Informed consent form for the community component (group one)

Title of study: Helicobacter pylori and its association with gastrointestinal dysfunction in children in Kampala, Uganda

Makerere University Department of Paediatrics and Child Health - Mulago Hospital and Centre for International Health, University of Bergen, Norway are carrying out this study.

Information to the caretaker and the participant in group one

Introduction:
A well functioning gastrointestinal tract is essential for growth and health in children. In Uganda, unfortunately, many children suffer from repeated episodes of gut infections and therefore do not have a good functioning gastrointestinal tract. If the gut is not functioning normally, certain nutrients are not absorbed and the child will not grow well. In addition he/she may suffer from repeated episodes of abdominal pain.

Purpose: The purpose of this study is to find out how common one of the gut germs that infect the gut called helicobacter pylori is. We also want to find out how well the gut of our Uganda children functions by carrying out some tests on stool and blood. This will help us improve on the way we care for children with infections of the gut.

Procedures: You will be asked questions about your family, income, the health of your child/children below 12 years of age, and their past medical care. You will be asked to collect about 20 gram of faeces from your child and put it in a container that we shall provide. The sample will be collected today or tomorrow. The faeces will be investigated for common germs and one specific one called Helicobacter pylori. A faecal test that will inform us about the gastrointestinal function will also be done. Since we know that HIV reduces someone’s ability to fight infections, and that HIV infected people tend to get frequent gut infections, we shall also test your child for HIV if you accept. We shall collect a drop of blood using a finger prick. The test will be availed to you if you also wish to test yourself. You will sign a separate HIV counselling form following appropriate counselling by one of our team members.
Possible risks or sides effects:
There are no risks associated with collection of faeces. Counselling and testing for HIV may cause some psychological discomfort but this will be minimised by appropriate counselling and if your child or yourself is found to be HIV infected, you will be referred for appropriate care. The finger prick will cause some minimal pain which will disappear shortly.

Possible benefits:
Any gut infections detected during this study will be treated free of charge. If the child has another problem that requires medical attention, he/she will be referred to hospital. If the child or caretaker is found to be HIV infected, he/she will be referred to an appropriate HIV treatment centre.

Costs: There will be no extra cost by participating in this study.

Right to withdraw from the study: You have the right to withdraw your child from the study at any time, if you wish, without any explanation. This will not affect the care provided to your child at the local health facility or any other health facilities.

Confidentiality: All information collected about you and your child (including laboratory results) will be confidential. It will only be available to the principal investigator, co-investigator and the Institutional Review Boards. All information leading to the identification of an individual child will not be disclosed in the reports.

Question from the parents/caretaker:
You are free to ask any question regarding the study and child’s rights now or at any time. You are free to contact the Principal Investigator, Professor James Tumwine, Department of Paediatrics, Mulago Hospital, telephone +256-772494120. E-mail: j tumwine@imul.com
OR Dr. Grace Ndeezi phone +256-772453191 at Mulago Hospital,
E-mail: gracendeezi@yahoo.com
OR Dr. Elin Hestvik, phone + 47-55974692, E-mail: Elin.Hestvik@cih.uib.no,
Centre for International Health, University of Bergen, Armauer Hansen Bd, N-5021 Bergen
**Authorisation statement:**

I have read the information about the study (or translated information) and I clearly understand the possible benefits, discomforts, inconvenience and risks of this study. *(If there is any part of this consent you have not understood, please ask the investigator before signing)*

I,………………………………………………………………….. (name of parent/caretaker),
Related to this child as………………………………………………….. (relationship),
Agree to the participation of………………………………………………….. (name of the child) in this research. I understand that I may refuse participation from the research at any time I wish.

Signed………………………………………………Date…………………………

The child is older than 8 years and has assented.
Yes: ☐
No: ☐
*(If no, do not proceed with the interview)*

**Witness** (not the person administrating the consent form):

Signature……………………………………………Date…………………………

**Consent administrated by:**

Signature……………………………………………Name…………………………

Title………………………………………………Date…………………………

Investigator’s signature…………………………Date…………………………
Informed consent form for the hospital based component.

Title of study: Helicobacter pylori and its association with gastrointestinal dysfunction in children in Kampala, Uganda

Makerere University Department of Paediatrics and Child Health - Mulago Hospital and Centre for International Health, University of Bergen, Norway are carrying out this study.

Information to the caretaker and the participant in group two

Introduction:
A well functioning gastrointestinal tract is essential for growth and health in children. In Uganda, unfortunately, many children suffer from repeated episodes of gut infections and therefore do not have a good functioning gastrointestinal tract. If the gut is not functioning normally, certain nutrients are not absorbed and the child will not grow well. In addition he/she may suffer from repeated episodes of abdominal pain.

Purpose: The purpose of this study is to find out how common one of the gut germs that infect the gut called helicobacter pylori is. We also want to find out how well the gut of our Uganda children functions by carrying out some tests on stool and blood. This will help us improve on the way we care for children with infections of the gut.

Procedures: You will be asked questions about your family, income, the health of your child/children below 12 years of age, and their past medical care. You will be asked to collect about 20 gram of faeces from your child and put it in a container that we shall provide. The sample will be collected today or tomorrow. The faeces will be investigated for common germs and one specific one called Helicobacter pylori. A faecal test that will inform us about the gastrointestinal function will also be done. We shall also take a teaspoon of blood and perform a similar test and in addition test for some of the nutrients that are lost in faeces when the gut is not functioning normally. The test on gut function and nutrients using blood will be carried out at the University of Bergen teaching hospital. You will therefore be requested to allow us store some of the blood (1ml of serum) and later send it to the University of Bergen for testing.
**Possible risks or sides effects:**
There are no risks associated with collection of faeces. However your child will be subject to a needle prick while collecting blood from the arm fold. This is a procedure that is acceptable in the medical field and the volume of blood taken is also acceptable. We shall try to minimise pain by using a gel (xylocane gel) that reduces pain at the time of blood collection.

**Possible benefits:**
Children infected by helicobacter pylori and having symptoms of disease will be treated free of charge. The other results will be availed to the attending paediatrician who will decide on further management.

**Costs:** There will be no extra cost by participating in this study.

**Right to withdraw from the study:** You have the right to withdraw your child from the study at any time, if you wish, without any explanation. This will not affect the care provided to your child while in hospital.

**Confidentiality:** All information collected about you and your child (including laboratory results) will be confidential. It will only be available to the principal investigator, co-investigator and the Institutional Review Boards. All information leading to the identification of an individual child will not be disclosed in the reports.

**Question from the parents/caretaker:**
You are free to ask any question regarding the study and child’s rights now or at any time. You are free to contact the Principal Investigator, Professor James Tumwine, Department of Paediatrics, Mulago Hospital, telephone +256-772494120. E-mail: jtumwine@imul.com
OR Dr. Grace Ndeezi phone +256-772453191 at Mulago Hospital,
E-mail:gracendeezi@yahoo.com
OR Dr. Elin Hestvik, phone +256774803686, E-mail: Elin.Hestvik@cih.uib.no,
Centre for International Health, University of Bergen, Armauer Hansen Bd, N-5021 Bergen
Authorisation statement:
I have read the information about the study (or translated information) and I clearly understand the possible benefits, discomforts, inconvenience and risks of this study. *(If there is any part of this consent you have not understood, please ask the investigator before signing)*

I,............................................................................................................ (name of parent/caretaker),
Related to this child as.................................................................................. (relationship),
Agree to the participation of........................................................................... (name of the child) in this research. I understand that I may refuse participation from the research at any time I wish.
Signed.................................................................Date.................................

The child is older than 8 years and has assented.
Yes: □
No: □
(If no, do not proceed with the interview)

I also understand that some tests will be performed at the University of Bergen and I have accepted that some of the blood sample can be stored and transferred at a later date for testing.
Signed .................................................................Date.................................

Witness (not the person administrating the consent form):
Signature.................................................................Date.................................

Consent administrated by:
Signature.................................................................Name.................................

Title.................................................................Date.................................

Investigator’s signature.................................................................Date.................................
Authorisation statement:
I have read the information about the study (or translated information) and I clearly understand the possible benefits, discomforts, inconvenience and risks of this study. (If there is any part of this consent you have not understood, please ask the investigator before signing)
I,........................................................................................................ (name of parent/caretaker),
Related to this child as...................................................................................... (relationship),
Agree to the participation of................................................................................. (name of the child) in this research. I understand that I may refuse participation from the research at any time I wish.
Signed.................................................................Date.................................

The child is older than 8 years and has assented.
Yes: ☐
No: ☐
(If no, do not proceed with the interview)

I also understand that some tests will be performed at the University of Bergen and I have accepted that some of the blood sample can be stored and transferred at a later date for testing.
Signed .................................................................Date.................................

Witness (not the person administrating the consent form):
Signature.................................................................Date.................................

Consent administrated by:
Signature.................................................................Name...........................

Title.................................................................Date.............................

Investigator’s signature........................................Date.............................
Questionnaire to caretaker of healthy children

"Helicobacter pylori and its association with gastrointestinal dysfunction in children in Kampala, Uganda"

Study participant identification

studid1 Consent form is obtained?  

studid2

studid3 Study participant number:  

studid4 Place of living LC1  

studid5 Phone number of the caretaker  
   If not available, write N/A

studid6 Date of interview  
   (example 02.10.2007)

studid7a Child's name, First name  
studid7b Second name

studid8 Is the child a boy or a girl?  

studid9a Child's age  
studid9b (months)

studid10 Child's date of birth  
   (example 09.05.2004)

studid11 Child's age in months, to be calculated  
   (age in years multiple 12, plus age in months)

studid12 Who is giving the information?  
   (only one answer)  
   1=Mother
   2=Father
   3=Stepmother
   4=Stepfather
5=Grandmother
6=Grandfather
7=Aunt
8=Uncle
9=siblings
10=Guardian
11=Not applicable

studid13 Age of the informant _____ (in years)

studid14 Is the mother alive? _____ 0=no 1=yes
    (If the mother is the informant, don't ask, just write 1)

studid15 If yes how old is the mother _____ (years)

studid16 Is the father alive? _____ 0=no 1=yes
    (If the father is the informant, don't ask, just write 1)

studid17 If yes how old is the father _____ (years)

Socio-demographic characteristics:

sodech1 Size of the family living together /sharing kitchen
    for the last 3 months:
    sodech1a Children less than 5 years _____ (number)
    sodech1b Children older than 5 years _____ (number)
    sodech1c Adults (18 years and above) _____ (number)

sodech2 With who is the child living at the moment? (Answer all questions!)
    sodech2a Mother _____ 0=no 1=yes
    sodech2b Father _____ 0=no 1=yes
    sodech2c Stepmother _____ 0=no 1=yes
    sodech2d Stepfather _____ 0=no 1=yes
    sodech2e Grandmother _____ 0=no 1=yes
    sodech2f Grandfather _____ 0=no 1=yes
    sodech2g Aunt _____ 0=no 1=yes
    sodech2h Uncle _____ 0=no 1=yes
    sodech2i Adopted _____ 0=no 1=yes
    sodech2j Not applicable _____ 0=no 1=yes

For question sodech3a, sodech4a and sodech5a use these codes:
1=No education
2=Completed Primary school
3=Completed Secondary School
4=Completed Collage/University

sodech3a Education of mother/ female caretaker? _____

sodech3b How many years has the mother /female caretaker been in school? _____ (number)
sodech4a Education of father /male caretaker? ____
sodech4b How many years has the father /male caretaker been in school? (number)

sodech5a Education of index child? ____
sodech5b How many years has the index child been in school? (number)

For question sodech6a and sodech7a use these codes:
1= Taking care of house / children
2= Working at the fields
3= Part time job outside the house (less than 30h/week)
4= Full time job outside the house (more than 30h/week)
5= No occupation
6= Disabled

sodech6a Mother/ female caretaker mainly daily occupation ____
sodech6b Mother/ female caretaker occupation/profession ______________________

sodech7a Father/ male caretaker mainly daily occupation ____
sodech7b Father/ male caretaker occupation/profession ______________________

Assets in the house:

assets1 How many of the following items do you have in your household? (Answer all questions!)
assets1a Chairs/stools ____ (number)
assets1b Foam mattresses ____ (number)
assets1c Lanterns ____ (number)

assets2 Does your household have a working cupboard? 0=no 1=yes
assets2b Radio ____ 0=no 1=yes
assets2c Mobile phone ____ 0=no 1=yes
assets2d TV ____ 0=no 1=yes
assets2e Fan ____ 0=no 1=yes
assets2f Refrigerator ____ 0=no 1=yes
assets2g Bicycle ____ 0=no 1=yes
assets2h Motorcycle/scooter ____ 0=no 1=yes
assets2i Car/truck ____ 0=no 1=yes

Sources of power
soupow1 What is the main type of fuel used for lightening in the house? 1=Open fire 2=Paraffin/ Kerosene
What is the main fuel used for cooking in your household?

1. Wood
2. Charcoal
3. Paraffin/Kerosene
4. Gas
5. Electricity
6. Not applicable

What is the main source of drinking water in your household?

1. Pond, river or stream
2. Unprotected natural spring
3. Rainwater
4. Open or unprotected well
5. Covered well
6. Borehole
7. Public tap
8. Piped into plot/house
9. Bottled water
10. Not applicable

Is it tapped water in the house?

0. No
1. Yes

Is it tapped water in the yard?

0. No
1. Yes

Do you own or rent the house you live in?

1. Own
2. Rent
3. Other, specify

Is the family cultivating land?

0. No
1. Yes

If yes, what are you growing?

(Check all that apply)

1. Crops
2. Maize
3. Rice
4. Sorghum/millet
5. Fruits
6. Legumes
7. Root/vegetable
8. Cotton
9. Tea
10. Coffee
econom3k Tobacco 0=no 1=yes

end3l Other, specify

2=Yes

end4 Is there someone in the family? 0=no 1=yes

end5 Are you in possession of land? 0=no 1=yes

end5 If yes, how much? (acre= area of a football field)

end5 If don’t know 0=Not enough for the need of the family

end5 2=Enough for the extended family

end5 3=Enough to sell to other people

end5 4=Enough to sell weekly at the market

end5 5=Enough to sell daily at the market

end6 Do you own domestic animals or birds? 0=no 1=yes

end7 Do you have the animals in the same compound as living? 0=no 1=yes

end8 How many animals do you have of the following?

end8a Cows (number)

end8b Oxen/bulls (number)

end8c Pigs (number)

end8d Goats (number)

end8e Sheep (number)

end8f Horses/donkey/mules (number)

end8g Other, specify

end9 Approximately how many fowl do you have? (number)

end10 Who is the head of the household? 1=A man

2=A woman

3=Not applicable

end11a Who is the main provider of income? 0=no 1=yes

end11b in the household? 0=no 1=yes

end11c Mother

end11d Stepfather

end11e Grandmother

end11f Grandfather

end11g Aunt

end11h Uncle

end11k Siblings
econom12 Is the "main provider of income" currently employed?  _____  0=no  1=yes

econom13 What are the main sources of income "the main provider" has?  _____  1=Regular employment
2=Irregular employment  3=Home employment  4=Contribution from others
5=Retention pension/grant  6=Relief program  7=Don't know
8=No response  9=Not applicable

econom14 How much money do the family earn per month [__________]  -includes all income even handouts in USH

Medical history of the index child

Disease prevention and caretaking

dispre1 Who is usually looking after the child during the day?  _____  1=Mother
2=Father  3=Stepmother  4=Stepfather
5=Grandmother  6=Grandfather  7=Aunt
8=Uncle  9=Older siblings  10=Neighbour
11=Housemaid  12= Not applicable

dispre2 Is the child using a bed net regularly?  _____  0=no  1=yes

dispre3 Where do you dispose the children's faeces?  _____  1= In the toilet
2= In the garden/compound  3= Together with water by washing clothes
4= Other

dispre3a 4=Other, specify

______________________________

dispre4 How would you describe the health status of your child?  _____  1= very good
2= good
3=Poor
4=Very poor

Ask question dispre5-8 only if child younger than 5 years!!!

dispre5 Was/is the child breast feed? 0=no 1=yes 2= Don’t know

dispre6 If the child was breast feed, how old was she/he when she/he stopped breastfeeding? (weeks)

dispre7 At what age was she/he when you started to give complementary feeds (e.g. porridge, milk, mashed food, water etc?) (weeks)

dispre8 Did the child receive prelactate feeding for instance for 1-3 days just after birth? 0=no 1=yes

Medical history

For question medhis 1-13 please use these codes 0=no 1=yes 2= Don’t know

medhis1 Has the child been ill with a fever at any time in the last 2 weeks?

medhis2 Has the child had any illness with cough at any time in the last 2 weeks?

medhis3 Has the child had diarrhoea at any time in the last 2 weeks?

medhis4 Has the child been given medicine from a health facility against worms in the last 6 months?

medhis5 If the child is younger than 5 years, has the child been given vitamin A (drops from the capsule) in the last 6 months?

medhis6 Is the child taking multivitamins/getting vitamin supplies daily?

medhis7 Is the child chronically ill?  
medhis7a If yes, describe

medhis8 Has the child been taking medication for more than 2 weeks now?
medhis9 Is the child taking daily medication?  
medhis9a  If yes, describe which with name

medhis10 Have the child taken any medication last 3 months?  
medhis10a  If yes, was this antibiotics  
medhis10b  antimalaria  
medhis10c  vitamins  
medhis10d  deworming medicine  
medhis10e  other

medhis11 Has the child been in a clinic/visited a health facility for the last 3 months? 
medhis11a  if yes, for what reason

medhis12 Has the child been admitted to a hospital the last 3 months? 
medhis12a  if yes, for what reason

medhis13 Have the child had any nose bleeding in the last two weeks?

medhis14 How often is the child having stool/bowel movement?  
1=more than 4 times/day  
2=3-4 times/day  
3=1-2times/day  
4=every 2nd-3th day  
5=more seldom

medhis15 How is the consistency of the stool?  
1=normal formed  
2=taking form of a containe  
3=watery  
4=hard

medhis16 Is the child having diarrhoea now?  
0=no  1=yes

medhis17 Have you observed blood in the stool?  
0=no  1=yes

medhis18 If yes, for how long ago?  
1=This week  
2=This month  
3=Last month
medhis19 Have you observed mucus/slime in the stool? 0=no 1=yes
medhis20 If yes, for how long time ago? 1=This week 2=This month 3=Last month 4=Longer time ago
medhis21 Have you observed any other irregularities in the stool? 0=no 1=yes
medhis21a If yes, describe ________________________________

If the child is a girl older than 10 years:
medhis22 Has she started having her menstrual period? 0=no 1=yes 2=Don’t know
medhis23 If yes, when was the last period? 1=Now 2=1-3 days ago 3=more than 4 days ago
medhis24 Do any member of the household have diarrhoea? 0=no 1=yes 2=Don’t know

nutrit Nutrition

nutrit1 How many times per week is the child eating meat? (number, 0=never)
nutrit2 How many times per week is the child eating fish? (number, 0=never)
nutrit3 How many times per week is the child eating egg? (number, 0=never)
nutrit4 How many times per week is the child drinking milk? (number, 0=never)
Ask to be able to see the child's immunization card / child health card!

Please record the immunization given

immuni2a At birth BCG 0=no 1=yes
immuni2b At 6 weeks Polio 0 0=no 1=yes
immuni2c At 6 weeks Polio 1 0=no 1=yes
immuni2d Polio 0 0=no 1=yes
immuni2e At 10 weeks Polio 2 0=no 1=yes
immuni2f Polio 1 0=no 1=yes
immuni2ag At 10 weeks Polio 3 0=no 1=yes
immuni2h Polio 2 0=no 1=yes
immuni2ai Between 6-9 months Measles 0=no 1=yes

Please record the weight of the child at birth?
grodew1a Weight

Observations

obsele1 Is it electricity in the house? 0=no 1=yes
obstoi2 Is there a toilet in the house/yard? 0=no 1=yes
obstoi2a If yes, is the family sharing this toilet with anyone in the neighbourhood? 0=no 1=yes

obstoi3 If yes, is the toilet a 1=Open pit
2=Pit latrine
3=VIP latrine
4=Flush toilet
obstoi3a Other, specify

obscom4 Status of compound 1= Littered
2= Not littered
3= Animal faeces on the ground
4= Human faeces on the ground

obshus5 Main material of the floor 1= Earth/dung
2= Cement
3= Tiles
4= Rudimentary wooden
5= Finished wooden
6= Carpet/vinyl
obshus6 Main material of the roof

1 = Thatch grass
2 = Iron sheet
3 = Tiles
4 = Concrete
5 = Wood
6 = Not applicable
7 = Not applicable

obshus7 Main material of the walls

1 = Mud and pole
2 = Wood
3 = Tin
4 = Bricks without mortar
5 = Burnt bricks with mortar
6 = Plastered walls
7 = Not applicable

obshus8 Main material of windows

1 = No Material
2 = Wood
3 = Nett
4 = Glass
5 = Not applicable

obshus9 Main material of doors

1 = No door
2 = Only outer door
3 = Outer and inner door
4 = Not applicable

obshus10 In what type of house is the child living

1 = Shack
2 = Traditional hut
3 = Semi-permanent house
4 = Permanent house
5 = Not applicable

obshus11 How many rooms are there in the house?

(number)

Anthropometric measurements

To be filled by the nurse/investigator

antrop1 Height/ Length

(cm)

antrop2 Weight

(kg)

antrop3 Head circumference

(cm)

antrop4 Mid upper arm circumference

(cm)

Control questions
contro2 Stool collection container is marked with date, name, date of birth or age and study ID number

contro3 Stool collection container is given to the caretaker?

contro4 Caretaker is explained how to fill the stool container and when it will be collected!

contro5 Stool collected on day of visit

c contro5b If no, date of call back is clarified (dd/mm/yyyy)

contro6 I have checked the questionnaire and all questions are answered!

contro7 My initials are (4 letters)

contro8 My colleague's initials are (4 letters)
Appendix IV: Questionnaire for the HIV-infected children

Questionnaire to caretaker of HIV+ children

"Helicobacter pylori and its association with gastrointestinal dysfunction in children in Kampala, Uganda"

Study participant identification

**studid1**

**studid2** Study participant number

**studid3** Consent form is obtained?

0=no    1=yes

**studid4** Hospital number (if available)

**studid4a** Ward nr

**studid4b** Bed nr

**studid5a** Place of living LC1

**studid5b** LC2

**studid5c** LC3

**studid5d** LC4

**studid6** Phone number of the caretaker

If not available, write N/A

**studid7** Date of interview

(example 02.10.2007)

**studid8a** Child's name, First (Christian name)

**studid8b** Second name

**studid9** Is the child a boy or a girl?

1=girl    2=boy

**studid10a** Child's age

**studid10b**

**studid10c** Child's date of birth if known

(example 09.05.2004)

**studid11** Child's age in months, to be calculated

(age in years times 12 plus age in months)
Who is giving the information? (only one answer)
1=Mother/adoption mother
2=Father/adoption father
3=Stepmother
4=Stepfather
5=Grandmother
6=Grandfather
7=Aunt
8=Uncle
9=Siblings
10=Guardian
11=Not applicable

Age of the informant (in years)

Is the mother alive? (If the mother is the informant, don't ask, just write 1)
0=no  1=yes

If yes how old is the mother (years)

Is the father alive? (If the father is the informant, don't ask, just write 1)
0=no  1=yes

If yes how old is the father (years)

Socio-demographic characteristics:
Size of the family living together /sharing kitchen for the last 3 months:
Children less than 5 years (number)
Children older than 5 years (number)
Adults (above 18 years) (number)

With who is the child living at the moment? (Answer all questions!)
Mother 0=no  1=yes
Father 0=no  1=yes
Stepmother 0=no  1=yes
Stepfather 0=no  1=yes
Grandmother 0=no  1=yes
Grandfather 0=no  1=yes
Aunt 0=no  1=yes
Uncle 0=no  1=yes
Adopted 0=no  1=yes
Not applicable 0=no  1=yes

For question sodech3b, sodech4b and sodech5b use these codes:
0=No education/not enrolled at school.
1=Not completed primary school.
2=Completed Primary school
3=Completed Secondary School
4=Completed Collage/University
9=Died/absent

sodech3a Education of mother/ female caretaker?  
[s]  
sodech3b How many years has the mother /female caretaker been in school?  
[number]  

sodech4a Education of father /male caretaker?  
[s]  
sodech4b How many years has the father /male caretaker been in school?  
[number]  

sodech5a Education of index child?  
[s]  
sodech5b How many years has the index child been in school?  
[number]  

For question sodech6a and sodech7a use these codes:
1= Taking care of house / children
2= Working at the fields
3= Part time job outside the house (less than 30h/week)
4= Full time job outside the house (more than 30h/week)
5= No occupation
6= Disabled
7= Died
9= Not applicable

sodech6a Mother/ female caretaker mainly daily occupation  
[s]  
sodech6b Mother/ female caretaker occupation/profession  
[text]  

sodech7a Father/ male caretaker mainly daily occupation  
[s]  
sodech7b Father/ male caretaker occupation/profession  
[text]  

Assets in the house:

assets1 How many rooms are there in the house?  
[number]
assets2  How many of the following items do you have in your household?

assets2a Chairs/stools  (number)
assets2b Foam mattresses  (number)
assets2c Lanterns  (number)

assets3  Does your household have a working
(Answer all questions!)

assets3a Cupboard  0=no  1=yes
assets3b Radio  0=no  1=yes
assets3c Mobile phone  0=no  1=yes
assets3d TV  0=no  1=yes
assets3e Fan  0=no  1=yes
assets3f Refrigerator  0=no  1=yes
assets3g Bicycle  0=no  1=yes
assets3h Motorcycle/scooter  0=no  1=yes
assets3i Car/truck  0=no  1=yes

Sources of power

soupow1 Is it electricity in the house?  0=no  1=yes

soupow2 What is the main type of fuel used for lightening in the house?
1=Fire
2=Paraffin/ Kerosene
3=Candle
4=Gas
5=Electricity
6=Not applicable

soupow3 What is the main fuel used for cooking in your household?
1=Wood
2=Charcoal
3=Paraffin/ Kerosene
4=Gas
5=Electricity
6=Not applicable

Sources of water

souwat1 Is it tapped water in the house?  0=no  1=yes
souwat2 Is it tapped water in the yard?  0=no  1=yes

souwat3 What is the main source of drinking water in your household?
1=Pond, river or stream
2=Unprotected natural spring
3=Rainwater
4=Open or unprotected well
5=Covered well
<table>
<thead>
<tr>
<th>Economic activities / likelihood</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>econom1</strong> Do you own or rent the house you live in? 1=Own&lt;br&gt;2=Rent</td>
</tr>
<tr>
<td><strong>econom1a</strong> 3=Other, specify</td>
</tr>
<tr>
<td><strong>econom2</strong> Is the family cultivating land? 0=no&lt;br&gt;1=yes</td>
</tr>
<tr>
<td><strong>econom3</strong> If yes, what are you growing? (Answer all questions!)&lt;br&gt;<strong>econom3a</strong> Crops 0=no&lt;br&gt;1=yes&lt;br&gt;<strong>econom3b</strong> Maize 0=no&lt;br&gt;1=yes&lt;br&gt;<strong>econom3c</strong> Rice 0=no&lt;br&gt;1=yes&lt;br&gt;<strong>econom3d</strong> Sorghum/millet 0=no&lt;br&gt;1=yes&lt;br&gt;<strong>econom3e</strong> Fruits 0=no&lt;br&gt;1=yes&lt;br&gt;<strong>econom3f</strong> Legumes 0=no&lt;br&gt;1=yes&lt;br&gt;<strong>econom3g</strong> Root/vegetable 0=no&lt;br&gt;1=yes&lt;br&gt;<strong>econom3h</strong> Tobacco 0=no&lt;br&gt;1=yes&lt;br&gt;<strong>econom3i</strong> Tea/coffe 0=no&lt;br&gt;1=yes&lt;br&gt;<strong>econom3j</strong> Potatoes 0=no&lt;br&gt;1=yes&lt;br&gt;<strong>econom3k</strong> Cassava 0=no&lt;br&gt;1=yes&lt;br&gt;<strong>econom3l</strong> Other, specify</td>
</tr>
<tr>
<td><strong>econom4</strong> Is there someone in the family owning land? 0=no&lt;br&gt;1=yes</td>
</tr>
<tr>
<td><strong>econom5</strong> If yes, how much? (acre= area of a football field)&lt;br&gt;<strong>econom5b</strong> If don't know 1=Not enough for the need of the family&lt;br&gt;2=Enough for the extended family&lt;br&gt;3=Enough to sell to other people&lt;br&gt;4=Enough to sell weekly at the marked&lt;br&gt;5=Enough to sell daily at the marked</td>
</tr>
<tr>
<td><strong>econom6</strong> Do you own domestic animals or birds? 0=no&lt;br&gt;1=yes</td>
</tr>
<tr>
<td><strong>econom7</strong> Do you have the animals/birds in the same compound as living? 0=no&lt;br&gt;1=yes</td>
</tr>
<tr>
<td><strong>econom8</strong> How many animals do you have of the following?&lt;br&gt;<strong>econom8a</strong> Cows (number)&lt;br&gt;<strong>econom8b</strong> Oxen/bulls (number)&lt;br&gt;<strong>econom8c</strong> Pigs (number)</td>
</tr>
</tbody>
</table>
econom8d Goat (number)
econom8e Sheep (number)
econom8f Horses/donkey/mules (number)
econom8g Birds (number)
econom8f1 Other, specify

econom9 Who is head of the household? 1=A man
2=A woman
3=Not applicable

econom10a Who is the main provider of income in the household? Mother 0=no 1=yes
Father 0=no 1=yes
Stepmother 0=no 1=yes
Stepfather 0=no 1=yes
Grandmother 0=no 1=yes
Grandfather 0=no 1=yes
Aunt 0=no 1=yes
Uncle 0=no 1=yes
Siblings 0=no 1=yes

econom11 Is the "main provider of income" currently employed? 0=no 1=yes

econom12 What are the main sources of income "the main provider" has? 1=Regular employment
2=Irregular employment
3=Home employment
4=Contribution from others
5=Retirement pension/grant
6=Relief program
7=Don't know
9=Not applicable/No response

econom13 How much money do the family earn per month -includes all income even handouts in USH

Housing/shelter

hushus What is the main material of the floor of the house the child lives in 1= Earth/dung
2= Cement
3= Tiles
4= Rudimentary wooden
5= Finished wooden
husrof What is the main material of the roof of the house the child lives in

1= Thatch grass
2= Iron sheet
3= Tiles
4= Concrete
5= Wood
6= Not applicable

huswal What is the main material of the walls of the house the child lives in

1= Mud and pole
2= Wood
3= Tin
4= Bricks without mortar
5= Burnt bricks with mortar
6= Plastered walls
7= Not applicable

huswind What is the main material of the windows of the house the child lives in

1= No Material
2= Wood
3= Netting
4= Glass
5= Not applicable

husdoor Does the house the child lives in have doors?

1= No door
2= Only outer door
3= Outer and inner door
4= Not applicable

hushus2 In what type of house is the child living

1= Shack
2= Traditional hut
3= Semi-permanent house
4= Permanent house
5= Not applicable

Medical history of the index child
Disease prevention and caretaking

dispre1 Who is usually looking after the child during the day?

1= Mother
2= Father
3= Stepmother
4= Stepfather
5= Grandmother
6= Grandfather
dispre2 Is the child using a bed net regularly? □ 0=no 1=yes

dispre3 Where do you dispose the children’s faeces? □ 1= In the toilet
2= In the garden/compound
3= Together with water by washing clothes
4= Other

dispre3a 4=Other, specify ______________________________________

dispre4 How would you describe the health status of your child? □ 1= very good
2= good
3= Poor
4= Very poor

Ask question dispre5-8 only if child younger than 5 years!!!
Use 999 if the child is still breast feed.

dispre5 Was/is the child breast feed? □ 0=no 1=yes 2= Don’t know

dispre6 If the child was breast feed, how old was she/he when she/he stopped breastfeeding? _______ (weeks)

dispre7 At what age was she/he when you started to give complementary feeds (e.g. porridge, milk, mashed food, water etc)? _______ (weeks)

dispre8 Did the child receive prelactate feeding for instance for 1-3 days just after birth? □ 0=no 1=yes

dispre9 Is it a toilet in the house/yard? □ 0=no 1=yes

dispre10 If yes, is the family sharing this toilet with anyone in the neighbourhood? □ 0=no 1=yes

dispre11 Is the toilet a □ 1=Open pit
2=Pit latrine
3=VIP latrine
4=Flush toilet

Medical history
For question medhis 1-13 please use these codes
0=no
1=yes
9= Don't know

medhis1 Has the child been ill with a fever at any time in the last 2 weeks?

medhis1b Is the child having fever today?

medhis2 Has the child had any illness with cough at any time in the last 2 weeks?

medhis3 Has the child had diarrhoea at any time in the last 2 weeks?

medhis3b Has the child had malaria within the last 2 weeks?

medhis4 Has the child been given medicine from a health facility against worms in the last 6 months?

medhis5 If the child is younger than 5 years, has the child been given vitamin A (drops from the capsule) in the last 6 months?

medhis6 Is the child taking multivitamins/getting vitamin supplies daily?

medhis7 Have the child taken any medication the last 2 weeks?

medhis7a If yes, was this antibiotics

medhis7b antimalaria

medhis7c vitamins

medhis7d deworming medicine

medhis7e other

medhis8 Is the child on any medication now?

medhis8a If yes, was this antibiotics

medhis8b antimalaria

medhis8c vitamins

medhis8d deworming medicine

medhis8e other

medhis9 Is the child chronically ill except from being HIV positive?

medhis9a If yes, describe
medhis10 Has the child been taking medication for more than 2 weeks now? 

medhis11 Is the child taking daily medication? 
medhis11a If yes, describe which with name 

medhis12 Have the child taken any medication last 3 months? 
medhis12a If yes, was this antibiotics 
medhis12b antimalaria 
medhis12c vitamins 
medhis12d deworming medicine 
medhis12e other 

medhis13 Has the child been in a clinic/visited a health facility for the last 3 months except from this time? 
medhis13a If yes, for what reason 

medhis14 Has the child been admitted to a hospital the last 3 months, except from this time? 
medhis14a If yes, for what reason 

medhis15 Have the child had any nose bleeding in the last two weeks? 

medhis16 How often is the child having stool/bowel movement? 
1=more than 4 times/day 
2=3-4 times/day 
3=1-2 times/day 
4=every 2nd-3rd day 
5=more seldom 

medhis17 How is the consistency of the stool? 
1=normal formed 
2=taking form of a container 
3=watery 
4=hard 

medhis18 Is the child having diarrhoea now? 
0=no 1=yes 

medhis19 Have you observed blood in the stool? 
0=no 1=yes 
medhis19a If yes, for how long ago? 
1=This week
medhis20 Have you observed mucus/slime in the stool? 0=no 1=yes
medhis20a If yes, for how long time ago? 1=This week 2=This month 3=Last month 4=Longer time ago
medhis21 Have you observed any other irregularities in the stool? 0=no 1=yes
medhis21a If yes, describe
medhis22 Is the child complaining about abdominal pain? 0=no 1=yes 2= Don`t know
medhis22a If yes, how often? 1=daily 2=4-6 times/week 3=2-3 times/week 4=1 time or less/week
medhis23 Do any member of the household have diarrhoea? 0=no 1=yes 2= Don`t know

If the child is a girl older than 10 years:
medhis24 Has she started having her menstrual period? 0=no 1=yes 2= Don`t know
medhis25 If yes, when was the last period? 1=Now 2=1-3 days ago 3=more than 4 days ago

nutrit Nutrition (if still breast feeding use 99)
nutrit1 How many times per week is the child eating meat? (number, 0=never)
nutrit2 How many times per week is the child eating fish? (number, 0=never)
nutrit3 How many times per week is the child eating egg? (number, 0=never)
nutrit4 How many times per week is the child drinking milk? (number, 0=never)

Immunization / Growth and development

Ask to be able to see the child's immunization card / child health card!
immunil Immunization card available/seen 0=no 1=yes
### Immunization

<table>
<thead>
<tr>
<th>Immunization</th>
<th>Date</th>
<th>Vaccine(s)</th>
<th>0=no</th>
<th>1=yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>immuni2a</td>
<td>At birth</td>
<td>BCG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>immuni2b</td>
<td>At birth</td>
<td>Polio 0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>immuni2c</td>
<td>At 6 weeks</td>
<td>Polio 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>immuni2d</td>
<td>At 10 weeks</td>
<td>Polio 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>immuni2e</td>
<td>At 14 weeks</td>
<td>Polio 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>immuni2f</td>
<td>At 9 months</td>
<td>Measles</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Anthropometric Measurements

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height/Length</td>
<td>cm</td>
</tr>
<tr>
<td>Weight</td>
<td>kg</td>
</tr>
<tr>
<td>Head circumference</td>
<td>cm</td>
</tr>
<tr>
<td>Mid upper arm circumference</td>
<td>cm</td>
</tr>
</tbody>
</table>

### Physical Examination

<table>
<thead>
<tr>
<th>Examination</th>
<th>0=Absent</th>
<th>1=Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axillary temp</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pallor</td>
<td>0=Absent</td>
<td>1=Present</td>
</tr>
<tr>
<td>Jaundice</td>
<td>0=Absent</td>
<td>1=Present</td>
</tr>
<tr>
<td>Degree of dehydration</td>
<td>0=No</td>
<td>1=Some</td>
</tr>
<tr>
<td>Oral thrash</td>
<td>0=Absent</td>
<td>1=Present</td>
</tr>
<tr>
<td>Pedal edema</td>
<td>0=Absent</td>
<td>1=Present</td>
</tr>
<tr>
<td>Perineal excoriation</td>
<td>0=Absent</td>
<td>1=Present</td>
</tr>
<tr>
<td>腹胀</td>
<td>0=Absent</td>
<td>1=Present</td>
</tr>
<tr>
<td>肝大</td>
<td>0=Absent</td>
<td>1=Present</td>
</tr>
<tr>
<td>脾大</td>
<td>0=Absent</td>
<td>1=Present</td>
</tr>
<tr>
<td>腹水</td>
<td>0=Absent</td>
<td>1=Present</td>
</tr>
</tbody>
</table>
Cardiovascular system:

carea1 Pulse rate _______ bits/min
carea2 Puls is _______ 1= Normal  
2= Bradycardia  
3= tachycardia

carea3 Heart sounds _______ 1=Normal  2= Abnormal  
carea2b If abnormal specify __________________________

carea4 Heart failure _______ 1=Yes  2= No

Respiratory system

respex1 Respiratory rate _______ (breaths/min)

respex2 Chest in drawing _______ 1=Yes  2=No

respex3 Percussion note _______ 1=Normal  2=Abnormal

CNS

cnsexa1 Level of consciousness _______ 1=Normal  2=Abnormal

cnsexa2 Localizing signs _______ 1=Yes  2=No

Clinical diagnosis (As indicated in patients' file/medical notes)

clidia1 __________________________

clidia2 __________________________

clidia3 __________________________

clidia4 __________________________

hivsta Which stage of HIV using WHO classification _______  
is the child in on enrolment (1-4)?

Control questions

contro2 Stool collection container is marked with date of _______ 0=no  1=yes  
collection, name, date of birth or age, sex  
and study id number

contro3 Stool collection container is given to the care taker? _______ 0=no  1=yes

contro4 Caretaker is explained how to fill the stool container  
and when it will be collected! _______ 0=no  1=yes
contro5 I have controlled the questionnaire and all questions are answered! 0=no 1=yes
contro6 My initials are (4 letters)

Helicobacter pylori (Hp) rapid test

hptest1 Hp test 0=negative 1=positive 2=weakly positive 3=not performed

Microbiology findings

microsc1 Parasites seen 0=no 1=yes
microsc1a If yes, what is seen: Ring worm 0=no 1=yes
microsc1b Hock worms 0=no 1=yes
microsc1c Giardia lamblia 0=no 1=yes
microsc1d Entamoeba histolytica 0=no 1=yes
microsc1e Cystis isospora belli 0=no 1=yes
microsc1f Hymenolepsis nana ova 0=no 1=yes
microsc1f1 Others
microsc1g

culture1 Growth of bacteria 0=no 1=yes
culture1a If yes, what is growing Salmonella 0=no 1=yes
culture1b Yersinia enterocolitica 0=no 1=yes
culture1c Shigella 0=no 1=yes
culture1d E.Coli 0=no 1=yes
culture1e If E.coli which subtype EPEC 0=no 1=yes
culture1f EHEC 0=no 1=yes
culture1g EIEC 0=no 1=yes
culture1h ETEC 0=no 1=yes
culture1i EaggEC 0=no 1=yes
culture1j Others

cryptos Microsporidia is found 0=no 1=yes

culture1 Growth of bacteria 0=no 1=yes

cryptos Cryptosporidia is found 0=no 1=yes
rotavir Rotavirus is found 0=no 1=yes
adenovi Adenovirus is found 0=no 1=yes

Faecal calprotectin (FC)
fcllev1
fcllev2
fcllev3 Middle of 1 and 2
Peacel elastase
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>hb</td>
<td>Hb on day of enrolment</td>
<td>g/dl</td>
</tr>
<tr>
<td>wbc</td>
<td>WBC on day of enrolment</td>
<td>m/mm3</td>
</tr>
<tr>
<td>lym</td>
<td>Lymphocytes on day of enrolment</td>
<td>%</td>
</tr>
<tr>
<td>mon</td>
<td>Monocytes on day of enrolment</td>
<td>%</td>
</tr>
<tr>
<td>gran</td>
<td>Granulocytes on day of enrolment</td>
<td>%</td>
</tr>
<tr>
<td>cd4</td>
<td>CD4 count absolute</td>
<td>/mm3</td>
</tr>
<tr>
<td>cd5</td>
<td>CD4 count percentage</td>
<td>%</td>
</tr>
<tr>
<td>albumin</td>
<td>Albumin level</td>
<td></td>
</tr>
<tr>
<td>amylase</td>
<td>Amylase level</td>
<td></td>
</tr>
<tr>
<td>vita</td>
<td>Vitamin A level</td>
<td></td>
</tr>
<tr>
<td>vitb</td>
<td>Vitamin D level</td>
<td></td>
</tr>
<tr>
<td>vitb1</td>
<td>Vitamin E level</td>
<td></td>
</tr>
<tr>
<td>zink</td>
<td>Zink level</td>
<td></td>
</tr>
<tr>
<td>sercal</td>
<td>Level of serum calprotectin</td>
<td></td>
</tr>
</tbody>
</table>
Appendix V: Ethical approval of proposal in Norway and Uganda

UNIVERSITETET I BERGEN
Regional komité for medisinsk og helsefaglig forskningsetikk, Vest-Norge (REK Vest)

Professor Thorkild Tylleskår
Senter for internasjonal helse, UiB
Arnaauer Hansens hus
5021 BERGEN

Deres ref Vår ref Dato
2007/13898-ANOL 05.12.2007

Ad. prosjekt: Fekale markører i vurderingen av gastrointestinal dysfunksjon hos barn Uganda.
(217.07)


Komiteen behandlet søknaden på ny i møte den 22.11.07.


Vedtak:

Prosjektet godkjennes på vilkår av at ovennevnte merknader tas til følge. REK Vest forutsetter at søknad om opprettelse av forskningsbiobank godkjennes av Sosial- og helsedirektoratet.

REK Vest tilråder at den søkte forskningsbiobanken blir opprettet.

Komiteens vurdering av søknad om opprettelses av forskningsbiobank videresendes Sosial- og helsedirektoratet for endelig vedtak der.

Komiteen ber om å få tilsendt sluttrapport evt. trykt publikasjon før studien når dette foreligger.

Vennlig hilsen

Jon Løkken
leder

Anne Berit Ølnheim
sekretær

Kopi:
-SHDir
Prof. James Tumwine  
Dept. of Paediatrics  

Dear Prof. Tumwine  

Re: Approval of Proposal  

Your proposal entitled "Helicobacter pylori and its association with gastrointestinal dysfunction in children in Kampala, Uganda." was considered and reviewed by the research and ethics committee. The proposal was found to be good but some amendments were suggested for incorporation in order to improve on the science of the study. I am happy the suggested changes have been incorporated.  

On behalf of the committee, I am glad to inform you that the proposal has been approved. You may now proceed with the process of data collection.  

Yours truly,  

[Signature]  

Prof. Katabira Elly  
Chair Research & Ethics Committee
## ANNEX C: WHO CLINICAL STAGING OF HIV FOR INFANTS AND CHILDREN WITH ESTABLISHED HIV INFECTION

All clinical events or conditions referred to are described in Annex D.

### Clinical stage 1
- Asymptomatic
- Persistent generalized lymphadenopathy

### Clinical stage 2
- Unexplained persistent hepatosplenomegaly
- Papular pruritic eruptions
- Extensive wart virus infection
- Extensive molluscum contagiosum
- Recurrent oral ulcerations
- Unexplained persistent parotid enlargement
- Linear gingival erythema
- Herpes zoster
- Recurrent or chronic upper respiratory tract infections (otitis media, otorhhea, sinusitis, tonsillitis)
- Fungal nail infections

### Clinical stage 3
- Unexplained moderate malnutrition not adequately responding to standard therapy
- Unexplained persistent diarrhea (14 days or more)
- Unexplained persistent fever (above 37.5 °C, intermittent or constant, for longer than one month)
- Persistent oral Candidiasis (after first 6 weeks of life)
- Oral hairy leukoplakia
- Acute necrotizing ulcerative gingivitis/periodontitis
- Lymph node TB
- Pulmonary TB
- Severe recurrent bacterial pneumonia
- Symptomatic lymphoid interstitial pneumonitis
- Chronic HIV-associated lung disease including bronchiectasis
- Unexplained anaemia (<8.0 g/dL), neutropenia (<0.5 x 10⁹/L²) or chronic thrombocytopenia (<50 x 10⁹/L²)

### Clinical stage 4 *
- Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy
- Pneumocystis pneumonia
- Recurrent severe bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)
- Chronic herpes simplex infection; (orolabial or cutaneous of more than one month’s duration, or visceral at any site)
- Extrapulmonary TB
- Kaposi sarcoma
- Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)
- Central nervous system toxoplasmosis (after the neonatal period)
- HIV encephalopathy
- Cytomegalovirus (CMV) infection; retinitis or CMV infection affecting another organ, with onset at age more than 1 month
- Extrapulmonary cryptococcosis including meningitis
- Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidioidomycosis, penicilliosis)
- Chronic cryptosporidiosis (with diarrhoea)
- Chronic isosporiasis
- Disseminated non-tuberculous mycobacterial infection
- Cerebral or B cell non-Hodgkin lymphoma
- Progressive multifocal leuкоencephalopathy
- HIV-associated cardiomyopathy or nephropathy

* Some additional specific conditions can be included in regional classifications (e.g. pemphigosis in Asia, HIV-associated cervical/ vaginal fistulae in Southern Africa, reactivation of typhoons or meningitis in Latin America).

Ref: https://www.who.int/hiv/pub/guidelines/WHO2010HIVInfantsFinal201007.pdf
