

**Maine Medical Center**  
**Authorization to Participate in a Research Project**

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STUDY TITLE: Web-based Program for Symptom Management in Fibromyalgia  
CONSENT VERSION DATE: May 26, 2006

INSTITUTIONAL REVIEW BOARD (IRB) PROVIDING OVERSIGHT FOR PROTECTION OF HUMAN  
SUBJECTS: Maine Medical Center

INSTITUTION CONDUCTING THE STUDY: Collinge and Associates

STUDY SPONSOR: National Institute for Arthritis, Musculoskeletal and Skin Diseases, National Institutes of  
Health

INVESTIGATOR: William Collinge, Ph.D., M.P.H.

SUBJECT'S NAME (printed): \_\_\_\_\_

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You are being asked to volunteer for a research study. Research studies include only patients who choose to take part. In order to decide whether you should agree to be part of this research study, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent. Please take your time to make your decision.

You are being asked to take part in this study because you have fibromyalgia (FM).

**WHY IS THIS STUDY BEING DONE?**

The symptoms of FM can be made better or worse by various daily life events, lifestyle habits and behaviors. We want to find out if a simple computer program that keeps track of these influences can help people find the ways that work best for them to reduce their symptoms and improve their well-being.

**HOW MANY PEOPLE WILL TAKE PART IN THE CLINICAL TRIAL?**

40.

**WHAT IS INVOLVED IN THE STUDY?**

If you take part in this study, you will have the following tasks and activities:

- Complete the following forms to enroll in the study:
  1. An Application Form which contains demographic information (your age, marital status, race/ethnicity, etc.) and contact information.
  2. A Medical Information Form which you will take to your health care provider (doctor or nurse who has access to your medical records) for them to sign confirming your diagnosis of fibromyalgia and date of diagnosis. You will personally take this form to them and have them sign it, and then you will return it to Dr. Collinge. No medical information will be transmitted directly to Dr. Collinge from any medical care providers.

- Complete a questionnaire packet once each month for five months, which should take less than 30 minutes each time. The questionnaires will consist of the following:
  1. Fibromyalgia Impact Questionnaire – ten questions asking you to rate the impact of FM on your daily life.
  2. SF-12 – twelve questions rating the quality of your life in terms of pain, functioning and well-being.
  3. Health-Related Self-Efficacy Scale – six questions rating how confident you are that you can influence your health.
  4. Health Locus of Control Scale – 18 questions rating how much you feel you can control aspects of your health.
- Attend a three-hour workshop with a group of other FM patients at MaineHealth Learning Resource Center (southern Maine/New Hampshire participants) OR Caritas Carney Hospital (Boston area participants) hosted by Dr. Collinge. The first half of the workshop will be a focus group. In the focus group you will be asked to (1) discuss your past experience, if any, with self-monitoring and self-management strategies for FM; and (2) discuss strategies, behaviors and events in your own life that you think might influence your symptom levels. This discussion will be recorded for research purposes, but no identifying information about you would be included in any publication of the findings.
- The second half of the workshop will introduce you to the SMART Log approach to self-monitoring (SMART=Self-Monitoring and Review Tool). The SMART Log is a brief questionnaire to help you keep track of strategies, behaviors and events over a 24 hour period that might influence your symptoms. Your SMART Log will include things found in research and clinical practice to influence symptoms of FM. You will also be able to “personalize” your SMART Log by adding things unique to your life that you believe might be relevant to your health (e.g., medicines, supplements you might want to try, life stresses, etc.).
- You will be given a private page on the project web site that will host your SMART Log for the remainder of the project. You will have your own user name and password to access your private page to complete your SMART Log regularly.
- For the next three months we will ask you to visit the web site several times each week to fill in your SMART Log for what occurred over the past 24 hours. This should take about five to ten minutes each time, and also will include a brief rating of your symptom levels.
- Your web page will also provide you an optional “journal” feature. This will be a place where you can record personal notes, comments, observations and reflections on your health and on the SMART Log experience whenever you wish. Using the journal is not required. However, it may be a helpful way for you to gain new insights into your health over time. Dr. Collinge will have access to the journal comments of all participants to use in evaluating the program and in planning future research studies. However, any use or publication of journal comments would not include any way of identifying you.
- After your first month of using SMART Log, you will be able to see your SMART Profile. Your SMART Profile will be produced by a statistical analysis program on the web site. This program will analyze all the information you have entered into your SMART Log over time, including your symptom levels. It will attempt to find relationships between the items in your SMART Log and your symptom levels over time. Your SMART Profile may confirm things you already suspect, and it may also show you things you may not have been aware of. For example, someone’s SMART Profile might tell them that if they have an average bed time of 9:45 for a week, their pain levels significantly decrease. Someone else may discover that having two or more cups of coffee in the morning makes their symptoms worse, but one cup is okay. The purpose of your SMART Profile

will be to give you personalized, useful feedback about what behaviors and lifestyle factors in your life may help you reduce your symptoms and improve your well being.

- In the second month of using SMART Log you will attend a two-hour review meeting with other participants at MaineHealth Learning Resource Center (southern Maine/New Hampshire participants) OR Caritas Carney Hospital (Boston area participants) hosted by Dr. Collinge. The purpose will be for the group to discuss their experiences with the SMART Log program and address questions or problems related to its use.
- After the third month of using the SMART Log program you will be finished with that portion of the project. At that time you will attend a focus group meeting with other participants for two hours to discuss your views and opinions about the program. Your responses will be recorded for research purposes, but no identifying information about you would be included in any publication of the findings.
- Procedures that are considered experimental and are being tested in this trial: the SMART Log and SMART Profile are experimental procedures to determine their feasibility and usefulness for people with FM in managing their symptoms and improving well-being.

#### HOW LONG WILL I BE IN THE STUDY?

About four and a half to five months, from initial enrollment to the final focus group.

The researcher may decide to take you off this study if you:

- Decline to complete and return the questionnaire packets in a timely manner.
- Do not attend the initial workshop.
- Decline to use the SMART Log program as instructed on the project web site.
- Begin treatment for another serious medical condition other than FM.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher about your reasons and your thoughts about the project.

#### WHAT ARE THE RISKS OF THE STUDY?

Psychological discomfort is possible as a result of completing questionnaires which ask you to think about your emotional well-being, quality of life, symptoms and health beliefs. Psychological distress is also possible if you judge yourself to be inadequate or ineffective in your use of the SMART Log program, or if you feel discouraged about feedback you may get or not get from your SMART Profile. We will attempt to prevent these possibilities during the workshop discussions and review meeting, and Dr. Collinge will also be available to you by phone to discuss such concerns if they come up.

For more information about risks contact Dr. Collinge at (207)439-8049.

#### ARE THERE BENEFITS TO TAKING PART IN THE CLINICAL TRIAL?

You may gain new insights into how your behavior, lifestyle and daily life events affect your symptom levels and well being. This may allow you to make new choices that improve your health over time.

You will also be contributing to knowledge that may help other FM sufferers in the future.

A total honorarium of \$320 will be paid for full participation, as follows: \$20 for each of the five questionnaire packets you complete (\$20 x 5 packets = \$100), \$50 for attending the workshop, and \$50 for attending the follow-up focus group. In addition you will receive \$2 for each time you complete the

SMART Log up to 5 times per week (\$10/week x 12 weeks=\$120). You will receive a check at the end of each month for the month's activities that you completed. You will not be compensated for activities you do not complete.

#### WHAT OTHER OPTIONS ARE THERE?

The alternative is to not participate.

#### WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

Paper questionnaires and forms. Dr. Collinge will control access to all paper materials collected in the study (consisting of the Enrollment Form, Medical Information Form and the five questionnaire packets). These materials will be kept in a locked file cabinet in his office. The only individuals with access to these materials will be Dr. Collinge and the research assistant (to be named) who does scoring and data entry.

You will be assigned a subject ID number. This number, and no identifying information about you, will be on the questionnaire packets that you complete and return to Dr. Collinge. The results of these questionnaires will be sent electronically in a database file to Dr. Paul Yarnold, the project statistician, who will conduct the statistical analysis. However, no identifying information will be transmitted. Only Dr. Collinge will have the identifying information to connect your identity to your subject ID number.

Web site data. You will enter your SMART Log and optional journal information into your page on the project web site from your home computer. You will have a username and password to access your page and enter this data. This data will be collected in a database on the project's secure server. Access to the database will be restricted through the use of public-key cryptography to access only by machines authorized by Dr. Collinge and the host system will be secured according to industry best-practices.

#### WHAT ARE THE COSTS?

There are no costs to you for participating.

In the case of injury or illness resulting from this clinical trial, emergency medical treatment is available, but will be provided at the usual charge. Maine Medical Center will not compensate you or your insurance company in the event of any injury.

#### WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is your choice. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

We will tell you about new information that may affect your willingness to stay in this study.

#### PERMISSION TO USE IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH PURPOSES

#### WHY AM I BEING ASKED TO PROVIDE THIS INFORMATION?

As part of this clinical trial, you are being asked to provide Dr. Collinge with health information about yourself. This information will be collected, entered onto a database with the health information from

others taking part in this clinical trial, and studied in order to determine the usability and possible benefits of the SMART Log program for managing symptoms of FM.

#### WHAT AM I BEING ASKED TO PROVIDE?

You are asked to provide the following information:

1. Basic information about your age, race/ethnicity, religion, education, employment and marital status.
2. Basic information about your diagnosis.
3. Questionnaire responses about your symptoms, the quality of your life, and attitudes and beliefs about your health.
4. Brief information about daily symptom levels and life events and behaviors related to your health.
5. Your opinions and experiences of this project when it is finished. These will be asked in the focus group meetings at the end of the project, and will be recorded and transcribed.

#### WHO WILL SEE THIS INFORMATION?

This information will be seen by the Investigator (Dr. William Collinge), a Research Assistant (to be named), and a statistician (Dr. Paul Yarnold) who will analyze the data.

Personnel or members of the Maine Medical Center Institutional Review Board, the National Institute for Arthritis, Musculoskeletal and Skin diseases, or the federal Office of Human Research Protections may also see parts of the information you provide for this study to assure that subjects' rights and safety are protected and, therefore, may see your name and other personally identifiable information about you. The information collected is the property of Collinge & Associates, and you will not be able to get it back.

#### WILL THE INFORMATION COLLECTED AS PART OF THIS STUDY BE DESTROYED WHEN IT IS NO LONGER NEEDED?

In the event of any publication regarding this study, your identity will not be disclosed. It is difficult for Dr. Collinge to know how long your information will be kept -- at least until the end of the clinical trial, but most likely it will be kept on a database at Dr. Collinge's office for an indefinite length of time. We do not know when your information will no longer be used, and there is no expiration date after which it will be discarded.

#### CAN I STOP MY INFORMATION FROM BEING USED?

If you leave the study, and do not wish to have any more of your personal data collected, you must **notify Dr. Collinge in writing**. You may also call Dr. Collinge at (207)439-8049 and your request to stop collecting information will be honored, but you must also notify Dr. Collinge in writing. To notify Dr. Collinge in writing, send your request to: William Collinge, Ph.D., P.O. Box 263, Kittery Point, ME 03905. Any data that has already been collected will continue to be seen and used as described previously.

#### WHAT IF I DO NOT AUTHORIZE YOU TO COLLECT MY HEALTH INFORMATION?

If you agree to be in this clinical trial, you are authorizing Dr. Collinge to collect and use the health information you provide as part of the trial. If you do not want this information collected or used, you may not take part in this clinical trial (do not sign this form if you do not want to take part in this clinical trial, or if you do not want your health information collected and used).

#### WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury contact Dr. William Collinge at (207)439-8049.

For questions about your rights as a research participant, contact the Maine Medical Center Institutional Review Board (which is a group of people who review the research to protect your rights) at (207) 885-8195. Dr. Kenneth Ault is the chairperson of the Maine Medical Center Institutional Review Board.

***I have read, or have had read to me, the above information before signing this consent form. I agree to participate in this clinical trial. I also authorize you my permission to use or disclose my personal health information for the purpose of this research. I have been offered ample opportunity to ask questions and have received answers that fully satisfy those questions.***

\_\_\_\_\_  
Signature of Patient or Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Patient or Authorized Representative

\_\_\_\_\_  
Signature of the Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

A signed copy of this consent form must be given to each subject entering the study.