Informed Consent Index Cover Page

Title: **S**top Comm**u**nity MR**S**A Colonizat**i**on **A**mong Pat**ie**n**t**s (SUSTAIN)

ICF Date: 8/5/2014

NCT: NCT02029872

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Stop Community MRSA Colonization among Patients (SUSTAIN)

Application No.: NA_00079147

Sponsor: Robert Wood Johnson Foundation

Principal Investigator: Jason E. Farley, PhD, MPH, NP
525 N. Wolfe Street, Room 525
Baltimore, MD 21205
Office: 410-502-7563
Fax: 443-873-5036

1. What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- For clinical trials: A description of this clinical trial will be available at www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time.
- If you have clinical tests done as part of this research study, a statement will be added to your medical record that you are in this research study. Results from any clinical tests you have will be included in your medical record. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- If children and adults can join this study, the word "you" in this consent form will refer to both you and your child.

- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.

2. Why is this research being done?

This research is being done to learn more about an approach to remove Methicillin resistant Staphylococcus aureus (MRSA) in patients who are carriers of the bacteria in outpatient settings and among their household members and sexual partners.

MRSA is a type of bacteria or germ that can cause bad infections of the skin that can make people very sick. The bacteria have been seen in a high number of persons in the Baltimore area and in hospitals throughout the country. MRSA can be spread from person to person, particularly in homes and among family members and sexual partners.

There are three things we hope to learn from this research study:

1) First, we want to find a way to prevent MRSA infections in outpatient settings. By asking questions, we want to look at the things that may increase the risk of having this type of bacteria in you and your family members.
2) Second, we have soaps and oral rinses (Chlorhexidine) and medications (antibiotics; Mupiricin ointment) that have been shown to be effective at removing MRSA. We want to determine if these antibiotics and soaps are best used for everyone in the household or only the individual with known MRSA.
3) Third, we want to learn more about the bacteria by looking at it on the inside. We will do laboratory tests on samples we collect, to learn how MRSA bacteria grow, reproduce and how it develops to behave differently than other types of MRSA bacteria.

People who carry the MRSA bacteria at any location on their body may join this study.

How many people will be in this study?

About 520 men, women and children could take part in this study in Baltimore City. About 50 participants will be assigned to the individual group and we anticipate screening about 4 members of the household/sex partner in this group. About 50 people will be enrolled in the household/sex partner group and we anticipate screening and treating 4 members of the household in this group. We believe 500 individuals in total will be enrolled in this study. Each person will be in this study for approximately 6 months.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

1) Complete a brief survey. This questionnaire will ask you for some demographic information and questions about your health history.
2) Allow us to look at the electronic or paper medical chart, if part of the Johns Hopkins Medical Institutions. This will include evaluating your medication, prior laboratory studies and past clinician visits.
3) Allow us to collect:

- If you are an adult over 18, a cotton swab of your nose, throat, groin (area between genitals and rectum), the rectum, and the vagina (for women). A single new swab is placed in each location and rotated in a circle to pick up cells.
- Male and female children, under the age of 18 will receive a swab of their nose, throat and rectum only.
- All participants, regardless of age will receive a cotton swab of any open or draining skin bump or wound.

Cotton swabs will be processed at the Johns Hopkins Hospital laboratory for the presence of the MRSA bacteria.

- If a wound is cultured and determined to be infected by MRSA, you and your primary medical provider will be notified of the result.

4) Discuss the study with your household member and sexual partners and inform them that the study team will be in contact with them.

- If your samples are positive for MRSA you and your household members and sexual partner will qualify for study participation. You will have completed the study if your MRSA result is negative.
- If you have an infection caused by MRSA, the study team will notify you and/or your treatment team or your healthcare provider who will determine the need for treatment of the infection.

If your MRSA result is positive you will then be assigned to one of two groups randomly (by chance, like "flipping a coin"). The same exact study procedures are followed for both groups except for those who receive MRSA testing, soap and antibiotics. These two groups are known as the individual group and the household group.

- Individual group: Fifty participants will be assigned to this group. Household members may receive screening if they choose, but will not receive soap or medication if you are assigned to this group. Only you will receive soap and medication. We ask that you not share this with your family. MRSA screening and use of the soap/antibiotic will focus only on you. After completion of the final study visit your household members/sexual partner may receive treatment.

- Household/sex partner group: Fifty participants will be assigned to this group. Household members and your main sexual partner will be able to participate in this group. We will set up a time that is convenient for you and your household members to participate. You will have the option of scheduling an appointment at Johns Hopkins or two members of the study team will make a home visit. It is your choice based on what best suits your needs. Soap and medication will be provided for the entire household based on age appropriate treatment plan.

After your group assignment:
Once you have been assigned to your specific group and your household members and/or sexual partner has agreed to be contacted, the research assistant will work with you to schedule either a home visit or clinic visits for your household members and sexual partner. This will need to be completed prior to receiving your study medications. This should occur within 7 days of your signing consent for participation.

You will be notified about your result before we screen anyone else in your household. If you are MRSA negative, you and your household members and/or sexual partner do not qualify for the study.

Once you are screened and we discuss your MRSA results with you by phone, **we will want to discuss the study with your household members and/or sexual partner if you are MRSA positive**. As you and your household and/or sexual partner are assigned, **as a group**, to the intervention or control parts of this study, we will ask you to make contact with your household and/or sexual partner when we inform you of your results. It is your choice if you would like to do that during our call to discuss your results or at another appropriate time. Once permission to discuss the study is granted by your household members and/or sexual partner, the study team member would schedule a time in clinic or during a home visit to enroll your household members and/or sexual partner. For your household members and/or sexual partner, we will notify each of these individuals separately of his/her MRSA result and will inform the adult participant about the status of children during the scheduled time after the screening/enrollment visit. Once your family has been screened, it usually takes about 48 hours after the MRSA test result reaches the lab to have the result.

If your family member has a wound, we will notify the person (or parent/legally authorized representative for a child). If the family member does not have a primary medical provider, we will provide details about clinic locations that would offer treatment for this infection.

Treatment regimen to remove MRSA colonization:
Everyone will receive mupiricin ointment for the nose twice daily for 7 days. Additionally, you will have chlorhexidine rinse for your throat twice daily for 7 days if you have MRSA in your throat. Everyone will be provided chlorhexidine soap to use in the bath/shower daily for 7 days. All of these treatments are used during the same 7 day period. You will be provided instruction sheets detailing how to use each of the treatment regimens. You will be rescreened for MRSA upon completion and, if positive, will receive an additional 7 days of MRSA treatment, followed by rescreening.

Request to collect and store biospecimens for future research
As part of this research study, we would like to ask you to let us store your biospecimens, the MRSA bacteria, if found, and health information for future MRSA research. This may include, comparing the bacteria on your swab to bacteria from sexual partners or in patients from other local hospitals. The same rules and procedures to protect your privacy discussed here will be taken for all future research.

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your biospecimens can be found in this consent document under the heading *What happens to Data and Biospecimens that are collected in the study?*.

Will you allow us to store the biospecimens which are the swabs that we collect for this study for use in future research?

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

How long will you be in the study?
You will be in this study for just over 6 months. This will include your baseline screening visit, baseline follow-up, your treatment period of 7 days, visit 1 (post treatment) followed by a follow up period of 6 months.

Timeline for Study Data Collection and Assessments for all participants

	Baseline Screening	Results Follow-up	Treatment Initiation	Visit 1	Phone	Visit 2	Phone	Visit 3
Data to be collected	Screening and Consent			Post-Treatment MRSA Screening	check-in	3 month	check-in	6 month
Full Risk Factor Questionnaire	X							
Abbreviated Risk Factor Questionnaire						X		X
MRSA Screening	X			X		X		X
Molecular Evaluation	X							X
Telephone contact	X (with family)	X (with family)			X		X	
Begin MRSA Soap/Antibiotics			X					

4. What are the risks or discomforts of the study?

The risks for this study are minimal; however, you do not require treatment for MRSA colonization. If you do nothing, you and your family, may live the remainder of your lives without an MRSA infection. If you have a history of MRSA infection, this could reduce your chance of repeat infection, but that is not guaranteed.

Risk of Obtaining the MRSA Swabs:
There is a very small risk of bleeding associated with swabbing mucosal membranes; however, our institution has a long standing history of obtaining nares surveillance cultures for MRSA without any reported adverse events. All swabs will be collected in a private exam room if at the hospital or in an appropriate area in the home. A female chaperone will be present at all times when specimens are being obtained from a female patient by a male clinician as is the standard in our clinic during gynecologic evaluations.

Risk with Study Medications and Soaps/Oral Rinse:
Allergic reactions to mupiricin ointment and/or chlorhexidine soap or oral rinse are rare. Patients with a known allergy will be excluded from the study. All agents are FDA cleared for the purposes used in this study. Below you will find a detailed listing of possible side effects.

Mupiricin Ointment:
Local adverse effects may be associated with mupirocin application in the nose. Mupirocin ointment or cream may commonly cause a sensation of itching, pain, stinging, and burning. Local effects from the nasal cream have included minor nose bleeding, runny nose, brief changes in taste, dry mouth, sore throat, burning, and cough. Stomach side effects may include nausea, abdominal pain, and diarrhea. Nervous system side effects associated with intranasal mupirocin have included headache. Dizziness has been reported with mupirocin ointment. Ocular side effects associated with mupirocin nasal ointment have included a possible inflammation in the eye.

Chlorhexidine gluconate Oral Rinse Possible Adverse Effects:
Oral irritation and local allergy-type symptoms have been reported as side effects associated with use of Chlorhexidine gluconate rinse. The following oral side effects were reported during adult clinical trails: painful ulcers, infection of the gums, trauma, redness, peeling of skin in your mouth, coated tongue, changes in tongue texture. Each occurred at a frequency of less than 1% (1 out of 100). Among post marketing reports, the most frequently reported oral mucosal symptoms associated with Chlorhexidine gluconate oral rinse are swelling and possible pain/inflammation in tongue and gums, ulcer, dry mouth, swelling of tongue, and numbness of mouth. Minor irritation and superficial peeling of skin of the oral mucosa have been noted in patients using Chlorhexidine gluconate oral rinse.

Chlorhexidine gluconate (Hibiclens) Topical Soap Possible Adverse Effects:
The soap may cause burning and dryness of the skin. It may cause burning of the eyes. Skin erythema and roughness, dryness, sensitization, allergic reactions are possible, but rare.

Interviews/Questionnaires:
You may get tired or bored when we are asking you questions or when you are completing questionnaires. You do not have to answer any question you do not want to answer. To protect the privacy of each individual family member, all interviews and questionnaires of the family will be conducted privately.

Home Visit:
If, as part of the study, we visit your home, Maryland law requires us to tell the local or state authorities if we suspect abuse or neglect of a child or dependent adult. If you tell us that you plan to harm someone, we are required to contact the police. We may also warn the person who is at risk.

5. Are there risks related to pregnancy?

Pregnant women are not eligible to participate in this study. Please tell us if you are pregnant or believe you may be pregnant. Please inform us if you become pregnant while participating in this study. While it is not expected, this research may hurt an embryo or fetus in ways we do not currently know.

6. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. If you take part in this study, you may help others in the future and will improve our understanding of how to prevent MRSA transmission in families.

7. What are your options if you do not want to be in the study?

If you decide not to join this study, other options are available. You do not have to join this study to get treatment. You can speak with your medical provider to discuss each of the options available to you in this study.

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet.

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).

- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

9. Will you be paid if you join this study?

You will receive a $25.00 gift card completing the treatment course and a $25.00 gift card at the end of the study. One gift card of $50 will be available for the household after completing treatment and $50.00 gift card at the completion of the study if you are assigned to the household/sex partner treatment group only. If you are assigned to the individual group arm of the study, your household/sex partners will be offered free screening but they will not receive any payment for the study.

You may be required to provide your Social Security number to be paid. If your payment for study participation exceeds $600 per year, this information must be reported to the Internal Revenue Service.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities**.**

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities**.**

12. How will your privacy be protected?

Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Hopkins who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

The use and disclosure of your information has no time limit. You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other healthcare providers. You will be asked to give us a list of other health care providers that you used.

14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

By signing this form you will not give up any rights you have to seek compensation for injury.

15. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?
Call the principal investigator, Dr. Jason Farley at 410-502-7563. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?
If you think you are injured or ill because of this study, call Dr. Jason Farley at 410-502-7563 (office line) or 443-326-5759 (clinic line) during regular office hours.

If you have an <u>urgent</u> medical problem related to your taking part in this study, call Dr. Jason Farley at 443-326-5759 during regular office hours and at 410-258-4506 (cell phone) after hours and on weekends.

d. What happens to Data and Biospecimens that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data, tissue, blood and specimens collected from you during this study are important to both this study and to future research.

If you join this study:

- You will not own the data, or the tissue, blood, or other specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research may study your data and the tissue, blood or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.
- If data, tissue, blood or other specimens are in a form that we believe does not identify you, they may be shared with other academic medical centers, non-profit organizations, corporate sponsors and other commercial companies without your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea.

16. Assent Statement

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

17. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time

NOTE: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

Informed Consent Family Cover Page

Title: **S**top Comm**u**nity MR**S**A Colonizat**i**on **A**mong Pat**ie**n**t**s (SUSTAIN)

ICF Date: 8/5/2014

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RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

FAMILY – HOUSEHOLD MEMBER – PARTNER CONSENT – TREATMENT ARM

Protocol Title: **Stop Community MRSA Colonization among Patients (SUSTAIN)**

Application No.: **NA_00079147**

Sponsor: **Robert Wood Johnson Foundation**

Principal Investigator: **Jason E. Farley, PhD, MPH, NP, FAAN**
525 N. Wolfe Street, Room 525
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- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- For clinical trials: A description of this clinical trial will be available at www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time.
- If you have clinical tests done as part of this research study, a statement will be added to your medical record that you are in this research study. Results from any clinical tests you have will be included in your medical record. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
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1) First, we want to find a way to prevent MRSA infections in outpatient settings. By asking questions, we want to look at the things that may increase the risk of having this type of bacteria in you and your family members.
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2) Allow us to look at the electronic or paper medical chart, if part of the Johns Hopkins Medical Institutions. This will include evaluating your medication, prior laboratory studies and past clinician visits.
3) Allow us to collect:
   - If you are an adult over 18, a cotton swab of your nose, throat, groin (area between genitals and rectum), the rectum, and the vagina (for women). A single new swab is placed in each location and rotated in a circle to pick up cells.

- Male and female children, under the age of 18 will receive a swab of their nose, throat and rectum only.
- All participants, regardless of age will receive a cotton swab of any open or draining skin bump or wound.

Cotton swabs will be processed at the Johns Hopkins Hospital laboratory for the presence of the MRSA bacteria.

We will notify each member of your household individually and will inform the adult participant about the status of children during the scheduled phone call after the enrollment visit. Once you have been screened, it usually takes about 48 hours after the MRSA test result reaches the lab to have the result.

If a wound is cultured and determined to be infected by MRSA, you and your primary medical provider will be notified of the result. If your family member has a wound, we will notify the person (or parent/legally authorized representative for a child). If the family member does not have a primary medical provider, we will provide details about clinic locations that would offer treatment for this infection.

- You have been assigned to the intervention part of this study. This includes use of antibiotics for the nose, if needed, and special soap for everyone who agrees to participate in your home.
- If you have an infection caused by MRSA, the study team will notify you and/or your treatment team or your healthcare provider who will determine the need for treatment of the infection.

How long will you be in the study?

You will be in this study for just over 6 months. This will include your baseline screening visit, baseline follow-up, your treatment period of 7 days, visit 1 (post treatment) followed by a follow up period of 6 months.

Timeline for Study Data Collection and Assessments for all participants

	Index Screening	Index Follow-up	Baseline Screening (Household)	Results Follow-up	Treatment Initiation	Visit 1	Phone	Visit 2	Phone	Visit 3
Data to be collected			Screening and Consent			Post-Treatment MRSA Screening	check-in	3 month	check-in	6 month
Full Risk Factor Questionnaire			X							
Abbreviated Risk Factor Questionnaire								X		X
MRSA Screening			X			X		X		X
Molecular Evaluation			X							X
Telephone contact				X			X		X	
Begin MRSA Soap/ Antibiotics					X					

Treatment regimen to remove MRSA colonization:
Everyone will receive mupiricin ointment for the nose twice daily for 7 days. Additionally, you will have chlorhexidine rinse for your throat twice daily for 7 days if you have MRSA in your throat. Everyone will be provided chlorhexidine soap to use in the bath/shower daily for 7 days. All of these treatments are used during the same 7 day period. You will be provided instruction sheets detailing how to use each of the treatment regimens. You will be rescreened for MRSA upon completion and, if positive, will receive an additional 7 days of MRSA treatment, followed by rescreening.

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As part of this research study, we would like to ask you to let us store your biospecimens, the MRSA bacteria, if found, and health information for future MRSA research. This may include, comparing the bacteria on your swab to bacteria from sexual partners or in patients from other local hospitals. The same rules and procedures to protect your privacy discussed here will be taken for all future research.

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your biospecimens can be found in this consent document under the heading *What happens to Data and Biospecimens that are collected in the study?*.

Will you allow us to store the biospecimens which are the swabs that we collect for this study for use in future research?

YES ☐ _____
Signature of Participant

No ☐ _____
Signature of Participant

4. What are the risks or discomforts of the study?

The risks for this study are minimal; however, you do not require treatment for MRSA colonization. If you do nothing, you and your family, may live the remainder of your lives without an MRSA infection. If you have a history of MRSA infection, this could reduce your chance of repeat infection, but that is not guaranteed.

Risk of Obtaining the MRSA Swabs:
There is a very small risk of bleeding associated with swabbing mucosal membranes; however, our institution has a long standing history of obtaining nares surveillance cultures for MRSA without any reported adverse events. All swabs will be collected in a private exam room if at the hospital or in an appropriate area in the home. A female chaperone will be present at all times when specimens are being obtained from a female patient by a male clinician as is the standard in our clinic during gynecologic evaluations.

Risk with Study Medications and Soaps/Oral Rinse:
Allergic reactions to mupiricin ointment and/or chlorhexidine soap or oral rinse are rare. Patients with known allergy will be excluded from the study. All agents are FDA cleared for the purposes used in this study. Below you will find a detailed listing of possible side effects.

Mupiricin Ointment:
Local adverse effects may be associated with mupirocin application in the nose. Mupirocin ointment or cream may commonly cause a sensation of itching, pain, stinging, and burning. Local effects from the nasal cream have included minor nose bleeding, runny nose, brief changes in taste, dry mouth, sore throat, burning, and cough. Stomach side effects may include nausea, abdominal pain, and diarrhea.

Nervous system side effects associated with intranasal mupirocin have included headache. Dizziness has been reported with mupirocin ointment. Ocular side effects associated with mupirocin nasal ointment have included a possible inflammation in the eye.

Chlorhexidine gluconate Oral Rinse Possible Adverse Effects:
Oral irritation and local allergy-type symptoms have been reported as side effects associated with use of Chlorhexidine gluconate rinse. The following oral side effects were reported during adult clinical trails: painful ulcers, infection of the gums, trauma, redness, peeling of skin in your mouth, coated tongue, changes in tongue texture. Each occurred at a frequency of less than 1% (1 out of 100). Among post marketing reports, the most frequently reported oral mucosal symptoms associated with Chlorhexidine gluconate oral rinse are swelling and possible pain/inflammation in tongue and gums, ulcer, dry mouth, swelling of tongue, and numbness of mouth. Minor irritation and superficial peeling of skin of the oral mucosa have been noted in patients using Chlorhexidine gluconate oral rinse.

Chlorhexidine gluconate (Hibiclens) Topical Soap Possible Adverse Effects:
The soap may cause burning and dryness of the skin. It may cause burning of the eyes. Skin erythema and roughness, dryness, sensitization, allergic reactions are possible, but rare.

Interviews/Questionnaires:
You may get tired or bored when we are asking you questions or when you are completing questionnaires. You do not have to answer any question you do not want to answer. To protect the privacy of each individual family member, all interviews and questionnaires of the family will be conducted privately.

Home Visit:
If, as part of the study, we visit your home, Maryland law requires us to tell the local or state authorities if we suspect abuse or neglect of a child or dependent adult. If you tell us that you plan to harm someone, we are required to contact the police. We may also warn the person who is at risk.

5. Are there risks related to pregnancy?

Pregnant women are not eligible to participate in this study. Please tell us if you are pregnant or believe you may be pregnant. Please inform us if you become pregnant while participating in this study. While it is not expected, this research may hurt an embryo or fetus in ways we do not currently know.

6. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. If you take part in this study, you may help others in the future and will improve our understanding of how to prevent MRSA transmission in families.

7. What are your options if you do not want to be in the study?

If you decide not to join this study, other options are available. You do not have to join this study to get treatment. You can speak with your medical provider to discuss each of the options available to you in this study.

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet.

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).

- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

9. Will you be paid if you join this study?

One gift card of $50.00 will be available for the household after completing the treatment and a $50.00 gift card at the completion of the study if you are assigned to the household/sex partner treatment group.

You may be required to provide your Social Security number to be paid. If your payment for study participation exceeds $600 per year, this information must be reported to the Internal Revenue Service.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

12. How will your privacy be protected?

Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and companies that sponsor the study.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Hopkins who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

The use and disclosure of your information has no time limit. You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other healthcare providers. You will be asked to give us a list of other health care providers that you used.

14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

By signing this form you will not give up any rights you have to seek compensation for injury.

15. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses

- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?
Call the principal investigator, Dr. Jason Farley at 410-502-7563. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?
If you think you are injured or ill because of this study, call Dr. Jason Farley at 410-502-7563 (office line) or 443-326-5759 (clinic line) during regular office hours.

If you have an <u>urgent</u> medical problem related to your taking part in this study, call Dr. Jason Farley at 443-326-5759 during regular office hours and at 410-258-4506 (cell phone) after hours and on weekends.

d. What happens to Data and Biospecimens that are collected in the study?
Johns Hopkins our research partners work to cure diseases. The biospecimens and/or data collected from you during this study are important to both this study and to future research.

If you join this study:
- You will not own the data, or the tissue, blood, or other specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research may study your data and the tissue, blood or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.
- If data, tissue, blood or other specimens are in a form that we believe does not identify you, they may be shared with other academic medical centers, non-profit organizations, corporate sponsors and other commercial companies without your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea.

16. Assent Statement

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

17. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time

_____

Signature of Legally Authorized Representative (LAR) for **ADULTS NOT CAPABLE of GIVING CONSENT** (*Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)* Date/Time

_____

Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker under Maryland Law) Date/Time

_____

Signature of Parent Date/Time

_____

Signature of Legally Authorized Representative (LAR) for **CHILD RESEARCH PARTICIPANT** Date/Time

_____

Description of LAR's authority under Maryland Law to act as surrogate health care decision-maker for child research participant (for example, Legal Guardian, court-ordered representative) Date/Time

_____

Signature of Parent #2 (required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study) Date/Time

_____

Signature of Child Participant (optional unless IRB required) Date/Time

_____

Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required) Date/Time

NOTE: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT;**
AND, IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.