Research Consent Form
Marshfield Clinic Research Foundation
A Division of Marshfield Clinic
1000 N Oak Avenue, Marshfield, WI 54449
SP Code: ELL10104 PI: Dr. Jay L.E. Ellingson

TITLE: **Association Between *Mycobacterium avium* subsp. *paratuberculosis* (MAP) Bacteremia and *NOD2/CARD15* Mutations in Crohn's Disease (CD) Patients**

Why have you been asked to take part in this research?

You are being asked to take part in a clinical research study because either you qualify to serve as a control subject or you have been diagnosed with Crohn's disease (CD). Joining this study is completely voluntary. For this study, we are asking you to allow us to analyze your blood for the presence of the MAP bacterium and to test your blood for the three genetic mutations that have been shown to increase the risk of developing CD.

We have attempted to write this consent form as clearly as possible for your understanding. Feel free to ask as many questions as you wish about this consent form, the procedures, and any information that you do not understand. Study personnel will explain all the procedures that you will be asked to follow.

Scientists think that some cases of CD are due to yet unidentified microorganisms. Increasing numbers of recent studies indicate possible involvement of one bacterium, known as *Mycobacterium avium* subspecies *paratuberculosis* (MAP), which causes a disease similar to CD in cattle called Johne's disease. Additionally, an increased risk of CD has been connected to three changes or mutations in human genetic material also known as DNA. It is possible to test for all three of these mutations.

The purpose of this investigational research study is to examine a possible association between a disease-causing bacteria and a genetic alteration in patients with CD. The information and samples resulting from this research may help the development of an effective treatment for CD.

How many people will be in this study and how long will this study last?

About 120 subjects may be involved in this research study. While this study may span four to seven months, your participation time would be less than one hour, during which consent is obtained and the blood sample is drawn.

What will happen to you if you agree to take part in the study?

If you decide to take part in this study, we will take a blood sample during a one-time collection visit. A total of sixteen (16) milliliters (2 ½ teaspoons) of blood will be obtained (in four 4-mL vials). No further participation would be required from you. Samples will be discarded at the end of this study.

What are the possible risks and discomforts of the study?

Risks or discomforts associated with participation in this study will be minimal. The risks of having blood drawn are bruising, infection, and minor pain or discomfort of a needle stick.

Although remote, there is a risk that information about your genetic make-up may be accidentally released to you or others. Although the chances are small, if there were a breach in confidentiality and a third party learned your genetic test results, this information could affect your ability to obtain health or life insurance as well as lead to discrimination in employment. At this time, there are no absolute legal protections against discrimination on the basis of genetic information. Even if you take part in this research study in which genetic testing is involved, you would have no genetic information to relay to an employer, insurance company or other inquiring third party. Researchers will take the steps outlined in this consent form to protect your personal information.

How will you benefit by being a part of the study?

You are unlikely to gain any direct benefits from participation in this study. Test results will not be made available to you since the results will be used for research purposes only. It is hoped that information learned from your taking part in this study will benefit you and others with CD.

If you do not want to take part in the study, are there other choices?

Your participation is voluntary. You can withdraw or refuse to answer any questions without consequences at any time.

You do not have to be in this study to receive medical care at any of the participating sites.

What are the costs and payments for taking part in this study?

There will be no additional costs to you to take part in this research study. You will not be paid to be in this study.

What happens if you get sick or hurt as a result of the study?

If you get sick or are injured because you took part in this study, medical care is available through Marshfield Clinic, St. Joseph's Hospital, or other medical facilities. Your health insurer may cover the cost of this medical care. This facility has no plans to compensate you, financially or otherwise.

If you take part in the study, who will have access to your medical records?

Absolute confidentiality cannot be guaranteed, however, your medical, hospital, or other billing records and research material that would identify you will be held confidential and

protected by Marshfield Clinic confidential policies. Medical records that identify you and the consent form signed by you, may be inspected by the following agencies:

- Marshfield Clinic Research Foundation's Institutional Review Board
- Other governmental regulatory (or health) agencies
- Medical professionals who need to access your medical record for your continuing care

Because of the need to release pertinent sections of information to these parties, all efforts will be made to maintain confidentiality, but again it cannot be guaranteed. These people must also keep the information private. Your name will not be given to anyone not associated with the study unless required by law.

The results of this study may be presented at scientific meetings or in scientific publications; however, your identity will not be disclosed.

Do you have to take part in this study?

Being in this study is completely voluntary. Refusing to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which you are otherwise entitled. If you choose not to sign this consent form, your relationship with your doctor and this institution will not change.

If you decide to leave the study, please let study staff know.

You are not giving up any legal rights by signing this consent document and taking part in this research study.

Who can you call if you get sick, injured, or want more information about this study?

For more information about this research study or to report injury or side effects, you may contact Dr. Jay Ellingson, Dr. Roy Radcliff or Becky Brey, Marshfield Clinic (**1-800-782-8581 ext. 7-9809**).

If you have any questions about your rights as a research subject, you may contact Marshfield Clinic Research Foundation's Institutional Review Board (lRB) at 1-800-782-8581 ext. 9-3022. The IRB is responsible for protecting human research subjects.

Informed Assent Form
(Required for Age 11 through 17)

Child/Adolescent's Understanding:

Have all your questions regarding how the research study might affect you been answered? Yes / No (Circle one)

If you want to be part of the study, please sign your name. If you do not want to be part of the study, then do not sign your name. **You can say no to being in the study, and you will not be disliked or treated differently.**

_____ _____
Child/Adolescent's Signature Date of Signature

_____
Printed Name of Subject

Parent's/Court-Appointed Guardian's Understanding:

Have all your questions about how the research study is going to affect your child and/or yourself been answered? Yes/No (Circle one)

I believe my child is fully informed and is willing to participate in this study.

_____ _____
Parent's/Court-Appointed Guardian's Signature Date of Signature

Investigator/Presenter

I have discussed this study and the possible risks and benefits of the study with the child, and I believe he/she is fully informed and is willing to participate in this study.

_____ _____
Presenter's Signature Date of Presentation
(Investigator or Designee)

What does signing this consent form mean?

A signature indicates that:

- You or your child has read the above.
- You or your child has freely decided to take part in the research study described above.
- The studies general purposes, details of involvement and possible risks and discomforts have been explained to you and your child.

You and your child will receive a signed copy of this consent/authorization form.

_____ _____
Signature of Subject Date of Signature
(If 18 or older and able to give informed consent)

_____
Printed Name of Subject

…….....OR……...

_____ _____
Signature of Parent (if subject is less than *18)* •••• ***OR*** •••• Date of Signature
Health Care Agent as Designated by Power of Attorney
For Health Care (if participant is 18 or *older)* •••••• ***OR*** •••••
Court-Appointed Guardian **(Circle appropriate title)**
Reason subject was unable to give informed consent: _____
_____

_____
Printed Name of the Above Signature

_____ _____
Signature of Presenter Date of Presentation

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Printed Name of Presenter

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