

Consent to Participate in Research Study

We invite you to participate in a national research study about arthritis and other arthritis-like conditions (rheumatic diseases). This study is being conducted by the National Data Bank for Rheumatic Diseases (NDB). The purpose of this study is to learn about best treatments for rheumatic diseases, to better understand the outcomes of your illness, and the safety of treatments. There will be several thousand people participating from all areas of the United States.

What will you have to do? If you agree to participate you will be asked to fill out a questionnaire by mail or internet every 6 months; allow your doctor to send us information about your pain, functional ability, joint examination and laboratory tests, talk to an interviewer on the telephone from time to time; notify us of any change in address; and give us permission to contact your doctors or hospitals for additional information about your care and regarding drug safety. The questionnaires will ask questions about your rheumatic disease, the treatments you are getting, the effects of the disease on your function, the amount of pain, and the costs which you incur. You will continue to receive questionnaires even if you move or decide to receive your medical care from other doctors. WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY, but your participation will help increase knowledge of and interest in arthritis and other rheumatic diseases, and may help to better understand how to treat and improve these illnesses.

No experimentation is involved in this study, and the study will not alter your care in any way. Your decision whether or not to participate will not prejudice you or your medical care. This is a long-term study, meaning that there is no fixed number of months or years in the study. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice to you or effect on your medical care.

There are no risks or costs to you involved in this study, and no payment will be provided to you. The information you give us will not be disclosed to anyone in any way which would reveal your identity. Any data that may be published in scientific journals will not reveal the identity of the subjects. Patient information may be provided to Federal and regulatory agencies as required.

Data from this study may be linked with data supplied by the National Center for Health Statistics, the Center for Medicare and Medicaid Services, and other administrative databases. An administrative database has information about diagnoses, medical visits and laboratory tests. Your social security number may be used to match your data in the administrative database. Your data will be kept confidential according to the Privacy Act of 1974, and will be used only for research purposes.

If you have any questions call us at 316- 263-2125 or 1-800-323-5871 and we will be happy to answer them. For further information please call the following who are associated with this research to whom you may address complaints about this study, as well as questions about research and your right as a research patient:

- Dr. Frederick Wolfe, 1035 N. Emporia, Suite 230, Wichita, KS 67214 316-263-2125
- Chairman, Via Christi Regional Medical Center Institutional Review Board, Via Christi Regional Medical Center, 929 N. St. Francis, Wichita, KS 316-268-5114

The project will provide important information that will aid in the development of the most effective methods to treat arthritis and other rheumatic conditions. We hope you will join us in this important study.

What do you do now? To enroll you into this program and to contact you, as well as for your doctor to release your status to us, we need your signature, name, address, phone number, and a few other details. Please review and sign this consent and complete all of the questions on the following pages.

USE AND DISCLOSURE OF YOUR MEDICAL INFORMATION: By signing this form, you are authorizing the use and disclosure of your health information collected in connection with your participation in this research study. Your information will only be used in accordance with the provisions of this consent form and applicable law. If you decide to terminate your participation in the study, you may revoke your authorization, except to the extent that the law allows us to continue using your information. You may also revoke your authorization to contact your doctors or hospitals in regard to treatment side effects and other aspects of your care by contacting the NDB in writing.

What Information Will Be Used or Disclosed? Your health information related to this study that you provided to us, including, but not limited to your medical history, symptoms, treatments, side effects, hospitalizations, infections, and work history. In addition, information from hospital or physician records used to clarify the information you provided.

Who May Use and Disclose the Information? The following parties are authorized to use and disclose your health information in connection with this research study: 1) The Director of the National Data Bank for Rheumatic Diseases (NDB), Frederick Wolfe, MD, and the research and data collection staff of the NDB, 2) A legally constituted review board charged to protect the safety of human subjects in medical research, called the Via Christi Institutional Review Board (IRB).

Who May Receive / Use the Information? *The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study: 1) Qualified medical researchers at other universities, 2) The US Food and Drug Administration (FDA), 3) Sponsors of the research study, 4) Your rheumatologist or physicians, 5) A legally constituted review board charged to protect the safety of human subjects in medical research, called the Via Christi Institutional Review Board (IRB). Except for the last two parties listed, 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 universities, 2) FDA, 3) and study sponsors.

*Your information may be redisclosed if the recipients described above are not required by law to protect the privacy of the information.

Your Access to Research Information: You will not be allowed to see or copy information in the NDB research records.



