈቃደኝነት የመስጫ ቅጽ 2 ገጽ 2</u>

የፕሮጀክቱ ርዕስ	በኢትዮጲያ ሲዳማ ዞን ያሉ ልጆች ውስጥ የካምፒሎ ባክተር የተላላፊነት ስርጭት መጠን እና የተለመደ መተላለፊያ መንገዶች ግንዛቤ
የተመራማሪው ስም	ሶፊ በጅ
የተመራማሪው መገኛ ዝርዝር	s.g.budge@cranfield.ac.uk;(+44)7472167267
የተሳታፊው ቁጥር	
ቀን	

ክፍል 1፡ የዳታ/መረጃ ማሰባሰብና ማጠናቀር/ማከማቸት

1. እኔ ዳታው/መረጃው በክራንፊልድ ዩኒቨርስቲ ለምርምር ብቻ ጥቅም/አገልግሎት ላይ እንደሚውል ተገንዝቤያለሁ/ተረድቻለሁ።
2. ከዚህ በላይ እንደተመለከተው የእኔ ቤትና ህጻን ልጅ የተሳታፊነት ቁጥር አለው። ተመራማሪው(ዎቹ) ዳታ/መረጃን ከዚህ ቁጥር አኳያ ያጠናቅራሉ። ጾታን፣ዕድሜንና መገኛ ቦታን የመሰሉ መለያዎች በትንተና ወቅት ይወገዳሉ/ይተካሉ። እንዲሁም ዳታው/መረጃው ሙሉ ለሙሉ የማይታወቅ ሆኖ ይጠበቃል/ይያዛል።
3. ዳታው/መረጃው በስታስቲክስ ሶፍትዌር ውስጥ እንዲጠቃለል እና እንዲተነተን ይደረጋል። ዳታው/መረጃው አንድ ግዜ እንዲተነተን ከተደረገ ማንኛውንም የግለሰብ መኖሪያ ቤት ወይም ህጻን ልጅ ለመለየት አይቻልም።
4. አንድ ግዜ ዳታው/መረጃው ከተተነተነ ሁሉም(ማንኛውም) ዳታ /መረጃ በፒፕል ኢኒድ እና በክራንፊልድ ዩኒቨርስቲ የመረጃ ድር በአስተማማኝ ጥበቃ እንዲከማች ይደረጋል። እንዲሁም ዳታው/መረጃው በ2019

በወጣው የዳታ/መረጃ አጠባበቅ አዋጅ (የመ/አ/አ 2018) መሰረት ለተፈቀደላቸው ተጠቃሚዎች ብቻ ተደራሽ ይሆናሉ።

5. ዳታው/መረጃው ምርምሩ/ጥናቱ ማብቂያ/ማለቂያ በኋላ 1 ዓመት ውስጥ በአስተማማኝነት እንዲሰረዝ/እንዲወገድ ይደረጋል።

ክፍል 2፡ የዳታ/መረጃ አይነቶች እና የሂደት ክንውን

አስቀድሞ ከተዘረዘሩት በተጨማሪ በዚህ ጉብኝት ወቅት ከዚህ የሚከተሉት የዳታ/መረጃ አይነቶች ይሰበሰባሉ።

- **አንድ የባክቴሪያ ናሙና** ከእኔ ከራሴ እጆችና ከእኔ ህጻን ልጅ እጆች ይወሰዳል።
- **አንድ የዶሮ ኩስ ናሙና** በቤቱ ውስጥ ካለ የእኔ ህጻን ልጅና ለማዳ ዶሮ እርባታ ይወሰዳል።

1. የባክቴሪያ ናሙና እና የዶሮ ኩስ ናሙናዎች ለጎንዮሽ ፍሰት ትንተና እና የዲኤንኤ ፒሲአር/ኪውፒሲአር ትንተና አገልግሎት/ጥቅም ላይ እንዲውሉ ተደርጎ ውጤቶቹ በቁጥር እና በንባብ/ቴክስት መልክ ማህደር ሆነው ይያዛሉ።
2. አንድ ግዜ በቂ የሆነ ማቴሪያል/ቁስ ለትንተናው በጥቅም/አገልግሎት ላይ እንደዋለ ናሙናዎቹ በአስተማማኝነት እንዲወገዱ ይደረጋል። ማንኛውም ማቴሪያል/ቁስ እንዲከማች ወይም እንዲጓጓዝ አይደረግም።
3. **ምንም አይነት የሰው ልጅ ዲ.ኤን.ኤ ቁስ/ማቴሪያል ትንተና አይደረግም።**
4. የጤንነት አቋም፣ የጤንነት መዛባቶች ወይም የሰው አካል አሰራር ውስጥ ምንም ምርምር አይኖርም።
5. የባክቴሪያ ናሙናዎች እና የዶሮ ኩሶች የዲ.ኤን.ኤ እና ኢንዛይም ትንተናው ልዩ የሆነውን በሽታ ማለትም ስሙ ካምፓይሎ ባክተር ጄጁኒ እና ካምፓይሎ ባክተር ካለ ብቻ ያገናዝባል።
6. ማናቸውም የተገኙ የሰው ልጅ ዲ.ኤን.ኤ ማቴሪያል/ቁስ አይወሰድም።(ከግንዛቤ ውስጥ አይገባም)
7. እኔ የባክቴሪያ ናሙናው እና የዶሮ ኩስ ማሰባሰቡ ዓላማ ስለዚህ በሽታ ብቻ ለመመልከት መሆኑን እና የእኔ ህጻን ልጅ ጤንነት ወይም ደህንነት ማንኛውንም ዳታ/መረጃ ለእኔ እንደማያቀርብ ተረድቻለሁኝ/ተገንዝቤያለሁኝ።

ክፍል 3፡ የፍቃደኝነት እና የተሳትፎ ማንሳት

1. እኔ ስለምርምር ፕሮጀክቱ ግብ እና አላማዎች አስመልክቶ መረጃ እንደተሰጠኝ እና ተሳታፊ ለመሆን መስማማቴን አረጋግጣለሁ።

2. እኔ ከእኔ እጆች እና ከእኔ ህጻን ልጅ እጆች የሚሰበሰበው የባክቴሪያ ናሙና እና ከእኔ ህጻን ልጅ የሚሰበሰበው የሰገራ ናሙና ሙሉ ለሙሉ ደህንነቱ የተጠበቀ እና ጣልቃ የማይገብ እና በማንኛውም መንገድ እኔን ወይም እኔን ህጻን ልጅ እንደማይጎዳ ተገንዝቤያለሁ/ተረድቻለሁ።
3. እኔ ከባክቴሪያ ናሙናዎቹ እና የኩስ ናሙናዎች ላይ የሚደረገው የሂደት ክንውን መረጃ በጥብቅ ሚስጥራዊነት እንደሚወሰድ/እንደሚታይ ተረድቻለሁ/ተገንዝቤያለሁ።
4. ማንኛውም ስሞች ወይንም መለያዎች በማንኛውም ሪፖርት ፣ህትመት ወይም ገለጻዎች ውስጥ በጥቅም/አገልግሎት ላይ አይውሉም። እንዲሁም ማንኛውም ዳታ/መረጃ ሙሉ ለሙሉ የማይታወቅ ሆኖ ይጠበቃል/ይያዛል።
5. እኔ በማንኛውም ወቅት/ግዜ የምርምር ቡድኑ አባል ለሆነ አንድ አባል በማሳወቅ/በመግለጽ እራሴን እና ወይም የእኔን ህጻን ልጅ እና ማንኛውንም ዳታ/መረጃ ከጥናቱ ለመውጣት ነጻ መሆኔን ተረድቻለሁኝ/ተገንዝቤያለሁኝ።የግንኙነት ተደራጊ(ኮንታክት) ዝርዝር መረጃ ቀርቧል/ተሰጥቷል። እኔ የእራሴን ፍቃደኝነት እስካነሳሁበት ግዜ ድረስ የሰጠሁት ናሙናዎች የሂደት ክንውን ይደረግበታል።

እኔ የመጨረሻ ትንተናው የምርምሩን ግኝቶች በመደገፍ እንዲታተም እንደሚደረግ እና የማይታወቅ እንደሚደረግ ተገንዝቤያለሁ/ተረድቻለሁ።

እኔ ይህ ዳታ/መረጃ እንዲታተም ደስተኛ ነኝ፡ አዎ/አይደለሁም
(እንደ አግባብነቱ አክብብ)

እኔ በዚህ ቅጽ ላይ የቀረበውን/የተገለጸውን መረጃ አንብቤ ሙሉ ለሙሉ የተረዳሁ/የተገነዘብኩ ስለሆነ በዚህ ምርምር ላይ ተሳታፊ ለመሆን ፍቃዴን መስጠቴን አረጋግጣለሁኝ።

የተሳታፊው ስም			
የተሳታፊው ፊርማ ወይም የጣት አሻራ		ቀን	
የተመራማሪው ስም			
የተመራማሪው ፊርማ		ቀን	

የዚህን ቅጽ አንድ ቅጂ/ኮፒ ለተሳታፊው መሰጠት እና አንድ ኮፒ/ቅጂ ደግሞ በተመራማሪው መያዝ አለበት።

ክራንፊልድ ዩኒቨርስቲ
የሚል አርማ አለ

ፒፕል ኢኒድ ቼክ ሪፐብሊክ
የሚል አርማ አለ

<u>በመረጃ ዕውቀት/ግንዛቤ ላይ የተመሰረተ</u>

<u>ፈቃደኝነት የመስጫ ቅጽ 1 ገጽ 2፡ የዳሰሳ ጥናት እና የህጻን ልጅ ክትትል ዳታ/መረጃ</u>

የፕሮጀክቱ ርዕስ	በኢትዮጲያ ሲዳማ ዞን ያሉ ልጆች ውስጥ የካምፒሎ ባክተር የተላላፊነት ስርጭት መጠን እና የተለመደ መተላለፊያ መንገዶች ግንዛቤ
የተመራማሪው ስም	ሶፊ በጅ
የተመራማሪው መገኛ ዝርዝር	s.g.budge@cranfield.ac.uk;(+44)7472167267
የተሳታፊው ቁጥር	
ቀን	

ክፍል 1፡ የዳታ/መረጃ ማሰባሰብና ማጠናቀር/ማከማቸት

1. እኔ ዳታው/መረጃው በክራንፊልድ ዩኒቨርስቲ ለምርምር ብቻ ጥቅም/አገልግሎት ላይ እንደሚውል ተገንዝቤያለሁ/ተረድቻለሁ።
2. ከዚህ በላይ እንደተመለከተው የእኔ ቤትና ህጻን ልጅ የተሳታፊነት ቁጥር አለው። ተመራማሪው(ዎቹ) ዳታ/መረጃን ከዚህ ቁጥር አኳያ ያጠናቅራሉ። ጾታን፣ዕድሜንና መገኛ ቦታን የመሰሉ መለያዎች በትንተና ወቅት ይወገዳሉ/ይተካሉ። እንዲሁም ዳታው/መረጃው ሙሉ ለሙሉ የማይታወቅ ሆኖ ይጠበቃል/ይያዛል።
3. ዳታው/መረጃው በስታስቲክስ ሶፍትዌር ውስጥ እንዲጠቃለል እና እንዲተነተን ይደረጋል። ዳታው/መረጃው አንድ ግዜ እንዲተነተን ከተደረገ ማንኛውንም የግለሰብ መኖሪያ ቤት ወይም ህጻን ልጅ ለመለየት አይቻልም።
4. አንድ ግዜ ዳታው/መረጃው ከተተነተነ ሁሉም(ማንኛውም) ዳታ /መረጃ በፒፕል ኢኒድ እና በክራንፊልድ ዩኒቨርስቲ የመረጃ ድር በአስተማማኝ ጥበቃ እንዲከማች ይደረጋል። እንዲሁም ዳታው/መረጃው በ2019

በወጣው የዳታ/መረጃ አጠባበቅ አዋጅ (የመ/አ/አ 2018) መሰረት ለተፈቀደላቸው ተጠቃሚዎች ብቻ ተደራሽ ይሆናሉ።

5. ዳታው/መረጃው ምርምሩ/ጥናቱ ማብቂያ/ማለቂያ በኋላ 1 ዓመት ውስጥ በአስተማማኝነት እንዲሰረዝ/እንዲወገድ ይደረጋል።

ክፍል 2

ከሚዘረዘሩት በተጨማሪ በዚህ ጉብኝት ወቅት ከዚህ የሚከተሉት የዳታ/መረጃ አይነቶች ይሰባሰባሉ።

- **የባክቴሪያ ናሙናዎች** ከአሻንጉሊቶች፣ ግዑዝ ነገሮች፣ የወለል ገጾች፣ ምግብ፣ የመጠጥ ውሃ በናሙና አወሳሰዶች
- **ከሁለት ዳሰሳ ጥናቶች** ፡-የዳሰሳ ዳታ/መረጃ ፣የህጻን ልጅ ጾታ እና እድሜ ፣ የመጸዳጃ ቤት አግልግሎት መስጫዎች እና አጠቃቀም፣ የእጅ መታጠቢያ አገልግሎት መስጫዎችና አጠቃቀም፣ የእንስሳት እርባታ ፣ የህጻን ልጅ ተቅማጥ ተከሳችነት አጋጣሚ
- **የክትትል/የጽሁፍ/ዳታ መረጃ፡**- በሁለት ሰዓት የህጻን ልጅ የክትትል ግዜ ወቅት የህጻን ልጅ ባህሪዎች፣ የእንስሳት እርባታ፣ የሰገራ አወጋገድ

1. የዳሰሳ ጥናት ዳታ/መረጃ ተጽፎ በቁጥር እና የንባብ(ቴክስት) ማህደር መልክ ይያዛል/ይጠበቃል።
2. የክትትል ዳታ/መረጃው (የንባብ ማህደሩ ተጽፎ በቁጥር እና የንባብ(ቴክስት) ማህደር መልክ ይያዛል/ይጠበቃል።
3. የባክቴሪያ ናሙናዎች የጎንዮሽ ፍሰት ትንተና እና የዲ.ኤን.ኤ ፒሲአር/ኪው ፒሲአር ትንተናን በመገልገል እንዲተነተን ተደርጎ ውጤቶቹም በቁጥር ማህደሮች መልክ እንዲጠበቅ/እንዲያዝ ይደረጋል።
4. አንድ ግዜ በቂ የሆነ ማቴሪያል/ቁስ ለትንተናው በጥቅም/አገልግሎት ላይ እንደዋለ ናሙናዎቹ በአስተማማኝነት እንዲወገዱ ይደረጋል። ማንኛውም ማቴሪያል/ቁስ እንዲከማች ወይም እንዲጓጓዝ አይደረግም።

ክፍል 3፡ የፍቃደኝነት እና የተሳትፎ ማንሳት

1. እኔ ስለምርምር ፕሮጀክቱ ግብ እና አላማዎች አስመልክቶ መረጃ እንደተሰጠኝ እና ተሳታፊ ለመሆን መስማማቴን አረጋግጣለሁ።

2. እኔ ከባክቴሪያ ናሙናዎቹ እና የኩስ ናሙናዎች ላይ የሚደረገው የሂደት ክንውን መረጃ በጥብቅ ሚስጥራዊነት እንደሚወሰድ/እንደሚታይ ተረድቻለሁ/ተገንዝቤያለሁ።
3. ማንኛውም ስሞች ወይንም መለያዎች በማንኛውም ሪፖርት ፣ህትመት ወይም ገለጻዎች ውስጥ በጥቅም/አገልግሎት ላይ አይውሉም። እንዲሁም ማንኛውም ዳታ/መረጃ ሙሉ ለሙሉ የማይታወቅ ሆኖ ይጠበቃል/ይያዛል።
4. እኔ በማንኛውም ወቅት/ግዜ የምርምር ቡድኑ አባል ለሆነ አንድ አባል በማሳወቅ /በመግለጽ እራሴን እና ወይም የእኔን ህጻን ልጅ እና ማንኛውንም ዳታ/መረጃ ከጥናቱ ለመውጣት ነጻ መሆኔን ተረድቻለሁኝ/ተገንዝቤያለሁኝ።የግንኙነት ተደራጊ(ኮንታክት) ዝርዝር መረጃ ቀርቧል/ተሰጥቷል። እኔ የእራሴን ፍቃደኝነት እስካነሳሁበት ግዜ ድረስ የሰጠሁት ናሙናዎች የሂደት ክንውን ይደረግበታል።

እኔ የመጨረሻ ትንተናው የምርምሩን ግኝቶች በመደገፍ እንዲታተም እንደሚደረግ እና የማይታወቅ እንደሚደረግ ተገንዝቤያለሁ/ተረድቻለሁ።

እኔ ይህ ዳታ/መረጃ እንዲታተም ደስተኛ ነኝ፡ አዎ/አይደለሁም
(እንደ አግባብነቱ አክብብ)

እኔ በዚህ ቅጽ ላይ የቀረበውን/የተገለጸውን መረጃ አንብቤ ሙሉ ለሙሉ የተረዳሁ/የተገነዘብኩ ስለሆነ በዚህ ምርምር ላይ ተሳታፊ ለመሆን ፍቃዴን መስጠቴን አረጋግጣለሁኝ።

የተሳታፊው ስም			
የተሳታፊው ፊርማ ወይም የጣት አሻራ		ቀን	
የተመራማሪው ስም			
የተመራማሪው ፊርማ		ቀን	

የዚህን ቅጽ አንድ ቅጂ/ኮፒ ለተሳታፊው መሰጠት እና አንድ ኮፒ/ቅጂ ደግሞ በተመራማሪው መያዝ አለበት።

ክራንፊልድ ዩኒቨርስቲ ፒፕል ኢኒድ ቼክ ሪፐብሊክ

የሚል አርማ አለ የሚል አርማ አለ

የተሳታፊ መረጃ ቅጽ፡ የህጻን ልጅ እና የእርባታ ዶሮ ሰገራዎች

የፕሮጀክቱ ርዕስ ፡ በኢትዮጲያ ሲዳማ ዞን ያሉ ልጆች ውስጥ የካምፒሎ ባክተር የተላላፊነት ስርጭት መጠን እና የተለመደ መተላለፊያ መንገዶች ግንዛቤ

የተመራማሪው ስም፡ ሶፊ በጅ

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የረቂቁ ቀን፡- ህዳር 20/2011

የመስክ ስራ ቀን፡- ሚያዚያ 2011

<u>በመረጃ/ዕውቀት ግንዛቤ ላይ የተመሰረተ ፈቃድ ማለት ምን ማለት ነው?</u>

እርስዎና የእርስዎ ህጻን ልጅ በእኛ የምርምር ጥናት ተሳታፊ እንዲሆኑ እኛ አስቀድሞ ግብዣ አድርገንላችኋል። እናም እርስዎ ተሳታፊ ለመሆን ያሎትን ምርጫና በማንኛውም ሰዓት/ግዜ ለማቆም እንደሚችሉ ስለመገንዘብዎ/ስለመረዳትዎ ተስፋ እናደርጋለን። እርስዎ ከመወሰንዎ በፊትም እኛ ከእርስዎ ህጻን ልጅ እና ከእርስዎ የዶሮ እርባታ ለመሰብሰብ የምንፈልገውን ሌላ ዳታ/መረጃ በተመለከተ ጥቂት ተጨማሪ(ሌሎች) መረጃዎችን ለእርስዎ ማቅረብ(መስጠት) ይገባናል።

እባክዎን በራስዎ ቋንቋ የሚከተለውን መረጃ ለማንበብ ወይም እንዲብራራሎት ስለሚፈልጉት መረጃ ለማወቅ ግዜዎን ይውሰዱ። በጥንቃቄ ያድምጡ እንዲሁም ስላልተረዱት/ስላልተገነዘቡት ማንኛውም ነገር ካለ ለመጠየቅ የነጻነት ስሜት ይሰማዎት። ከዚህ በተጨማሪነትም እርስዎ በጥናቱ ተሳታፊ ለመሆን ከመወሰንዎ በፊት የእራስዎን ባለቤት ፣የቤተሰብ አባላት ወይም ሌሎች ሰዎችን ማማከር ሊፈልጉ ይችላሉ። እርስዎ ለራስዎና ለእርሶ ህጻን ልጅ ጥናቱን ለመቀላቀል ከወሰኑ እርስዎ በጥናቱ ተስማምቻለሁ በማለት በፍቃደኝነት መስጫ ቅጹ መፈረም ወይም በጣት አሻራ መፈረም ያስፈልጎታል።

ይህ ጥናት ለምን እንደሚሰራ ልታሳውቀኝ/ልታስረዳኝ ትችላለህን?

የምርምር ጥናቱ ዋና አላማ የህጻን ልጆች እድሜ እየጨመረ ሲሄድ ከቁመታቸው ማደግ ጋር የተለያዩ ባክቴሪያዎችን የመሰሉ፡- የትኛዎቹ ተጨባጮች የሚዛመዱ ናቸው የሚለውን እኛ ለመረዳት/ለማወቅ እንዲረዳን ለማድረግ ነው።

እኔ ለማቀርበው/ለምሰጠው ምን ማድረግ ያስፈልገኛል?

እኛ እንደጠቀስነው (እንደገለጽነው) እኛ ስለ እርስዎ ንፅህና አጠባበቅ አገልግሎት መስጫዎችና እርስዎ እንሰሳትን የሚይዙ ከሆነ እነዚህን የተመለከቱ ጥቂት ጥያቄዎችን ለመጠየቅ እኛ በእርስዎ ቤት እርስዎን እንጎበኛለን። በተጨማሪነትም እርስዎ ቤት እኛ ጉብኝት በምናደርግበት ወቅትም የተወሰኑ/ጥቂት የባክቴሪያ ናሙናዎች እንሰበስባለን። ይህ ማለትም እኛ ለጥቂት ባክቴሪያዎች የተወሰኑ ገጽታዎች እና ቁሶች የናሙና ሙከራ እናደርጋለን።

በተጨማሪም እርስዎ ከተሰማሙ እኛ ከእርስዎ ህጻን ልጅ የሰገራ አንድ ናሙና ፣ ከእርስዎ የዶሮ እርባታ አንድ ናሙና ለመውሰድ እንወዳለን።

ከእኔ ህጻን ልጅና ከእርባታ ዶሮ ሰገራ ለመሰብሰብ ለምን ተፈለገ?

እኛ የህጻን ልጅ እና ከእርባታ ዶሮ የዶሮ ኩስ የምንሰበስበው ለምርምር ዓላማዎች ብቻ ነው። ይህ እንዳልነው በመሆኑም እኛ ካንፒሎ ባክተር ተብሎ ስለሚጠራው ባክቴሪያ ለመመልከት የተወሰኑ/ጥቂት የላብራቶሪ/ቤተ ሙከራ/ቴክኒኮችን ልንጠቀም/ልንገለገል እንችላለን። እኛ ማንኛቸውም የጄኔቲክ መረጃ ላይ ጥናት/ምልከታ አናደርግም። እንዲሁም ማንኛውንም ህመም ወይም በሽታ ላይ ምልከታ/ጥናት የማናደርግ በመሆኑም አንድ ግዜ ናሙናዎቹን ሙከራ ካደረግንባቸው በኋላ እኛ ናሙናዎቹን እናስወግዳቸዋለን።

በዚህ ጥናት ውስጥ በተሰበሰቡት የዶሮ ኩሶችና የዲኤንኤ ዳታ/መረጃዎች ላይ ምን ያደረጋል?

እኛ ከእርስዎ ህጻን ልጅ ስገራዎች አንድ አነስተኛ ናሙናና ከእርስዎ የዶሮ እርባታ አንድ ናሙና በእኛ ቦርሳ(ሽንጣ) ውስጥ እንሰበስባለን። እነዚህም ወደ እኛ አገልግሎት መስጫዎች ይወሰዳሉ። በኋላም/በቀጣይነትም ጥቂት(የተወሰኑ) የተለዩ ቴክኒኮችን ጥቅም/አገልግሎት ላይ በማዋል ናሙናዎቹን እኛ እንተነትናቸዋለን።

ከሰገራዎች የተሰበሰበው ዳታ/መረጃ መረጃው/ዳታው እንዳይታወቅ ለማስቻል የእርስዎን ህጻን ልጅ ስምና የትውልድ ቀን ወደ ምናሰወግድበት ስፍራ ወደ ሆነው ኮምፒውተር እንዲገባ ይደረጋል። መረጃው/ዳታው ከፒፕል ኢኒድ እና ከክራን ፊልድ ዩኒሸርስቲ ጋር እንዲከማች ይደረጋል።

አስታውሱ ከሰገራዎቹ የሚሰበሰበው መረጃዎች ሚስጢራዊና እርስዎን ወይም የእርስዎን መኖሪያ ቤት በአዎንታዊም ሆነ በአሉታዊ በማናቸውም መንገድ አይነካም። እኛ እርስዎን ወይም የእርስዎን ህጻን ልጅ ከናሙናዎቹ ጋር ንክኪ/ግንኙነት እንዲኖራቸው አናደርግም። ይህ ሙሉ ለሙሉ የማይታወቅ ነው።

ከዚህ ጥናት ውስጥ እርስዎ ምን ጉዳት ወይም አለመመቸት ሊጠብቁ ይችላል?

እኛ ናሙናዎቹ ሳይነሱ በቦርሳ/ሻንጣችን ውስጥ የምናስቀምጠው በአነስተኛ ማንኪያ ከእርስዎ ህጻን ልጅ አንድ የሰገራዎች ናሙና እና ከእርስዎ ዶሮ እርባታ አንድ ናሙና እንሰበስባለን፡፡ እኛ ከዚህ ጥናት ማንኛውንም ጉዳት ወይም የአለመመቸት ስሜት አንጠብቅም፡፡

በማሰባሰቢያው ቀን የእርስዎ ህጻን ልጅ ከታመመና በዚያ ምክንያትም የእርስዎ ህጻን ልጅ (እሱ/እሷ) በጥናቱ ለመሳተፍ አይችልም(አትችልም) ብለን ከወሰንን እርስዎ እንዲያውቁት ይደረጋል፡፡

ከዚህ ጥናት ውስጥ ተሳታፊ በመሆን ካሳ ይከፈሎታልን?

እርስዎ ወይም የእርሶ ህጻን ልጅ ከዚህ ጥናት ውስጥ ተሳታፊ በመሆንዎ እርስዎ ክፍያ አያገኙም፡፡ እኛ እርስዎን ከርስዎ ቤት ስለምንነሳበኝ ለእርስዎ የመጓጓዣ ወጪዎች ክፍያ አይኖርም፡፡

ከጥናቱ የእኔን ህጻን ልጅ በተመለከተ ምን ልትነግረኝ ትችላለህ?

እኛ ከናሙናዎቹ ወይም መጠይቆቹ የግል ህጻን ልጁን ለመለየት ስለማንችል እኛ የግለሰብ ግብረ መልስ አናቀርብም፡፡ ከዚህ በተጨማሪነትም ከእርስዎ ህጻን ልጅ ወይም ከእነሱ የጤናአቋም ጋር የተዛመዱ ማናቸውንም የጤና ላይ ሁኔታዎች የማንመለከት በመሆኑም እኛ በእነርሱ ጤና ላይ ማንኛውንም መረጃ አናቀርብም(አንሰጥም)፡፡ ሁሉም መረጃ እንዲተነተን በሚደረግበት ወቅት(ግዜ) እኛ ለእርስዎ ማህበረሰብ ግብረ መልስ እናቀርባለን፡፡ ነገር ግን ግብረ መልሱ እንዳይታወቅ/እንዳይለይ ይደረጋል፡፡

እርስዎ በጥናቱ ውስጥ ለመሳተፍ እንቢተኛ ከሆኑ ወይም በቀጣይ ግዜ ሀሳብዎን ከቀየሩ/ከለወጡ ምን ይከሰታል?

እርስዎ በጥናቱ ውስጥ ለመሳተፍ ወይም ላለመሳተፍ ነጻ ኖዎት፡፡ እንዲሁም እርስዎ በማንኛውም ግዜ ምንም ምክንያት ሳይሰጡ ከተሳታፊነት ለማቆም መብት አሎት፡፡

በጥናት ወቅት እርስዎ ተሳታፊነቶን ለማንሳት የወሰኑበትን ክስተት ከተከሰት እርስዎ ፈቃድዎን ከገለጹበት አስቀድሞ ከተሰበሰቡ ናሙናዎች የመነጩ ማናቸውም መረጃ የሚተነተኑእና መረጃዎቹ ጥቅም/አገልግሎት ላይ ይውላሉ፡፡

በጥናቱ ወቅት የእርስዎን ተሳታፊነት የሚነካ/የሚጎዳ ማንኛውም አዲስ መረጃ ከተገኘ እርስዎ በተቻለ ፍጥነት እንዲያውቁት ይደረጋል።

<u>የግለሰብ ማህደሮች እንዴት ምስጢራዊነታቸው ተጠብቆ ሊያዝ እና ማን ተደራሽ ሊሆን ይችላል?</u>

ፒፕል ኢኒድ እና እኔም እራሴ ለእርስዎ ግዜና ታጋሽነት እጅግ አድናቆት አለን። ሁሉም (ማንኛውም) በጥናቱ ሂደት ስለ እርስዎና ስለ እርስዎ ህጻን ልጅ የተሰበሰቡ መረጃዎች በጥብቅ ሚስጢራዊነት ይጠበቃሉ/ይያዛሉ። መረጃዎቹ ለጥናት ቡድኑ ብቻ ተደራሽ ሊደረጉና ምናልባትም በካርን ፊልድ ዩኒቨርስቲ የስነ ምግባር ኮሚቴ ፣ የኢትዮጲያ የምርምር የስነ ምግባር ኮሚቴና ፒፕል ኢኒድ ትክክለኛ በሆኑ ጥቂት ግለሰቦች ብቻ እንዲታዩ ሊደረግ ይችላል። እርስዎን ወይም የእርስዎን ህጻን ልጅ ከዳታው/መረጃው ጋር እንዲያያዝ/እንዲገናኝ ለማድረግ አይቻልም። ይሄ ሙሉ ለሙሉ ሚስጢራዊነቱ ይጠበቃል።

<u>እርስዎ ጥያቄዎች ካሎት የሚገናኙት ከማን ጋር ነው?</u>

እርስዎ ማንኛውም ጥርጣሬዎች ወይም ስጋቶች ካሎት እርስዎ እኛ ለእርስዎ በምንሰጡት የግብረ መልስ ምላሽ አሰጣጥ ሜካኒዝም(ግመምአ) ቁጥር ሁል ግዜ ጥሪ ማድረግ ይችላሉ። ከዚህ በተጨማሪነት እኛ የእርስዎን ቤት በምንጎበኝበት ወቅት የምርምር ጥናቱን በተመለከተ ማንኛውም ጥያቄዎች ካሎት ጥያቄዎቹን ለመጠየቅ የነጻነት ስሜት ይሰማዎት።

<u>ይህንን ጥናት የከለሰው ማነው?</u>

ይህ ጥናት በክራን ፊልድ ዩኒቨርስቲ የሳይንቲስቶች ፓናል እና የእርስዎን እና የእርሰን ህጻን ልጅ መብቶች እና ደህንነት በሚከላከለው የሀዋሳ ዩኒቨርስቲ ተቋም የክለሳ ቦርድ አማካኝነት የተከለሰና የጸደቀ ነው።

ስለ ግዜዎም እጅግ አድርገን እናመሰግንዎታለን።

ክራንፊልድ ዩኒቨርስቲ	ፒፕል ኢኒድ ቼክ ሪፐብሊክ
የሚል አርማ አለ	የሚል አርማ አለ

የተሳታፊ መረጃ ቅጽ

የፕሮጀክቱ ርዕስ ፡ በኢትዮጲያ ሲዳማ ዞን ያሉ ልጆች ውስጥ የካምፒሎ ባክተር የተላላፊነት ስርጭት መጠን እና የተለመደ መተላለፊያ መንገዶች ግንዛቤ

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የረቂቁ ቀን፡- ህዳር 20/2011
የመስክ ስራ ቀን፡- ሚያዚያ 2011

<u>በመረጃ/ዕውቀት ግንዛቤ ላይ የተመሰረተ ፈቃድ ማለት ምን ማለት ነው?</u>

እርስዎና የእርስዎ ህጻን ልጅ በእኛ የምርምር ጥናት ተሳታፊ እንዲሆኑ ግብዣ አድርገንላችኋል። የምርምር ጥናቱ ዓላማ መረጃ ለማሰባሰብ ነው። እናም እርስዎ ተሳታፊ ለመሆን ያሎትን ምርጫና በማንኛውም ሰዓት/ግዜ ለማቆም ይችላሉ። እርስዎ ከመወሰንዎ በፊትም እርስዎ ይህንን ጥናት እና ምን እንደሚሸፍን በተመለከተ ሁሉንም መረጃዎች መገንዘብ ይኖርብዎታል። እባክዎን በራስዎ ቋንቋ የሚከተለውን መረጃ ለማንበብ ወይም እንዲብራራሎት ስለሚፈልጉት መረጃ ለማወቅ ግዜዎን ይውሰዱ። በጥንቃቄ ያድምጡ እንዲሁም ስላልተረዱት/ስላልተገነዘቡት ማንኛውም ነገር ካለ ለመጠየቅ የነጻነት ስሜት ይሰማዎት። ከዚህ በተጨማሪነትም እርስዎ በጥናቱ ተሳታፊ ለመሆን ከመወሰንዎ በፊት የእራስዎን ባለቤት ፣የቤተሰብ አባላት ወይም ሌሎች ሰዎችን ማማከር ሊፈልጉ ይችላሉ።

እርስዎ ለራስዎና ለእርሶ ህጻን ልጅ ጥናቱን ለመቀላቀል ከወሰኑ እርስዎ በጥናቱ ተስማምቻለሁ በማለት በፍቃደኝነት መስጫ ቅጹ መፈረም ወይም በጣት አሻራ መፈረም ያስፈልጎታል።

<u>ይህ ጥናት እንዲሰራ የሚደረገው ለምንድ ነው?</u>

በሲዳማ ዞን የሚደረገው ይህ ጥናት በእኔ ሶፊ በጅ በዩ.ኬ የክራፊልድ ዩኒቨርስቲ ውስጥ ፒፕል ኢኒድ የተባለውን በኢትዮጲያ የበጎ አድራጎት ተቋም የሆነውን በመወከል አሸናፊ በሆንኩት ተመራማሪ የሚመራ ነው። እኛ እናቶችን፣ ወይም ተንከባካቢዎችንና ህጻናት ልጆቻቸው በዚህ ጥናት ውስጥ ተሳታፊ እንዲሆኑ እንጠይቃለን። የጥናቱ ዋነኛ ዓላማ ህጻናት ልጆች በቁመታቸው እያደጉ ሲሄዱ ከእነዚህ ጋር የተገናኙ፡- እንደ ተለያዩ ጀርሞች እና ልዩ ልዩ አካባቢዎች የተዛመዱ ተጨባጮች ናቸው የሚለውን ለመረዳት እንዲረዳን ነው። ከዚህ በተጨማሪም እኛ እንዴት የእርስዎ ልጅ በሚጫወትበት አካባቢ ዝቅተኛ የጀርሞች ተጋላጭነት ጥሩ አካባቢን ለመፍጠር ይቻላል የሚለውን ለመረዳት በመጣር ላይ እንገኛለን። የጥናቱ ውጤቶች ለእርስዎ እና ለእርስዎ ህብረተሰብ ተደራሽ ይደረጋል።

ይህ ጥናት ምን ይሸፍናል?

እርስዎ በጥናት ምርምሩ እንዲካፈሉ የተጠየቁት እርስዎ በክልሉ ውስጥ ነዋሪ እና እድሜው ከ2 ዓመት ያነሰ ህጻን ልጅ እናት ወይም ተንከባካቢ በመሆንዎ ነው።።

እርስዎ በዚህ ጥናት ከተካፈሉ/ከተሳተፉ እኛ ስለ እርስዎ ቤት እና የእርስዎ የንጽህና/የጽዳት አገልግሎት መስጫዎች እና እርስዎ ስለያዙት እንስሳት አስመልክተን ጥቂት/የጠወሰኑ ጥያቄዎችን ለመጠየቅ በእርስዎ ቤት ውስጥ ጉብኝት እናደርጋለን። ከዚህ በተጨማሪነትም እኛ እርስዎን ስለ እራስዎ ህጻን ልጅ እና ህጻኑ/ኗ ባለፉት 7 (ሰባት) ቀናት ውስጥ ተቅማጥ እንደነበረው/እንደነበራት በሚመለከት ጥያቄዎችን እንጠይቅዎታለን። በሁለተኛነትም የእርስዎን ቤት በምንነበኝበት ወቅት እኛ ተቀምጠን የእርስዎ ልጅ/ልጆች በተለምዶ/እንደ ወትሮአቸው እንደሚጫወቱት ሆነው ሲጫወቱ ለ2:00 ሰዓታት ለመመልከት እንሻለን። እዚህ ጋር የእርስዎ ህጻን ልጅ በሚጫወትበት ወቅት ልጅዎ በምን እንደሚጫወት እና ወደ አፉ ምን እንደሚከት/እንደሚያስገባ በሚመለከት ማስታወሻዎችን እናሰባስባለን። ከዚህ በተጨማሪነትም ለአብነትም በዙሪያው እንስሳት ካሉ ህጻን ልጁ የሚጫወትበት አካባቢ ላይ ማስታወሻዎችን እናጠናቅራለን።

በዚህ ጉብኝት ወቅት እኛ የተወሰኑ/ጥቂት የማይክሮ ባዮሎጂካል ናሙናዎችን እናሰባስባለን። ይህ ማለትም እኛ በተወሰኑ/ጥቂት ገጽታዎች እና ግኡዝ አካላት ላይ ሙከራ/ምርመራ እናከናውናለን። እነዚህም ማናቸውም ልዩ የሆነ/የተለዩ የጀርሞች አይነቶች መኖራቸውን ለመመልከት/ለማየት ሲባል የእርስዎን የመጠጥ ውሃ ፣የምግብ ናሙና፣ የወለል ገጽታ ናሙና እና የእርስዎን እና የእርስዎን ህጻን ልጅ እጆች እና መጫወቻ አሻንጉሊቶች ያካትታል። ከዚህ ተጨማሪነትም እኛ የእርስዎን ህጻን ልጅ አይነ ምድር እና በቤቱ ዙሪያ ማንኛውም ዶሮዎች ካሉ የዶሮ ኩስ ናሙናዎችን ለመውሰድ እንወዳን። በመቀጠልም እኛ እነዚን ናሙናዎች የተወሰኑ ልዩ ቴክኒኮችን በጥቅም ላይ በማዋል እንተነትናቸዋለን። እኛ አንድ ግዜ እነዚህን ናናዎች እንደተነተንን ናሙናዎቹን አንይዛቸውም።

በተሰበሰቡት ዳታ/መረጃ ላይ ምን ያደረጋል?

በዚህ ጥናት ውስጥ የተሰበሰበው ዳታ/መረጃ አስቀድሞ የእርስዎ መረጃ/ዳታ እንዳይታወቅ /እንዳይለይ ለማስቻል የእርስዎን ስም እንዲሰረዝ/እንዲወገድ ወደምናደርግበት ስፍራ ወደ ሆነው ኮምፒውተር ውስጥ እንዲገባ ይደረጋል። መረጃው/ዳታው ከፒፕል ኢኒድ እና ከክራን ፊልድ ዩኒቨርስቲ ጋር እንዲከማች ይደረጋል። እናም በመቀጠል በእንግሊዝ የክራንፊልድ ዩኒቨርስቲ ውስጥ እንዲተነተን ይደረጋል። ከገጽታዎች፣ ቁሶች እና

ከእርስዎ እና ከእርስዎ ህጻን ልጅ እጆች ላይ የተሰበሰበው ናሙና እኛ በፒፕል ኢኒድ ጽ/ቤት ከጎበኘን በኋላ እንዲተነተኑ ተደርጎ በተጨማሪም ናሙናዎቹ ወደ ኮንፒውተር እንዲገቡ ይደረጋል።

እባክዎን እርስዎ ለእኛ የሚሰጥዋቸው ምላሾች አስታውሱ ከሰገራዎቹ የሚሰበሰበው መረጃዎች ሚስጢራዊና እርስዎን ወይም የእርስዎን መኖሪያ ቤት በአዎንታዊም ሆነ በአሉታዊ በማናቸውም መንገድ እንደማይነካ ይወቁት። እኛ እርስዎን ወይም የእርስዎን ህጻን ልጅ ከናሙናዎቹ ጋር ንክኪ/ግንኙነት እንዲኖራቸው አናደርግም። ይህ ሙሉ ለሙሉ የማይታወቅ ነው።

<u>ከዚህ ጥናት ውስጥ እርስዎ ምን ጉዳት ወይም አለመመቸት ሊጠብቁ ይችላል?</u>

እኛ ከእርስዎና ከእርስዎ ልጅ እጆች ናሙና በምናሰባስብብት ግዜ ልክ እርስዎ እጆችዎን በውሃ እየታጠቡ መሆኑን የሚመስል ነው። እኛ ከዚህ ጥናት ማንኛውንም ጉዳት ወይም የአለመመቸት ስሜት አንጠብቅም።

ተመራማሪው እርስዎ ወይም የእርስዎ ልጅ መታመሙን ከደረሰበት እና በዚያ ምክንያትም የእርስዎ ህጻን ልጅ (እሱ/እሷ) በጥናቱ ለመሳተፍ አይችልም(አትችልም) ብሎ ከወሰነ ወይም የምርምር ጥናቱ መቆም የሚገባው ከሆነ እርስዎ እንዲያውቁት ተደርጎ እኛ እርስዎ የአካባቢውን የጤና ኬላ እንዲጎበኙ እንመክራለን።

<u>ከዚህ ጥናት ውስጥ ተሳታፊ በመሆን ካሳ ይከፈሎታልን?</u>

እርስዎ ወይም የእርሶ ህጻን ልጅ ከዚህ ጥናት ውስጥ ተሳታፊ በመሆንዎ እርስዎ ክፍያ አያገኙም። እኛ እርስዎን ከርስዎ ቤት ስለምንጎበኝ ለእርስዎ የመጓጓዣ ወጪዎች ክፍያ አይኖርም።

<u>እርስዎ በጥናቱ ውስጥ ለመሳተፍ እንቢተኛ ከሆኑ ወይም በቀጣይ ግዜ ሀሳብዎን ከቀየሩ/ከለወጡ ምን ይከሰታል?</u>

እርስዎ በጥናቱ ውስጥ ለመሳተፍ ወይም ላለመሳተፍ ነጻ ኖዎት። እንዲሁም እርስዎ በማንኛውም ግዜ ምንም ምክንያት ሳይሰጡ ከተሳታፊነት ለማቆም መብት አሎት።

በጥናት ወቅት እርስዎ ተሳታፊነቶን ለማንሳት የወሰኑበትን ክስተት ከተከሰት እርስዎ ፈቃድዎን ከገለጹበት አስቀድሞ ከተሰበሰቡ ናሙናዎች የመነጩ ማናቸውም መረጃ የሚተነተኑእና መረጃዎቹ ጥቅም/አገልግሎት ላይ ይውላሉ።

በጥናቱ ወቅት የእርስዎን ተሳታፊነት የሚነካ/የሚጎዳ ማንኛውም አዲስ መረጃ ከተገኘ እርስዎ በተቻለ ፍጥነት እንዲያውቁት ይደረጋል።

<u>የግለሰብ ማህደሮች እንዴት ምስጢራዊነታቸው ተጠብቆ ሊያዝ እና ማን ተደራሽ ሊሆን ይችላል?</u>

ድርጅቱ እና እኔም እራሴ ለእርስዎ ግዜና ታጋሽነት እጅግ አድናቆት አለን። ሁሉም (ማንኛውም) በጥናቱ ሂደት ስለ እርስዎና ስለ እርስዎ ህጻን ልጅ የተሰበሰቡ መረጃዎች በጥብቅ ሚስጢራዊነት ይጠበቃሉ/ይያዛሉ። የግል መረጃዎቹ ለጥናት ቡድኑ ብቻ ተደራሽ ሊደረጉና ምናልባትም በካርን ፊልድ ዩኒቨርስቲ የስነ ምግባር ኮሚቴ ፣ የኢትዮጲያ የምርምር የስነ ምግባር ኮሚቴና ፒፕል ኢኒድ ትክክለኛ በሆኑ ጥቂት ግለሰቦች ብቻ እንዲታዩ ሊደረግ ይችላል።

<u>እርስዎ ጥያቄዎች ካሎት የሚገናኙት ከማን ጋር ነው?</u>

እርስዎ ማንኛውም ጥርጣሬዎች ወይም ስጋቶች ካሎት እርስዎ እኛ ለእርስዎ በምንሰጡት የግብረ መልስ ምላሽ አሰጣጥ ሜካኒዝም(ግመምአ) ቁጥር ሁል ግዜ ጥሪ ማድረግ ይችላሉ። ከዚህ በተጨማሪነት እኛ የእርስዎን ቤት በምንጎበኝበት ወቅት የምርምር ጥናቱን በተመለከተ ማንኛውም ጥያቄዎች ካሎት ጥያቄዎቹን ለመጠየቅ የነጻነት ስሜት ይሰማዎት።

<u>ይህንን ጥናት የከለሰው ማነው?</u>

ይህ ጥናት የእርስዎንና የእርስዎን ህጻን ልጅ መብቶች እና ደህንነት በሚከላከለው በክራን ፊልድ ዩኒቨርስቲ የሳይንቲስቶች ፓናል የጸደቀ እና የተከለሰ ነው።

ስለ ግዜዎም እጅግ አድርገን እናመሰግንዎታለን።

Appendix F – Participant information sheet (English)

Participant information sheet

Title of the project: The role of a play space in reducing infant Campylobacter infection in SNNPR region, Ethiopia
Name of the researcher: Sophie Budge
Researcher's contact details: s.g.budge@cranfield.ac.uk, (+44)7472167267

What is informed consent?
You and your infant are invited to take part in a research study.The purpose of a research study is to gather information. It is your choice to take part and you can stop any time. Before you decide you need to understand all information about this study and what it will involve. Please take time to read the following information or get the information explained to you in your language. Listen carefully and feel free to ask if there is anything that you do not understand. Ask for it to be explained until you are satisfied. You may also wish to consult your spouse, family members or others before deciding to take part in the study.
If you decide for yourself and your infant to join the study, you will need to sign or thumbprint a consent form saying you agree to be in the study.

Why is this study being done?
This study in Sidama is run by me, Sophie Budge, a researcher from Cranfield University in the UK won behalf of the organisation People in Need which is a humanitarian organisation working in Ethiopia. We are asking mothers, or the caretaker, and their infants to take part in our study. The main purpose of the study is to help us understand which factors – such as different germs and different environments – are related to improvements in height in infants as they grow. We are also trying to understand how we can best create an environment in which your infant can play which will reduce exposure to germs.
The results of the study will be made available to you and your community.

What does this study involve?
You are being asked to take part because you live in the region and you are a mother or caretaker to an infant of less than 2 years of age.
If you take part in this study we will visit you in your home **three times** to ask you some questions about your home and your sanitary facilities and the animals you keep. We will also ask you questions about your infant and if he or she has had diarrhoea in the last 7 days. We will collect some data on the height and weight of your child and their arm circumference which tell us about their current weight.
Secondly, during each visit to your home, we will collect notes on the environment in which the infant plays, for example if there are animals around and any faeces in the environment.
During this visit we will be collecting some microbiological samples. This means we will collect a sample of your infant's faeces. Later on we will analyse these samples using some special techniques. We are looking for a bacteria called *Campylobacter* in your infant faeces at three different time points. We will not keep the samples once we have tested them.

What will happen to the data collected in this study?
The data collected in this study will firstly be entered into a computer where we remove your name and your infant's name so that the data is anonymous. The data will be stored with People in Need and with Cranfield University, and it will later be analysed at Cranfield University in England. The faecal sample infant's hands will be analysed after our visit at the laboratory in Hawassa University and the results from the sample will be entered into a computer also.

Please remember that the answers you will give us will not affect you or your household in any way, neither positive, nor negative.

What harm or discomfort can you expect in the study?
We do not anticipate any harm or discomfort from this study.
In case the researcher discovers you or your infant is sick and decides that you or he or she cannot participate in the study because of that, or if the research study needs to be stopped, you will be informed and we will recommend that you visit your local health post.

Will you be compensated for participating in the study?
You will not get paid for participation of you or your infant in the study. We will visit you in your home, so there will be no transportation costs. If you **do receive** a play space for us as part of that group, you will be able to keep the play space after the trial has finished. If you are part of the group that **does not receive** a play space during the study, we are going to provide you with a play space after the trial which you will be able to keep.

What happens if you refuse to participate in the study or change your mind later?
You are free to participate or not in the study and you have the right to stop participating at anytime without giving a reason. In case you decide to withdraw your participation during the study, any information already generated from the samples until the time of withdrawal will be used and samples already collected, for which you have given consent, will also be analysed and data used. Should any new information become available during the study that may affect your participation, you will be informed as soon as possible.

How will personal records remain confidential and who will have access to it?
Both myself and the organisation are very grateful to you for your time and patience. All information that is collected about you or your infant in the course of the study will be kept strictly confidential. Your personal information will only be available to the study team members and might be seen by some rightful persons from the Cranfield University Ethics Committee, and People in Need.

Who should you contact if you have questions?
If you have any queries or concerns you can always call the Feedback Response Mechanism (FRM) number that we will give you.
Whilst we visit you in your home, please also feel free to ask any question you might have about the research study.

Who has reviewed this study?
This study has been reviewed and approved by a panel of scientists at Cranfield University and also a panel at Hawassa University which protects you and your infant's rights and wellbeing.

Thank you very much for your time.

Appendix G – Participant information sheet (Amharic)