UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Acceptance and Commitment Therapy for Chronic Pain in SCI: Testing of an eHealth program, *My SCI Toolkit*

Company or agency sponsoring the study: Craig H. Neilsen Foundation

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Anna Kratz, PhD., Department of Physical Medicine & Rehabilitation, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether changing an individual's behaviors may have an impact as a treatment or outcome for pain in adults with spinal cord injury (SCI). This research will test the feasibility and acceptability of My SCI Toolkit, and eHealth-delivered ACT intervention for adults with SCI. Your self-reported health and symptom information will be collected for this research study.

This study involves a process called randomization. This means that the treatment group you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or

procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include frustration and/or fatigue when using the My SCI Toolkit website or completing the online surveys. There is also a low risk of a loss of confidentiality. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by improving your self-management skills to address pain. Additionally, other people with SCI may benefit in the future from the knowledge gained from this study. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about 8 weeks.

You can decide not to be in this study. Alternatives to joining this study include continuing with your care as usual.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: Pain is very common among people with SCI. Though prevalence estimates for chronic pain in SCI vary widely due to differing definitions and measurements of pain, estimates range from 26% to 95%[1] with an average prevalence rate across studies of about 65%. Unfortunately, despite its high prevalence and grave impact, it is estimated that 50-60% of those with SCI do not receive adequate treatment for their pain. There are a number of different evidence-based approaches to managing pain within the field of psychology. Acceptance-based pain management interventions, such as Acceptance and Commitment Therapy (ACT), have been shown to improve emotional and physical health and functional outcomes. Unfortunately, current ACT-based treatment for chronic pain are not readily accessible to many people with pain and SCI. This study is addressing these current limitations through creation of the My SCI Toolkit online ACT intervention for SCI-related chronic pain. This study will test the newly-developed My SCI Toolkit program in two formats – unguided use of the program and use supported by a coach. These two active treatment formats will be compared to treatment as usual (waitlist control) in a sample of 80 adults with chronic pain and SCI.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Diagnosis of SCI (all injury levels included);
2. Age 18 years or older
3. Has clinically significant pain
4. Fluent in English and able to read English at a 6th grade level
5. Access to internet connected device (phone, tablet, computer) and telephone
6. Willingness to maintain stable pain medication regimen during study period.

An individual who meets any of the following criteria will not be eligible to participate in this study:

1. Currently in inpatient care or intensive outpatient physical therapy
2. Has significant cognitive impairment.

3.2 How many people are expected to take part in this study?

80 participants are expected to participate in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

You will first be asked to complete some online surveys, asking about some demographic, health, and symptom information. You will then be randomized to 1 of 3 groups - unguided use of the My SCI Toolkit program, coached My SCI Toolkit, or wait-list control, for an 8-week treatment period. This means there is a one in three chance of being in any given group.

If you are randomized to the unguided use of the My SCI Toolkit program, you will be asked to use the My SCI Toolkit program on your own for 8 weeks, following the prompts and guides built into the program. You will be encouraged to go through all modules on the website and learn and practice the skills in your daily life. You will be given the contact information of the study team to call if you have any questions or concerns.

If you are randomized to the coached My SCI Toolkit program, you will be asked to use the My SCI Toolkit program for 8 weeks, following the prompts and guides built into the program. You will also have weekly phone calls (the first is about 30-45 minutes, and the rest are about 15 minutes) with a study coach. The coach can help answer questions and tailor the skills more to your goals and needs. The coaching sessions will be audio recording for fidelity purposes.

If you are randomized to the waitlist control group, you will not access the My SCI Toolkit program during the 8-week study period and will be asked to continue your daily life, including management of your pain, as usual.

All participants will also be asked to complete online surveys at baseline (before being randomized to a group), half-way through the 8-week study period, and after the 8-week study period is over. The surveys are online and can be completed from home. They ask questions about demographics and your health and symptoms and take approximately 20-30 minutes to complete. All participants will also be asked to complete a weekly online survey that takes approximately 5 minutes to complete. The survey asks about changes in medication use, as well as use of the website in the past week (if in the unguided or coached program).

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you attend at all of your scheduled phone appointments and report any adverse reactions you may have during the study.

4.2 How much of my time will be needed to take part in this study?
Every participant will be asked to complete online surveys at baseline, 4-weeks, and 8-weeks that will take approximately 20-30 minutes to complete.

Each participant in the unguided group will be asked to access the My SCI Toolkit website at least one time per week and practice the skills learned in their daily life. This could take approximately 20 minutes to an hour depending on the person. Participants in this group will also be asked to complete a weekly survey about changes in medication use and their use of the website, taking approximately 5 minutes.

Each participant in the coached group will be asked to access the My SCI Toolkit website at least one time per week and practice the skills learned in their daily life. This could take approximately 20 minutes to an hour depending on the person. Each participant in this group will also have weekly phone calls (the first is about 30-45 minutes, and the rest are about 15 minutes) with a study coach. Participants in this group will also be asked to complete a weekly survey about changes in medication use and their use of the website, taking approximately 5 minutes.

Each participant in the waitlist control group will be asked to complete a weekly survey about changes in medication use, taking approximately 5 minutes.

4.3 When will my participation in the study be over?
Your participation in the study will be over once you've completed the 8-week follow-up survey or any time you decide to end your participation. The My SCI Toolkit website may not be available after the close of the trial.

4.4 What will happen with my information and/or biospecimens used in this study?
Your collected information may be shared with the Craig H. Neilsen Foundation.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are:

My SCI Toolkit eHealth Program: It is possible that participants may become frustrated/fatigued while exploring all the aspects of the website or find it difficult or uncomfortable to practice some of the skills.

Study Questionnaires: Risks of study questionnaire completion include discomfort, frustration, or boredom.

The researchers will try to minimize these risks by allowing participants to stop using the My SCI Toolkit website at any time and can skip any modules that they would like. Participants may also refuse to answer any questions that make them frustrated or uncomfortable and may take breaks as needed when completing the surveys.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. However, some participants may see an improvement in their self-management skills to address pain as a result of being in this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
There may be other ways of treating your condition. These include physical therapy, pain medication, acupuncture, psychotherapy, massage, stretching, exercise, etc. Although My SCI Toolkit is available as part of this clinical study, you should check with the researcher and/or your primary care physician to discuss your options including how to obtain any alternative treatments and whether they must be obtained through a physician or require medical supervision.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There will be no harm to you if you decide to leave the study before it is finished. The study coordinator may ask for and document your reason for ending your participation early.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.

- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

There are no costs or billing for this study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

Yes. You will receive $50 each for completing the surveys at baseline, 4-weeks, and 8-weeks for a total of $150.

8.3 Who could profit or financially benefit from the study results?

No one stands to profit or financially benefit from the study results.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
To reduce the risk to confidentiality, no personal identifying information will appear on or with the participant data. Each participant will be assigned a number to maintain confidentiality. Study personnel will keep a master list of the participant names and matching participant numbers. This master list will be kept by site personnel in a password-protected file on a secure server or in a locked cabinet in a locked office. No one other than study team members will have access to the master list. The electronic data collection and storage system used (REDCap) is a secure system, approved for research use, with access limited to the study team. The identities of all participants will be held in strict confidence to the extent provided by law. If findings from the study are published and/or presented at professional meetings, no participant will be identified by name.

Because the study is conducted virtually, the participants' privacy during study activities is in their own hands; they can determine when and where to engage in study activities. The study coordinator and coach will work with each participant to determine their preferred means of communication and whether and where study messages can be left for the participant.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Demographic information
- Personal identifiers
- Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.

- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
  - Make sure the study is done safely and properly
  - Learn more about side effects
  - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Anna Kratz, PhD
Mailing Address: 2800 Plymouth Rd, NCRC B016-G031N, Ann Arbor, MI 48109
Telephone: 734-647-5982

Study Coordinator: Keara Ginell
Mailing Address: 2800 Plymouth Rd, NCRC Building 16, Ann Arbor, MI 48109
Telephone: 734-936-2844

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to audio recording solely for purposes of this research

This study involves audio recording. If you do not agree to be recorded, you CAN STILL take part in the study.

_____ Yes, I agree to be audio recorded.

_____ No, I do not agree to be audio recorded.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____