

HOSPITAL FOR SPECIAL SURGERY

535 East 70th Street
New York, NY 10021

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Imaging Biomarkers in Crohn's Associated Spondyloarthritis

PROTOCOL NO.: 2015-491

SPONSOR: Clinical and Translational Science Center of Weill Cornell Medical College (CTSC/WCMC) and Hospital for Special Surgery (HSS).

INVESTIGATOR: Fardina Malik, MD,
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SITE(S): Jill Roberts Center of Inflammatory Bowel Disease (Weill Cornell Medical College) and Hospital for Special Surgery

STUDY-RELATED PHONE NUMBER(S): 212-606-1203

IRB #:

You are being asked to take part in a research study conducted by Hospital for Special Surgery (HSS) and Weill Cornell Medical College (WCMC). You are being asked to participate in this study because you have Crohn's Disease.

You will still be responsible for the cost of your medical care just as you would be if you were not part of this study. For example, any co-pays, deductibles, and co-insurance associated with your medical care.

This document provides you with information about this study. After reading this document, any questions you may have will be answered. You may take home a copy of this document to consider or discuss with family and friends before making your decision.

1. WHY IS THIS STUDY BEING DONE?

Form 10 - ICF Document (Template Version 2/14/13)

Page 1 of 11

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Hospital for Special Surgery Institutional
Review Board Approval
1/18/2017 Thru 1/17/2018

The purpose of this study is to determine presence of inflammation of the spine and sacroiliac joints in patients who also have Crohn's Disease.

2. WHAT WILL YOUR PARTICIPATION REQUIRE?

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

Study Visit	Clinical Interview (focused)	Surveys / Questionnaires	Joint Exam	Stool sample*	Blood draw (2 tsp)	MRI
#1	X	X	X	X	X	X

- **X= Research procedures**
- *You will be asked to provide on the day of MRI or will be provided stool sample collection kit to take home and bring it back another day.
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You and/or your insurance will be responsible for any costs of all procedures performed that are standard of care, that is, care that you would receive even if you were not in this study.

A total of 30 subjects will participate in this study.

Your participation will involve only one study visit. Study visit is expected to last 2 to 3 hours.

3. WHAT ADVERSE (BAD) EFFECTS CAN HAPPEN FROM BEING IN THE STUDY? WHAT RISKS ARE KNOWN ABOUT THE STUDY DRUG/STUDY DEVICE?

RISK RELATED TO CLINICAL INTERVIEW, PHYSICAL EXAM, ANSWERING SURVEY QUESTIONNAIRES:

Risks related to above are minimal. Some questions may make you uncomfortable thinking about symptoms related to Crohn's disease or pain.

RISK RELATED TO BLOOD DRAW:

Blood draws can uncommonly cause pain and mild bruising.

RISK RELATED TO STOOL SAMPLE COLLECTION:

Minimal to none unease during collection

RISK RELATED TO MRI (Magnetic Resonance Imaging):

The potential risks of MRI are minimal. There is no ionizing radiation involved with MR imaging. All imaging protocols and imaging coils used in this study are FDA approved, are validated for safety and are in current clinical use at the Hospital for Special Surgery.

MRI is generally a well-tolerated procedure and you will be fully screened for MR safety before any imaging is started. In particular, you will be asked if you have any of the following: aneurysm clips on a cerebral artery, a deep brain stimulator, cardiac pace maker, wires or defibrillator, inner ear or cochlear implants, hearing aid, infusion pump or metal fragments in your eye. Please let a study investigator know if any of these apply to you. Other potential risks include claustrophobia, coil element heating and peripheral nerve stimulation, although the latter two are considered highly unlikely, given that you will be imaged within preset safety guidelines to eliminate peripheral nerve stimulation. Coil element heating ranges from a mild sensation of heat to a potential burn. This is considered highly unlikely, as the coils have all undergone extensive testing and clinical use, and special pads are placed surrounding all contact points. Hospital for Special Surgery operates the MRI units within the safety guidelines established by General Electric Health Care, Milwaukee, Wisconsin.”

RISK TO PATIENT PRIVACY:

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.

There may be risks or side effects that are unknown at this time. 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 participate in the study.

4. WHAT BENEFIT CAN YOU EXPECT?

- This study includes investigational procedures which are unlikely to give you immediate benefit or any benefit. The knowledge gained may benefit others in the future.

5. COST

There will be no cost to you for participation in this study.

You will still be responsible for the cost of your medical care, 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.

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

Form 10 - ICF Document (Template Version 2/14/13)

IRB Administrative Use Only

Hospital for Special Surgery Institutional
Review Board Approval
1/18/2017 Thru 1/17/2018

have health insurance, or if your health insurance does not pay for your medical care, you may seek financial assistance from HSS. For more information about the Financial Assistance Program or to request a [Financial Assistance Application](#) call (212) 606-1505 to speak with a Financial Assistance Counselor or you can visit the following site: <http://www.hss.edu/patient-financial-assistance-notice.asp>.

6. PREGNANCY

Women who are pregnant or nursing a child may not participate in this study. You must confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant before your scheduled study visit. If you suspect that you have become pregnant by that time, you must notify the study doctor immediately.

7. PAYMENT FOR PARTICIPATION

You will be reimbursed US \$ 25.00 (either cash or check) to cover the cost of your transportation to Hospital For Special Surgery on the day of study.

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

There are no plans to compensate you for the use of the findings of this study, or any of the information or biologic materials (e.g. blood and serum) 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. ALTERNATIVES: WHAT OTHER TREATMENT IS 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. This study is not designed to administer any therapy.

You should ask the study doctor treatments that may be available for your condition.

10. WHO WILL BE ABLE TO SEE YOUR RECORDS AND PERSONAL INFORMATION AND KNOW THAT YOU ARE IN 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 any health information that might identify you.

What information may be used or given to others?

If you choose to be in the study, the study doctor will get personal information about you. The information might identify you. The study doctor may also get information about your health including:

- Medical and research records
- Records about phone calls
- Records about your study visit
- Records of physical exams
- Laboratory, x-ray, and other test results
- Questionnaires
- Records about any study device you received

Who may use, disclose, or receive my information?

The following person(s) class(es) of persons, and/or organization(s) may use, disclose, or receive my information:

The Principal Investigator and other Investigators for this study, including your study doctor.
The research coordinator, research nurses, and other members of the HSS and WCMC research team working on this study.

Every research site for this study, including Hospital for Special Surgery and its affiliate, New York-Presbyterian Hospital. This includes the research staff and medical staff at each institution.

The Patient Advocate or Research Ombudsman at these institutions.

Staff members of HSS responsible for administering clinical trials and other research activities
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, or are owned by 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 and New York-Presbyterian Hospital. 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.

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.

Why will this information be used and/or given to others?

Form 10 - ICF Document (Template Version 2/14/13)

Page 5 of 11

IRB Administrative Use Only

Hospital for Special Surgery Institutional
Review Board Approval
1/18/2017 Thru 1/17/2018

Your health information may be given to others who are carrying out this study.

The results of this study may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

What if I decide not to give permission to use and give out my health information?

By signing this informed consent form, you are giving permission to use and give out your health information as described above. If you refuse to give permission, you cannot be in this study.

May I review or copy the information obtained from me or created about me?

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.

May I revoke (take back) my permission?

Yes. Your permission will never expire unless you revoke it. To revoke your permission, you must write to the study doctor at Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021.

You may revoke your permission to use and disclose your health information at any time. If you revoke your permission, you cannot continue to participate in this study.

After you revoke your permission, no new health information that might identify you will be gathered. Information that has already been gathered may still be used and given to others. This would be done if the information is needed for this study to be reliable.

Is my health information protected after it has been given to others?

Some persons who receive your health information may not be required to protect it, and they may share your information with others without your permission, if permitted by laws governing them. Therefore, there is a risk that your information will be released to others without your permission.

11. CONFLICT OF INTEREST NOTIFICATION

HSS and WCMC are concerned about possible conflicts of interest in research, and has policies that require all investigators and senior research staff to report to HSS and WCMC 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

Form 10 - ICF Document (Template Version 2/14/13)

IRB Administrative Use Only

Hospital for Special Surgery Institutional
Review Board Approval
1/18/2017 Thru 1/17/2018

research studies. When an investigator reports a significant financial interest or relationship that relates to one of his/her studies, HSS and WCMC'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 and WCMC 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. VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to take part in this study is completely voluntary. You are free to choose not to take part in the study and may change your mind and withdraw at any time. Your relationship with physicians at WCMC and HSS and your medical care at these institutions, now or in the future, will not be affected in any way if you withdraw or refuse to participate. You will not lose any benefits to which you are otherwise entitled.

The study doctor and may terminate your participation in this study at any time without your consent if, in their judgment, it is inadvisable for you to continue.

13. 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 routinely provide compensation for additional 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.

14. SOURCE OF FUNDING

Clinical and Translational Science Center at Weill Cornell Medical College and Hospital For Special Surgery.

15. 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, Fardina Malik can be reached at 212-606-1203 during office hours.

Form 10 - ICF Document (Template Version 2/14/13)

IRB Administrative Use Only

Hospital for Special Surgery Institutional
Review Board Approval
1/18/2017 Thru 1/17/2018

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 Manager of the HSS Institutional Review Board at (212) 774-7154.

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.

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.

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

NOTE TO INVESTIGATORS:

- **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 HOSPITAL MEDICAL RECORD IF THE PARTICIPANT IS (OR WILL BE) HOSPITALIZED AT ANY TIME DURING THE STUDY.**

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.

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1/18/2017 Thru 1/17/2018



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1/18/2017 Thru 1/17/2018