ADULT VERBAL CONSENT/ASSENT (16-17)/PARENTAL PERMISSION FOR PARTICIPATION IN A RESEARCH PROJECT

<Healthcare Facility Name(s)>

ADULT VERBAL CONSENT

Study Title: Surveillance for *Clostridium difficile* Infection (CDI)
Principal Investigator: _____
Funding Source: Emerging Infections Program; Centers for Disease Control and Prevention

Invitation to Participate and Description of Project

You (Your child) are invited to take part in a research study to learn more about an illness in your community called *Clostridium difficile* (also called *C. diff*). You have been asked to take part because you (your child) had a positive test for *C. diff* and you may not have had contact with a healthcare system in the past 3 months.

Procedures

If you agree to take part (have your child take part) in this study, we will ask you to take a short survey over the phone. The survey will ask about you (your child) and if you (your child has) have had health care contact in the past few months. The survey will also ask some questions about your (your child's) environment and foods you (they) might have eaten. The survey will take about 30 to 40 minutes.

Risks and Benefits

What we learn from this study may help us to develop programs to prevent this illness in the future. . There are no risks to you (your child) for being in this research study. There are no direct benefits to you (your child) for joining this study. There is no penalty for not being in this study. You (your child) may refuse to answer any questions. You (your child) may stop at any time.

Confidentiality

We will keep your (your child's) information secure, to the extent allowed by law. Nothing that would reveal your (your child's) identity will be included in reports of results from this study.

We will keep your (your child's) answers and identifiable information in a locked file cabinet in a locked office, where only study staff can see them. The computer used to enter your (your child's) answers will be password protected and only study personnel will have access to the password. The authorized staff from <EIP site> and staff at the Centers for Disease Control and Prevention (CDC) will have access to your health information to conduct this study. However, your (your child's) name, address and phone number will not appear in any of the health information that is sent to CDC.

Voluntariness

You are free to choose not to (have your child) take part in this study. Your (your child's) health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not agree to take part. If you choose not to take part, or if you withdraw, it will not harm your (your child's) relationship with your (his or her) own doctors or with <referring medical center>. If you decide later that you want to stop, you should write to <EIP CDI PI or responsible site investigator> at the following address <EIP site address>. 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 #5558 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)

Have I answered all of your questions to your satisfaction? (if no, probe, and answer any remaining questions)

Do you agree to take part in this study? (Verbal consent given) Yes _____ No _____

_____ _____

Interviewer signature Date

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