Enterics for Global Health: *Shigella* Surveillance Study (EFGH)

Central Consent Form Appendix

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For questions or feedback contact: Local PI/Local Emergency Contact Name & Number

Researcher's statement
Hello, my name is _____, and I am part of the research team at _____[implementing institution name]. We are conducting a study at _____[recruitment facility name] called Enterics for Global Health ("EFGH"), which is a study about diarrhea in children taking place in 7 countries around the world. We would like to ask if you would be willing to answer a few questions about your child's health to determine whether they might be eligible to participate in the study. If your child is eligible to participate in this study, we will tell you more details about the study and will give you an opportunity to decide whether you would like your child to participate.

All of your responses will remain confidential and will only be used for this research study. You may choose to not answer any of our questions and can stop the questions at any time. This first process should take approximately 5 minutes.

Do you have questions about the study or interview process?

Do I have your permission to begin the interview questions?

If you have any questions about this study in the future, you can contact [XXXXX [EFGH study site the Principal Investigator/delegate contact details]].

Enterics for Global Health (EFGH): *Shigella* Surveillance Study
Name of Implementing Institution
Child Consent for Study Participation
For questions or concerns contact: Local PI/Local Emergency Contact Name & Number

Researcher's statement
You and your child are being asked to take part in a research study. Through this form (also known as the "consent form"), we will provide you the information that you need to help you decide whether you want your child to participate in the study or not. Please ask any questions for clarification. You may also talk to your family, friends, or others before agreeing to participate in the study. We will give you a paper copy of this consent form for your records if you agree to join.

Purpose of the study
Diarrhea caused by a specific bacteria (or germ) called "*Shigella*" is responsible for about 60,000 child deaths each year. The purpose of this study is to determine the number and rate of new cases of diarrhea caused by *Shigella* among children 6 to 35 months of age. There are vaccines against *Shigella* in development and this study will collect information to help implement future *Shigella* vaccine studies. Over a two year period, the Enterics for Global Health (or "EFGH Study") will enroll 1400 children with diarrhea from each of the following seven countries: Peru, Pakistan, Bangladesh, Mali, Malawi, Kenya, and The Gambia.

Study procedures
If you agree to have your child participate in this study, we will briefly examine your child to assess their health status, including any signs of malnutrition or dehydration. We will also ask you a few questions about you, your child's recent health history (including HIV status, HIV treatments, and testing history), and your household and living conditions. For example, we will ask if your child vomited during the current diarrheal episode, and if so, how many times your child vomited in a day. We will also ask you about the cost of this medical visit and this information will be used to document how much cost could be saved if *Shigella* is prevented. If you feel uncomfortable answering any questions you may refuse to answer. We will also look at your child's medical records to collect information on their diagnosis and the care they have received during this health facility visit including medicines used, vaccine history, and the costs associated with the care. If you have any questions about the study or procedures, please ask me at any point or contact XXXXX [EFGH study site the Principal Investigator or delegate contact details].

We will swab your child's bottom to collect three rectal swabs. The tip of these swabs will be inserted into your child's bottom to collect fecal matter. These samples will be sent to the laboratory to see if *Shigella* is present. If *Shigella* is present, this information will be shared with you and the clinician managing your child today. If the clinician decides they should change your child's treatment, you will be contacted to bring your child back to the hospital to be examined by the clinician and the appropriate treatment will be provided at no cost to you. If your child passes stool during our time together, we will also collect a whole stool sample from your child. This stool will be stored and used to test for markers that are the body's response to infection.

A very small amount of blood (0.5 mL or approximately 1/8 of a teaspoon) will be collected from your child today and at the 4-week follow up visit. This process will involve pricking your child's heel or finger and placing on a paper card to create something called a "dried blood spot." The dried blood spot will be used to measure your child's immune system response to a bacterial infection that may be making them sick and not be used for any purposes outside of the study purpose. This process may

cause your child temporary discomfort and they may cry. The study team will take every measure possible to minimize discomfort and infection at the site of blood draw.

The study procedures will take approximately 1-2 hours today. Prior to leaving the health facility, we will also gather information from you about the costs associated with your child's illness and stay at the health facility.

Follow-up visits
We will ask you to come for two follow-up appointments at 4 weeks and 3 months from today. This visit will take about 1 hours. The follow-up appointment will take place at this same facility, or at your home if you prefer. We will not collect any rectal swabs or stool samples during the follow-up visits, but will collect another dried blood spot from your child at the 4 week visit. We will ask you to provide your contact information (your phone number or a phone number that you have access to) so we can remind you of the visit one week and then one day prior to the follow-up appointments. If you miss the follow-up appointments, the study staff will call or text you to reschedule the visit. Today we will also ask you to provide key descriptors to find the child's home. This information will be used to confirm that your child lives in the study area and will be used to find your home in the case of missed follow-up visits and no contact by phone or SMS.

Compensation
You will be reimbursed for the cost of your transportation to attend the health facility follow-up visits, in addition to a small amount of compensation for your time to attend those two visits. We will also cover the cost of your return transportation from today's visit. If your child needs to return to the facility after the clinician receives your child's stool results, your transportation for that visit will also be provided.

Storage of specimens, exportation of samples and future studies
The swab and stool samples collected from your child, or the *Shigella* from those samples, may be stored and used for other future studies. Stool samples will be labeled with a number that is unique to your child and your personal information will not be written on the sample container. Samples collected as part of this study may be shipped to other research institutions outside of the country for future research and quality control purposes. There is the possibility the samples and data collected as part of this study may be shared with other investigators who are not a part of the current study. However, no personal identifying information will ever be shared along with the samples.

Potential risks or discomforts
The study may collect personal information that may be sensitive to discuss. The process of collecting a rectal swab from your child's bottom or taking a dried blood spot can make your child uncomfortable for a few seconds and they may cry. We will take all possible measures to reduce any discomfort to you and your child. Since there is no new medical intervention being evaluated in this study, your child may not receive any direct medical benefit from participating in this study.

Potential benefits
Your child may benefit from the additional examination and treatment he/she obtains, free of charge, as part of the study. All participants will benefit from free clinical and laboratory monitoring, both of which can improve the medical providers' ability to make important decisions about your child's care.

Confidentiality

All information about you and your child will be kept confidential. Only the study staff involved in the management and follow-up of your child will have access to your child's name and the location of where you live. All data collected in paper forms will be coded and kept in locked files in a locked room until it is transferred via a secure system daily to the central data office in the main study site in [the location of the central study office]. All electronic data will be password protected and saved securely. Only study investigators and key members of the study staff, such as the data manager, will have access to study data. Approved external study entities, such as study monitors, may be granted view-only permission to view de-identified data and signed consent forms. Documents containing your and your child's name and contact information will be destroyed three years after completion of the study.

Participation in the study, discontinuation, and withdrawal

Participation in this study is voluntary; therefore, you can decide to have your child join or not. If you decide to join, you can withdraw your child's participation at any time. Whether you agree or decline to participate in the study, your child will continue to receive usual care and treatment for the condition your child currently has. The Principal Investigator and sponsor retain the right to stop the study in the event of loss of approval from overseeing agencies, funding being withdrawn, or when the adequate sample size is reached. Your child may also be withdrawn from the study if you and your child are unable to return to the health facility for the scheduled follow-up visits and cannot be traced at your residence as per the locator information you provided at enrollment. Your child may also be withdrawn from the study for other reasons beyond our control.

Sources of funding

This study is funded by the Bill & Melinda Gates Foundation in the United States.

Subject's statement

This study has been explained to me in detail and I have had a chance to ask questions and I have received satisfactory answers. I therefore volunteer to take part in this study with my child. I give permission to the researchers in this study to use my child's medical records and laboratory specimens as described in this consent form. I also understand that I will receive a copy of this consent form for my records.

I, being the guardian/parent of_____ (Name of child) have understood all that has been read and my questions have been answered satisfactorily.

Please tick the boxes below as they apply:

I agree for my child to participate in this research study	☐ Yes	☐ No
I agree for blood to be collected from my child for the purpose of this research study	☐ Yes	☐ No
I agree to being contacted by phone or visited at home (in person) for the follow-up visits	☐ Yes	☐ No
I agree to have my child's samples stored for future use in research	☐ Yes	☐ No
I agree to have my child's samples sent to the United States or other offshore country for further testing	☐ Yes	☐ No

SIGNATURE OF LEGALLY AUTHROIZED REPRESENTATIVE (PARENT/GUARDIAN)	
_____	_____
Parent/Guardian Printed Name:	Date (DD-MM-YYYY)
_____	_____
Parent/Guardian Signature	Time (hh:mm, 24:00 hr)

OR **THUMBPRINT IF PARENT/GUARDIAN CANNOT WRITE**	

SIGNATURE OF WITNESS: (only required if Parent/Guardian cannot read or write)
This individual must be independent from study staff.

I attest the information in this form was accurately explained to, and apparently understood by, the Parent/Guardian, and that informed consent was freely given by the Parent/Guardian

_____	_____
Witness Printed Name:	Date (DD-MM-YYYY)
_____	_____
Witness Signature	Time (hh:mm, 24:00hr)

SIGNATURE OF STUDY STAFF
This section can only be signed by an investigator or staff approved to administer consent.

I have followed the study protocol to obtain consent from the parent/guardian. He/she apparently understood the nature and the purpose of the study and consents to her child's participation in the study. He/she has been given opportunity to ask questions which have been answered satisfactorily.

_____	_____	_____
Study Staff Printed Name	Study Staff Signature	Date (DD-MM-YYYY)

Please provide copies to the Participant's accompanying caregiver and place a copy of the Consent Form in the Participant's study folder.

Enterics for Global Health (EFGH): *Shigella* Surveillance Study
Name of Implementing Institution
Consent for Verbal Autopsy
For questions or concerns contact: Local PI/Local Emergency Contact Name & Number

Researcher's statement
Your child is enrolled in a research study called "EFGH." We would like to remind you about this study and the role of your child. Our team is contacting you after being informed that your child passed. away. We are deeply saddened to hear this and extend our deepest condolences to you and your family.

Purpose of the study
We would like to understand why child deaths occur to identify how deaths in other children can be prevented. For this reason, we would like to interview the person who knows the child best. We will collect information on the causes and factors that could have led to the child's death **.**

Study procedures
We will ask you a few questions about what happened before your child died and ask you to describe the conditions surrounding your child's death. These questions are designed to try to find out what may have caused the death of your child. We will also ask you information about your child's diarrheal illness tounderstand if that illness was related.

Risks, stress or discomforts
You may feel sadness and grief related to the loss of your child. If this affects your participation, the interview can be stopped at any time and resumed later or stopped completely.

Benefits
Your participation in this study will help us to understand the cause of death of your child. It will also contribute to overall knowledge on causes of child deaths that can be used to find ways to reduce the risk of child mortality.

Confidentiality information
All information we plan to collect as part of this verbal autopsy will be kept confidential. Information collected in the verbal autopsy will be available to you and the local and international study teams. No other persons will be able to review records from this study. All data collected in paper forms will be coded and kept in locked files in a locked room until it is transferred via a secure system daily to the central data office in the main study site in [the location of the central study office]. All electronic data will be password protected and saved securely. Only study investigators and key members of the study staff will have access to study data. Documents containing your personal information, including your contact information, will be destroyed three years after completion of the study.

Although we will make every effort to keep the information about you and your child confidential, no system for protecting confidentiality and privacy can be completely secure and it is possible that unauthorized persons may discover that you and your child are in this study, or might obtain information about you and your child. University and government offices sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your child's records may be examined. The reviewers will protect your privacy. The study records will not be used to put you or your child at legal risk of harm.

Who to contact if you have questions
If you or your family ever have any questions about the study, please inform any of the study staff in charge or contact any of the numbers provided on your participant information card.

If you have questions about your rights as a research participant, you can contact [Local PI/Local Emergency Contact Name & Number].

Sources of funding

This study is funded by the Bill & Melinda Gates Foundation in the United States.

Subject's statement

I, being the guardian/parent of_____ (Name of child), have understood all that has been read and my questions have been answered satisfactorily. I therefore volunteer to participate in the verbal autopsy for this research study.

Please tick the boxes below as they apply:

I agree to participating in this interview	☐ Yes	☐ No
I agree to the study team documenting my testimony during this interview	☐ Yes	☐ No

SIGNATURE OF LEGALLY AUTHROIZED REPRESENTATIVE (PARENT/GUARDIAN)	
_____	_____
Parent/Guardian Printed Name:	Date (DD-MM-YYYY)
_____	_____
Parent/Guardian Signature	Time (hh:mm, 24:00 hr)

OR **THUMBPRINT IF PARENT/GUARDIAN CANNOT WRITE**	
SIGNATURE OF WITNESS: (only required if Parent/Guardian cannot read or write) *This individual must be independent from study staff.* I attest the information in this form was accurately explained to, and apparently understood by, the Parent/Guardian, and that informed consent was freely given by the Parent/Guardian	
_____	_____
Witness Printed Name:	Date (DD-MM-YYYY)
_____	_____
Witness Signature	Time (hh:mm, 24:00hr)

SIGNATURE OF STUDY STAFF		
This section can only be signed by an investigator or staff approved to administer consent. I have followed the study protocol to obtain consent from the parent/guardian. He/she apparently understood the nature and the purpose of the study and consents to her child's participation in the study. He/she has been given opportunity to ask questions which have been answered satisfactorily.		
_____	_____	_____
Study Staff Printed Name	Study Staff Signature	Date (DD-MM-YYYY)

Please provide copies to the caregiver and place a copy of the Consent Form in the Participant's study folder.

Enterics for Global Health (EFGH): *Shigella* Surveillance Study
Name of Implementing Institution
General Medical Record Release Form
For questions or concerns contact: Local PI/Local Emergency Contact Name & Number

Purpose of Form:
The study, "Enterics for Global Health [EFGH]" may collect information about your child's current health facility visit, and any hospital admission in the next 3 months. We request permission to review your child's medical records during this period and for an additional 6month period after your child has completed enrollment in the study in case there is a delay in retrieving your child's records (but we will only record hospitalizations from the 3month period during which they were enrolled in the study). By signing this form, you authorize study staff to review your child's medical records for the duration listed below, and for today's health facility visit related to your child's diarrhea. This form will be kept with your consent form in a secure locked file cabinet.

Study Participant Name: _____

Date of Birth: _____ *(dd-mm-yyyy)*

Date of Enrollment: _____ *(dd-mm-yyyy)*

I authorize the release of any of my child's medical records including their current health facility visit and from any hospital visit at any hospital location (inpatient) that occurs in the next 3 months (through study completion):

_____ *(dd-mm-yyyy)*
START (Use today's date)

to

_____ *(dd-mm-yyyy)*
END (6 months post enrollment date to allow for record abstraction to occur after last follow-up visit)

I permit my medical records to be reviewed by the study team and transcribed into study patient records. These records may include hospital notes, laboratory and radiology reports and pharmacy records to the EFGH study team. I understand that these records may be photocopied to verify that what was transcribed matches the original records but that all photocopies will be kept confidential in a locked cabinet accessible only to authorized personnel of EFGH, including study monitors.

I understand that a photocopy of this authorization shall have the same force and effect as an original.

SIGNATURE OF LEGALLY AUTHROIZED REPRESENTATIVE (PARENT/GUARDIAN)	
_____	_____
Parent/Guardian Printed Name:	Date (DD-MM-YYYY)
_____	_____
Parent/Guardian Signature	Time (hh:mm, 24:00 hr)

OR **THUMBPRINT IF PARENT/GUARDIAN CANNOT WRITE**	

SIGNATURE OF WITNESS: *(Only required if Parent/Guardian cannot read or write. Witness must be independent from study staff.)* I attest the information in this form was accurately explained to, and apparently understood by, the Parent/Guardian, and that permission was freely given by the Parent/Guardian	
_____	_____
Witness Printed Name:	Date (DD-MM-YYYY)
_____	_____
Witness Signature	Time (hh:mm, 24:00hr)

SIGNATURE OF STUDY STAFF

This section can only be signed by an investigator or staff approved to administer consent.

I have followed the study protocol to obtain consent from the parent/guardian for the participant's medical records to be reviewed by the study team and transcribed into study patient records. He/she apparently understood the nature and the purpose of the study and consents to these activities. He/she has been given opportunity to ask questions which have been answered satisfactorily.

_____	_____	_____
Study Staff Printed Name	Study Staff Signature	Date (DD-MM-YYYY)

Please provide copies to the Participant's accompanying caregiver and place a copy of the Medical Record Release Form in the Participant's study folder.

Enterics for Global Health (EFGH): *Shigella* Surveillance Study
Name of Implementing Institution
Key Informant Consent Verbal Script for Demography Survey
For questions or feedback contact: Local PI/Local Emergency Contact Name & Number

Researcher's statement

Hello, my name is _____, and I am a field staff from the [implementing institution name]. I would like to ask if you would be willing to answer a few questions for a survey that is part of a research study called Enterics for Global Health ("EFGH"). This study is about diarrhea in children. We hope to understand how much diarrhea children have in your community that is caused by a specific germ, *Shigella*. If you agree to respond to this survey, I will ask you a few questions about members in your household including children and whether any of the children had diarrhea recently. These questions should take about five minutes. If, after answering these questions, we identify there are children between 6 to 35 months of age living in your household we will seek your permission to ask you additional questions. We will only ask you these questions once.

I will take notes during the survey, which will be stored securely. I will not collect your name. All information you provide will remain strictly confidential. Responding to the survey is optional and you may choose not to answer any of the survey questions asked. You can also tell me if you want to stop the survey at any time.

Do you have questions about the study or anything I just mentioned?

Would it be okay to begin the survey questions?

If you have any questions about this study in the future, you can contact [EFGH study site the Principal Investigator/Delegate contact details].

Enterics for Global Health (EFGH): *Shigella* Surveillance Study
Name of Implementing Institution
Key Informant Consent for Healthcare Utilization Survey
For questions or feedback contact: Local PI/Local Emergency Contact Name & Number

Researcher's statement
You have been identified as the key person in your household with knowledge about your child's health history. We invite you to participate in this survey that is conducted by the Enterics for Global Health Study (EFGH) funded by the Bill & Melinda Gates Foundation in the United States. We are conducting this survey in six other countries in Africa, Asia, and South America.

This survey is about diarrhea in children who are aged between 6 and 35 months.

Interview procedures
The interview will take approximately 15 minutes. I will ask you questions about:

- Your child's diarrhea to understand its severity
- What treatments you provided your child with diarrhea and whether you brought them to a healthcare facility
- Socio-demographics questions (income, health expenditure, etc.)

The information you provide will be used to understand better how and when healthcare services are used when children are ill with diarrhea. The data generated from this survey will help to accurately determine how much diarrhea is occurring among children in your community and understand what leads to care-seeking for diarrhea.

Confidentiality
The information that you provide today is confidential. You and your family members' names and other personal information will not be collected in the survey. You will receive a copy of this consent form and the study will maintain a signed copy in a locked office accessible to only the authorized research team and study monitors.

Participation in the study
Participation in this study is voluntary. You can stop the survey at any time. If you feel uncomfortable answering any questions, you have the right to refuse to answer any questions even though you agreed to participate in the study. If you have any questions about the survey, please ask me or contact [EFGH study site the Principal Investigator/Delegate contact details].

Agreed and Signed by Respondent ☐ Yes ☐ No	
_____ Respondent Printed Name:	_____ Date (DD-MM-YYYY)
_____ Respondent Signature	_____ Time (hh:mm, 24:00 hr)

	_____ Date (DD-MM-YYYY)
OR **THUMBPRINT IF RESPONDENT CANNOT WRITE**	_____ Time (hh:mm, 24:00 hr)
_____ Interviewer Printed Name:	_____ Date (DD-MM-YYYY)
_____ Interviewer Signature	_____ Time (hh:mm, 24:00 hr)