NARRATIVE CONSENT

Title of this Research Study
RAIN - Rheumatology and Arthritis Investigational Network

You are invited to participate in this research database because you are 19 years of age or older and have been diagnosed with arthritis or a related condition. The information in this consent form is provided to help you make an informed decision whether or not to participate. Please ask if you have any questions.

The purpose of this database is to collect clinical information about you and your arthritis (or related condition) and store it in the Division of Rheumatology at the University of Nebraska Medical Center. The information in the database will be obtained from your hospital or doctors office records. We will not do any additional tests to get more information specifically for the database.

There is a chance of a loss of confidentiality if an unauthorized person gains access to this database. To help lessen this risk, the database will be encrypted and kept in the password protected computer system at the University of Nebraska Medical Center.

You have rights regarding the privacy of your medical information collected and placed in this database. This medical information, called protected health information (PHI), includes demographic information, the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures, as well as your medical history. You have the right to limit the use and sharing of your PHI, and you have the right to see your medical records and to know who else is seeing them.

This database and any research project using information from this database must be approved by the UNMC Institutional Review Board (IRB). The IRBs job is to protect the rights of people taking part in research and as a result, the IRB may also review your information. Your information might be disclosed to other researchers within the Rheumatology and Arthritis Investigational Network at UNMC as well as the American College of Rheumatology and the National Databank for Rheumatic Diseases as part of ongoing IRB-approved research studies. It is also possible that government officials with responsibility for this type of research, such as officials of the Department of Health and Human Services or other research oversight bodies, will have access to this information. All of these people or groups are obligated to protect this information.

IRBVersion 4

IRB
Approved 09/19/2018
Valid until 09/19/2019
Your information will be kept in the database indefinitely. We may disclose your information to the people or groups listed above at any time.

The information from this study may be published in scientific journals or presented at scientific meetings, but you will not be identified by name.

Allowing us to store your information in the database is entirely voluntary. Your decision about participating will not influence your treatment, or affect your relationship with your doctor. If you change your mind later and do not want to continue participating, you may notify us in writing at the above address and your records will no longer be used for research.

By signing this document, you are saying that the information in this document has been explained to you, that you have read and understand this document, that your questions have been answered, and that you have decided to participate. If you think of any questions, please ask your doctor or one of the investigators listed at the end of this form. You will be given a copy of this consent to keep.

Signature of Person Consenting:  
___________________________________________  
Date:_____________________

I certify that all of the elements of informed consent described in this consent form have been explained fully to the subject. In my judgment, the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research.

Signature of Person Obtaining Consent: ____________________________  
Date: _____________________

AUTHORIZED STUDY PERSONNEL

Principal Investigator Kaleb Michaud, PhD (402) 559-7288  

See http://www.unmc.edu/intmed/rheum/research.htm for all study personnel.
Institutional Review Board (IRB)

What Do I Need To Know
Before Being In A Research Study?

You have been invited to be in a research study. Research studies are also called "research surveys", "research questionnaires" or "scientific protocols." Research is an organized plan designed to get new knowledge about health, disease, behaviors, attitudes and interactions of, among and between individuals, groups and cultures. The people who are in the research are called research subjects. The investigator is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your consent to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the purpose of the research? Why is the investigator doing the research?

What are the risks of the research? What bad things could happen?

What are the possible benefits of the research? How might this help me?

How is the research different than what will happen if I'm not in the research?

Will being in the research cost me anything extra?

Do I have to be in this research study? How will it affect my status at the institution if I say no?

Can I stop being in the research once I've started? How?

Who will look at my records?

How do I reach the investigator if I have more questions?

Who do I call if I have questions about being a research subject?

Make sure all your questions are answered before you decide whether or not to be in this research.
THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT

to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

to freely decide whether or not to take part in the research.

to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.