Who may receive / use the information?

The NDB uses your health information related to this study in specific research projects. The information we use includes, but is not limited to, your medical history, symptoms, treatments, side effects, hospitalizations, infections, and work history. In addition, information from hospital or physician records is used to clarify the information you provide.

What will be used or disclosed?

• The Director of the National Data Bank for Rheumatic Diseases (NDB), Frederick Wolfe, MD, and the research and data collection staff of the NDB.
• Sponsors of the research study.
• Qualified medical researchers at other universities.
• The US Food and Drug Administration (FDA).
• The Via Christi Institutional Review Board (IRB).

Can I be identified personally?

No. Anyone who signs a consent form for the NDB before April 14, 2003 does not need to fill out an additional form.

If I have already signed an authorization or consent do I need to sign another one?

Yes. The National Institute of Environmental Health Sciences (part of NIH) has created a new group called the National Data Bank (NDB) for Rheumatic Diseases. So, we have added this section to the questionnaire as simple and straightforward as possible so you will not be identified personally (e.g., name, address, social security number, etc.) will be removed from all information used by medical researchers at other institutions, 2) FDA, 3) medical researchers at other universities, 4) FDA, 5) study sponsors.

HIPAA and the NDB - Frequently Asked Questions: The Health Insurance Portability and Accountability Act went into effect April 14, 2003. The law covers several elements of healthcare information transfer, but the most important element is most people in the Privacy Rule. This rule protects your health information from being shared with anyone unless you give authorization. This law protects the information that we collect from the NDB. Before are some frequently asked ques- tions about how the NDB uses and shares your information.

Does the NDB share information and if so what information will be used or disclosed?

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• A legally constituted review board charged to protect the safety of human subjects in medical research, called the Via Christi Institutional Review Board (IRB).
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• If I have already signed an authorization or consent do I need to sign another one?

News from the NDB Staff:

Celebrating our 5th Year! The NDB has reached the 5-year mark. A lot has changed through 10 questionnaires, and we are continuing to make the questionnaire as simple and straightforward as possible without losing any critical information needed for our research.

Below are a few changes you can expect to see in July’s questionnaires:

1. The questionnaire has been reorganized so that questions dealing with specific types of information (i.e., medical conditions, economic information, medications) are grouped within a few pages. This means you won’t have to flip back and forth from one part of the questionnaire to another to make sure you answered questions consistently.

2. The Intractable Medication page has been eliminated. All intractable drugs are VERY important to us, but to help streamline the questionnaire we removed this page. Now ALL intractable drugs should be written in like your other medications. There are special instructions on the first page of the drug section. PLEASE review these instructions to make sure you reflect the dosage and frequency of use accurately.

3. You will also see some new questions associated with a new osteoporosis section. The questions ask for information about fractures, bone density tests, and a special “Women Only” section. Since osteoporosis largely affects post-menopausal women this section is very important.

Many of you have asked for information about new medica- tions or treatments, and what other things are happening in arthritis research. So, we have added this section to the newsletter hoping these items will be of interest to you:

• The American College of Rheumatology News reported in the May 2003 issue that new biologics have been developed for the treatment of psoriasis which may greatly improve the quality of life for patients living with psoriasis and psoriatic arthritis. Alefacept is the first biologic to be approved by the FDA for this treatment. Enbrel® (Etanercept), efalizumab, and Infliximab (Remicade®) are other biologic agents that are in the final phases of testing to be approved for psoriasis treatment.

• The National Institute of Environmental Health Sciences (part of NDB) has created a new group called the Environmental Autonomy Group (EAG) that will conduct pioneering research in the area of genetic and environmental risk factors that may result in autoimmune diseases such as rheumatoid arthritis. The EAG is currently enrolling patients for a new study.

• The Minnesota Department of Health announced that the Minnesota Department of Health is currently enrolling patients for a new study.

• The National Institute of Environmental Health Sciences (part of NDB) has created a new group called the Environmental Autonomy Group (EAG) that will conduct pioneering research in the area of genetic and environmental risk factors that may result in autoimmune diseases such as rheumatoid arthritis. The EAG is currently enrolling patients for a new study.

• The FDA recently approved a new drug called “Forteo” (parathyroid hormone [PTH]) for the treatment of osteoporosis. Forteо is used as an injectable drug to increase bone mass in osteoporosis patients who are at high risk for fractures. Forteо also increases bone mass in osteoporosis patients who have not previously been enrolled in a clinical trial.

• The NDB has presented safety data on Enbrel® at the FDA meeting. NDB research, in agreement with a number of other studies, found no evidence of increased risk of heart failure among persons using Enbrel®. We did find, however, that the risk of another rare condition, tuberculosis, was increased among persons treated with Remicade®. This information has been submitted for publication and to the American College of Rheumatology (ACR) meeting in October 2003. Tuberculosis may occur shortly after starting Remicade® in a very few persons who have a positive skin test for tuberculosis. The actual rate was 53 cases for every 100,000 patients treated with Remicade® for one year. It appears, however, that this rare condition can be prevented by skin testing for previous tuberculosis infection before starting Remicade®.

• In some other breaking research, the NDB and the 2002 CHORD fellowship program reported to the ACR that the risk of occurrence of cancer was reduced among persons receiving anti-TNF therapy. We also found no association between heart failure and the use of TNF agents.

Three $1,000 Awards to Arthritis Research Participants:

Return your research questionnaire within two weeks of receiving it and be eligible for one of three $1,000 awards. The research data bank can best contribute to research when the mailed questionnaires are completed and returned as soon as possible. Anyone who completes the questionnaire within two weeks of receiving it will be eligible for the award – as a given of our interest in helping with arthritis research.

The winners from the last questionnaire were Ella Williams of Rayso, WV; Donald Mead of Wichita, KS; Judd Pickering of Brookhaven, MS.

Congratulations to all!
Costs of Medications.

If you have been following the debate just starting in congress about payment for drugs under the Medicare program, you may also have seen articles about people buying their medications from Canada. Some state legislatures, congressmen and patient organizations have strongly supported purchasing drugs from Canada. However, the US Food and Drug Administration (FDA) and drug manufacturers are opposed. How much of a problem are costs for people with arthritis? Who has the problem?

During the last 18 months we have been asking about your ability to pay for medications in our NDB questionnaire. Overall, about 20% of persons with arthritis or fibromyalgia did not get some medications because of cost and 3% didn’t have surgery because of costs. The graphs on this page provide some insight into possible reasons. Figure 1 shows that the worse function you have, the more difficulty you have obtaining medications or having surgery. Almost 30% of persons in the worst category did not get some medications because of cost. Figure 2 gives some further insight into the issue. It shows that total family income is a major factor in the ability to get needed medical services. Function and income go together. The more difficulty you have with function, the less likely you are to be working, the lower your salary if working, and the higher your medical bills.

20% of persons with arthritis or fibromyalgia did not get some medications because of cost

And the situation is getting worse. To cut their costs, insurance plans are covering less and insurance rates and Medicare premiums are going up. Are there any villains? Certainly many drugs cost too much – thus the reason people are trying to buy medications from Canada. A second serious problem in the US is the inability to get insurance for many people whose work ability is limited because of arthritis or who are not working. Still another problem is the higher insurance costs that are sometimes charged to those who are ill with arthritis. These types of problems are societal, although they affect each of us individually. If you see this as a problem, you might want to let your congressman know.

Two years ago, at the request of many of you, we launched an Internet version of the NDB research questionnaire. We call it WebQuest. Most people who have used it were quite pleased. In many respects, it is easier to use than the larger paper questionnaire. Here are some of its features.

WebQuest is smart. Depending on your answers, WebQuest can skip many unnecessary questions. This makes the questionnaire shorter and filling it out quicker. WebQuest also makes sure you don’t inadvertently miss some questions, which limits having to call you about missing items.

WebQuest remembers your answers from questionnaire to questionnaire when you use the WebQuest, it shows the treatments you reported last. That makes it easier for you to identify changes, or even to correct errors. You don’t have to do WebQuest all at once. If you log off, WebQuest remembers where you stopped and starts you there again.

On the [right] are some actual pictures of WebQuest from the Internet to show you how simple and friendly it is to use. Even if you received a paper questionnaire, you can do WebQuest instead.

If you are interested in trying the on-line questionnaire for the first time, or if your email address has changed, please let us know at webquest@arthritis-research.org or call us at 1-800-323-5871.

FOR MORE INFORMATION OR TO PARTICIPATE

Arthritis Research Center Foundation, Inc. 1035 North Emporia • Suite 288, W Chita, KS 67241 Director – Frederick Wolfe, MD Executive Director – Kathleen Urbansky
please call 1-800-323-587-1 ext. 133 or email info@arthritis-research.org

WebQuest: Trying the Questionnaire on the Internet

CHORD Health Outcomes in Rheumatoid Arthritis Program Update

CHORD is a program sponsored by Centocor, Inc. and directed by NDB director, Frederick Wolfe, Theodore Pincus of Vanderbilt University, and Hyon K. Choi of Harvard.

Physicians who were named as fellows in this program are training to be rheumatologists. During the yearlong fellowship training, CHORD fellows will study with Drs. Wolfe, Pincus and Choi using the research data from the National Data Bank. In the last newsletter we listed the physicians participating in the 2002 program. Many of these fellows have already submitted their research results to the 2003 American College of Rheumatology meeting. We will report more information on their research in the January 2004 newsletter.

The figure below is a list of the fellows and their affiliations for both the 2002 and 2003 programs.

For more information on this program, please contact

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Thank you for your feedback and patience. We expect this version of the WebQuest to be the best yet.

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1035 North Emporia • Suite 288
Wilton, KS • 67264
Director – Frederick Wolfe, MD
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The figure below is a list of the fellows and their affiliations for both the 2002 and 2003 programs.

The CHORD fellowship directors are proud to acknowledge the outstanding contributions of the ongoing 2002-2003 CHORD fellows.

We hope that your interest in fellowship training continues to support growth and expansion in rheumatology.

WELCOME 2002-2004 CHORD FELLOWS

Now incoming CHORD fellows can have the same opportunity for broad experience in clinical arthroseology, and outcomes research.

We welcome you, and look forward to a dynamic and challenging year!
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Over the last year we have been doing additional research into arthritis costs and will be publishing these results soon. For this information see the “Notes from the Director” section on page one.
The Health Insurance Portability and Accountability Act went into effect April 14, 2003. The law covers several elements of healthcare information transfer, but the most important element is to protect your health information from being shared with anyone unless you give authorization. This law protects the information that we collect from the NDB. Below are some frequently asked questions about how the NDB uses and shares your information.

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If I have already signed an authorization or consent do I need to sign another?

No. Anyone who signed a consent form for the NDB before April 14, 2003 does not need to fill out an additional form.

Can I be identified personally?

No, with exceptions 1) you may share identifying information with your rheumatologist or physicians if, for example, we contact your physician to clarify information you have provided; 2) if requested by the human subjects safety board (IRB); 3) if ordered by a court. Otherwise, information that will allow you to be identified personally (e.g., name, address, social security number, etc) will be removed from all information used by 1) medical researchers at other institutions, 2) FDA, and 3) study sponsors.

New Arthritis Drug Released.

Earlier this year, Abbott Laboratories released Humira® (generic name: adalimumab) for treatment of rheumatoid arthritis. Humira® is an anti-TNF agent that appears to be as effective as the other two anti-TNF agents, Remicade® and Enbrel®. One advantage of Humira® is that it is given by self-injection every two weeks, compared with Enbrel® that requires two injections per week, and Remicade® that requires intravenous infusions. Like Enbrel® Humira® will not be covered under Medicare reimbursement, and like the other TNF agents it is expensive with costs in excess of $15,000 per year. Other biologic agents are also being tested, including CTLA4i and Rituxan. These drugs may be available starting in 2005.

In Brief, What’s Coming…

Many of you have asked for information about new medications or treatments, and what other things are happening in arthritis research. So, we have added this section to the newsletter hoping these items will be of interest to you.

1. The American College of Rheumatology. News reported in the May 2003 issue that new biologic agents have been developed for the treatment of psoriasis which may greatly improve the quality of life for patients living with psoriasis and psoriatic arthritis. Alefacept is the first biologic to be approved by the FDA for this treatment. Enanrectum (Enbrel®), efalizumab, and infliximab (Remicade®) are other biologic agents that are in the final phases of testing to be approved for psoriasis treatment.

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3. The English Medicines Inspectorate has published its findings that there is some evidence that Remicade® for one year. It appears, however, that this rare condition can be prevented by skin testing for previous tuberculosis infection before starting Remicade®.

4. In some other breaking research, the NDB and the 2002 CHORD fellowship program reported to the ACR that the risk of recurrence of cancer was reduced among persons receiving anti-TNF therapy. We also found no association between heart failure and the use of TNF agents.

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3. You will also see some new questions associated with the new questionnaire study. The questions ask for information about fractures, bone density tests, and a special “Women Only” section. Since osteoporosis largely affects post-menopausal women this section is very important.

So far 2003 has been a very exciting and busy year. Earlier this spring, we presented NDB data at two meetings of the FDA. At the first meeting, NDB results for lymphoma, a kind of lymph cancer, were discussed. NDB research showed that lymphoma was rare among persons with RA, occurring in about 90 persons with RA and 69 patients without RA each year. NDB research did not show evidence of increased risk with Enbrel® or Remicade®, the TNF drugs. These results have been submitted for publication. The “bottom line” is that this is a very rare condition, and it does not seem to be associated with RA treatments.

The NDB also presented survey data on Anakinra at the FDA meeting. NDB research, in agreement with a number of other studies, found no evidence of increased in acute liver failure among persons using Anakinra®.

We did find, however, that the risk of another rare condition, tuberculosis, was increased among persons treated with Remicade®. This has been submitted for publication and to the American College of Rheumatology (ACR) meeting in October 2003. Tuberculosis may occur shortly after starting Remicade® in a very small percentage of people who have a positive test skin for tuberculosis. The actual rate was 53 cases per every 100,000 patients exposed to Remicade® for one year. It appears, however, that this rare condition can be prevented by skin testing for previous tuberculosis infection before starting Remicade®.

The winners from the last questionnaire were Ella Williams of Roswell, WV; Donald Mead of Wichita, KS; Judd Pickering of Brookhaven, MS. Congratulations to all!

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Research Notes from the Director

July 2003

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