a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

Vancouver Coastal Health Research Institute
Healthier lives through discovery

icord

Consent Form

Adult Arthrogryposis Research Registry: For patients by patients.

Principal Investigators: Bonita Sawatzky, PhD
Department of Orthopaedics, University of British Columbia
Principle Investigator, ICORD

Ann Marie Davison, PhD,
Department of Biology, Kwantlen Polytech University

Noemi Dahan-Oliel, PhD,
School of Physical & Occupational therapy, McGill University

Co-Investigators: Adult AMC Registry Team

Primary Contact: Bonita Sawatzky, PhD
bonita.sawatzky@ubc.ca

1. INVITATION TO PARTICIPATE
You are invited to participate in this Adult AMC registry if you have been diagnosed with arthrogryposis and are 16 years of age or older.

2. YOUR PARTICIPATION IS VOLUNTARY
Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study as well as the possible benefits, risks and discomforts.

If you wish to participate, you will be asked to consent online. If you decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide any reason for your decision not to participate. Please take time to read the following information carefully and to discuss it with your family, and/ or friends before you decide.

3. WHO IS CONDUCTING THIS STUDY?
A group of international researchers led from the University of British Columbia in Vancouver CANADA, are creating an online AMC registry. These are the investigators listed and the Adult AMC Registry team. This registry has been funded in part by the grant-in aid the Canadian Institute for Health Research, the University of BC in Vancouver and the AMC Support Inc.

4. BACKGROUND
Arthrogryposis Multiplex Congenita (AMC) is a condition where primarily the limbs have

significant limitation in motion at birth. Many individuals undergo many surgeries and extensive physiotherapy to improve range of motion. Adult with AMC at AMC support group raised concerns about surgical outcomes in adult with AMC such pain, fatigue or pain, physical challenges they face when they grow older, including financial burden or what treatment works best for long term function outcome. They want to be able to participate in longitudinal study to provide data to clinician to help make them better informed decision for ongoing care. We propose the international online database and registry for Adults with AMC by Adults with AMC. We as researchers are very interested in learning more about the natural progress and best therapies for various types of AMC and create a longitudinal online data registry.

It is increasingly common for researchers to invite participants to bank their data for use in future research studies. Often the exact nature of these studies is not entirely known because of new discoveries lead research in new and not always foreseen directions. For this reason, we ask you to consider allowing us to store the data from into a registry for future studies that are as yet undetermined.

If in the future, other researchers not involved in this study request your information, they may be given access only to the coded data but they will not know your identity. All future studies will also need to get proper research ethics approval to be allowed access to the database.

5. WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to learn more about the natural progress and best therapies that have worked for various types of AMC through a longitudinal (annual) online data registry.

6. YOU ARE ELIGIBLE TO PARTICIPATE IF:

1. You have been diagnosed with a type of arthrogryposis
2. Are 19 years or older
3. Understand written and spoken English
4. Have access to the internet

7. WHAT DOES THE STUDY INVOLVE?

The study involves participating in an *Initial Questionnaire* that you complete online which will take about 30-40 minutes. The questionnaire uses questions targeted about arthrogryposis and also general questions that have been used for a variety of populations. We ask about your demographics, your education and work life, living situation, diagnosis, treatments you've had, quality of life, functional abilities, physical and mental health.

At the anniversary of when you have submitted the *Initial Questionnaire,* we will send you another link via the email address you provide, at the end of the questionnaire. This link will direct you to an *Annual Questionnaire.* This will be done at years 1, 2 and 3 post the first questionnaire. This questionnaire will take 5-10 minutes to complete. On the 5th year we will send you a longer questionnaire again similar to the first questionnaire. We hope to repeat this process for another 5 years.

If you do not feel comfortable answering a specific question, you may choose not to answer. There are places for longer answers if you wish to provide information no specifically asked as well.

8. WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS OF PARTICIPATING?
There are no known harms to participating.

9. WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?
There are no benefits to individuals for participating in this study other than contributing to the advancement of knowledge.

10. HOW WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?
Your confidentiality will be respected. Your data will only be referenced via an assigned unique participant number and all the collected data will be identified only by this number. No information that discloses your identity will be released or published without your specific consent to the disclosure. No records, which identify you by name will be allowed to leave the Investigators' offices, only deidentified data will be used in the data analysis.
Your data will be stored on a Canadian server in Toronto, Ontario managed by the Praxis Insititute (formally Rick Hansen Institute). Data will be stored for 10 years. Only the researchers and registry committtee will have access to the data.

11. REIMBURSEMENT
No reimbursement for your time is offered in this study.

12. WHAT HAPPENS IF SOMETHING GOES WRONG?
By clicking the “I consent” button in the online registry, you do not give up any of your legal rights and you do not release the study investigators, participating institutions, or anyone else from their legal and professional duties.

13. WHAT WILL HAPPEN IF I DECIDE TO WITHDRAW FROM THE STUDY?
You are entitled to withdraw from the study at any point. No questions will be asked regarding your reason for withdrawing from the study. Please email the principle investigator directly if you wish to do so.

14. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?
If you have any questions or desire further information about this study before or during participation, you can contact the Principle Investigator, Dr Bonita Sawatzky, bonita.sawatzky@ubc.ca

15. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT MY RIGHTS AS A RESEARCH PARTICIPANT?
If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

Check List

- *I have read and understood the information in this consent form.*
- *I have had enough time to think about the information provided.*
- *I have been able to ask for advice if needed.*
- *I have been able to ask questions and have had satisfactory responses to my questions.*
- *I understand that all of the information collected will be kept confidential and that the result will only be used for purposes.*
- *I understand that my participation in this study is voluntary.*
- *I understand that I am completely free at any time to refuse to participate or to withdraw from this study at anytime*
- *I understand that I am not waiving any of my legal rights as a result of signing this consent form.*
- *I understand that there is no guarantee that this study will provide any benefits to me (if applicable).*
- *I have read this form and I freely consent to participate in this study.*
- *I have been told that I will receive a dated and signed copy of this form.*

PARTICIPANT CONSENT

Your participation in this study is entirely voluntary and you may refuse to participate or withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. Your future medical care will not be affected. Agreeing to consent in no way limits your legal rights against the sponsor, investigators, or anyone else.

"I consent" yes ☐