

ADULT VERBAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

<Healthcare Facility Name(s)>

ADULT VERBAL CONSENT

Study Title: Risk Factors for Invasive Methicillin-Resistant *Staphylococcus aureus* (MRSA) Infections among Recently Discharged Patients

Principal Investigator: _____

Funding Source: Emerging Infections Program; Centers for Disease Control and Prevention

Invitation to Participate and Description of Project

You are invited to take part in a research study to learn more about an illness called MRSA. *Staphylococcus aureus* or staph is a germ that lives on the skin of people. Most of the time it is not harmful. However, in some instances, staph can cause infections of the skin and serious problems if it gets inside the body and infects the bones or blood. MRSA is a type of staph germ that is resistant to some antibiotics. This means that those drugs can no longer be used to treat infections with the staph germ. People in hospitals are at most risk of getting this germ, but MRSA can also occur after a hospitalization. We don't know why this occurs. The goal of this study is to learn more about MRSA in these people who have been recently hospitalized so that steps can be taken to prevent this infection. You have been asked to take part of this study because either you or someone who was hospitalized at the same time as you has developed MRSA infection.

Procedures

If you agree to take part in this study, we will ask you questions about your health and your exposures to health care after your hospitalization on <Date of Most Recent Hospitalization>. The survey will take about 15-20 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 for being in this research study. There are no direct benefits to you for joining this study. There is no penalty for not being in this study. You may refuse to answer any questions. You may stop at any time. After your participation in the study, a \$10 Target gift card will be sent to you to show our appreciation for your time and effort.

Confidentiality

We will keep your information private, to the extent allowed by law. Nothing that would reveal your identity will be included in reports of results from this study.

We will keep your 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 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 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 take part in this study. Your 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 relationship with your own doctors or with <referring medical center>. If you decide later that you want to stop, you should write to <EIP MRSA 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 #XXXX 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 _____

If NO: Thank you for your time. If you change your mind please call me at (____)____-_____

If Yes: Thank you. Now I will ask you some questions. You may refuse to answer any question that makes you feel uncomfortable.

Interviewer signature

Date

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