Clinical Health Assessment Questionnaire (ClinHAQ II)

Consent to Participate

To help your doctor understand how your arthritis is affecting your abilities, please fill out the questions on the next pages. Please try to answer each question, even if you do not think it is related to you at this time. There are no right or wrong answers. Please answer exactly as you think or feel.

If this is the first time you are completing a CLINHAQ questionnaire, please read the consent below and provide the information on page 2 before going on. Otherwise, just go on to page 3 now.

To have your questionnaire scored by a computer and your information reported back to your doctor, we need your consent, your name and address, and some identifying information. You only need to provide this information once. In follow-up questionnaires, your initials and date of birth will be all that is needed to identify you to the databank.

If you give your consent, your information will be stored in a computer database and reported back to your doctor for the purposes of your medical care. All of the information you provide is absolutely confidential. Except for your doctor and the National Databank for Rheumatic Diseases staff, no one will ever be able to identify you or your information. You will also receive an invitation to participate in a national arthritis research study that involves completing questionnaires every 6 months. Whether you choose to participate or not, your medical care will not be affected in any way.

I agree to have my questionnaires scored and reported back to my doctor. I understand that my medical care will not be affected if I choose not to answer this or any future questionnaires, and all information will remain confidential. If I answer no, this questionnaire will remain in my rheumatology medical record.

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.

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 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 human subjects in medical research, called the Via Christi Institutional Review Board (IRB).

*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.

Can I be identified personally? No, with 3 exceptions. 1) We may share identifying information with your rheumatologist or physicians if, for example, we contact your physicians 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 universities, 2) FDA, 3) and study sponsors.

Expiration: Your authorization for the use and/or disclosure of your health information will continue indefinitely. However, you may withdraw from the research study at any time.

I will participate in the Arthritis Research Project.

_____ Patient Signature

_____ Date Signed

Consent

☐ ☐

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45962

Instructions

1. You will need a blue or black pen that won't bleed through the paper. Please do not use pencil or red ink.

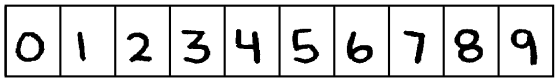
2 . You will see a lot of small squares like this: ☐ Yes ☐ No

These squares should be marked with an X like this: ☒ Yes ☐ No

Be sure to make your X inside the box, and fairly heavy, so the computer can read it.

3. You will also see some boxes that look like this:

For optimum accuracy, please print carefully and avoid contact with the edges of the box. The following will serve as an example:



Please--no fractions or decimals!!

4. You will also see some scales like the one below. You will need to make a mark in the box that best corresponds to your answer. These scales are usually 0-100. Read carefully to determine what the question is asking. In this example, the box marked with an X represents a person having a great deal of pain.

0 **100**

NO PAIN ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☒ ☐ ☐ SEVERE PAIN

First Name | MI | Last Name

Street Address

City | State | Zip | Area Code and Telephone Number

Best time to call you?

If we may contact you by email, please provide address:

Alternate Area Code and Telephone Number

How many years of school have you completed? Please X the box to the left of the number of years of school.

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17+ _____

----------Grade School ------- ----High School--- -------College------ Post college or Other

Please tell us your date of birth: **mm** / **dd** / **yyyy** 1 9

And are you: ☐ Male ☐ Female

Please tell us your ethnic background:

☐ White, not of hispanic origin ☐ Asian or Pacific Islander ☐ American Indian or Alaska Native

☐ Black, not of hispanic origin ☐ Hispanic ☐ Other

What is your primary rheumatic disease diagnosis (e.g.. rheumatoid arthritis, osteoarthritis, other rheumatic disease etc.)

Rheumatoid Arthritis? ☐ Osteoarthritis? ☐ Fibromyalgia? ☐ Other? (e.g. lupus, psoriatic arthritis, back pain, tendonitis, etc.) ☐

If you selected "other" for your diagnosis above, please give us the name of your diagnosis (for example: lupus, psoriatic arthritis, backpain, tendonitis, etc.):

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Date of birth: ☐☐ / ☐☐ / ☐☐☐☐ Last 4 digits of social security number: ☐☐☐☐

Patient Initials: ☐☐☐ Patient Name: _____

mm dd yyyy

Visit Date: ☐☐ / ☐☐ / ☐☐☐☐

How much of a problem has sleep (i.e. resting at night) been for you IN THE PAST WEEK? Place an X in the box below that best describes how much of a problem sleep has been for you on a scale of 0-10.

SLEEP IS NO PROBLEM **0** ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ **10** SLEEP IS A MAJOR PROBLEM

We are also interested in learning whether or not you are affected by pain because of your illness.
How much pain have you had because of your illness in the past week? Place an X in the box that best describes the severity of your pain on a scale of 0-10.

NO PAIN **0** ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ **10** SEVERE PAIN

We are interested in learning how your illness affects your ability to function in daily life. Place an X in the box which best describes your usual abilities OVER THE PAST WEEK:

Are you able to:	Without Any Difficulty (0)	With Some Difficulty (1)	With Much Difficulty (2)	Unable To Do (3)
Stand up from a straight chair?	☐	☐	☐	☐
Walk outdoors on flat ground?	☐	☐	☐	☐
Get on/off toilet?	☐	☐	☐	☐
Reach and get down a 5 pound object (such as a bag of sugar) from just above your head?	☐	☐	☐	☐
Open car doors?	☐	☐	☐	☐
Do outside work (such as yard work)?	☐	☐	☐	☐
Wait in a line for 15 minutes?	☐	☐	☐	☐
Lift heavy objects?	☐	☐	☐	☐
Move heavy objects?	☐	☐	☐	☐
Go up two or more flights of stairs?	☐	☐	☐	☐

How much trouble have you had with your stomach (i.e., nausea, heartburn, bloating, pain, etc.) in the past week? Place an X in the box that best describes the severity of your stomach problems on a scale of 0-10.

NO STOMACH PROBLEMS **0** ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ **10** SEVERE STOMACH PROBLEMS

Considering ALL THE WAYS THAT YOUR ILLNESS AFFECTS YOU, RATE HOW YOU ARE DOING on the following scale. Place an X in the box below that best describes how you are doing on a scale of 0-10.

VERY WELL **0** ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ **10** VERY POORLY

These questions are about how you feel and how things have been with you during the past month. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the 4 weeks:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐
Have you been a happy person?	☐	☐	☐	☐	☐	☐

We are interested in knowing about any problems that you may have been having with fatigue. How much of a problem has fatigue or tiredness been for you IN THE PAST WEEK? Place an X in the box below that best describes the severity of your fatigue on a scale of 0-10.

FATIGUE IS NO PROBLEM **0** ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ ☐ ☐ ☐ ○ **10** FATIGUE IS A MAJOR PROBLEM

How satisfied are you with your HEALTH NOW?

☐ Very satisfied ☐ Somewhat satisfied ☐ Neither satisfied nor dissatisfied ☐ Somewhat dissatisfied ☐ Very dissatisfied

FOR PHYSICIAN'S USE ONLY

ESR: _____ *mm/hr* **CRP:** _____ ☐ *mg/dl* ☐ *mg/L*

Number of joints: Swollen _____ **Tender** _____ **Which joint count used?** ☐ 28 ☐ 32-34 ☐ 68 ☐ Other _____

Date of first symptom: (i.e. date of onset) If month is not known, just enter year. **month** ☐☐ / **year** ☐☐☐☐

Diagnoses: Please indicate all rheumatic disease diagnoses by checking the appropriate boxes below.

☐ Rheumatoid arthritis ☐ Fibromyalgia ☐ Osteoarthritis of the hands

☐ Osteoarthritis of the knee ☐ Osteoarthritis of the hip

☐ Other arthritis-type diagnosis (e.g. lupus, psoriatic arthritis, etc.) _____