APPENDIX E: VERBAL CONSENT FOR PARTICIPATION WITH AND WITHOUT HIPPA LANGUAGE

VERBAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

(Non-HIPPA language)

Study Title: Community- Associated *Clostridium difficile* Risk Factor Study
Principal Investigator: _____
Funding Source: (State Department of Public Health); Centers for Disease Control and Prevention

Invitation to Participate and Description of Project

We are asking you to take part in an assessment to look at how people get infections with *Clostridium difficile*, a germ that can make people sick with diarrhea and might put them in the hospital. This study is being conducted by staff at <state health department>in conjunction with the Centers for Disease Control and Prevention (CDC). 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.

We are contacting you to ask [you to participate / you to participate on your child's behalf] because [you/your child] or someone who lives in your area had this infection.

Procedures

The <state health department> routinely tracks how often people in your area get sick from *C.difficile* infections and is notified whenever a person develops this infection. Your medical doctor is required to report cases of *C. difficile* to the state health department. If you agree to take part in this study we will ask you to complete a survey over the phone. To understand where these infections come from and how they can be prevented we need to talk to people who got sick **and** to people who **did not** get sick. We will ask both groups about [your/your child's] healthcare, household, medications, and about the types of food [you/ your child] eat(s).

The interview will take about 30 minutes. You can refuse to answer any of the questions. You are free to not participate, if you don't want to.

Risks and Inconveniences

There are no risks to you for being in this research study, other than the possibility that some questions may be uncomfortable or difficult to answer. There are no direct benefits to you for joining this study. There is no penalty for not being in this study. You do not have to answer any questions you are uncomfortable with. You may stop at any time. After your participation in the study, we will send you a $20 gift card to show our appreciation for your time and effort.

Security of Information

All we learn about [you/ your child] and your family will be kept private as much as the law allows. We will only use information grouped with information from many other participants, without using names or other personal information. Any information collected that could identify your child will be destroyed when the evaluation is done.

Voluntariness and Withdrawal

You are free to choose not to take part in this study. Refusing to take part will not affect any medical care or benefits [you/your child] receive. If you decide later that you want to stop, you should write to (state Principal Investigator _____) at the following address:_____.If you choose to withdraw from the study, the data collected in this interview will be destroyed and removed from any database associated with this project. You can also refuse to answer any questions or stop the interview at any time.

Questions

If you have questions about this study or you feel you may have been harmed by this study, you may call the <EIP site> at <contact number>.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, <name of EIP CDI investigator and contact number>. If you have any questions about your rights as a research subject, you may contact the < name and contact number to the Chair of the local IRB or Research Ethics, etc>.

If you feel you have been harmed in any way by taking part of this study, or if you have questions about your rights, you may also contact CDC's Human Research Protection Office at 1-800-584-8814; leave a message with your name, phone number, and refer to CDC protocol #6542.0 and someone will call you back.

Authorization

Now that I have told you about the study, do you have any questions for me about the study? (Answer all questions before proceeding to next question)

Do you agree to participate (on behalf of your child)? (Verbal consent given)
Yes _____**IF YES**-> say "Thank you. Now I will ask you some questions. You may refuse to answer any question that makes you uncomfortable"
No _____ **IF NO**-> say "Thank you for you time. If you change your mind please call me at: (_) -_____.

_____
Name of Subject

_____
Name of Parent/Guardian

*Interviewer signature*_____*Date*_____

I will be happy to mail a copy of this consent form as well as information about *C. diff* infection if you would like. (Record mailing information separately)

MATCHED CASE PATIENT ID: _____

VERBAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
HIPPA LANGUAGE VERSION

Study Title: Community- Associated *Clostridium difficile* Risk Factor Study
Principal Investigator: _____
Funding Source: (State Department of Public Health); Centers for Disease Control and Prevention

Invitation to Participate and Description of Project

We are asking you to take part in an assessment to look at how people get infections with *Clostridium difficile*, a germ that can make people sick with diarrhea and might put them in the hospital. This study is being conducted by staff at <state health department>in conjunction with the Centers for Disease Control and Prevention (CDC). 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.

We are contacting you to ask [you to participate / you to participate on your child's behalf] because [you/your child] or someone who lives in your area had this infection.

Procedures

The <state health department> routinely tracks how often people in your area get sick from *C.difficile* infections and is notified whenever a person develops this infection. Your medical doctor is required to report cases of *C. difficile* to the state health department If you agree to take part in this study we will ask you to complete a survey over the phone. To understand where these infections come from and how they can be prevented we need to talk to people who got sick **and** to people who **did not** get sick. We will ask both groups about [your/your child's] healthcare, household, medications, and about the types of food [you/ your child] eat(s).

The interview will take about 30 minutes. You can refuse to answer any of the questions. You are free to not participate, if you don't want to.

Risks and Inconveniences

There are no risks to you for being in this research study, other than the possibility that some questions may be uncomfortable or difficult to answer. There are no direct benefits to you for joining this study. There is no penalty for not being in this study. You do not have to answer any questions you are uncomfortable with. You may stop at any time. After your participation in the study, we will send you a $20 gift card to show our appreciation for your time and effort.

Security of Information

All we learn about [you/ your child] and your family will be kept private as much as the law allows. We will only use information grouped with information from many other participants, without using names or other personal information. Any information collected that could identify your child will be destroyed when the evaluation is done.

HIPAA Authorization

While we will make every effort to keep what we learn about you private, this cannot be guaranteed. Results of the research may be presented at meetings or in publications, but your name will not be used. The Federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information collected as part of research. This permission is called an Authorization. We will use information we collect about [you/your child] including information from the survey such as exposures and demographics [and information about your/ your child's illness]. If you decide to take part, the Authorization for this study will not expire unless you cancel (revoke) it. The information collected will be kept until the study is completed and all data is analyzed and presented/published. You can always cancel by writing to the (study investigator). If you cancel your Authorization, you will also be removed from the study. By giving consent, you give us permission to use and/or share your health information.

Voluntariness and Withdrawal

You are free to choose not to take part in this study. Refusing to take part will not affect any medical care or benefits [you/your child] receive. If you decide later that you want to stop, you should write to (state Principal Investigator _____) at the following address:_____.If you choose to withdraw from the study, the data collected in this interview will be destroyed and removed from any database associated with this project. You can also refuse to answer any questions or stop the interview at any time.

Questions

If you have questions about this study or you feel you may have been harmed by this study, you may call the <EIP site> at <contact number>.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, <name of EIP CDI investigator and contact number>. If you have any questions about your rights as a research subject, you may contact the < name and contact number to the Chair of the local IRB or Research Ethics, etc>.

If you feel you have been harmed in any way by taking part of this study, or if you have questions about your rights, you may also contact CDC's Human Research Protection Office at 1-800-584-8814; leave a message with your name, phone number, and refer to CDC protocol #6542.0 and someone will call you back.

Authorization

Now that I have told you about the study, do you have any questions for me about the study? (Answer all questions before proceeding to next question)

Do you agree to participate (on behalf of your child)? (Verbal consent given)
Yes _____**IF YES**-> say "Thank you. Now I will ask you some questions. You may refuse to answer any question that makes you uncomfortable"

No _____ **IF NO**-> say “Thank you for you time. If you change your mind please call me at: ( ) -_____.

_____
Name of Subject

_____
Name of Parent/Guardian

*Interviewer signature*_____*Date*_____

I will be happy to mail a copy of this consent form as well as information about *C. diff* infection if you would like. (Record mailing information separately)

MATCHED CASE PATIENT ID: _