

WAIVER OF DOCUMENTATION OF CONSENT SCRIPT

INVESTIGATOR'S NAME: KAREN L. SMARR, PHD.

PROJECT # 1037679

DATE OF PROJECT APPROVAL: 06/26/03

STUDY TITLE: RAHELP.ORG: AN ONLINE SELF-MANAGEMENT PROGRAM FOR ADULTS WITH RHEUMATOID ARTHRITIS

1. I would like to ask you to participate in a study that involves research.
2. Participation is voluntary and your decision not to participate will not involve any penalty or loss of benefits. In order to take part in this study you must have rheumatoid arthritis, be over the age of 18, live in the United States, have access to an Internet-connected computer and a telephone, and have not participated in previous research conducted by Karen L. Smarr, Ph.D., who is the Principal Investigator, or in research in which she was involved. You may provide confirmation of your age and diagnosis by asking your doctor to complete a short form that we will provide or by sending a copy of a doctor's appointment receipt that includes your date of birth and diagnosis code to the study staff at the following address:

Karen L. Smarr, PhD
VA Research
Harry S Truman Memorial Veterans' Hospital
800 Hospital Dr.
Columbia, MO 65201

You could also fax these documents to Dr. Smarr at 573 814-6554.

This study is being sponsored by the Missouri Arthritis Rehabilitation Research and Training Center, funded by the Department of Education's National Institute on Disability and Rehabilitation Research.

This research is being done because we would like to see if 12 months of online education and communication among adults with RA leads to improved quality of life and overall functioning.

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in a group that will receive the program at the start of the study or a group that will receive the program at the conclusion of the study.

If you take part in this study, you will complete online questionnaires about your health status, psychological status, pain, and social function five times during your participation. These will require approximately 30 minutes every three months. They will be completed at the start of the study and 3 months, 6 months, 9 months, and 12 months after you enroll in the study. It will not be necessary to travel for this study.

There will be two groups in this study. One group will complete the online questionnaires five times during the first 12 months of the study and will participate in the online self-management program (OSM) during the following twelve months. This group's questionnaires will be compared to the other group's when everyone has completed the first 12 months of the study.

The second group will complete the questionnaires 5 times during the 12 months and participate in the 12-month online self-management program (OSM). The OSM will consist of 10 individual, once a week psycho-educational sessions about living and coping with rheumatoid arthritis. Participants will answer brief questionnaires following each of the 10 sessions. These sessions will address such topics as:

- The effect of RA on life goals
- The effect of RA on self esteem
- The effect of RA on personal relationships
- The effect of RA on coping skills
- The effect of RA on emotional responses
- Tools for pain management
- Tools for stress management

The sessions will be conducted by a counselor through a website that requires a special pass code to enter. Each person will receive their pass code when they enroll in the study. There will also be chat rooms and bulletin boards that participants will be encouraged to use to talk to each other and share information about what they are learning. Participants will not be encouraged to share personally identifying information on the website. If you do share identifying information on the website, it will no longer be protected by privacy regulations and might be disclosed to other people. Each person will have an individual sign-on code or name (an alias) for use in the website so their name will never be online. The website will be monitored by the counselor to make sure that no one shows symptoms of depression or severe distress. There will also be links to other arthritis-related websites for educational purposes. Following the 10-week psycho-educational program, participants will continue to visit and use the website until their year of participation ends. Participants who elect to continue participating in the online community after 12 months should be aware that the research team will be collecting data about the content and themes of the discussion board and chat room postings.

Persons in the waiting group will complete the questionnaires during the first 12 months and will participate in the OSM during the next 12 months.

3. The purpose of this study is to compare the effects, good and bad, of an online self-management program for persons with rheumatoid arthritis to the effects of having no access to the program on you and your overall well-being, health, and social functioning.
4. We are asking approximately 140 subjects to participate in this study.
5. The study staff may withdraw you from the study at any time after explaining to you the reason for withdrawal.
6. No serious risks are anticipated from participation in this study. It is possible that you may become mildly anxious or distressed while learning to use the online community, but this should go away quickly as you learn.
7. If you agree to take part in this study, there may or may not be direct benefit to you. You will have access to expert health information in a secure, noncommercial website. You may expect to benefit from taking part in this research to the extent that you are contributing to medical knowledge. We hope the information learned from this study will benefit other people with rheumatoid arthritis. There is no guarantee that taking part in this research will result in any improvement in your condition.
8. Instead of participating in this study, you could seek information about rheumatoid arthritis and/or other support groups on the Internet on your own without the OSM. Good quality information about RA may be found from the following organizations:

The Arthritis Foundation www.arthritis.org
National Institute for Musculoskeletal and Skin Diseases (NIAMS)
www.niams.nih.gov
9. Information produced by this study will be stored in the investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the study in a form that could identify you without your written consent, except as required by law. If you withdraw from the study, the investigator will be able to use any information that has already been collected as part of the study. You will not have access to personal information that has been collected until the study has been completed.
10. There will be no cost to you to participate in the study except the expenses you already have to maintain your telephone, computer, and Internet access.
11. You will receive \$25.00 at the end of your participation to compensate you for the time required to complete the questionnaires.

12. It is not the policy of the University of Missouri to compensate clinical research subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, provides medical, professional, and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty or staff. The University of Missouri also will provide facilities and medical attention to subjects who suffer injuries while participating in research projects at the University of Missouri.
13. If you have any problems or questions, you may contact Dr. Karen Smarr or Kathy Donovan Hanson, M.Ed., the project coordinator, at 1-888-740-6626.
14. I would be happy to answer any questions that you may have.
15. You may either print a copy of this document on the RAHelp web site, or we will send one to you. Which would you prefer?
16. We will follow the guidelines for protection of your personal health information (PHI) as outlined by HIPAA guidelines. For the purpose of the study, the following PHI will be obtained: your name, address, telephone number, date of birth, demographic information, medical diagnoses, the names of your rheumatoid arthritis medications, screening information, and the answers to study questionnaires. The data collected may be released to the Institutional Review Board of the University of Missouri, the Research and Development Committee at the Harry S Truman Memorial Veterans' Hospital, the study sponsor, federal or state government agencies in the course of carrying out their duties. . The primary investigator and study staff in the study will collect the PHI. The PHI will be used and or disclosed for purposes of auditing the study. Authorization to use these data will not expire. You may revoke our right to use the PHI by submitting a letter to the Dr. Smarr at:

VA Research
Harry S Truman Memorial Veteran's Hospital
800 Hospital Drive
Columbia, MO 65201

Revocation is not effective to the extent that persons you have authorized to use and/or disclose the PHI may have already acted in reliance upon this authorization. If you share the PHI with those not involved in the study, the law will no longer protect this information. You have the right to refuse authorization to the use of your PHI. In such cases, you should refuse to participate in this study. Participation is totally voluntary and refusal to participate will in no way affect the care that you receive.