Informed Consent Form Cover Page:

(Periop Flare) Perioperative Flare in Rheumatoid Arthritis: Characterization of Clinical and Biological Features (Old IRB#13146)

NCT Number: N/A

Document date: September 2nd 2016

_____
Study Volunteer Initials

HOSPITAL FOR SPECIAL SURGERY
535 East 70th Street
New York, N.Y. 10021

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY INVOLVING GENETIC TESTING

You are being asked to volunteer to be a subject in a research study conducted by the Hospital for Special Surgery (HSS). This form is designed to provide you with information about the Study, which you should know and understand. After reading this form, you will have an opportunity to ask any questions you may have

NOTE: Only the current IRB-stamped approved consent form may be used.

IRB#:**13-146**

Principal Investigator: **Dr. Susan Goodman** Telephone (212) 606-1163

NAME OF RESEARCH STUDY: **Perioperative flare in Rheumatoid Arthritis: Characterization of clinical and biologic features**

The sponsor(s) of the study is/are: **None**
(Name of company or other sponsors)

Subject Population: Inpatient: **X** Outpatient: **X** Other:_____

We expect to enlist the following number of subjects for this study: **200**

Your participation will involve this many visits: **3-4 visits**
These will occur when you are here at HSS getting ready for your operation, having your surgery, or returning for your follow-up visits.
There are no *extra* visits for this study.

Each of these visits is expected to take the following amount of time: **1 hour**

Will there be reimbursement for participation in this study? Yes_____ No**X**

IRB Administrative Use Only

Hospital for Special Surgery Institutional Review Board Approval
9/4/2016 Thru 9/3/2017

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

INTRODUCTION:

You are being asked to volunteer as a subject in a research study being conducted at Hospital for Special Surgery (the "Hospital") that involves genetic testing. This consent form provides you with the information you will need when considering whether to participate in this research study and in the aspects of the study that relate to genetic testing.

The researcher will explain the purpose of the study. He or she will explain how the study will be carried out and what you will be expected to do. The researcher will also explain the possible risks, possible benefits and alternatives of being in the study. You should ask the researcher any questions you have about any of these things before you decide whether you wish to take part in the study. If you decide to participate in this research study, you will be asked to sign and date this consent form, to indicate that you agree to participate. This process is called informed consent. You will be given a copy of this form to keep.

1. STUDY PURPOSE – WHY IS THIS STUDY BEING DONE:

Researchers at Hospital for Special Surgery are trying to learn more about how people living with rheumatoid arthritis (RA) do after orthopedic surgery. The study will help us to identify early factors that may influence long-term outcomes of joint replacements in RA patients and determine how the condition behaves after surgery. This study aims to understand the reasons that some people experience a flare of RA after total joint replacement surgery and what the impact of flaring is over the year after the surgery. In this study we will regularly ask you about your RA, whether it has gotten worse, and whether you are able to achieve your goals in physical therapy. During the course of this study, we will also draw blood before and after surgery to better understand how RA behaves around the time of surgery and as you recuperate from your joint replacement. Based on your previous diagnosis of rheumatoid arthritis and your upcoming surgery you are eligible to participate in this study. Your overall participation in this study will continue over the course of 12 month. We might learn how to better manage patients like you with RA when you have a joint replacement. If RA patients who flare are unable to fully participate in physical therapy or have worse function 12 month after their total joint replacement, more effective treatment approaches could be developed.

You are being asked to participate in this study because you have RA, you have Osteoarthritis (OA), or because you have another Inflammatory Arthritis (IA). Your participation will allow us to compare inflamed (sore) tissue to non-inflamed tissue.

A secondary purpose of this study is to determine whether there is a genetic basis for worsening of rheumatoid arthritis, and if so, how genes function if rheumatoid arthritis worsens. Only by comparing the functions of genes from patients affected and unaffected (those with OA), will we be able to determine if a given gene is truly linked to worsening of RA.

It is not the aim of this research study to provide you with clinically relevant genetic information that could be used to guide you or your physicians in making health care decisions. Therefore, at the present time and during the course of the study, it is likely that we will not be able to provide you with any information regarding whether your rheumatoid arthritis will become active or worse. Genetic counseling, which is available for established genetic tests, is not offered through participation in this research study, as this is a research study and counseling for results of testing in this study is not possible. (We tell you this because New York law requires us to advise you of the availability of genetic counseling prior to your signing this consent form and participating in this study.)

The National Institutes of Health (NIH) is the funding agency for this study through the Accelerating Medicines Partnership (AMP) initiative. The AMP initiative is a collaboration between the NIH, biopharmaceutical companies, and non-profit organizations. The goal of AMP is to increase the number of new diagnostics and therapies for patients, and to reduce the time and cost of developing these new treatment options. The AMP Network for Rheumatoid Arthritis is composed of various sites across the United States and Hospital for Special Surgery is a part of this network as a site.

2. WHO SHOULD NOT BE IN THE STUDY:

You should not participate if you have recently had anemia.

3. STUDY PROCEDURES – WHAT YOU WILL BE ASKED TO DO:

If you decide to be part of this study, the following routine and/or experimental procedures will be performed:

Clinical Data:

- Upon enrolling we will give you a pre-operative questionnaire/survey containing questions about your demographic information (for example your race, ethnicity, age, weight), your medical history, your assessment of your joint function, and symptoms as they relate to your condition. Your responses will be coded to maintain your confidentiality. This survey should take about 30-60 minutes.
- The research staff will work with you to complete a second survey that will ask about your medical history and medication history. This survey should take about 5-10 minutes.
- **OA and IA Patients:** We will repeat both questionnaires at 6 weeks after surgery at the time of your regularly scheduled appointment. The surveys should take about 30 minutes.
- **RA Patients only:**
- Just before surgery and before you leave the hospital we will ask you questions about RA flare. Questions about your RA will also be asked by telephone or by e-mailing an electronic survey each week for six weeks, and then once every three months for the rest of the year. These telephone or e-mail surveys should each take about 15 minutes.

- All questionnaires can be completed in any of the following ways throughout the course of the study: in person at the hospital, over the phone, via e-mail using a secure survey, or by mailing paper forms to and from the hospital.

Blood sample:

- **RA & IA Patients:** During your surgery, a professional will draw a maximum of 4 tablespoons (59 ccs) of blood from a vein in your arm. At your 6 week and/or 12 month follow-up visits, a professional will draw a maximum of 2.5 tablespoons (36.5 ccs) of blood from a vein in your arm.
- **OA Patients:** During your surgery, a professional will draw an additional 2.5 tablespoons (32.5 ccs) of blood. At your 6 week and 12 month follow-up visits a professional will draw a maximum of 1.5 tablespoons (20 ccs) of blood from a vein in your arm.
- **All:** In the event that you are hospitalized at Hospital for Special Surgery or one of its affiliates at any time between your enrollment on the day of surgery and your 6-week follow-up appointment with your surgeon, we may ask for an additional blood draw of 20mL of blood to take place at the time of your routine morning blood draw.
- *If for any reason routine lab work is not required at your study visits, we would still require 2 tubes of blood for study purposes and would make arrangements to do so.* All samples will be de-identified.

Surgical sample:

- During your surgery, your surgeon will take samples of the tissue removed as part of your surgery from your operated joint. We will take this tissue and analyze it to learn more about the cellular activity that occurs with RA flare. We will also photograph the specimen using the Pathology Lab equipment. This photograph will be de-identified before it is used for research purposes. If you choose not to participate in the study, this material will be discarded, which is what usually happens during total joint replacement surgery.

As part of this study we will test blood and tissue specimens for genetic markers associated with RA. Genetic material (DNA & RNA) will be collected from your blood and surgical samples, and will be checked for genes related to RA. Blood and surgical samples will be shared with other investigators in the AMP network who have the expertise required to perform the molecular analyses. Each study subject will be assigned an identification number. Only this number will be used to identify the samples if the samples are transferred to other sites.

4. STUDY RISKS – WHAT ADVERSE (BAD) EFFECTS CAN HAPPEN TO YOU BY PARTICIPATING IN THE STUDY:

One additional risk from this study is that it may generate information about you or your family that could relate to your genetic predisposition to specific diseases or medical conditions. Although every effort 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. As described below, however, in the section entitled "Confidentiality and Privacy," we will take major precautions to protect your medical information from being wrongly used or disclosed.

Biological specimens including the blood and tissue that you contribute for this study will be maintained for as long as it is deemed useful for research purposes, after which time the specimen will be destroyed. If your specimen is used for any future studies, it will either be completely stripped of any information that could be used to identify you, or it will be coded in such a way as to protect your identity, under the supervision of the Hospital's research review committee.

You have the right to withdraw your consent to the storage and/or future genetic testing of your biological specimens at any time by contacting the Principal Investigator of this study, Dr. Susan Goodman. If you do so, any portion of your specimen that has not already been used for research purposes will be destroyed. Once your specimen has been stripped of all information that could identify you, however, it will not be possible to remove your specimen from those specimens that are stored for future research.

If the Hospital, the Hospital's Institutional Review Board, and the company or government agency funding the research agree, study information, genetic information, and biological materials may be transferred to other hospitals and research institutions. This could happen if one or more of the investigators in this study relocates to another institution, or if HSS, in consultation with the investigators, believes that transferring these materials will allow important scientific research to be done.

You should be aware that insurance companies sometimes use information on medical testing to evaluate whether a person should be able to purchase a life, health or disability insurance policy, and an insurance carrier may request, or condition benefits upon, disclosure by you to them of certain medical information. Because this study likely will not provide you with any clinically meaningful genetic information about yourself, participation in this study should in no way affect your ability to obtain insurance coverage. **If asked by an insurance carrier whether participation in this study provided you with any information regarding your vulnerability or predisposition to certain illnesses, you should respond that it did not.**

The known effects, discomforts and foreseeable risks of physical, psychological, sociological, or other harm which you may reasonably expect to occur from being in this study are:

You will be answering a survey. There are very few risks in answering these questions.
Likely: Nothing bad will happen.
Less likely: Your private answers could be seen by somebody not involved in this study. We have put in place all possible precautions to keep all your answers private. Your answers will be kept locked up. The people who work for this study are well trained and understand the importance of confidentiality and privacy.

Rarely: You could be upset or embarrassed by a few of the questions. We ask everyone these questions. You don't have to answer them if you don't want to.

There are certain risks and discomforts associated with blood draws for laboratory testing.
Likely: The drawing of blood involves minor discomfort. You may experience bruising and/or bleeding at the site of blood draw.
Less likely: Occasionally some people experience dizziness or feel faint during a blood draw. There are risks of introducing infection with blood draws.

5. THERAPEUTIC OBJECTIVES:

__X__ This study includes experimental/investigational procedures, which may not give you immediate or any benefits. It is hoped the knowledge gained will be of benefit to others in the future.

_____ This study is planned to select your treatment by chance, since you will be assigned at random to one or more groups of people in the study who will receive different treatments, or no treatment. **It is not known if any treatment you receive will be of benefit to you.**

6. STUDY BENEFITS:

You are not expected to benefit personally from this research study. Participation in this study will not provide you with any therapeutic benefits, nor will it provide you with information regarding whether you are genetically predisposed to developing any known illnesses. This study includes drawing blood for investigational procedures, which may not give you immediate benefit or any benefit. The knowledge gained may benefit others in the future.

Benefits for society may include providing further information about the genetic basis of worsening of rheumatoid arthritis as well as the development of safe and effective therapies for that condition.

7. ALTERNATIVES TO PARTICIPATING IN THE RESEARCH STUDY:

You are not required to participate in this study, and you have the alternative of not participating at all. If you do not want to participate in the study, your decision will not affect in any way your ability to continue to receive care at the Hospital and from Hospital doctors.

8. COSTS TO THE SUBJECT and COMPENSATION: [1]

[1]HSS is committed to providing financial assistance when financially warranted and consistent with its resources, regardless of age, gender, religion, race or sexual orientation. So if you do not have health insurance, or if your health insurance does not pay for your medical care, you may seek financial assistance from HSS. Eligibility determinations are made on a case-by-case basis in accordance with HSS's financial assistance policy. You will be responsible for any costs not

There are no charges or expenses associated with your participation in this study. Nor will you receive money or any other form of compensation in return for such participation; participation is voluntary rather than paid.

However, you will still be responsible for the cost of your medical care (which will be billed to you or your health insurance company), and for any co-pays, deductibles, and co-insurance associated with your medical care, just as you would be if you were not part of this study. You will also be financially responsible for any costs of your medical care not covered by your health insurance.

Those research procedures listed in Section 3 will be covered by the study and will not be your financial responsibility.

There are no plans to compensate you for the use of the findings of this study, or any of the information or biologic materials (such as blood or tissue) collected from you during the study, even if they are used to develop or make a commercial product (such as a drug, device, biologic substance, or test).

9. COMPENSATION FOR INJURY:

All forms of medical diagnosis and treatment – including the drawing of blood or the collection of bodily tissues for this study – involve some risk of injury. In spite of all precautions, there is a small chance that you might develop medical complications from participating in this study. If such complications arise, the researchers will provide emergency medical treatment as necessary and will assist you in obtaining appropriate follow-up medical treatment, but this study does not provide compensation for additional medical or other costs. Additionally, The NIH will not compensate for research related injury.

10. CONFIDENTIALITY and PRIVACY:

Any and all 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 and the related authorization form you will sign. 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.

---

covered by financial assistance, which could be all of the costs (if HSS determines that you are not eligible for financial assistance) or some of the costs (if financial assistance awarded by HSS does not cover all of the costs).

Accelerating Medicines Partnership (AMP) research studies may share study samples and data with other research sites in the AMP Network for testing or storage. All samples and/or data collected from this study will be identified by a unique study ID number. A document linking you to your study ID number will be maintained by the Principal Investigator. Your Protected Health Information (PHI), or certain information that identifies you, such as your name or birthdate, will never be shared with other AMP research sites and personal information from your records will not be released without your written permission. In the future, if any publications are written on analyses including your data, you will not be identified in these publications in any way.

Your samples may be used for testing even after this study has been completed. Further research tests may help us learn more about your disease and response to drugs or treatment. However, future testing on your biological samples may be used for any type of biomedical research, which may or may not be related to the purpose of this study. The results of these future tests will not be shared with you.

Study datasets with your health information may be shared with other AMP sites and deposited in AMP project data repositories for sharing with the broad biomedical research community. The purpose is to make study data available to other researchers as the value of these data increase when they are shared with the broader research community and not restricted in use to a particular disease or for a limited period of time. Information from this study may be put into databases along with information from other studies. These data will not include your name or other information that can identify you. The common databases may have different levels of accessibility – some databases may be open to the public, while others may only be accessed with the permission of a NIH Data Access Committee. Any personal information that could identify you will be removed before the data and/or results from this study are made available to other researchers or the public. These datasets may be used for any type of biomedical research, which may or may not be related to the purpose of this study. Many of these datasets are useful beyond the specific aims of the study for which they were originally collected especially as various diseases turn out to have mechanisms in common.

If you agree to take part in this study, some of your genetic and health information will be placed in a database called "dbGaP" that is maintained by the NIH. A researcher who wants to study the information must apply and be approved to use the database by a NIH Data Access Committee. These datasets may be used for any type of biomedical research, which may or may not be related to the purpose of this study. Many of these datasets are useful beyond the specific aims of the study for which they were originally collected especially as various diseases turn out to have mechanisms in common.

Your privacy is important to us and we will use safety measures to protect your privacy. In spite of all the safety measures that we use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may

be possible that genetic information from you could be used to help identify them. Genetic information concerning non-paternity or non-maternity will not be divulged under any circumstances.

While we will not use information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It is also possible there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. There may also be other privacy risks that we have not foreseen.

After your part in this study has been completed, we would like to be able to contact you, 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. You have the right, however, not to have us contact you after your part in the study is over. 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. Please indicate below whether we have your permission to contact you (and only you) in the future:

☐ **Yes**, you may contact me in the future, after my part in this study is over.

☐ **No**, you may not contact me in the future, after my part in this study is over.

☐ **Yes**, you may ask my next of kin or the representative of my estate for consent to do further testing on my samples after my death and disclose the results to my family.

☐ **No**, you may not ask my next of kin or the representative of my estate for consent to do further testing on my samples after my death and disclose the results to my family.

If you allow us to contact you in the future, we will <u>not</u> disclose your medical information, including any results of genetic tests done as part of the study, to any member of your family for clinical, research or any other purpose, without your further specific written informed consent. If we do think that your family members could benefit from knowing any information we have received about you during this study, we may ask you for permission to contact them, and would explain our reason for wanting to do so. But we will contact no one (other than you yourself) unless and until you specifically tell us to do so. If you do not consent to be contacted in the future, this also means that if you die and we later obtain information that might help your family, we would not be able to contact your family to share that information.

If you consent to participate in this research, your personal information will not be released without your written permission, except as required by law or for regular Hospital treatment,

payment, and Hospital management activities. **(We will not, however, release any genetic testing information to any insurance company unless you specifically tell us to do so).** If you agree to participate in this study, the researcher will ask for your separate written permission (on a form called an "authorization") to use and disclose your personal information for certain purposes related to the study. For example, the researcher will ask permission to share your information with the research staff, with the Hospital's research review committee (known as the "Institutional Review Board") and research oversight staff/government agencies that regulate research (OHRP and NY State), with other researchers and scientists working on this study, with your treating physicians or your other health care providers, and/or with any other people who need your personal information in order to conduct or oversee the study. The researcher will also ask you to allow the sharing of your personal information with the research sponsor, and with those who help the research sponsor manage the study. Your personal information will usually be shared on research forms without your name or other identifying information, except when your name or other identifying information is necessary to make sure that the information on the research forms is accurate. Your name will not be used in any publication without your prior permission; only the data obtained as a result of your participation in this study will be made public.

11. SAMPLES STORAGE AND SHARING INFORMATION

We are asking your permission to store and share samples of biological specimens (e.g., blood, tissue, and urine) collected during the course of this study. Samples will be stored to be used in the future for tests that aren't yet planned. Such samples may also be shared with researchers at other Accelerated Medicines Partnership (AMP) sites during the course of the study for further testing and storage. The purpose of storage and sharing of samples and data is to make information and samples available to other researchers for use in health research. Collecting, storing and sharing information and making it available for other studies may help people in the future. These tests may or may not be related to the study of Rheumatoid Arthritis.

Your stored samples may be used to obtain knowledge about genetic information in relation to your disease, related diseases, and/or the immune system. Genetic tests study an individual's inherited characteristics, found in DNA, which is present in each of the cells of your body. DNA contains information needed to construct and operate the human body. When we study the DNA from your blood samples, we will also generate data about your entire genetic code.

Genetic tests may be performed on your blood and tissue samples to obtain knowledge about the way genetic information relates to your disease, related diseases, and/or the immune system. Genetic tests study your inherited characteristics, which are stored in the form of a "genetic code" in your DNA. A copy of your DNA is present in each of the cells in your body, and your cells read and interpret the genetic code to produce your inherited characteristics. Some of the genetic tests we plan to perform allow us to read your entire genetic code (Whole Genome/Exome Sequencing), while others let us look at the parts of your DNA your cells are reading and what parts they are ignoring (transcriptomics and epigenomics). Some of the specific genetic tests we plan to use include "RNAseq," "ChIPseq," and "ATACseq."

Genetic tests that read your entire genetic code may theoretically generate data that could be used to tell whether you have a pre-disposition to certain diseases. However, the genetic tests performed in this study are not designed nor licensed for diagnosing diseases. Because information from the genetic testing in this study will be obtained solely to be entered into a large data-base made up of cumulative genetic information from many patients, we will not be able to provide any specific genetic information to you or your physician.

The results of tests performed on stored or shared samples or reports resulting from the analysis of your samples will not be given to you or your doctor and they will not be put in your medical record. They will not identify you and will not affect your routine medical care.

There is no benefit to you from the storage of samples and information. However, the use of your samples and information may help researchers learn more about your disease or the genetics related to a specific condition.

If you decide to allow storage, your samples and information may be stored for an unknown length of time. Although your stored research samples will not be sold, the information obtained from the research performed on your samples may in the future lead to the development of commercial products. You will not receive any money from research using your stored samples and information.

There may be unknown risks associated with the storage of samples and information. For example, if the future research involves genetic testing and because genetic information is unique to you, there is a small chance that someone could trace it back to you. We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known.

You can change your mind at any time and ask to have your samples destroyed or request that the resulting genetic data from your stored samples be withdrawn from dbGaP. This request should be made in writing to the study investigator. If you make this request, all remaining stored samples will be destroyed and your genetic data will be withdrawn from any dbGaP, if possible. However, the results of any previous tests using your stored samples that have already been distributed, or were not stored on dbGaP, may still be used. Your decision regarding the storage of samples or the information resulting from the analysis of your samples will not affect your ability to participate in this study. The future use of your samples and information may contribute to learning more about disease or help to study the genetics related to a specific condition.

_____
Study Volunteer Initials

Please indicate your response below:

I agree to the storage and sharing of samples (urine, blood and/or tissue) for biological assays and genetic tests not currently planned.

☐ Yes ☐ No

_____
Initials of Research Subject

I agree to the storage and sharing of samples (urine, blood and/or tissue) and information resulting from the analysis of my samples for other tests not currently planned.

☐ Yes ☐ No

_____
Initials of Research Subject

IRB Administrative Use Only

Hospital for Special Surgery Institutional Review Board Approval
9/4/2016 Thru 9/3/2017

12. 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 has determined that there are no conflicts associated with this study.**

☐ **The Conflict of Interest Committee has determined that there is a potential conflict of interest.**

13. VOLUNTARY PARTICIPATION IN, AND WITHDRAWAL FROM, THE STUDY:

Your participation in this study is completely voluntary. You can refuse to participate, or withdraw from the study at any time, and such a decision will not affect your medical care at the Hospital, either now or in the future. Signing this form does not waive any of your legal rights. During the course of the research study, you will be told of any significant new findings or risks that may influence your willingness to continue to participate in the research.

As described earlier in this form, if you agree to participate in this research study, your biological specimens and information will be maintained for as long as it is deemed useful for research purposes, after which time they will be destroyed. You have the right to withdraw your consent to the storage and/or future testing of your specimens at any time, and your specimens that have not already been used for research will be promptly destroyed. If you decide to withdraw from the study and also withdraw consent of your genetic data to be used for research, you must contact the principal investigator in writing. In this event, your genetic data will be withdrawn from "dbGaP", a database maintained by NIH, if possible. However, the genetic data that has already been distributed for research use will not be retrieved.

14. QUESTIONS:

If you have any questions, please ask, and we will do our best to answer them. If you have additional questions in the future, you can reach the Principal Investigator, **Dr. Susan Goodman**, at **(212) 606-1163**, **GoodmanS@hss.edu**. For information about your rights as a research subject, or if you are not satisfied with the manner in which this study is being conducted and would like to discuss your participation with an institutional representative who is not part of this study, please contact the Manager of the Institutional Review Board at (212) 774-7154.

IRB Administrative Use Only

Hospital for Special Surgery Institutional Review Board Approval
9/4/2016 Thru 9/3/2017

_____
Study Volunteer Initials

14. STATEMENT OF CONSENT:

I have discussed this study with the investigator / a research assistant to my satisfaction. I understand that my participation is voluntary and that I can withdraw from the study at any time without prejudice. Signing this form does not waive any of my legal rights. I will be given a copy of this informed consent form for my future reference.

I ACKNOWLEDGE THAT I HAVE READ THE ABOVE EXPLANATION OF THIS STUDY, THAT ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY.

_____ _____
Signature of study volunteer/authorized representative Date and Time signed

I ACKNOWLEDGE THE PROCESS AND/OR SIGNATURE OR STATEMENT SET FORTH ABOVE

_____ _____
Signature of witness (required if consent is presented orally or at the request of the IRB) Date and Time Signed

I CERTIFY THAT I HAVE EXPLAINED FULLY TO THE ABOVE PATIENT THE PURPOSE, PROCEDURES, POSSIBLE RISKS, POTENTIAL BENEFITS AND ALTERNATIVES OF THIS RESEARCH STUDY.

_____ _____
Signature of researcher or designate Date and Time Signed

_____An interpreter in the Study subject's language was provided (check if applicable).

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

IRB Administrative Use Only

Hospital for Special Surgery Institutional Review Board Approval
9/4/2016 Thru 9/3/2017

HOSPITAL
FOR
SPECIAL
SURGERY

535 East 70th Street, New York, NY 10021 • (212) 606-1000

IRB#: 2014-233

RESEARCH AUTHORIZATION

Title of Protocol: Perioperative Flare in Rheumatoid Arthritis: Characterization of clinical and biologic features

Patient Name: _____ **ID Number:** _____

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment, we must obtain your written authorization before we may use or disclose your protected health information for the research purposes described below. This form provides that authorization and helps us make sure that you are properly informed of how this information will be used or disclosed. Please read the information below carefully before signing this form.

USE AND DISCLOSURE COVERED BY THIS AUTHORIZATION

A representative of Hospital for Special Surgery must answer these questions completely before providing this authorization form to you. DO NOT SIGN A BLANK FORM. You or your personal representative should read the descriptions below before signing this form.

Who will disclose, receive, and/or use the information? This form will authorize the following person(s), class(es) of persons, and/or organization(s) to disclose, use, and receive the information:*

- ☒ Every research site for this study, including Hospital for Special Surgery and its affiliates, New York-Presbyterian Hospital and Memorial Sloan-Kettering Cancer Center, and including each sites' research staff and medical staff
- ☒ Every health care provider who provides services to you in connection with this study or who are caring for you during the time you are enrolled in this study
- ☒ Any laboratories and other individuals and organizations that analyze your health information in connection with this study in accordance with the study's protocol
- ☒ The following research sponsors and the people and companies they use to oversee, administer, or conduct the research: Investigators of the NIH-funded AMP (Accelerating Medicines Partnership) Study.
- ☒ The United States Food and Drug Administration and the Federal Office of Human Research Protection
- ☒ The members and staff of the affiliated Institutional Review Boards at Hospital for Special Surgery, New York-Presbyterian Hospital and Memorial Sloan-Kettering Cancer Center.
- ☒ Principal Investigator and other Investigators
- ☒ Study Coordinator
- ☒ Additional members of the Research Team
- ☒ The Patient Advocate or Research Ombudsman
- ☒ Members of Hospital for Special Surgery's administrative staff responsible for administering clinical trials and other research activities
- ☒ Contract Research Organization (A contract research organization 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.)
- ☒ Data Safety Monitoring Boards and others authorized to monitor the conduct of the study, for example a Clinical Events Committee
- ☐ Others (as described below):

_____

_____

_____

_____

* If, during the course of the research, one of the companies or institutions listed above merges with or is purchased by another company or institution, this authorization to use or disclose protected health information in the research will extend to the successor company or institution.

Hospital for Special Surgery
Institutional Review Board

SEP 28 2016 To SEP 03 2017

APPROVAL

What information will be used or disclosed? The appropriate boxes should be checked below and the descriptions should be in enough detail so that you (or any organization that must disclose information pursuant to this authorization) can understand what information may be used or disclosed.

☐ The entire research record and any medical records held by the Hospital may be used and disclosed.

☒ The following information:

Anonymized data collected via data collection forms (eDC), anonymized lab results.

SPECIFIC UNDERSTANDINGS

By signing this research authorization form, you authorize the use and/or disclosure of your protected health information described above. The purpose for the uses and disclosures you are authorizing is to conduct the research project explained to you during the informed consent process and to ensure that the information relating to that research is available to all parties who may need it for research purposes. Your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable), and to run the business operations of the Hospital.

Hospital for Special Surgery staff members and physicians who are performing this research will use and disclose your information only as described earlier. However, once we disclose your information to others for research purposes, Hospital for Special Surgery cannot directly control their future uses and disclosures of it. For this reason, Hospital for Special Surgery has requested that the research sponsor and its agents use your information only for this research and not for other purposes.

You have a right to refuse to sign this authorization. While your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form, you will not be able to participate in the research described in this authorization and will not receive treatment as a study participant if you do not sign this form.

If you sign this authorization, you will have the right to revoke it at any time, except to the extent that the Hospital has already taken action based upon your authorization or needs the information to complete analysis and reports of data for this research. This authorization will never expire unless and until you revoke it. To revoke this authorization, please write to the Principal Investigator, Vivian Bykerk MD at Hospital for Special Surgery, 535 East 70th Street New York, New York 10021.

You also have a right to receive a copy of this form after you have signed it.

SIGNATURE

I have read this form and all of my questions about this form have been answered. By signing below, I acknowledge that I have read and accept all of the above.

_____
Signature of Patient or Personal Representative

_____
Print Name of Patient or Personal Representative

_____
Description of Personal Representative's Authority

_____
Date

CONTACT INFORMATION

The contact information of the patient or personal representative who signed this form should be filled in below.

Address:

_____

_____

_____

_____

Telephone:

_____ (daytime)

_____ (evening)

Email Address (optional):

_____

THE PATIENT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED WITH A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED.