

## **Implied Consent Information for Participation**

### ***Measurement validation and value implications of a PROM-ED tool in the Alberta context***

#### ***(Testing a questionnaire on emergency department outcomes)***

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### **WHY AM I BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?**

- This study is about testing a questionnaire that measures self-reported outcomes for emergency department patients.
- We are inviting patients who have recently visited an emergency department to get care for themselves to tell us about how they're doing after their emergency department visit.
- Your participation is important to ensure the questions focus on results that matter most to you.
- Your participation in this questionnaire is entirely voluntary, and you do not need to answer any question you do not feel comfortable answering.
- If you decide to take part in this study you are free to drop out or end the questionnaire at any time without having to provide a reason and without penalty.
- This project is being conducted by the HQCA under the authority of the *Health Quality Council of Alberta Act*.

### **HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

- At least 1,000 recent emergency department patients (age 16 or older) from 14 large urban and regional hospitals in Alberta will take part in this study by completing the questionnaire.
- The hospitals included are:
  - Chinook Regional Hospital (Lethbridge)
  - Foothills Medical Centre (Calgary)
  - Grey Nun's Community Hospital (Edmonton)
  - Medicine Hat Regional Hospital
  - Misericordia Community Hospital (Edmonton)
  - Northern Lights Regional Health Centre (Fort McMurray)
  - Peter Lougheed Centre (Calgary)
  - Queen Elizabeth II Hospital (Grande Prairie)
  - Red Deer Regional Hospital
  - Rockyview General Hospital (Calgary)

- Royal Alexandra Hospital (Edmonton)
- South Health Campus (Calgary)
- Sturgeon Community Hospital (St. Albert)
- University of Alberta Hospital (Edmonton)

## **WHAT WILL HAPPEN DURING THIS STUDY?**

- If you decide to participate, you will be asked to complete an online questionnaire about how you're doing after your recent emergency department visit.
- The questionnaire should only take about 15 to 20 minutes to complete.
- The information you provide to us will **NOT** be monitored by a doctor. Taking part in this questionnaire should not replace a follow-up with your family doctor or other primary healthcare provider.
- Your information will be combined with answers from other patients and used to test this questionnaire that measures self-reported outcomes for emergency department patients.
- Your information will be combined with answers from other patients and used with service providers to discuss how questionnaire results about patient outcomes could be used to improve patient care.
- This study should take the study team approximately 2 years to complete and the results should be known in about 18 months.

## **WHAT WILL HAPPEN IF I CHOOSE TO WITHDRAW FROM THE STUDY EARLY?**

- If you decide to take part in this study you are free to drop out or end the questionnaire at any time without having to provide a reason and without penalty.
- Information that was recorded before you withdrew will be used by the researcher for this study, but no additional information will be collected after you withdraw your participation.
- If at any point you no longer want your information to be used in this study, please contact the study team at [Emerg.Dept.Survey@hqca.ca](mailto:Emerg.Dept.Survey@hqca.ca), or reach us by phone at 1-855-508-8162.
- You can request your information be removed from the study up until the results of the study are published, in about 2 years.

## **WHAT ARE THE RISKS/DISCOMFORTS OF PARTICIPATING IN THIS STUDY?**

- There is no risk to being involved in this study.
- The information you provided to us will NOT be monitored by a doctor. If you have unresolved, acute, or urgent concerns about your health, please contact Health Link Alberta for nurse advice and health service information 24 hours a day, by dialing 811. If you are outside of Alberta, you can call Health Link Toll-Free at 1-866-408-5465.

## **WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING IN THIS STUDY?**

- There is no direct personal benefit to being involved in this study.
- However, based on the results of this study, it is hoped that in the long-term, follow-up on emergency department patient care can be improved.

## **HOW WILL MY PERSONAL INFORMATION BE KEPT PRIVATE?**

- Your name and email address will be used by members of the study team to invite you to participate in this study by completing the questionnaire. However, your name and contact information will not be connected with anything you say, will be kept strictly confidential, and will not appear in any reports of results.
- If you decide to participate, the researcher and study staff will only collect information they need for this study. They will do everything that they can to make sure that this data is kept private/confidential. All data collection and analysis will happen at the Health Quality Council of Alberta (HQCA) office in Calgary by members of the study team who are employees of the HQCA. The HQCA has strategies in place to make sure your data is kept private/confidential. These strategies include: secure log-on codes and password protection on all workstations; secured office doors 24 hours/day (no public access to HQCA offices and visitors are screened before entering); Firewalls are in place to restrict access to your data to specific members of the study team; and data servers are located in a secured room and protected by a full range of environmental protection features.
- No data relating to this study that includes your name will be released outside of the study site nor will it be published by the researcher. Sometimes, by law, the researcher may have to release information including names and therefore absolute confidentiality cannot be guaranteed. However, every effort will be made to make sure that your information is kept confidential.
- The researcher or study staff may need to look at your medical files/records or at those kept by other health care providers that you may have seen in the past (e.g., your family doctor). Identifiable information is only used for linking data and will be removed from further analysis. Therefore, any information that they get from these records will be unidentifiable and only what is needed for the purpose of this study. It will be kept confidential to the extent permitted by the applicable laws and will not be disclosed or made publicly available.
- After the study is done, we will still need to securely store your data that was collected as part of the study. We will keep your data and study records stored for 5 years after the end of the study.

### **WILL THERE BE COSTS INVOLVED WITH PARTICIPATING IN THIS STUDY?**

- There are no costs involved with participating in this study.

### **WILL I BE COMPENSATED FOR PARTICIPATING IN THIS STUDY?**

- You will not be paid for taking part in this study.

### **WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY?**

- Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.
- If you decide to take part in this study, your participation is voluntary and your medical care or legal rights will not be affected.
- If you decide to take part in this study you have the right to drop out or end the questionnaire at any time without having to provide a reason and without penalty.

### **WHO DO I CONTACT FOR QUESTIONS RELATED TO THIS STUDY?**

- If you have questions about taking part in this study you should contact the study team at [Emerg.Dept.Survey@hqca.ca](mailto:Emerg.Dept.Survey@hqca.ca), or reach us by phone at 1-855-508-8162.
- If you have questions about your rights as a participant or about ethical issues related to this study and you would like to talk to someone who is not involved in the conduct of the study, please contact the Office of the Health Research Ethics Board of Alberta by phone at 1-780-423-5727 (or toll-free at 1-877-423-5727).

**BY CLICKING ON THE LINK PROVIDED IN THE EMAIL INVITATION AND NAVIGATING TO THE QUESTIONNAIRE YOU ARE GIVING CONSENT TO PARTICIPATE IN THIS STUDY.**