



INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Study Title:	Assessing Implant-Related Biofilm Microbiome in Primary Anterior Cervical Fusion Patients		
Protocol No:		Sponsor:	HSS
Principal Investigator:	Frank Cammisa, Jr., MD	Phone Number:	212-606-1946
Research Coordinator:	Philip Paschal, MS	Coordinator Contact:	917-260-4285
IRB #	2023-1514	Funding Support from:	HSS

Participating Site(s)	Location	Participating Investigator	Site Phone Number
HSS Main Campus	East Side, NY	Frank Cammisa, Jr., MD., Darren Lebl, MD., Andrew Sama, MD.	212-606-1946, 212-606-1052, 212-606-1946,

Hospital for Special Surgery
535 East 70th Street
New York, NY 10021

When we use the term “HSS” in this consent, that refers to Hospital for Special Surgery and its affiliates, including HSS-Florida Physicians LLC.

1. OVERVIEW OF KEY INFORMATION REGARDING THIS RESEARCH STUDY.

You are being asked to take part in a research study conducted by Hospital for Special Surgery (HSS). You are being asked to participate in this study because you are about to undergo cervical fusion surgery. The information in this form is meant to help you decide whether or not to participate in this research study.

- Your **participation is voluntary**.
- You may decide not to participate in this research study.
- If you do participate, you may withdraw from the research study at any time.
- You do not have to participate in this study to receive treatment for your condition.

This document provides you with information about this study, including:

- Information about the procedures and the research, including risks, benefits, and alternatives, so you can make an informed decision about participating.
- Description of how your information will be used and shared.

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Ask your study doctor or study staff to explain any words or information in this document that you do not understand. You may take home a copy of this document to consider or discuss with family and friends before making your decision. You will need to sign this document to participate in this research.

Funding for this study will be provided by HSS.

A. DOES THIS STUDY INVOLVE GENETIC TESTING OF YOUR BIOLOGICAL SAMPLES?

☐ No, there is no genetic testing of your biological samples involved with this Study.

☒ Yes, the Study involves genetic testing of your biological samples.

(If yes, please see Section 4 below for more information regarding genetic testing of your samples.)

B. WHY IS THIS STUDY BEING DONE?

The purpose of this study is to better understand the presence of bacteria in cervical spine surgery, using next-generation sequencing to identify bacteria in fluid samples. A total of 76 subjects will participate in this study at HSS.

HSS may use the results of the study to gain scientific knowledge, as described in Section 1(E) of this document, including a more comprehensive analysis of the bacteria present in tissue in the surgical site.

C. YOUR INVOLVEMENT:

- Four visits are required by you over the next 24 months.
- Visits may occur at HSS main campus or satellite site(s) listed on page 1.
- Each of these visits may take up to 1 hour. These visits are standard-of-care and not extra visits.
- Procedures will include anterior cervical discectomy and fusion.
- This surgery is standard of care even if you do not choose to participate in the research study.
- We will draw blood (approximately one teaspoon) during your cervical surgery.
- Please see the chart listed in Section 2 below for additional information.

Your responsibilities as a participant in this study include:

- Signing this informed consent form;
- Following all study rules;
- Telling the study doctor truthfully about your complete medical history and other medications and supplements you are taking;
- Reporting any new problems, illnesses, or changes in medication during the study;
- Following the instructions of the study doctor and staff, including attending all your scheduled visits

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- Telling other doctors, nurses, and health care providers who provide treatment to you about your participation in this study; and
- Refraining from participating in any other studies while you are participating in this study unless your first notify your study doctor and discuss with your study doctor any potential risks posed by participation in more than one study.
- Your participation in this study may be terminated early by HSS. This may happen for reasons such as: it is determined that you no longer meet the eligibility criteria to participate, you fail to follow the instructions given to you, or if HSS decide[s] to end the study early.

D. MOST COMMON POSSIBLE RISKS AND DISCOMFORTS ASSOCIATED WITH YOUR PARTICIPATION IN THE RESEARCH STUDY:

All research has some risk, which may include some side effects that make you feel unwell or uncomfortable or that could harm you. Ask the study doctor or staff if you have any questions about the risks or discomforts that may occur during this study.

During the study, you may have risks, discomforts and side effects from the study procedures. Most of these are listed in this informed consent form. Risks, discomforts and side effects may vary from person to person. Everyone taking part in the study will be watched carefully; however, doctors do not know all the risks, discomforts and side effects that may happen. These may be mild or serious, and in some cases may be very serious, long-lasting, or may never go away. Your condition may or may not get worse from being in this study. If we learn about new risks that may affect your willingness to continue your participation, we will make you aware of them and you will be asked to re-consent to continue your participation in the study.

Let your study doctor know immediately if you experience any side effects or other health issues. Ask your study doctor to explain any side effects that you do not understand. If your side effects are severe, your study doctor may advise you to withdraw from the study.

Possible risks, discomforts and side effects that you may experience include:

Intraoperative blood draws could increase the risk of more bleeding during your surgery, increase risk of infection, and potential damage nearby nerves or tissue. Intraoperative blood draws can also lead to various side effects, including minor bruising at the needle insertion site, which is common, although large bruises are less frequent. Some bleeding at the insertion site and subsequent soreness may also occur. Lightheadedness or dizziness can affect some individuals, particularly after blood donation. Additionally, skin irritation from adhesive bandages may develop, potentially leading to a rash. There is also a possibility of a temporary drop in heart rate or blood pressure, which may be accompanied by sweating and paleness. These side effects, while generally mild and transient, will be monitored to ensure patient safety as this is a standard risk for all surgical procedures.

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Additionally, there will be an approximate 3-5 minute delay in procedure in the OR for the sample draw which will include anesthesia. Prolonged anesthesia, even for a few minutes, can increase the risk of complications such as respiratory issues, hemodynamic instability, and an increased likelihood of postoperative nausea and vomiting. 3-5 minute delays in operative time are a standard risk for all surgical procedures. There are no other additional risks associated with this study beyond those you would encounter as part of your surgery. Your surgeon will discuss these with you prior to surgery.

Participation in this research involves the potential risk of a breach of confidentiality to your stored health information. HSS tries to minimize those risks by (i) removing some direct identifiers from stored information (i.e., names, social security numbers, medical record numbers); (ii) securing, in a separate location, and limiting access to information that would identify you; and (iii) limiting access to information stored to HSS investigators.

The collection of microbiologic data in this study presents several potential risks, including contamination during sample handling, which could lead to false positives, and improper sample collection resulting in false negatives. There is also a risk of infection to patients during sample collection, and delays in culture results may affect timely diagnosis and treatment. Additionally, discordant results between different methodologies, sample degradation during transport, and data privacy concerns further emphasize the need for strict adherence to protocols to mitigate these risks.

There may be some risks associated with genetic testing that may be performed on your biosample. This can include a breach of private health information. These risks are described more in depth in Section of the document entitled “GENETIC TESTING”.

E. BENEFITS OF PARTICIPATING IN THE RESEARCH STUDY:

Participants will have enhanced testing, which may improve their clinical outcomes by identifying the presence of bacteria more accurately. Understanding the bacteria present in the patient’s tissues can help physicians manage negative symptoms more effectively after surgery. There are no potential direct benefits for participating in this study. However, participants will have enhanced testing, which may improve their clinical outcomes by identifying the presence of bacteria more accurately. Understanding the bacteria present in the patient’s tissues may help physicians manage negative symptoms more effectively after surgery.

The knowledge gained from this study may benefit others in the future. Specifically, this study may help scientists to (1) understand how certain bacteria might cause problems after surgery (2) identify patients who are at higher risk for complications (3) allow us to come up with better ways to prevent these issues. (4) Our goal is to improve how we plan and carry out surgeries, especially for the neck, and (5) to find better ways to help patients who continue to have problems after their operation.

F. ALTERNATIVES TO BEING IN THE STUDY

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ALTERNATIVES: IS TREATMENT STILL AVAILABLE IF YOU DON'T WANT TO BE IN THE STUDY?

You do not have to participate in this study to receive treatment for your condition. If you decide not to participate in this study, you may receive the standard treatment for your condition. There may be other studies available that you could participate in.

The following medications and/or procedures are available as common alternative treatments for your condition: exact same surgical treatment, during surgery only standard-of-care microbiology swabs will be taken, there will be no collection of tissue for metagenomics testing. The samples that are collected will be sent to the lab at HSS for standard analysis instead of Weill Cornell for enhanced analysis.

The following procedures are available as common alternative treatments for your condition: exact same surgical treatment, during surgery only standard-of-care microbiology swabs will be taken, there will be no collection of tissue for metagenomics testing. The samples that are collected will be sent to the lab at HSS for standard analysis instead of, as described more fully in Section 2 below, to the lab at Weill Cornell for enhanced analysis for purposes of this study.

G. WHAT HAPPENS IF YOU CHANGE YOUR MIND?

Your participation in this study is voluntary. You may decide not to participate at any time by informing your study doctor in writing that you no longer wish to participate in the study. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you decide to leave the study before the last study visit, it is important that you tell the study doctor so that the study doctor can evaluate risks to you and discuss any follow-up care that could be helpful to you. It is helpful if you could explain your reasons for leaving the study.

If you decide to leave the study, no new information or samples will be collected from you after you withdraw. Information collected about you before you withdraw may be used by HSS in connection with the study for certain reasons, such as to check the accuracy of the study, maintain the integrity of the study data, or account for you leaving the study.

If you withdraw your consent to use the samples before they are sent to the laboratory for processing and analysis as part of the research and you wish to have the samples destroyed, reasonable efforts will be made to ensure your samples are destroyed. If your samples have already been processed and analyzed, the results cannot be destroyed and will continue to be available to and HSS.

2. WHAT WILL YOUR PARTICIPATION REQUIRE?

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If you decide to be in this study, the following procedures will be performed:

Study Visit #	Blood Draw	Surveys / Questionnaires	Surgery	X-Rays	CTs	Physical Exam
#1 Day of Surgery	RES	RES	SOC	SOC		
#2 (6 weeks post-operatively)		RES		SOC		SOC
#3 (6 months post-operatively)		RES		SOC		SOC
#4 (12 months post-operatively)		RES		SOC	SOC	SOC
#5 (24 months post-operatively)		RES		SOC		SOC

At your first visit you will receive surgery, which will occur even if you do not participate in the study. During surgery your doctor will collect about a teaspoon of blood for analysis in the form of fluid samples and swabs from the operative field. These samples will either be sent to the microbiology department at HSS for standard-of-care examination or to Weill Cornell for enhanced examination as part of the research. Patient data will be safe-guarded through the use of unique study numbers and removing information that might directly identify you. Weill Cornell will not have access to information that directly identifies you, ensuring privacy and confidentiality. Surgery can only occur on the main campus of HSS. At follow up appointments, you will be asked to fill out a survey indicating any pain or discomfort you may have. You will also receive an X-ray and a physical exam; these are all standard follow-up procedures. 12 months after your surgery you will also get a CT scan which is also a standard of care follow-up procedure. These follow-up visits and imaging will occur even if you decide not to participate in the study. These follow-ups will take approximately one hour and questionnaires will be included in that time. The data analyzed as a part of the study will be the questionnaires and any standard-of-care radiographs.

3. COST TO YOU

The items and services that you receive because you are participating in the study will be provided to you at no charge. These research procedures are marked as “RES” in Section 2 of this document.

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You or your insurance company are financially responsible for the costs of routine medical care provided to you over the course of the study that you would have received as part of the treatment of your condition even if you were not participating in the study. These procedures are marked as “SOC” in Section 2 of this document. You will be responsible for any co-pays, deductibles, and co-insurance associated with your medical care, just as you would be for any costs billed to your health insurance outside of this study, and any costs for procedures marked “SOC” that are not covered by your health insurance. Financial assistance may be available in certain cases. To learn about whether financial assistance may be available in your case, please call (212) 606-1505 to speak with a Financial Assistance Counselor or you can visit the following site: <https://www.hss.edu/financial-assistance.asp>.

4. GENETIC TESTING

What is a Gene?

DNA is the material that allows for the inheritance of many human traits, such as hair and eye color or the risk of some diseases. DNA is contained in the cells that make up the body and carries the instructions for your body’s development and functions.

A piece of DNA that determines a specific function of a cell is called a “gene.” Everyone’s DNA is different, and differences in DNA are called “variants.” Some variants do not cause any medical problems, but other variants in a gene can lead to disease. Sometimes, we do not have enough information to know whether a specific variant causes disease or not. The goal of genetic research is to identify genetic variants that cause disease.

Genetic testing as part of research is not for clinical care or treatments

Collection and Use of DNA: Researchers collect and analyze your DNA and/or RNA (RNA is a molecule made from your DNA) to answer a research question. It is important for you to understand that this analysis is being performed in order to conduct research, and not to provide you with medical care. Reports about research done with your sample will not be given to you or your doctor and will not have an effect on your medical care. It is likely that we will not be able to provide you with any information regarding whether you currently have or are predisposed to developing bacterial infection.

Participation in this research study does not replace a clinical genetics evaluation or clinical care. Whether or not you decide to participate in this study, you may want to discuss pursuing clinical genetic testing with your treating physician. You may ALSO wish to obtain professional genetic counseling prior to signing this informed consent. Please note, however, genetic counseling is not offered as part of your participation in the research study.

General Description of The Genetic Test That Will Be Done On Your Biosample As Part Of This Study:

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We will conduct next-generation sequencing (metagenomics) to understand the bacteria present in patient tissues and the hardware that is removed during surgery. This is an enhanced testing that can identify a larger range of bacteria with greater accuracy than standard-of-care microbiology swabs. No full genetic analysis of the patient's sample will be conducted. Only the bacteria that is found in samples will be sequenced.

The purpose of the genetic testing is to identify the presence of bacteria in the surrounding tissue. Any genetic information that is collected throughout the study will be destroyed after completion of the study.

The specific disease or condition for which the genetic tests will be testing for is/are: bacterial presence in tissue of cervical spine surgery patients.

Statement Regarding Retention, Maintenance, and Disclosure of Genetic Test Results: The genetic testing performed in connection with this study is performed for research purposes and generally has no clear meaning for your health or the health of your family members. We have no plans to return genetic test results to you or your doctor. However, we may return results to you or your doctor if we believe the results have important meaning for your health

With Whom Will the Results of the Genetic Test Be Shared: The results of the genetic tests will be shared with researchers involved with the study. Only the research team and attending surgeon will have access to the test results. Please note that the results of the genetic tests on your samples will not be shared directly with you, but may be shared with your doctor if we believe the results have important meaning for your health and will be made available to your physician.

Use and Retention of Your Samples: No tests other than the ones that you authorize in this form or in subsequent authorization forms will be performed on your identifiable samples and your identifiable samples will be destroyed at the end of the study unless you authorize retention of the samples as part of a research repository.

Risk Involved With Genetic Testing: Genetic testing may generate information about you or your family that could relate to your genetic predisposition to specific diseases or medical conditions. Genetic testing may also confirm that you currently have a particular medical condition. Although reasonable efforts will be made to ensure that any information about you will not be wrongly disclosed or used, there is always the possibility that it may be inadvertently disclosed, which could cause emotional distress to you or your family.

A federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.



- **Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.**
- **Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.**

All health insurance companies and group health plans and all employers with 15 or more people must follow this law. Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Additionally, any collection, storage and transfer of data related to your biological material in the context of medical research projects entails the risk of breaches of confidentiality (e.g. the possibility of identifying you). These risks are low but cannot be completely excluded and rise with increasing amounts of linked data, particularly when you make information available on the internet. As described below, however, in the section entitled “Confidentiality and Privacy,” we will take precautions to protect your medical information from being wrongly used or disclosed.

5. PREGNANCY

Due to the risks associated with anterior cervical discectomy and fusion surgery, pregnant women may not receive the type of intervention needed to participate in this research study. Therefore, women who are pregnant or nursing a child are not permitted to participate in this study. For the safety of yourself and any unborn child, before participating in this study, women are required to confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant during the next two years. If you suspect that you have become pregnant during this study, you must notify the study doctor immediately. Additionally, if you are capable of getting pregnant and are sexually active with someone of the opposite gender, you must use a form of contraception that has been approved by your study doctor while participating in the study. In some cases, your study doctor may instruct you and/or your partner to use two forms of contraception, such as birth control (IUD, pill, etc.) and a condom.

6. PAYMENT FOR PARTICIPATION

You will not be paid for your participation in this study.

7. COMMERCIAL ISSUES: YOUR RIGHTS IN THE RESULTS OF THE STUDY

Use of the findings of this study, information derived from your participation in the study and/or samples you have donated which are used in research may result in new products, tests, or discoveries, including establishing a cell line that could be patented and licensed. In some instances, these may have potential commercial value

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and may be developed and owned by the investigators, by Hospital for Special Surgery and/or by others. There are no plans to provide financial compensation to you should this occur. Therefore, you would not share in any financial benefits from these products, tests, or discoveries or cell lines.

8. AUTHORIZATION FOR USE AND DISCLOSURE OF PRIVATE HEALTH INFORMATION FOR THE STUDY.

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to see your information and why they will be able to see it. The study doctor must obtain your authorization (permission) to use or give out your private health information for purposes of this study. *Private health information* means the health information in your medical or other healthcare records that can identify you.

Your Private Health Information Will Be Used and Disclosed to Accomplish the Study: We are asking you to authorize the use and disclosure (release of your private health information) for this research study. The **private health information** that will be used and/or disclosed to accomplish the study include:

- Medical records from the past five years that relate to your surgery
- Any prescribed medications and non-prescribed pain management treatments taken in the past five years
- Biological samples collected during surgery
- DNA samples collected during surgery

HSS and the HSS Study Team Can Use and Disclose Your Private Health Information to accomplish the Study: By signing this consent, you permit HSS and HSS the study doctor and the study doctor's research team at HSS to use your private health information for the study. You also permit HSS and HSS-Florida Physicians LLC to release your private health information to the people and organizations listed below to accomplish this study.

With Whom HSS May Share Your Private Health Information to accomplish the purposes of the Research Study:

- The Principal Investigator and other Investigators for this study, including your study doctor.
- The research coordinator, research nurses, and other members of the HSS research team working on this study.
- Every research site for this study, including Hospital for Special Surgery and its affiliates, New York-Presbyterian Hospital, Weill Cornell Medical Center, Rockefeller University, Memorial Sloan-Kettering Cancer Center and HSS-Florida Physicians LLC. This includes the research staff and medical staff at each institution.
- The Patient Advocate or Research Ombudsman at these institutions.
- Staff members of HSS main campus or HSS satellite site(s) responsible for administering clinical trials and other research activities, as well as other administrative or management activities of HSS.

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- Any laboratories and other individuals and organizations that analyze your health information for this study.
- Any health care provider that you have used in the past or may use up to the time this study ends.
- The sponsor of this study. “Sponsor” includes any persons or companies that are working for or with the sponsor, are owned by the sponsor, or acquire rights to the product under study from the sponsor.
- Any Contract Research Organization (CRO) the sponsor may use. (A CRO is an independent entity with which a research sponsor contracts to oversee and facilitate various aspects of the clinical research process on the research sponsor’s behalf.)
- The United States Food and Drug Administration (FDA), the federal Office for Human Research Protections (OHRP), any federal agency that provides support for this study, and any federal, state, or local agency responsible for overseeing HSS, the study doctor, or any other member of the HSS research team involved in this study.
- The members and staff of the affiliated Institutional Review Boards (IRBs) at HSS, New York-Presbyterian Hospital, Weill Cornell Medical Center and, Memorial Sloan-Kettering Cancer Center. An IRB is a committee of health care providers, community representatives, and others that initially approves and periodically reviews biomedical and behavioral research that involves human subjects in order to protect the rights, safety and welfare of study participants.
- HSS contractors to assist in achieving the purposes of the study but only where such contractors agree to keep your information confidential.
- Data Safety Monitoring Boards and others authorized to monitor the conduct of this study for safety or quality assurance, for example a Clinical Events Committee.

The Purpose for Which Your Private Health Information Will Be Used or Disclosed:

Your private health information will be released to the people and organizations listed above to carry out this study. Specifically, this information will be used to determine whether you meet the conditions for participation in this study; to compare your earlier test results to the findings from this study; to use your previous laboratory results in place of, or in addition to, some of the lab results needed for this study.

Your private health information may be disclosed to the FDA and to governmental agencies in other countries so the sponsor can get approval to market new products or to continue marketing existing products. Your private health information may also be used to meet the reporting requirements of governmental agencies.

While the results of this study may be published in scientific journals or presented at medical meetings, your private health information will not be disclosed in any publications without your consent.

You Can Refuse to Authorize the Use and Disclosure of Your Private Health Information for the Research Study: You do not have to give HSS permission to use or disclose your private health information. Such permission is voluntary. However, if you do not give HSS this permission, you will not be able to join the research study. Your decision to not sign this permission will not affect your current and/or future treatment, health care services, or eligibility for benefits you receive from HSS or your HSS health care providers.

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Expiration Date of This Authorization to Use and Disclose Your Private Health Information: This permission to use and disclose your private health information will never expire unless you revoke it.

Can You See the Private Health Information Collected as Part of the Study? You have the right, in accordance with Hospital policy and applicable law, to review and copy your health information that is created or obtained in the course of this study. However, if you decide to be in this study and sign this informed consent form, you will not be able to look at or copy your information until after the study is completed if doing so would impact the validity of the study (for example, if the study is “blinded” so that during the study you will not know what treatment or other intervention you are receiving).

You May Revoke This Authorization: You may change your mind and take back this Authorization at any time. If you take it back and no new health information that might identify you will be gathered. However, the researchers may still use the private health information they have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization. **To take back the Authorization, you must write to the Principal Investigator at Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021. To withdraw your participation from the study, you may provide oral or written notification to the Principal Investigator using the address provided above or by phone at the number listed in Section 15, below].**

Once Disclosed Your Private Health Information May No Longer Be Protected by the Privacy Laws: Some persons or organizations who receive your private health information may not be required by law to protect it in the same way as HSS, and they may share your information with others without your permission, if permitted to do so by laws governing them. Therefore, your private health information may be released to others without your permission.

9. CONFIDENTIALITY and PRIVACY.

Any and all private health information about you obtained through this study, including any results of genetic testing, is private and confidential, and will not be disclosed, unless permitted or required by law or by this consent form. If a disclosure of information is not authorized by law or by this consent form that disclosure will not be made without your further written informed consent.

Identifiers might be removed from your private health information or your identifiable samples and, after such removal, the information or biosamples could be used for future research studies by HSS or distributed to another investigator, institution or company for future research studies without HSS getting additional consent from you. As noted above, FDA and other regulatory agencies may have access to identifiable information about you in connection with the study, including through inspecting your records at HSS or remotely



All research data will be stored in a secure, password-protected Excel file located on the PI's computer. Surveys and genetic data will only be accessed through HSS secure computers. The PI will be the sole holder of the password and will grant access only to approved study personnel. No one outside the study team will have access to study records or data. Each subject will be assigned a unique study number that is not derived from any patient identifiers. The key linking these numbers to subjects will be stored in a separate database accessible only to the attending surgeons. After the study concludes, this database will be destroyed.

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. In order to comply with journal submission requirements, the Web site may also include a plan describing how your de-identified data may be shared with other investigators. You understand that we may share your de-identified data with other researchers due to these requirements.

10. CONTACTING YOU AFTER THE CONCLUSION OF THE STUDY:

Do you give the HSS researchers permission to contact you in the future? Such contact could be, for example, to get more information from you that may be needed for this research, to explain the results of this study, or to notify you of medical information that could help you or your family member, discuss how your samples might be used, or to discuss possible participation in another research project?

Yes ☐ No ☐

Do you give permission to have information derived from your samples given to other researchers at Hospital for special surgery or others outside of HSS for use in research which research may be either related or unrelated to the purpose of the study?

Yes ☐ No ☐

Do you give the researchers your permission to ask your next of kin or the representative of your estate for consent to do further testing on your biosample after my death and disclose the results to my family.

Yes ☐ No ☐

Please note that, except for the above with your permission, in no event will we contact your family members for clinical, research or other purposes without your consent with respect to the specific family members who will be contacted and the specific purpose of the contact.



Risks and Benefits of Allowing Future Contact: The risks of allowing us to contact you are that we may have information that cause some emotional distress, but the benefits are that we may have information that could help you in your medical planning and decision-making. Benefits for society may include providing further information about the genetic basis of post operative infections as well as the development of safe and effective therapies for that illness.

11. CONFLICT OF INTEREST NOTIFICATION

HSS is concerned about possible conflicts of interest in research, and has policies that require all investigators and senior research staff to report to HSS significant financial interests (such as stock ownership, royalty payments, and consulting agreements) and relationships (such as membership on a scientific advisory board) that are related to their research studies. When an investigator reports a significant financial interest or relationship that relates to one of his/her studies, HSS's Conflict of Interest Committee for Research reviews the information to evaluate the risk that the interest or relationship might influence how the investigator conducts the study or interprets the results of the study. HSS may also take steps to minimize that risk.

☒ The Conflict of Interest Committee for Research has determined that there are no conflicts of interest associated with this study.

☐ The Conflict of Interest Committee for Research has determined that there is a potential conflict of interest associated with this study. Please read the information below carefully.

12. COMPENSATION FOR INJURY

If you are injured as a result of participating in this study, the study doctor, other members of the research team, or other HSS professional medical staff will provide you with emergency medical treatment (or arrange to have such treatment provided to you), and will assist you in obtaining appropriate follow-up medical treatment. However, there is no plan to provide you compensation or reimbursement for medical care or other costs.

Your health insurance may or may not pay for treatment of injuries as a result of your participation in this study.

13. QUESTIONS

If you have any additional questions later on, or if you wish to report a medical problem that may be related to this study, Frank Cammisa Jr. MD., can be reached at 212-606-1946 during office hours.



If you have any questions about your rights as a participant in this study or any questions about your participation that you would like to ask an institutional representative who is not part of this study, you can call the HSS Institutional Review Board at (212) 774-7123.

If you would like to have more information about the Hospital's financial disclosure review process in general, or in regard to this study, you may contact the Hospital's Office of Legal Affairs at (212) 606-1592. You may also ask the Hospital's patient advocate at (212) 774-2403, to arrange for you to have this information.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

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Agreement to Participate: Witnessing and Signature

To be in this study, you or your legal representative must sign the next page of this informed consent form. By signing the next page, you are voluntarily agreeing to be in this study at HSS.

Before signing, you should be sure of the following:

- You have read all of the information in this “Informed Consent to Participate in Research” form (or had it read to you).
- You have discussed the implications of your being in this study with your doctor, your study doctor and/or the study coordinator.
- You have had the chance to ask questions about this study.
- You received answers to your questions.
- If you did not understand any of the answers, you asked the study doctor or the study coordinator to explain them to you.
- The information given to you is based on what is now known about the study drug(s), device(s), or procedure(s). There may be other risks or complications that are not known at this time.
- You have had time to think about the information and decide whether or not to be in the study.

Please check one of the following:

- ☐ I AM NOT in another research study at this time.
- ☐ I AM in another research study at this time.



If you decide to be in this study:

- You are expected to follow the study procedures.
- You are expected to provide the information needed by the study doctor, the study coordinator, nurses, or other staff members for the study.
- You will be told in a timely manner of any significant new information that may affect your willingness to stay in the study.
- You may freely choose to stop being in the study at any time.

By signing below, you are voluntarily agreeing to be in this study.

By signing this consent, you also are acknowledging that you have received a copy of the HSS Notice of Privacy Practices. This Notice also is available at the following website: <https://www.hss.edu/notice-of-privacy-practices.asp>

You must be given a signed copy of this informed consent form to keep for yourself.

_____	_____	_____
Print Name of Participant	Signature of Participant	Date

_____	_____	_____
Print Name of Parent/Legal Guardian (if applicable) ¹	Signature of Parent/Legal Guardian	Date

_____	_____	_____
Print Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

As an HSS representative, and the person obtaining consent, please sign here to indicate that you have given a signed copy of this informed consent form to the participant

NOTE TO INVESTIGATORS:

¹ The parent or legal guardian of a child participant should sign this form on behalf of the child. The signature of one parent is sufficient when the research is of minimal risk to the child, or when the research presents the prospect of direct benefit to the child. The signature of both parents is required when the research involves greater than minimal risk with no prospect of direct benefit to the child. The requirements for signature of both parents may be waived if one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has sole legal responsibility for the care and custody of the child. If the participant is a child who is capable of giving assent, the child should also sign the attached Assent Form.

Form 10a - ICF Document (Template Version March 6, 2024)

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- **THE ORIGINAL OF THIS INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S STUDY FILE.**
- **A SIGNED COPY OF THIS INFORMED CONSENT FORM MUST BE GIVEN TO THE PARTICIPANT.**
- **A COPY OF THE INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S ELECTRONIC MEDICAL RECORD.**

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