CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND HIPAA AUTHORIZATION
ADULT

TITLE: Dalbavancin as an Option for Treatment of *S. aureus* Bacteremia (DOTS): A Phase 2b, Multicenter, Randomized, Open-Label, Assessor-Blinded Superiority Study to Compare the Efficacy and Safety of Dalbavancin to Standard of Care Antibiotic Therapy for the Completion of Treatment of Patients with Complicated *S. aureus* Bacteremia

PROTOCOL NO: 20-0002
WCG IRB Protocol # 20203500

SPONSOR: National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID)/Division of Microbiology and Infectious Diseases (DMID)

<<CF-Main Header Block - Investigator>>
STUDY RELATED PHONE NUMBER(S): <<CF-Main User Defined #1>>

Subject Initials _____

You are being asked to participate in a study that involves research. The purpose of this study is to compare an investigational study drug called dalbavancin to the current standard of care for treatment of bloodstream infections with a bacteria called *Staphylococcus aureus*. "Investigational" means that the study drug is currently being tested. It is not approved by the U.S. Food and Drug Administration (FDA) for the bloodstream infection that you currently have. The current standard of care is daily intravenous (IV, into a vein) administration of antibiotics that usually lasts from 4 to 6 weeks. Dalbavancin is an antibiotic that is being studied as an alternative treatment option because it is possible that 2 doses of dalbavancin might improve outcomes and offer the benefit of less frequent dosing.

You will have up to 6 total times that you will need to come in to see your doctor during this study. The total duration of this study could be up to approximately 77 days (11 weeks). Some subjects may be asked to participate for a total of approximately 6 months, if they have a condition called osteomyelitis (bone infection) at baseline, which means when you enroll in the study. You will be randomly assigned to one of the two groups noted above, the standard of care group or the dalbavancin group. You have equal chances of being in each group, like the flip of a coin. If you participate in this study, your vital signs will be measured, you will receive physical exams, have an echocardiogram, have blood draws, and receive IV antibiotics. You will also be asked questions about your medical history, medications you take, and how you are doing.

The more likely risks resulting from being in this study are nausea, vomiting, headache, diarrhea, rash, and localized itch. Less likely risks are flushing (red face), hives, anaphylactic reaction (severe allergic reaction), infusion-related reactions (flushing of the upper body, hives, itching, rash, and/or back pain, which are avoided or minimized by slowing or stopping the infusion), abnormal liver tests (which may indicate liver injury), or C. difficile diarrhea (a type of diarrhea which can be triggered by receipt of nearly any antibiotic).

Your participation in this study is voluntary, and your decision not to participate in this study will not involve any penalty or loss of benefits to which you are otherwise entitled and will not affect your access to health care at the study site. You will still receive treatment for your infection. If you choose to participate in this study, you can withdraw from it at any time for any reason. Your decision to withdraw from the study early will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you are signing for an adult who is not able to give consent to be in this study, "you" refers to you as the decision-maker and/or the individual being asked to participate in this research throughout this consent document.

If you are interested in learning more about this study, please continue to read below.

WHAT ARE SOME GENERAL THINGS TO KNOW ABOUT RESEARCH STUDIES?
You are being asked to take part in this research study because you have been diagnosed with a complicated *Staphylococcus aureus* bloodstream infection. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Refusal to participate will not involve any penalty or loss of benefits to which you are otherwise entitled; you will continue to receive care, just not in this study.

Please tell the study doctor or study staff if you are taking part in another research study.

WHO WILL PROVIDE FUNDING?
This study is being conducted by the Antibiotic Resistance Leadership Group (coordinated by Duke University), which is funded by a grant from the National Institutes of Health (NIH). Portions of the study doctor's salary and the study doctor's research staff's salaries are being paid by the NIH grant. <<CF-Main Financial Disclosure>>Allergan Pharmaceuticals, Inc., a subsidiary of AbbVie, will be responsible for providing the drug being studied, which is named dalbavancin.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, the principal investigator who is listed on the first page of this form will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to compare two treatment options for your *Staphylococcus aureus* bloodstream infection. The current standard of care treatment is 4 to 6 weeks of daily intravenous (IV) antibiotics, usually administered through a special type of long-term IV known as a PICC line (peripherally inserted central catheter). Dalbavancin is an antibiotic that is approved by the FDA for certain skin infections, but has not been approved for bacteremia (blood infections) and is considered investigational in this study. This study is being completed to see if only 2 doses of dalbavancin via IV administration will work as well or better than the current standard of care mentioned above. Because dalbavancin is cleared from the body much more slowly than many other antibiotics, just two doses may remain active in the bloodstream for the usual 4-6 weeks of treatment needed for *Staphylococcus aureus* bacteremia.

Staphylococcus aureus bloodstream infections are serious, and treatment failures could occur with either standard of care or with dalbavancin. Your physician will monitor you closely regardless of the treatment you receive to ensure you are responding appropriately. If at any point your physician feels that additional testing or treatment is needed, this will still be provided – regardless of which treatment group you are in.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 200 people will take part in this study at 20 different hospitals and medical facilities in the United States and Canada.

WHAT IS INVOLVED IN THE STUDY?
Your study doctor and/or staff has reviewed your medical records, and you are being invited to participate in this study because you may be eligible to enroll. If you agree to be in this study, you will be asked to sign and date this consent form. You will have the below tests and procedures done to make sure that you are eligible to enroll in the study.

- Physical exam and medical history review
- Vital signs
- Blood tests
- Pregnancy test (women who are able to become pregnant)
- Echocardiogram (ECHO) (if not performed already)

Participants in this study will be randomly assigned (like the flip of a coin) to the dalbavancin group or the standard of care group. There is a 50% chance you will receive dalbavancin. You will have up to 6 total times that you will need to come in to see your doctor during this study. If assigned to the dalbavancin group, you will receive 1 dose of IV antibiotic at Day 1 and 1 dose at Day 8. If you are assigned to the standard of care group, you will receive daily IV antibiotics for up to 6 weeks or until your infection has been cured. The entire duration of the study could last up to 77 days (11 weeks) as it includes a post treatment visit and a test of cure visit. If you are diagnosed with osteomyelitis (bone infection) when you enroll in the study (at baseline), you will also have an additional follow up visit 6 months following the start of the study. A complete description of study procedures is below along with a table so that you can understand when these procedures will take place.

- **Medical and Surgical History:** Your doctor will review your medical records including surgical history.
- **Medication History**: Your doctor will review your medication history for up to 60 days before the study, any medications you begin to take while on the study, and any non-drug treatments you begin while on the study.

- **Vital Signs**: Your doctor will measure your blood pressure, respiration rate, pulse rate and temperature.
- **Physical Exam**: Your doctor will review your general appearance, examine your head, eyes, ears, nose, throat, neck, skin, heart, lungs, abdomen, brain and nerve system, limbs, height, and weight.
- **Pregnancy Test:** If you are a female of child-bearing potential, you will be asked to take a pregnancy test.
- **Echocardiogram:** A painless test that uses sound waves to take pictures of your heart. This is performed only if it has not already been done as standard of care during this episode of illness.
- **Review of Side Effects**: Your doctor will discuss your current state and see if anything abnormal has happened to you recently.
- **Safety Blood Sampling**: All patients will require periodic safety blood draws. Safety blood counts and blood chemistries are routinely performed for patients on long-term antibiotics and will help your physician ensure you are responding to treatment while also monitoring for potential side effects.
- **Quality of Life (QoL) Surveys**: You will be asked a list of questions regarding your current quality of life from three surveys (ARLG Bloodstream Infection QoL Measure, EQ-5D-5L, and PROMIS Global Health Short Form), which will take about 15 minutes total to complete. The questions will be reviewed with you to make sure that you understand. These surveys will be completed if you are able.
- **Pharmacokinetic Blood Sampling**: For patients receiving dalbavancin, additional blood samples will be collected to help determine how long the antibiotic remains at effective levels in the bloodstream and whether this differs from person to person. These blood draws are called Pharmacokinetics (PK). The extra blood necessary for adequate PK sampling will be approximately 8 mL (about 2 teaspoons) at each draw. The dalbavancin levels will be used for research purposes only and will not alter your care in any way. A schedule of the PK draws is below. If you receive dalbavancin, you will have 9 samples drawn during the study, 5 of which will be at your baseline (Day 1) visit. If your participation in the study ends early, you will have a sample drawn at the early termination visit. The timing of the PK samples is as follows: at Day 1 (1) prior to dose, (2) at end of dose + 10 minutes, (3) 6 ± 2 hours post end of dose, (4) 12 ± 4 hours post end of dose, (5) 24 ± 6 hours post end of dose, (6) Day 8 prior to 2nd dose, (7) Day 22 ± 2 days at the time of clinic visit, (8) Day 42 ± 3 days, (9) Day 70 ± 7 days, or with any early termination visit.
- **IV Antibiotic Therapy:** How the antibiotics will be administered remains up to your treating physician. In general, current standard of care requires a special type of longer-term IV known as a PICC line (peripherally inserted central catheter). While the PICC line still enters a vein in the arm, the tip of the catheter ends in a larger vein within the chest – allowing antibiotics to be safely delivered for a longer period of time. PICC lines are usually placed by a specialized nursing

team in the hospital or clinic. Either home health nurses or infusion clinic nurses assist with caring for the line – including weekly dressing changes – and will remove the line when treatment is complete. Your medical team will provide contact information on whom to contact if there are any issues with your PICC line (generally your home health nursing team).

For patients receiving dalbavancin, the body clears this antibiotic much more slowly – meaning that just two total doses may last long enough in the blood stream to complete the whole course of treatment without needing a PICC line or repeated dosing. Patients receiving dalbavancin will likely only require a temporary peripheral IV, which is the standard type of venous access most hospitalized patients receive. For patients receiving dalbavancin while hospitalized, it can likely be given through an existing IV. For patients receiving any of their doses after discharge, this will usually be done at either an infusion clinic or by home nursing staff where nurses can place a temporary IV. The temporary IV can then be removed once the dose is complete.

Table 1: Summary of Study Procedures at Each Visit

Visit	Medical History	Surgical History	Medication Review	Vital Signs	Physical Exam	Echocardiogram	Side Effects	Quality of Life Surveys	Safety Blood Draw	*PK Blood Draw	IV Antibiotic Therapy	Pregnancy Test
Screening (Visit 1)	X	X	X	X	X	X			X			X
Baseline (Visit 2)	X	X	X	X	X		X	X		X	X	
Day 8 (Visit 3)			X	X	X		X	X	X****	X	X	
Day 22 (Visit 4)			X	X	X		X	X	X	X	X***	
Day 42 (Visit 5)	X	X	X	X	X		X	X	X	X	X***	
Day 70 (Visit 6)	X	X	X	X	X		X	X		X		
**6-Month FU (Visit 7)			X	X	X			X				
Early Termination	X	X	X	X	X		X	X		X		

* only if you are randomized to the Dalbavancin group

**visit only take place if you are diagnosed with osteomyelitis (bone infection) at baseline
***only if you are randomized to the Standard of Care arm
****a safety blood draw to check your kidney function will be required within the 72 hours prior to the second (Day 8) dalbavancin dose

Early Termination Visit: If you decide to end your participation in this study, we ask that you return for a final visit. This visit is also required if your doctor decides to end your participation in this study. If your doctor finds anything that is abnormal or significant, you will be followed until the condition has gotten better or until your condition is stable.

Blood Draws: As described in the table above, there are two types of blood samples on this study—safety and pharmacokinetic. While the amount of blood drawn will depend on your medical office and which treatment arm you are in, below are the estimated *maximum* amounts of blood that may be drawn at each visit:

- Screening (Visit 1): 17 mL or about 3 teaspoons
- Baseline (Visit 2): 40 mL or about 8 teaspoons
- Day 8 (Visit 3): 12 mL or about 2 teaspoons
- Day 22 (Visit 4): 17 mL or about 3 teaspoons
- Day 42 (Visit 5): 17 mL or about 3 teaspoons
- Day 70 (Visit 6): 8 mL or about 2 teaspoons
- 6-Month FU, *if needed* (Visit 7): None
- Early Termination: 8 mL or about 2 teaspoons

HOW LONG WILL I BE IN THIS STUDY?

You will be in this study for up to approximately 77 days (11 weeks), but if you are diagnosed with osteomyelitis at baseline, you will also have one additional follow up at 6 months from your start date of this study. You can choose to stop participating at any time without penalty or loss of any benefits to which you are otherwise entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider, if you choose.

Dalbavancin

Dalbavancin may cause some, all, or none of the side effects listed here. More likely to occur are nausea, vomiting, headache, diarrhea, rash (face/neck/torso), and localized

itch. The risks that are less likely to occur are flushing (red in the face), hives, anaphylactic reaction (severe allergic reaction), infusion-related reactions (flushing of the upper body, hives, itching, rash, and/or back pain, which are avoided or minimized by slowing or stopping the infusion), abnormal liver tests (which may indicate liver injury), or C. difficile diarrhea (a type of diarrhea which can be triggered by receipt of nearly any antibiotic). Your treating physician will manage any potential side effects, if they occur.

Standard of Care Therapies
For patients randomized to the standard of care group, antibiotic therapy will be chosen by your treating clinician in agreement with the study doctor. All of the standard of care antibiotic therapies are commonly used for treatment of *S. aureus* bacteremia and consist of the treatment you would receive if you did not participate in the study. Risks of the standard of care treatments will depend on exactly which treatment is chosen by your treating clinician and your study physician, but could include: allergic reactions (including anaphylaxis, a life-threatening allergic reaction), localized reactions such as skin changes and swelling in the vein, kidney abnormalities including kidney failure, gastrointestinal problems like diarrhea, nausea, and anorexia, *C. difficile* diarrhea, blood changes including low levels of blood cells (e.g. neutrophils, platelets), and worsening of liver function that generally resolves when treatment is stopped. In addition to these, two of the standard of care antibiotics—nafcillin and oxacillin—can rarely cause a dangerously low number of white blood cells. One of the standard of care antibiotics, vancomycin, can cause a variety of skin reactions (including rashes and flushing), infusion site reactions (pain, tenderness, and even necrosis [death of skin tissue]), and hearing damage including hearing loss and tinnitus (ringing in the ears).

You should discuss these treatment options and risks with the study doctor and your regular health care provider, including how these risks are similar to or different from your treatment options if you choose not to participate in the study.

Pregnancy Risks: Female Contraception
The effects of dalbavancin or of the standard of care antibiotics on a developing pregnancy or breastfeeding infant are unknown. To reduce the risk of any harmful effects, women who are pregnant or breastfeeding are not allowed to participate in studies using dalbavancin. Women of childbearing potential must agree to use an effective method of contraception for the duration of the trial. Acceptable methods of birth control (contraception) during the study are as follows:

- Non-male sexual relationships only
- Abstinence from sexual intercourse with a male partner
- Monogamous relationship with vasectomized partner who has been vasectomized for at least 180 days before receiving the first dose of study drug
- Barrier methods such as condoms or diaphragms

- Effective intrauterine devices (IUD)
- NuvaRing®
- Licensed hormonal methods such as implants, injectables, and oral contraceptives

If you think you may be pregnant or are no longer able to properly use birth control, you must notify the study doctor as soon as possible. If you become pregnant, this will require you to stop participating in the study or discontinue study product. The study doctor may ask for information about the pregnancy and the birth of the child and follow up visit(s) may be needed for safety assessments. The study doctor may share this information with the Sponsor and the Institutional Review Board (IRB). To confirm that you are not pregnant, you must agree to have a pregnancy test done before beginning this research study.

Risks of PICC Line/IV Catheter Placement
The risks associated with peripheral (arms, legs, hands, feet) IV placement are minimal and include minor bruising/bleeding, localized discomfort at the site, and rarely infection or a superficial clot.

The risks associated with peripherally inserted central venous catheters (PICC lines) or central lines include bleeding, discomfort at the site, deep venous thrombosis (blood clot), infection, and rarely nerve injury or an irregular heartbeat.

Risks of Drawing Blood
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

ECHO Discomforts
Cold gel used for probe and slight pressure may be experienced

Other Risks
There may be risks, discomforts, drug interactions, and side effects that are not yet known.

WILL I BE TOLD ABOUT NEW INFORMATION THAT MAY AFFECT MY DECISION TO PARTICIPATE?
If new findings come up that might change your decision to be in this study, you will be given information about those findings as soon as possible. If you choose to remain in the study, you may be asked to sign a new version of this consent form.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

The benefits of dalbavancin as treatment for this condition are unknown. If you receive dalbavancin and it is effective for you, it may offer a potential alternative treatment option, which would eliminate the need for indwelling central venous access (meaning not using a catheter that would normally remain in your arm for 4-6 weeks) and its potential complications as well as reducing the frequency and number of dosings (meaning you could potentially clear your infection with fewer antibiotic doses and fewer overall lab draws). Your participation will provide information about the study drug. This might benefit others in the future.

ALTERNATIVES IF YOU DO NOT PARTICIPATE IN THE STUDY?

Your decision not to participate in this study will not involve any penalty or loss of benefits to which you are otherwise entitled and will not affect your access to health care at the study site. You will still receive treatment for your infection. If you decide not to take part in this study, there are other alternatives of antibiotics approved for complicated staphylococcal blood infections, including those in the 'standard of care' arm of this study. Your study doctor will discuss these options, and their risks and benefits, with you.

CONFIDENTIALITY

Purpose for Collecting Protected Health Information

If you sign this form and join in this study, you are giving permission for your health information to be collected, used, and disclosed as described in this consent form. The study site and all physicians and health care providers, nurses, scientists, and other hospital staff including the study doctor involved in this study (collectively the "Research Staff") will use this information to find out the benefits or risks of dalbavancin. Your identifiable health information (also called Protected Health Information) is protected by law, including the Health Insurance Portability and Accountability Act (HIPPA). By signing this consent form, you give permission for your Protected Health Information to be collected, used, and disclosed in the U.S. and outside the U.S. for research involving dalbavancin and for other purposes described in this consent.

The information that will be collected could be a part of your medical record filed at the study site. To maintain the integrity of this research study, you generally will not have access to your Protected Health Information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to your health information that the study site maintains in a designated record set, which means a set of data that includes medical or billing records or other records used in whole or in part by your doctors or other health care providers at the study site to make decisions about you. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by the study site. If it

is necessary for your care, your health information will be provided to you or your doctor.

Your agreement to allow the study site and the Research Staff to use and disclose (release) your information begins when you sign this document.

If you do not withdraw this Authorization, it will remain in effect.

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin this authorization will expire on 31Dec2070.

There is no expiration of this authorization except for research conducted in the states listed above.

Information collected from you, as part of this research, will have your identifying information removed after the research study ends. This de-identified information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Information to be Collected, Used, and Disclosed
You will be assigned a code number, and your Protected Health Information will be associated with that number and not your name or other identifying information for this study to ensure confidentiality. Your Protected Health Information will be collected, used, and disclosed for this study. This information includes, but is not limited to the following:

- Laboratory results from blood samples
- Any medications you are taking
- Your medical history
- Your demographics, such as whether you are male or female, your race, etc.
- Results of your physical examinations
- Vital signs, such as blood pressure, heart rate, respiratory rate, temperature, height, and weight
- Results of any pregnancy tests
- Any changes in your medical condition or problems that you may have
- Details about any doctor or hospital visits you have while on the study
- Medical records (from any doctor, hospital or other healthcare provider)

Except when required by law, you will not be identified by name, address, telephone number or other facts that could identify the health information as yours.

How Protected Information will be Used and Disclosed

The study site and the research staff will use and disclose your Protected Health Information to treat you and for research purposes. Medical information about you will be combined with information about other people in the study. This study information will be used to learn about the study drug, prepare research publications, make submissions to government agencies, monitor your safety and the safety of others participating in the study, and as otherwise permitted by law.

You should know that by signing this form, you are also giving permission for the entities and persons listed below to see your Protected Health Information that is disclosed under this consent form. This makes it possible for your safety to be ensured, for the research procedures and result of the study to be verified as reliable, to ensure that the study is being run properly, to report adverse events (negative effects of the study drug or other drugs), and to locate you as necessary to follow up on your condition. To the extent that the law allows, your original health information or copies may be given to, used by, and/or shared by the following groups:

- Any health care providers, professionals, or agencies who have provided you with health services or treatment, such as physicians, clinics, hospitals, home health agencies, diagnostic centers, laboratories, treatment, or surgical centers or government health agencies
- Any agencies that provide payment for health care, such as insurers or government agencies
- Investigators listed on this consent form as well as the supporting research team
- The Institutional Review Board (IRB), which is responsible for reviewing studies to protect research participants. The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects.<<CF-Main SMO Company 1>><<CF-Main Affiliated IN Language 1>>
- Duke Clinical Research Institute, the research organization that is managing this study, and their collaborators
- National Regulatory Agencies such as The U.S. Food and Drug Administration (FDA) and Health Canada
- The U.S. Department of Health and Human Services (DHHS) and/or the National Institute of Health (NIH) and their representatives
- Allergan Pharmaceuticals, Inc., a subsidiary of AbbVie

A description of this clinical trial will be available on *http://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 this Web site at any time.

Your health information may be further shared by the groups above. If shared by them, the information will no longer be covered by this Authorization. Those persons who receive your health information may not be required by federal privacy laws (such as HIPPA Privacy Rule) or state law to protect it and may share your information with others without your permission, if permitted by laws governing them; however, it is possible to use or share your information in a way that will not identify you or anyone else individually in the study. If the results of this study are made public, information that identifies you individually will not be used.

You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

You may withdraw your permission to use and disclose your health information at any time. You can do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in the research study.

Information that has already been gathered may still be used and given to others. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

HOW WILL MY PRIVACY BE PROTECTED?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out, if required by law.

As part of the study, results of your study-related laboratory tests and procedures may be reported to the Division of Microbiology and Infectious Diseases (DMID) at National Institute of Allergy and Infectious Disease (NIAID) and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from national regulatory agencies (e.g. the FDA), representatives and affiliates of the Division of Microbiology and Infectious Diseases (DMID) at National Institute of Allergy and Infectious Disease (NIAID), the IRB, and

others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

A copy of this consent form will go in to your medical record. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

- there is a law that requires disclosure (such as to report child abuse or communicable diseases. but not for legal proceedings);
- you have consented to the disclosure, including for your medical treatment; or
- the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least two years after the study is completed. At that time, either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at the study site. Any research information in your medical record will be kept indefinitely.

Some information collected in research studies is maintained in your medical record. However, for this study, that information will be inaccessible until the end of the study, unless your physician(s) decide that it is necessary for your care.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name and other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of the study site, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO ME IF I PARTICIPATE IN THIS STUDY?
There are no additional costs to you for participating in this study. Neither you nor your insurance company will be billed for dalbavancin (if assigned to the dalbavancin treatment group) or any of the additional labs requested as part of this study. You or your insurance company will have to pay for routine care you would receive whether or not you are in the study. This includes the antibiotics prescribed if you are randomized to standard of care. You may wish to contact your insurance representative and study doctor to discuss costs further before making your decision about participating in the study.

WILL I BE COMPENSATED FOR MY PARTICIPATION?
You will be reimbursed $XX for each completed study visit for your expenses related to your participation (parking, gas, and time). Your study doctor or staff will go over the reimbursement process and other patient travel management services available to you.

OR You will not receive any payment for taking part in this research study.

<<CF-Main Payment for Part. Paragraph>>

WHAT IF I AM INJURED WHILE PARTICIPATING?
If you are injured or get sick because of being in this research, call the study doctor immediately. Immediate necessary medical care is available at the study site in the event that you are injured as a result of your participation in this research study. Your study doctor will treat you or refer you for treatment. However, there is no obligation by Duke University (including its Duke Clinical Research Institute), the study site, or your physician to provide monetary payment or free medical care to you in the event of a study-related injury. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government.

For questions about the study or research-related injury, contact the study doctor at the phone number(s) listed on the first page of this form.

By agreeing to participate in this study, you do not waive any of your legal rights.

WHAT IF I WANT TO STOP BEFORE MY PART IN THE STUDY IS COMPLETE?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are otherwise entitled and will not affect your access to health care at the study site. If you do decide to withdraw, we ask that you contact the study doctor and let him/her know that you are withdrawing from the study. If you do decide to withdraw from the study, the study doctor may ask you to return for an early termination visit before you stop your study drug if he/she thinks that stopping the drug suddenly may harm you. He/she may also request, with your permission, to complete the tests at the early termination visit that would ordinarily occur when a person completes the study.

Your study doctor or sponsor may decide to take you off this study without your consent if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. Reasons why this might occur include, but are not limited to: you no longer meet eligibility criteria, noncompliance with study procedures, or safety concerns. The sponsor or regulatory agencies, such as the FDA may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

RESPONSIBILITIES
If you decide to take part in this study, it is important that you agree to:

- Truthfully answer any questions from your study doctor or the study staff when asked about any changes in your health, or changes in your medication, including prescribed medications, over the counter medications, and herbal remedies.
- Speak with your study doctor before taking part in any other clinical trial. Tell your study doctor or research study staff if you change your mind about taking part in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact the study doctor or research team at the phone number(s) listed on the first page of this form.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at by phone at 1-855-818-2289 or Researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

STATEMENT OF CONSENT

The purpose of this study, the procedures to be followed and the study's risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have bene answered to my satisfaction. I have been told whom to contact if I have questions, to talk about problems, concerns, or suggestions related to the research or to obtain information or offer input about the research. I have read this consent form (or it has been read to me), and I agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form and that a copy of this form will become part of my medical record <<CF-Main California Bill of Rights>>.

I authorize the use and disclosure of health information from my medical record to the people or groups identified in this consent form for the purposes described in this document.

_____

Signature of Subject Date Time

_____

Printed Name of Subject

_____

Signature of Legal Authorized Representative Date Time

_____

Printed Name of Legal Authorized Representative (LAR)

_____

Relationship to Subject

PERSON EXPLAINING CONSENT STATEMENT:
You have carefully explained to the subject or LAR the nature and purpose of the above study, in language he/she understood. The subject or LAR signing this consent form has been given adequate time and a place to read and review this consent form; been given the opportunity to ask questions regarding the nature, risks and benefits of participation in this research study; and appears to understand the purpose of the study and the demands required of participation.

_____

Signature of Person Obtaining Consent Date Time

_____

Printed Name of Person Obtaining Consent

Consent to Continue Participation
(For Subjects who previously could not consent for themselves but have regained capacity to consent).

Previously, you could not legally agree to take part in research. You took part in research based on the permission of someone else. Now that you can consent for yourself, you are being asked for your consent to continue to take part. Please read the entire consent form and HIPAA Authorization before signing below.

Your signature documents your consent to take part in this research.

_____
Printed Name of adult subject capable of consent

_____ _____
Signature of adult subject capable of consent Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

<<CF-Main California HIPAA>>

CALIFORNIA HIPAA AUTHORIZATION

****This HIPAA section will be for sites that are only located in CA****

In this consent form "you" generally refers to the research subject.

Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study doctor must obtain your authorization (permission) to use or release any health information that might identify you.

What information may be used and shared?
The study doctor and study staff will use and share your health information as part of this research study. Except when required by law, you will not be identified by name, address, telephone number or other facts that could identify the health information as yours.

Examples of the information that may be used are:

- Medical records (from any doctor, hospital or other healthcare provider)
- Information created or collected during the research. This could include your medical history, and dates or results from any physical exams, laboratory tests or other tests.

Who will receive information about you?
The study doctor and study staff will share your personal health information with:

- the sponsor, including persons or companies working for or with the sponsor
- the Institutional Review Board (IRB)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- other regulatory agencies

Why will this information be used and/or given to others?
The sponsor and the groups above will use your health information:

- to complete this research
- to evaluate the results of the study
- to check that the study is being done properly
- to obtain marketing approval for new products resulting from this research

Is my health information protected after it has been given to others?
Your health information may be further shared by the groups above. If shared by them, the information will no longer be covered by this Authorization. These groups are committed to keeping your health information confidential.

What if I decide not to allow the use of my health information?
You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

May I withdraw or revoke (cancel) my permission?
YES. You may withdraw your permission to use and disclose your health information at any time. You can do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in the research study.

What happens if I want to withdraw my authorization?
Information that has already been gathered may still be used and given to others. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

Will my authorization expire?
This Authorization will expire December 31, 2070, unless you withdraw it in writing before then.

May I review or copy the information obtained or created about me?
YES. You have the right to review and copy your health information. However, your access to this information may be delayed until the study is complete.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

AUTHORIZATION
By signing this form, I allow the use or disclosure of my health information. I will receive a signed and dated copy of this Authorization.

Printed Name of Subject

Signature of Subject **Date**

I certify that I am the legally authorized representative of the subject named above. I am permitted under state law to sign this form on behalf of the subject.

Printed Name of Legally Authorized Representative (LAR)

Signature of Legally Authorized Representative **Date**