

# THE NDB Research

## NEWSLETTER

News for Participants in the National Data Bank for Rheumatic Diseases

July 2014

## Notes from the Directors

Frederick Wolfe, MD • Kaleb Michaud, PhD

### Update from Kaleb Michaud, PhD

This past month was a busy one. I gave invited talks about our research in 4 cities over 3 weeks including Atlanta, Montreal, Seattle, and a rheumatology conference with 15,000 others in Paris, France. I don't know about you, but when I travel a lot, my joints sure get sore. Whether it is the pressure-change, the jet lag, time-change, or just walking a lot more, it's never easy. In fact, I spent a whole week sick at home after the last trip as my body was just worn out.

Why tell you about this? First, I've been using our Ginger.io smart phone app that about 150 of you have joined with me in using and have been watching it tell me how far I have travelled and how much I have used my phone. Very soon it will also report back to me my answers over time in a graph so I can see my ups and downs when I travel (see more later in this newsletter). Second, while it may sound like I was complaining about the travel, I am so excited that researchers and their organizations around the world find a lot of value in the work that you, our patient participants, have helped make possible. It takes a special someone who has plenty to do every day and still chooses to help contribute to our rheumatology research. And I would make those trips over again in a heartbeat, as I know how important the work you make possible is to patients now and in the future. So thank you again!

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In our last newsletter I mentioned our completely optional but exciting new study that asks our patients with RA to tell us about their biological family members and to have them participate by answering a few questions and donating blood. Most of you have not yet been asked to participate, as we want to get this right. We understand that it may be difficult or even sensitive to discuss your disease with family members and that many of those members may not

know that you contribute to our research. Some of you may not even be in touch with all of your family members. In our first attempt several of you mistakenly thought that we only wanted to know about your family members with arthritis. We want to know about ALL of your biological family members, with and without any health conditions.

***“By better understanding how we get Rheumatoid Arthritis, we can also better understand how to postpone or prevent Rheumatoid Arthritis.”***

For example, let's say RA patient “Jane Doe” who is 64 years old is asked to participate. She would tell us on our family tree website briefly about her mother and father, if they are alive or not, and if they have any important arthritis diseases. Jane would then do the same thing for each of her biological sisters, brothers, sons, and daughters. For the relatives that are alive and reachable, Jane would then be able to invite them through our website to participate in our study. Initially we would only contact her family members through email, but if they did not have email we could mail a letter or call them on Jane's behalf.

Why do we want to learn about your family members? Over the past decade there have been many advancements in understanding what triggers our immune system to attack our joints in rheumatoid arthritis. Have you seen billboards advertising that smoking causes RA? That was figured out only 8 years ago! About a third of the time we have a specific genetic makeup that makes getting RA more possible, although people with these same genes often will

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# LATEST RESEARCH

In June 2014 at the Annual European League Against Rheumatism (EULAR) Meeting, the NDB worked directly on 3 research abstracts and was cited as a reference on 15. EULAR is an important international meeting similar to the annual American College of Rheumatology (ACR) in that it helps communicate research and information on all rheumatic diseases to rheumatologists, researchers, and patients throughout the world. Both annual meetings help to continue to find better and safer treatments, and work towards the same goal of finding a cure for the many rheumatic diseases present around the world.

We again thank each and every one of you for your help in guidance and participation in NDB research studies—for these research abstracts and publications could not be done without you!

Here are some overviews of the research from the meeting:

## *Assessment of Characteristics of the Abatacept-Treated Patients in Select Real-World Rheumatoid Arthritis Data Sources*

Some of you were enrolled into the NDB via the safety registry for abatacept and the data that has been collected so far was used for this publication.

The data from abatacept patients, from the NDB and other registries in North America and Europe, showed that abatacept users were similar in age and gender distribution across all registries and that greater than 80% had previously taken one or more biologics. Future studies need to be done in abatacept real world-users and other world-treated biologic and non-biologic patients to further evaluate the real-world safety outcomes of this drug.

## *Infection Risk for Patients with Rheumatoid Arthritis (RA) Compared to Non-Inflammatory Rheumatic Disease Controls*

NDB and the University of Nebraska Medical Center (UNMC) researchers evaluated data collected over the many years on infections that all NDB participants have been reporting. From this data they were able to see that RA patients have an increased risk of serious infections (hospitalized for the infection or required intravenous antibiotics) when compared to non-inflammatory arthritis patients. RA patients also tend to have an increased risk for pneumonia, bone/joint infections, and sepsis/blood serious infections.

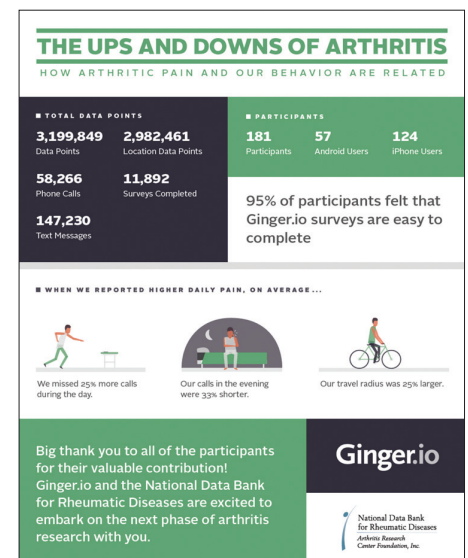
We are continuing research to break down the risk for serious infection type by individual drug type starting with RA patients.

## *Smart Phones and Rheumatic Disease Patient Outcomes*

About a year ago we had asked in the 6-month questionnaires a couple of questions on whether or not participants had smart phones and if they would be interested in doing a study using an application on their smart phone (this is the same app Dr. Michaud mentioned in his update). The smart phone study consists of the patient providing consent, downloading the app to their smart phone, and completing two daily questions on pain and function for 2 months while also answering 12 weekly questions from the Patient Activity Scale-II (PAS-II) for a total of 6 months. The app during this time also collected the number of unique calls and text messages, call duration, call counts, number of calls missed, and the total distance traveled. This “passive” data only had numbers recorded and no

personal information was collected. Distance measurements were collected to represent just the general distance traveled (so if the patient was just walking around in their house, it would not be able to collect any distance traveled). We invited 700 patients and 189 successfully downloaded the app and submitted data. From data collected so far, the results show that high pain is associated with missed calls, shorter call length, and greater phone mobility/movement. This overall outcome is showing that you can associate smart-phone behavior with disease activity. The smart phone app also has Arthritis Tips for patients, and every so often will ask an extra couple of questions prompting for opinions on the app, and for comments on how to improve the app and the study overall.

Here is a diagram of some of these results from this pilot study and was used on the poster at EULAR:



We plan on continuing this research study and will be inviting more patients to participate this year. We will also start testing it within a couple of clinics to get feedback on what other advances and improvements we can make to help the doctors and patients with both treatments and care. We thank all of you that have been able to help and continue to do the smart phone study!

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never actually get RA. But biological family members of RA patients are much more likely to get RA than a person without a family member with RA. While the risk is still relatively low (8 to 12% over a lifetime), it is still a group that can help us understand how we get RA.

We are working with leading researchers at the University of Colorado who have helped figure out how to prevent type I diabetes and who are now working to prevent RA. They have recruited over a 1000 family members of RA patients through a few clinical centers over the past decade. While this is an important group, they have been limited to family that lives near the centers to make in-person visits. Since we work with many patients directly all over the country, we are hoping that we can get family members to participate from all over, too. By better understanding how we get RA, we can also better understand how to postpone or prevent RA. In fact, we are working with researchers right now who have created the first-ever clinical trials to prevent RA. All of the participants in these trials are family members of RA patients with the highest risk of developing RA (as determined by antibodies in their blood).

There is no obligation for you or any of your family members to participate, but when we send you an invitation, we really hope you will consider helping out a little bit more. It takes only a few minutes to fill out—just depends on how big your family is—and we will never contact any of your family without your permission. Currently this study is just limited to our participants with RA, but there are a lot of reasons to believe that if it is successful, that we will expand this to other rheumatic diseases.

And on a personal note, my family will be growing as I get married this summer. She and I have had the very important, personal, and difficult conversation about

whether or not we want to have kids in the future knowing the potential health risks. And so our family study is not one that I take lightly as I venture happily and nervously into the unknown of creating a new family, but I thank you in advance for helping and for those of you who had such conversations with your own family.

### *Update from Dr. Fred Wolfe*

The National Health Interview Survey (NHIS) is a US government survey of the health of the entire US population. We have been trying to get the data that NHIS has collected to be used in participants with fibromyalgia. There is a problem, however, because NHIS doesn't collect the kind of information that ordinarily is used to diagnose fibromyalgia. Instead, they collect information about joints, but not the large painful body regions we need for a fibromyalgia diagnosis. So we used joint information that we had collected in the NDB to determine if joints could be substituted for painful regions in analyses. We found that it was possible. Our next step was to try out our substitution method in real life. So we asked two rheumatology practices if they would give out to their patients the standard fibromyalgia questionnaire as well as the NHIS questionnaire. The dual questionnaire was completed for 415 patients in the practices. We analyzed the data and built a set of instructions that mapped the results of the fibromyalgia questions to the NHIS questionnaire. With that done, we took the instructions to the NHIS survey of the entire US population for 2012 and applied it. We found that about 2% of the population could be diagnosed with fibromyalgia. We are currently analyzing the NHIS fibromyalgia data to understand the characteristics of the fibromyalgia group compared with the rest of the US population. The main work is being done by Dr. Brian Walitt at the National Institutes of Health and myself from the NDB. We expect to complete this exciting work in the next two months.



WebQuest is the online version of our questionnaire. The questions are the same as what you get on the paper questionnaire. People who are comfortable using computers should find it easier than the paper version. If you would like to try it, follow the links from our home page, [www.ndb.org](http://www.ndb.org) and make the request, or send us an email at [webquest@ndb.org](mailto:webquest@ndb.org).

# Arthritis Internet Registry (AIR) News

AIR is an internet-based patient registry and biospecimen collection using the combination of the patient-study infrastructure of the NDB, the nation-wide availability of Quest Diagnostics blood collection sites, and the patient outreach of the Arthritis Foundation. Participants in AIR complete the same questionnaires as the participants in the NDB, but are noted as AIR participants due to the way they enrolled into the data bank. Some AIR participants consent to donate blood samples for the biospecimen collection. We currently have had over 5,360 participants join and we have collected over 970 biospecimens on a variety of rheumatic diseases.

AIR recognizes the importance of research to improve the lives of arthritis patients and the needs of patients to discuss their disease with other patients. The purpose

of AIR is to bring together a community of arthritis patients to enable discovery research and social networking via the internet.



## Latest Research from AIR

The SAGE Networks/DREAM project: Rheumatoid Arthritis Responder Challenge has now

started. This project brings together investigators from all over the world who have contributed genetic data on many thousands of samples from patients with RA, with the goal

of identifying genetic predictors of response to therapy with a class of drugs known as TNF inhibitors. This project will challenge data analysts all over the world to come up with the best method of prediction, and will then be tested and refined in additional studies. The AIR project is one of two extra data sets that can be used in testing and refining methods to predict response to therapy.

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AIR is a partnership between leading academic researchers, the Arthritis Foundation, and Quest Diagnostics. The main researchers and advisors working on and supporting AIR are the following:

**Kaleb Michaud, PhD**

*NDB and the University of Nebraska Medical Center*

**Peter Gregersen, MD**

*The Feinstein Institute for Medical Research*

**Stanley J. Naides, MD**

*Quest Diagnostics Nichols Institute*

**John Hardin, MD**

*Arthritis Foundation*

**Join us on  
Facebook  
& Twitter**



You can find us on Facebook as "National Data Bank for Rheumatic Diseases." We will try to keep you up to date with any news items that occur between questionnaires. You can also connect with other participants and NDB staff who have joined our group.



You can find us on Twitter as "@ndb.org". We have added this for those that may be on Twitter but not on Facebook and we will be tweeting news and research items.

## Welcome New Participants!

Everyone who works for the NDB and all of the doctors and researchers who benefit from our research are extremely grateful for the dedication of you, the participant, in helping this project. Many of you have been with us for several years or more. But every 6 months we are also glad to see many new people join us. Here is a quick primer on the NDB for the new and a refresher for the old timers.



The NDB is a non-profit organization that performs research in rheumatoid arthritis, osteoarthritis, fibromyalgia,

lupus and other rheumatic diseases. The research is designed to improve the treatment and outcomes of these conditions.

The NDB is an independent organization that conducts its own research without influence from pharmaceutical, insurance, financial or other outside interests. Our research is so well respected that we are often hired to provide independent drug safety verification to the government.

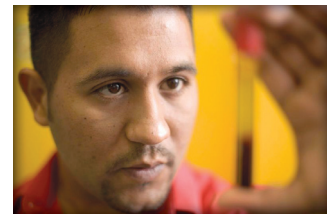
Your personal information will always remain private. We do not sell or share any identifying information about NDB participants. Before we work with researchers or collaborate with other research groups we remove any of your answers that could be used to identify you.

Nearly all of our research is available for you to read on our website. We are glad to answer your general questions about rheumatic diseases and treatments, but we are not able to give personal medical advice.

NDB research is different from other research endeavors in an important way: Participants report on themselves; thus data is not collected by doctors or medical staff. With patient-reported data, researchers get a perspective that short, small clinical trials cannot provide. Our long-term study offers a much broader view of treatment and results. Clinical trials are good at identifying common side effects, but rare or subtle problems, or problems that take longer to develop, are better detected by studies like the NDB. The same is true when looking at the long-term effectiveness of a treatment.

So, welcome to the NDB, or thanks again for your continuing participation! If you ever have any questions or need help with your questionnaire, feel free to contact us.

## Donate Blood for Research!



You can help advance arthritis research by donating a blood sample. By analyzing your blood in combination with your answers to the NDB questionnaires, we hope to discover biological reasons why some treatments work better and why some are more toxic to an individual.

As always, your privacy is protected and there is absolutely no cost to you. Your lab results will be available directly to you through a secured login on our website. You can also print out the lab results and take them with you to your next doctor appointment.

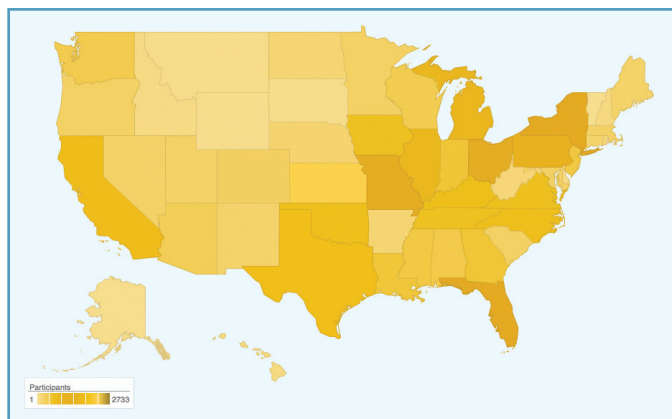
Blood collection takes place only at Quest Diagnostics laboratory sites, which are located in many cities across the US.

To donate blood, you must first sign a consent form, which we will mail to you. If you are interested in donating a blood sample, please contact Kimberly Harp by email at [kim@ndb.org](mailto:kim@ndb.org) or by phone at 1-800-323-5871 ext. 143.

## NDB Participants on the Map

Participants who have set up an account on our website will be able to see maps that show where participants are from and overall pain scores for each US state and also per specific diagnosis groups. The maps are set up for the following diagnosis groups: rheumatoid arthritis (RA), fibromyalgia, lupus, other inflammatory rheumatic diseases (which include psoriatic arthritis, ankylosing spondylitis, etc.), and non-inflammatory rheumatic diseases (which include osteoarthritis, osteoporosis, etc.).

You can view this map by logging into your account on our website or if you don't already have an account on our website, you can set one up by going to this page on the web: <http://www.ndb.org/user/register>



## *NDB Questionnaires and Primary Diagnosis*

We are asked a couple times every 6-months “Why did I get a questionnaire for RA/Fib, but my diagnosis is Psoriatic Arthritis (or some other diagnosis)?” As you may see on the cover of the paper questionnaires that are mailed out, it states a diagnosis on the cover, i.e. RA/Fib, OA, Lupus and Gout. The NDB Questionnaires first started out with only one version to cover all diagnoses, which was called “RA/Fib.” But over the years, as the NDB has been able to work with experts in other diagnoses, we have added on other questionnaires geared to ask more specific questions for certain diagnoses. The main one is still called “RA/Fib” to keep the questionnaire naming consistent over all the years of data collection. We wish we could have a questionnaire for each and every diagnosis, and might do so in the future, but currently we have the following questionnaires:

- **RA/Fib** is sent to all RA, Fibromyalgia and all other diagnoses (i.e. Psoriatic Arthritis, Ankylosing Spondylitis, Lower back pain, polyarthralgia, etc.). This questionnaire asks all the questions that will help aide the researchers to get the entire view of how a patient’s disease affects their lives.
- **OA** is sent to all osteoarthritis patients and asks the majority of the questions in the RA/Fib questionnaire and a certain set of questions that are used by rheumatologists to help with OA patient care.



- **Lupus** is sent to all lupus patients and has majority of the questions in the RA/Fib questionnaire and asks specific questions for understanding how lupus is affecting lupus patients. This one has undergone major changes this year.
- **Gout** is sent to all gout patients. Dr. Ted Mikuls and other researchers at the University of Nebraska Medical Center have helped to design this shorter and unique questionnaire specifically for patients with gout.

As you can now see, this is the reason why we ask on the enrollment forms for your primary diagnosis. In turn, we can make sure that we are sending you the correct questionnaire that will ask you the questions that best reflect how your disease is affecting your life. Please let us know at any time if your primary disease changes or if you have any questions about these questionnaires by emailing us at [webquest@ndb.org](mailto:webquest@ndb.org) or call us at 1-800-323-5871.

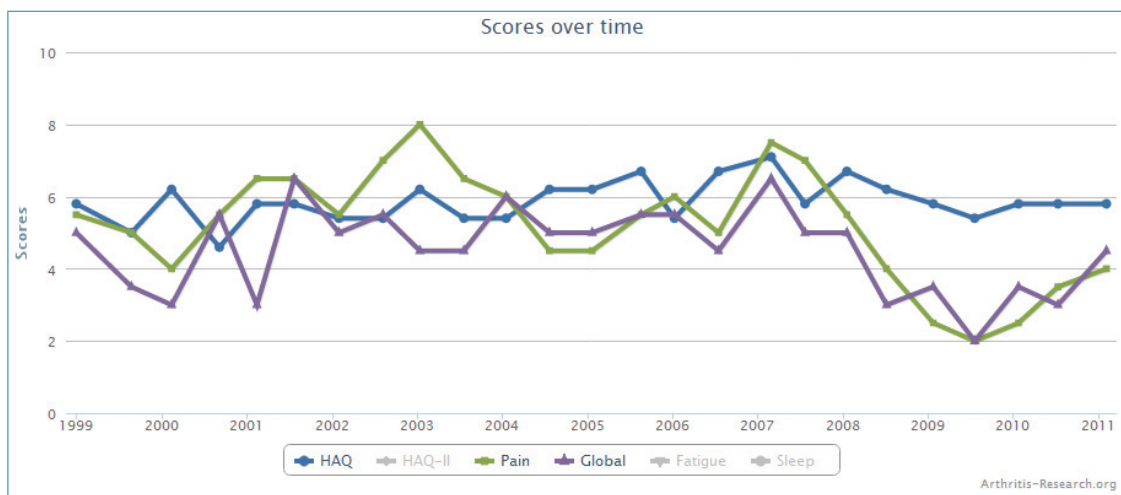


## *Changes to the Lupus Questionnaire*

Those of you who receive the lupus version of the questionnaire will notice some changes in July. As we wrote in the last newsletter, Dr. Patricia Katz, Professor of Medicine at the University of California, San Francisco (UCSF), has joined the NDB as a lupus research consultant. Two of her primary goals are to increase the number of people with lupus who are part of NDB research and to make the questionnaire more meaningful for them. The first step in meeting those goals was to add more questions specifically focused on lupus symptoms and impact, so in the July questionnaire we have added several new questions about lupus disease activity and long-term effects. The addition of these questions will help set the stage for more lupus-related studies within the NDB. Please let us know if there are other topics you think are important for us to include.

## View Your NDB Results Online

Many of the questions we ask every six months give researchers and doctors valuable scores that show how you're doing. We have heard from many of you that you want to see your results. You can now get



these scores any time you need them on our website. If you don't already have an account on our website, start on this page: <http://www.ndb.org/user/register>. Having an account protects your privacy and lets you access your scores.

You will be able to see scores for every questionnaire you've ever completed for the NDB, and print them for your own information or to show to your doctor. Please email us at [webquest@ndb.org](mailto:webquest@ndb.org) if you have any questions about the website or in regards to your scores.

## Lottery Winners!

The research data bank can best contribute to research when the questionnaires are completed and returned as soon as possible. We conduct the lottery as a token of our gratitude in help with rheumatology research.

Our lottery drawings consist of:

**2 drawings for \$1,000 each for those who complete a large questionnaire via mail, web or phone within the first 4 weeks of receiving a questionnaire.**

**2 drawings for \$500 each for those who complete a large questionnaire via mail, web or phone any time within the 5 ½ months of receiving a questionnaire.**

**4 drawings for \$50 each for those who complete a shorter questionnaire via mail or phone anytime within the 5 ½ months of receiving a questionnaire.**

The \$1,000 winners from the last questionnaire were Denise Watkins, Royersford PA and Nancy Morse, Crete IL. Winning smaller amounts were Vivian Waage, Goodell IA; Alicia Wright, Smyrna TN; a participant from Valley, AZ; Donald Hay, Ottawa KS; Joyce Frazier, Orlando FL; a participant from Knox, ME. Congratulations to all!

## Helping the NDB in Other Ways

Achieving the NDB's goals of telling the rheumatology community about patient experience depends on a large group of participants. Available for your support group for arthritis, fibromyalgia, or lupus meetings, our pamphlets explain what we do and how you and others can help. Each one has a postage-paid postcard to request more information or an enrollment form to join the project.



The pamphlets and a small table-top stand are available free from the NDB. Just contact us at [info@ndb.org](mailto:info@ndb.org) or 800-323-5871 ext. 133. Thank you!



## Refer a Friend

Here's a really easy way to let a friend know about the NDB. Just give us your friend's email address and we'll send out an email invitation to join the study. Go to <http://www.ndb.org/participate/tell-friend>.

## Support Rheumatic Disease Research With A Financial Donation

As a non-profit project conducting ongoing research to improve conditions for people with arthritis, fibromyalgia, lupus and other conditions, the NDB is an organization with ongoing financial needs.

If you would like to make a tax-deductible monetary donation to the NDB to help support this research, we would be very appreciative of your support.

If you would like to make your donation in memory of, or honor of someone, please let us know. We will send a card to the person of your choice to acknowledge your gift.

Donations should be payable to:

**Arthritis Research Center Foundation Inc.**

and sent to:

**Arthritis Research Center Foundation Inc.  
1035 N. Emporia, Suite 288  
Wichita, KS 67214**

Or you can donate online by visiting [www.JustGive.org](http://www.JustGive.org) and type in Arthritis Research Center Foundation.

For more information please contact Rebecca Schumacher at 1-800-323-5871, ext. 119 or [Rebecca@ndb.org](mailto:Rebecca@ndb.org).

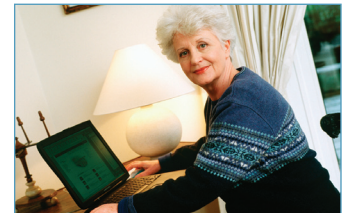
Thank you very much for considering a donation to support this important research.

## Important Information about Email

For patients using WebQuest, email is our primary method of getting in touch with you. Even if you're not using WebQuest, we'd like to be able to send you important information by email.

We cannot emphasize enough how important it is for you to let us know whenever you change your email address. To update your email address, go to our website and look in the participant's links, or call us.

Here's a VERY IMPORTANT step you can take to make sure our email gets to you: Add us to your email address book. Our address is [webquest@ndb.org](mailto:webquest@ndb.org). This will ensure that our mail makes it through the spam blockers. You will need to do this every time you change your email address. Thank you!



## Reminders

While working on your questionnaire, if you have ANY questions about the questionnaire, please contact us right away by email or phone. These might be about technical difficulties or how to interpret a question. If you put your immediate questions in the comments section we probably won't see it in time to answer.

Please use the comments section for any information you think we should have that isn't covered in the questionnaire. This could be about a change in medication that needs explanation or information about other considerations of your condition that you think we need to know. You may also ask general questions that don't require an immediate answer.

## FOR MORE INFORMATION OR TO PARTICIPATE

**Arthritis Research Center Foundation, Inc.**  
**1035 N Emporia | Suite 288 | Wichita, KS 67214**

**DIRECTORS: Frederick Wolfe, MD | Kaleb Michaud, PhD**  
**EXECUTIVE DIRECTOR: Rebecca Schumacher**

Please call 1-800-323-5871 or email [info@ndb.org](mailto:info@ndb.org)

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