FoodNet Study of non-O157 Shiga-producing *Escherichia coli (STEC)*

Introductory script and verbal consent for participation of adult patients

(≥18 years old)

(IF CASE-PATIENT IS < 18 YEARS OLD, USE CONSENT FORM AND ASSENT FORMS FOR PERSONS < 18 YEARS OLD)

Case name: _____ Age:_____ (years)

CASE ID: __ __ __ __ __

State Laboratory ID Number*_____ **(***required)

Introductory telephone script (the script needs to be strictly followed; practice beforehand so that it sounds natural. Sounding natural will likely improve study recruitment):

Hello. My name is _____ and I am calling from the <*state*>

Department of Health. May I speak with _____ (CASE'S NAME)

If YES→ REINTRODUCE IF NECESSARY [Hello. My name is _____, and I am working with the <*state*> Department of Health. I'm calling today because we are conducting a study with the Centers for Disease Control and Prevention (CDC) investigating how people get ill from certain types *E. coli*. We are contacting you because you had this infection.
(READ CONSENT)

If NO→ Is there a better time to call or a different telephone number that we could use to speak with _____ (CASE's NAME)?

If YES→ Thank you. (RECORD INFORMATION ON CALL LOG)

If NO→ It would be very helpful if we could speak with _____ (CASE's NAME) about a study that is being done by your state health department. May we schedule a time to talk that would be more convenient?

If YES→ Thank you. (RECORD INFORMATION ON CALL LOG)

If NO→ We will try calling again later. Thank you and goodbye.

(RECORD INFORMATION ON CALL LOG)

Consent script:

The <*state*> Department of Health and CDC are doing a research study to learn how people get certain kinds of *E. coli* infections like the one you had. These infections are very important. We are doing this study to try to learn more about where they come from and how to prevent them. Doctors and labs must report every case to the health department. We would like to ask you some questions about your illness and about foods you might have eaten and activities you might have done in the days before you got sick. Your responses to the questions will be compared to the responses of people **who did not** become ill. We will combine the information you tell us with other information collected by the health department and lab results on the E. coli that was found in the sample you gave at the doctor's office.

The questions will take about 20 to 30 minutes. You are free to not participate, if you don't want to. You may refuse to answer any questions for any reason, and may stop at any time. You may ask questions if there is anything that you don't understand. There is no penalty if you choose not to participate in this study.

All of your answers will be kept private to the extent allowed by law. We will keep your answers locked up where only study staff in <*state*> can see them, and we will not keep your name on the forms with your answers. Your name or personal information will not be sent to CDC.

There is no direct benefit to you from being in the study. The study might identify ways to help prevent these infections, which could help everyone. There is no risk to you, besides the unlikely risk of loss of confidentiality.

If you have any questions, you may contact CDC at 404-639-2260. Please leave your name, phone number and CDC protocol number XXXX, and someone will call you back. Here in ,<*state*>, you may contact _____ at XXX-XXX-XXXX. If you have questions about your rights in this research study, please call the <*state*> Human Research Review Committee at XXX-XXX-XXXX

I would be happy to mail or email a copy of this consent form with these phone numbers. Would you like me to? Do you have questions for me? Are you willing to participate?

Flesch-Kincaid Grade Level: 6.9]

WAS CONSENT OBTAINED? *(circle one):* YES NO

If YES→ Thank you. Let's begin. (Begin CASE QUESTIONNAIRE)

If NO→ Thank you for your time. (RECORD INFORMATION ON CALL LOG)

Name of Interviewer: _____

Signature: _____ Date:_____

Please attach this consent to the questionnaire used to interview the case-patient or parent/guardian for IRB assurance

Appendix B. Adult control consent form

Matched Case ID # _____

Matched Control 1 2 3

FoodNet Study of non-O157 Shiga-producing *Escherichia coli (STEC)*

Introductory script and verbal consent for participation of adult controls

(≥18 years old)

(IF CONTROL IS < 18 YEARS OLD, USE CONSENT FORM AND ASSENT FORMS FOR CONSENT < 18 YEARS OLD)

Introductory telephone script (the script needs to be strictly followed; practice beforehand so that it sounds natural. Sounding natural will likely improve study recruitment):

Hello. My name is _____ and I am calling from the <*state*> Department of Health. I'm calling today because we are conducting a study with the Centers for Disease Control and Prevention (CDC) investigating how people get ill from certain types *E. coli*. *E. coli* are bacteria that, if ingested, can cause severe diarrhea and can sometimes result in serious kidney problems. As part of our investigation, we need to talk to people **who did not** become ill with *E. coli*, but live in the same county as someone who did.

We'd like to speak to someone between the ages of _____ and _____. Is there anyone in your household between these ages who might be willing to participate?

If NO→ Thank you for your time. (END INTERVIEW AND RECORD)

If YES→ May I please speak with them?

If YES→ Thank you. (REINTRODUCE IF NECESSARY, then READ CONSENT)

If NO→ It would be helpful if we could speak with them about our study. May we schedule a time to talk with them that would be more convenient?

If YES→ Thank you. (RECORD CALL BACK INFORMATION)

If NO→ Thank you for your time. (END INTERVIEW AND RECORD)

CONSENT: The <*state*> Department of Health and CDC are doing a research study to learn how people get certain kinds of *E. coli* infections. These germs can make people sick to their

stomachs and might put them in the hospital. Other people who live in your county recently got sick from these germs. To understand where these infections come from and how they can be prevented we need to talk people who got sick **and** to people who **did not** get sick. We are contacting you to ask you to participate in the study by answering some questions about foods you have eaten and activities you have done. Your responses to the questions will be compared to the responses of people who got sick.

The questions will take about 20 to 30 minutes. You are free to not participate, if you don't want to. You may refuse to answer any questions for any reason, and may stop at any time. You may ask questions if there is anything that you don't understand. There is no penalty if you choose not to participate in this study.

All of your answers will be kept private to the extent allowed by law. We will keep your answers locked up where only study staff in <*state*> can see them, and we will not keep your name on the forms with your answers. Your name or personal information will not be sent to CDC.

There is no direct benefit to you from being in the study. The study might identify ways to help prevent these infections, which could help everyone. There is no risk to you, besides the unlikely risk of loss of confidentiality.

If you have any questions, you may contact CDC at 404-639-2260. Please leave your name, phone number and CDC protocol number XXXX, and someone will call you back. Here in, <*state*>, you may contact _____ at XXX-XXX-XXXX. If you have questions about your rights in this research study, please call the <*state*> Human Research Review Committee at XXX-XXX-XXXX

I would be happy to mail or email a copy of this consent form with these phone numbers. Would you like me to? Do you have questions for me? Are you willing to participate?

[Flesch-Kincaid Grade Level: 6.6]
WAS CONSENT OBTAINED? *(circle one):* YES NO

If YES→ Thank you. Let's begin. (Begin CONTROL QUESTIONNAIRE)

If NO→ Thank you for your time. (RECORD INFORMATION ON CALL LOG)

Name of Interviewer: _____

Signature: _____ Date: _____

Please attach this consent to the questionnaire used to interview the control or parent/guardian for IRB assurance

FoodNet Study of non-O157 Shiga-producing *Escherichia coli* (STEC*)*

Introductory script and verbal consent for participation of parents or guardians of patients <18 years old and assent for patients 12-17 years old

(IF CASE-PATIENT IS ≥18 YEARS OLD, USE CONSENT FORM FOR PERSONS ≥ 18 YEARS OLD)

Case name: _____ Age:_____ *(circle one):* years months

CASE ID: __ __ __ __ __

State Laboratory ID Number*_____ (*required)

Introductory telephone script (the script needs to be strictly followed; practice beforehand so that it sounds natural. Sounding natural will likely improve study recruitment):

Hello. My name is _____ and I am calling from the <*state*> Department of Health.

May I speak with a parent or guardian of _____ (CASE'S NAME)

If YES→ REINTRODUCE IF NECESSARY [Hello. My name is _____, and I am working with the <*state*> Department of Health. I'm calling today because we are conducting a study with the Centers for Disease Control and Prevention (CDC) investigating how people get ill from certain types *E. coli*. We are contacting you because your child had this infection.
(READ CONSENT)

If NO→ Is there a better time to call or a different telephone number that we could use to speak with a parent or guardian of _____ (CASES'S NAME)?

If YES→ Thank you. (RECORD INFORMATION ON CALL LOG)

If NO→ It would be very helpful if we could speak with <his/her> parent or guardian about a study that is being done by your state health department. May we schedule a time to talk that would be more convenient?

If YES→ Thank you. (RECORD INFORMATION ON CALL LOG)

If NO→ We will try calling again later. Thank you and goodbye.
(RECORD INFORMATION ON CALL LOG)

CONSENT, *(when given the choice between "you" and "you or your child", say "you" when case is <12 years old and say "you or your child when case is ≥12 years old):*

The <*state*> Department of Health and CDC are doing a research study to learn how people get certain kinds of *E. coli* infections like the one your child had. These infections are very important. We are doing this study to try to learn more about where they come from and how to prevent them. Doctors and labs must report every case to the health department. We would like to ask <*you/you or your child*> some questions about <*his/her*> illness and about foods <*he/she*> might have eaten and activities <*he/she*> might have done in the days before <*he/she*> got sick. Your responses to the questions will be compared to the responses of people who **did not** become ill. We will combine the information <*you/you or your child*> tell us with other information collected by the health department and lab results on the E. coli that was found in the sample <*he/she*> gave at the doctor's office.

The questions will take about 20 to 30 minutes. You are free to not participate, if you don't want to. <*You/You or your child*> may refuse to answer any questions for any reason, and may stop at any time. <*You/You or your child*> may ask questions if there is anything that you don't understand. There is no penalty if you choose not to participate in this study.

All of <*your/your or your child's*> answers will be kept private to the extent allowed by law. We will remove your child's name from what <*you/you or your child*> tell us. We will also keep your child's answers locked up where only study staff in <*state*> can see them, and we will not keep your child's name on the forms with your answers. Your child's name or personal information will not be sent to CDC.

There is no direct benefit to you or your child from being in the study. The study results might identify ways to help prevent these infections, which could help everyone. There is no risk to you or your child, besides the unlikely risk of loss of confidentiality.

If you have any questions, you may contact CDC at 404-639-2260. Please leave your name, phone number and CDC protocol number XXXX and someone will call you back. Here in <*state*>, you may contact _____ at XXX-XXX-XXXX. If you have questions about your rights in this research study, please call the <*state*> Human Research Review Committee at XXX-XXX-XXXX

I would be happy to mail or email a copy of this consent form with these phone numbers. Would you like me to? Do you have questions for me? Are you willing to participate? [Flesch-Kincaid Grade Level: 7.0]

WAS CONSENT OBTAINED? *(circle one):* YES NO

Consent not obtained→ Thank you for your time. (RECORD INFORMATION ON CALL LOG)

Consent obtained→

IF CASE-PATIENT IS AGED ≤12, Thank you. Let's begin. (Begin CASE QUESTIONNAIRE)

Name of Interviewer: _____

Signature: _____ Date: _____

Please attach this consent to the questionnaire used to interview the control or parent/guardian for IRB assurance

IF CASE-PATIENT AGED 12-17, Because your child is 12 to 17 years old, we would ideally like to interview him/her directly, but if you prefer you could answer the questions for _____

(CASE'S NAME). Either way, we would first need to talk with _____ (CASE'S NAME) to make sure <*he/she*> is ok with being included in the study. Is it alright if we interview _____(CASE'S NAME) directly, or do you prefer to answer for him/her?

(Check one):

Parent/guardian gives permission to directly interview case-patient (READ ASSENT 1)

Parent/guardian prefers to answer questions on behalf of case-patient (READ ASSENT 2)

ASSENT 1: Is {insert child's name} available at this time?

Yes (READ ASSENT 1 TO CHILD)

No (SCHEDULE A CALL BACK TO SPEAK TO CHILD; RECORD INFORMATION ON CALL LOG)

To child:

We are calling because the <state> health department and CDC are doing a study to learn how people get certain kinds of *E. coli* infections like the one you had. Your parents said it's ok for you to participate in this study. If you agree, I will ask some questions about what you ate and did before your illness. It should only take 20 to 30 minutes. We will use what you tell us to help us learn how to prevent this illness in other people. There are no right or wrong answers. It is up to you if you want do it. There is no direct benefit to you. We are careful to keep your answers and name private. So it is very unlikely that anybody else will know what you tell us. You may refuse to answer any question. You can stop the survey at any time. You may ask questions if there is anything that you don't understand. We will combine the information you tell us with other information collected by the health department and the test results from the sample you gave at the doctor's office.

Do you have any questions for me?

Do you understand and agree with the decision to participate?

[Flesch-Kincaid Grade Level: 5.7]

Assent obtained: *(circle one):* **YES** **NO**

If CONSENT=Yes AND ASSENT=Yes: Thank you. Let's begin. (Begin CASE QUESTIONNAIRE with)

If No, Thank you for your time. (RECORD INFORMATION ON CALL LOG)

Name of Interviewer: _____

Signature: _____ Date:_____

Please attach this consent to the questionnaire used to interview the case-patient or parent/guardian for IRB assurance

ASSENT 2: Is {insert child's name} available at this time? We need to be sure that [he/she] understands that you will be answering questions about [his/her] recent illness. Would it be possible to speak with {insert child's name} and confirm that [he/she] understands and agrees?

Yes (READ ASSENT 2 TO CHILD)

No (SCHEDULE A CALL BACK TO SPEAK TO CHILD; RECORD INFORMATION ON CALL LOG)

To child:

We are calling because the <state> health department and CDC are doing a study to learn how people get certain kinds of *E. coli* infections like the one you had. Your parents agreed to answer some questions about your illness. They would answer questions about what you ate and did before your illness. We will use what your [parent/guardian] tells us to help us learn how to prevent this illness in other people. There are no right or wrong answers. It is up to you if you want your [parent/guardian] to do this. There is no direct benefit to you. We are careful to keep your answers and name private. So it is very unlikely that anybody else will know what your [parent/guardian] tells us. You or your [parent/guardian] may refuse to answer any question. We will combine the information your [parent/guardian] tells us with other information collected by the health department and the test results from the sample you gave at the doctor's office.

Do you have any questions for me?

Do you understand and agree that your [parent/guardian] will answer questions for you?

[Flesch-Kincaid Grade Level: 7.1]

Assent obtained: *(circle one):* **YES** **NO**

If CONSENT=Yes AND ASSENT=Yes: Thank you. Would you please hand the phone back to your [parent/guardian]? (Begin CASE QUESTIONNAIRE with parent or guardian)

If No, Thank you for your time. (RECORD INFORMATION ON CALL LOG)

Name of Interviewer: _____

Signature: _____ Date:_____

Please attach this consent to the questionnaire used to interview the case-patient or parent/guardian for IRB assurance

Matched Case ID # _____

Matched Control 1 2 3

FoodNet Study of non-O157 Shiga-producing *Escherichia coli* (STEC)

Introductory script and verbal consent for participation of parents or guardians of controls <18 years old and assent for controls 12-17 years old

(IF CONTROL IS ≥18 YEARS OLD, USE CONSENT FORM FOR PERSONS ≥ 18 YEARS OLD)

Introductory telephone script (the script needs to be strictly followed; practice beforehand so that it sounds natural. Sounding natural will likely improve study recruitment):

Hello. My name is _____ and I am calling from the <*state*> Department of Health. I'm calling you today because we are conducting a study with CDC investigating how people get ill from certain types *E. coli*. *E. coli* are bacteria that, if ingested, can cause severe diarrhea and can sometimes result in serious kidney problems. As part of our investigation, we need to talk to people **who did not** become ill with *E. coli*, but live in the same county as someone who did.

We'd like to speak to the parent or guardian of a child between the ages of _____ and _____.

Is there a parent or guardian with a child between these ages available to talk to?

If NO→ Thank you for your time. (END INTERVIEW AND RECORD)

If YES→ May I please speak with them?

If YES→ Thank you. (REINTRODUCE IF NECESSARY, then READ CONSENT)

If NO→ It would be helpful if we could speak with them about our study. May we schedule a time to talk with them that would be more convenient?

If YES→ Thank you. (RECORD CALL BACK INFORMATION)

If NO→ Thank you for your time. (END INTERVIEW AND RECORD)

CONSENT: *(when given the choice between "you" and "you or your child", say "you" when case is <12 years old and say "you or your child when case is ≥12 years old):*

The <*state*> Department of Health and CDC are doing a research study to learn how people get certain kinds of *E. coli* infections. These germs can make people sick to their stomachs and might put them in the hospital. Other people who live in your county of the same age group as your child recently got sick from these germs. To understand where these infections come from and how they can be prevented we need to talk people who got sick **and** to people who **did not** get sick. We are contacting you to ask <*you/ you and your child*> to participate in the study by answering some questions about foods he or she might have eaten and activities he or she might have done. Your responses to the questions will be compared to the responses of people who got sick.

The questions will take about 20 to 30 minutes. You are free to not participate, if you don't want to. <*You/You or your child*> may refuse to answer any questions for any reason, and may stop at any time. <*You/You or your child*> may ask questions if there is anything that you don't understand. There is no penalty if you choose not to participate in this study.
All of <*your/your or your child's*> answers will be kept private to the extent allowed by law. We will keep your child's answers locked up where only study staff in <*state*> can see them, and we will not keep his or her name on the forms with the answers. Your child's name or personal information will not be sent to CDC.

There is no direct benefit to you or your child from being in the study. The study might identify ways to help prevent these infections, which could help everyone. There is no risk to you or your child, besides the unlikely risk of loss of confidentiality.

If you have any questions, you may contact CDC at 404-639-2260. Please leave your name, phone number and CDC protocol number XXXX, and someone will call you back. Here in, <*state*>, you may contact _____ at XXX-XXX-XXXX. If you have questions about your rights in this research study, please call the <*state*> Human Research Review Committee at XXX-XXX-XXXX

I would be happy to mail or email a copy of this consent form with these phone numbers. Would you like me to? Do you have questions for me? Are you willing to participate?

[Flesch-Kincaid Grade Level: 6.8]
WAS CONSENT OBTAINED? *(circle one):* YES NO

Consent not obtained→ Thank you for your time. (RECORD INFORMATION ON CALL LOG)
Consent obtained→
IF CONTEROL IS AGED ≤12, Thank you. Let's begin. (Begin CONTROL QUESTIONNAIRE)

Name of Interviewer: _____

Signature: _____ Date: _____

Please attach this consent to the questionnaire used to interview the control or parent/guardian for IRB assurance

Appendix D. Child control consent and assent forms

IF CONTROL AGED 12-17, Because your child is 12 to 17 years old, we would ideally like to interview him/her directly, but if you prefer you could answer the questions for. Either way, we would first need to talk with him/her to make sure he/she is ok with being included in the study. Is it alright if we interview your child directly, or do you prefer to answer for him/her?

(Check one):

Parent/guardian gives permission to directly interview case-patient (READ ASSENT 1)

Parent/guardian prefers to answer questions on behalf of case-patient (READ ASSENT 2)

ASSENT 1: What is your child's name? Is _____ (CHILD'S NAME) available at this time?

Yes (READ ASSENT 1 TO CHILD)

No (SCHEDULE A CALL BACK TO SPEAK TO CHILD; RECORD INFORMATION ON CALL LOG)

To child:

We are calling because the <*state*> health department and CDC are doing a study to learn how people get certain kinds of *E. coli* infections. These germs can make people sick to their stomachs and might put them in the hospital. Other people who live near you recently got sick from these germs. To understand where these infections come from and how they can be prevented we need to talk people who got sick **and** to people like you who **did not** get sick.

Your parents said it's ok for you to participate in this study. If you agree, I will ask some questions about what foods you have been eating and activities you have done. Your answers will be compared to answers from people who got sick.

It should only take 20 to 30 minutes. We will use what you tell us to help us learn how to prevent this illness in other people. There are no right or wrong answers. It is up to you if you want do it. There is no direct benefit to you. We are careful to keep your answers and name private. So it is very unlikely that anybody else will know what you tell us. You may refuse to answer any question. You can stop the survey at any time. You may ask questions if there is anything that you don't understand.

Do you have any questions for me?

Do you understand and agree with the decision to participate?

[Flesch-Kincaid Grade Level: 5.2]

Assent obtained: *(circle one):* **YES** **NO**

If CONSENT=Yes AND ASSENT=Yes: Thank you. Let's begin. (Begin CASE QUESTIONNAIRE with)

If No, Thank you for your time. (RECORD INFORMATION ON CALL LOG)

Name of Interviewer: _____

Signature: _____ Date:_____

Please attach this consent to the questionnaire used to interview the case-patient or parent/guardian for IRB assurance

ASSENT 2: What is your child's name? Is _____ (CHILD'S NAME) available at this time? We need to be sure that <*he/she*> understands that you will be answering questions about <*his/her*> recent illness. Would it be possible to speak with {insert child's name} and confirm that <*he/she*> understands and agrees?

Yes (READ ASSENT 2 TO CHILD)

No (SCHEDULE A CALL BACK TO SPEAK TO CHILD; RECORD INFORMATION ON CALL LOG)

To child:

We are calling because the <*state*> health department and CDC are doing a study to learn how people get certain kinds of *E. coli* infections. These germs can make people sick to their stomachs and might put them in the hospital. Other people who live near you recently got sick from these germs. To understand where these infections come from and how they can be prevented we need to talk people who got sick **and** to people like you who **did not** get sick.

Your parents agreed to answer some questions about foods you have recently eaten and activities you have done. We will use what your [parent/guardian] tells us to help us learn how to prevent this illness in other people.

There are no right or wrong answers. It is up to you if you want your [parent/guardian] to do this. There is no direct benefit to you. We are careful to keep all answers and name private. So it is very unlikely that anybody else will know what your [parent/guardian] tells us. You or your [parent/guardian] may refuse to answer any question.

Do you have any questions for me?

Do you understand and agree that your [parent/guardian] will answer questions for you?

[Flesch-Kincaid Grade Level: 6.5]

Assent obtained: *(circle one):* **YES** **NO**

If CONSENT=Yes AND ASSENT=Yes: Thank you. Would you please hand the phone back to your [parent/guardian]? (Begin CONTROL QUESTIONNAIRE with parent or guardian)

If No, Thank you for your time. (RECORD INFORMATION ON CALL LOG)

Name of Interviewer: _____

Signature: _____ Date:_____

Please attach this consent to the questionnaire used to interview the case-patient or parent/guardian for IRB assurance