Official Title: Decision Support for Adults Facing Implantable Cardioverter-Defibrillator Pulse Generator Replacement

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UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

PARTICIPANT INFORMED CONSENT FORM

Title of Study:
Evaluation of Decision Support for Adults Considering Implantable Cardioverter-Defibrillator (ICD) Pulse Generator Replacement: A Pilot Randomized Controlled Trial

Principal Investigator (PI):

Dr. David Birnie MD 1-613-798-5555 ext. 14705

Sponsor (or Funding Agency): Canadian Council of Cardiovascular Nurses

Participation in this study is voluntary. Please read this Participant Informed Consent Form carefully before you decide if you would like to participate. Ask the study team as many questions as you like. We encourage you to discuss your options with family, friends, and your health care team.

Why am I being given this form?

You or your family member is being asked to participate in this research study because the battery in your ICD is depleting.

Why is this study being done?

The ICD is a small medical device that can detect unsafe heart rhythms. If detected, the ICD can deliver a shock to stop them. ICDs need a battery to function. It needs to be replaced by surgery every 5 to 7 years to maintain normal function. The aim of this study is to see how best we can support patients faced with the decision to replace their ICD. We plan to enroll 80 people in this study from the Heart Institute. We are asking patients with ICDs that are nearing the time when they would need to replace their ICD to participate.

How is the study designed?

This study compares a new approach to support patients who are facing ICD battery replacement with the current way we do it. We refer to the new strategy as *intervention*. We refer to the current way as *usual care*. Whether you get the intervention or usual care is decided at random. This means that you are put into a group by chance – like a flip of a coin.

What is expected of me?

There will be a total of four visits over the course of 12 months.

1. At the **first visit** you will meet a member of the study team. They will find out if you can be in this study. If you can and you agree to participate, you will be assigned at random to one of two groups. Whether you are assigned to *usual care* or *intervention*, you will talk about ICD replacement with a study nurse and receive information about it. You will be asked questions about yourself, your ICD, your quality of life, and your preference towards replacing your ICD battery after your clinic visit.

2. The **second visit** will be 2-4 weeks later. This can either be done in-person or over the phone. It will last 30 to 60 minutes. At this visit we will answer any questions you may have about ICD replacement, and ask you questions about your preference towards replacing your ICD battery, your thoughts on how easy or difficult it is to make the decision, your knowledge about your ICD and the ICD replacement surgery, and what risks and benefits of ICD replacement are most important to you. You may skip any questions that make you uncomfortable or that you do not wish to answer.

3. The **third and fourth visits** will occur 6 and 12 months later. Each will last about 15-30 minutes. These can either be done in-person, or over the phone. At this visit we will ask you questions about whether you chose to replace or not replace your ICD, your thoughts on how easy or difficult it was to make the decision, how involved you felt in making the decision, and your quality of life.

Table 1. Boxes marked with an X show what questions will be asked at each visit.

Survey (number of items per survey)	**Visit 1**	**Visit 2 (1 month)**	**Visit 3 and 4 (6 and 12 months)**
Demographics (6)	X	-	-
ICD Acceptance (15)	X	-	-
Quality of Life (36)	X	-	X
Acceptability and Usability of New Approach *(Intervention group only)* (21)	-	X	-
Knowledge (6)	-	X	-
Your values about ICD replacement (4)	-	X	-
Decisional Comfort (16)	-	X	X
Preferred Choice (1)	X	X	X
Your involvement in the decision (1)	-	-	X

Actual Choice (1)	-	-	X

Will my research data be used in future research?
The data collected from this study will be used to inform whether we should conduct a larger trial with patients who are faced with the decision to replace their ICD.

How long will I be involved in the study?
The entire study will last approximately 1-2 years. Your participation in the study will last about 6 months. Over this time, we will make contact with you at least 3 times. Follow-up visits can be arranged in person, over the phone, or by mail.

What are the potential risks I may experience?
Decision support strategies like the ones we are evaluating in this study do not pose direct risks. You may find the questions distressing, tiring, or lengthy. Or, you might not like the content of it. You do not have to answer any questions that make you uncomfortable.

Can I expect to benefit from participating in this research study?
You may not receive any direct benefit from your participation in this study. Your participation may allow the study team to improve the decision support strategy being developed. This may benefit future patients.

Do I have to participate? What alternatives do I have?
Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later without affecting the medical care, education, or other services to which you are entitled or are presently receiving at this institution. If you choose not to participate, usual care and a discussion with your health care team about your options are available. Your study doctor can discuss these options with you.

If I agree now, can I change my mind and withdraw later?
You may withdraw from the study at any time. You are under no obligation to participate or to answer any questions. If you choose not to participate, your choice will not affect your care. If you choose to withdraw, all data gathered until the time of withdrawal will be for the study unless you do not approve, in which case it will be destroyed.

Will I be paid for my participation or will there be any additional costs to me?
You will not be paid for your participation in the study. There will be no additional costs.

How is my personal information being protected?
We will take all reasonable steps to keep your research information confidential.

- All personal health information (PHI) and your personal identifying information (PII), such as your name, date of birth, medical history related to your ICD, etc. will be kept confidential.
- Release of your PHI/PII information will only be allowed if it is legally required.

- The data collected as surveys and study notes will be kept in a secure locked office. The study staff will have access to the data.
- As a participant, you will be assigned a coded study number that will be used throughout the study on all your study records.
- A Master List provides the link between your personal information and the coded study number. This list will only be available to the Principal Investigator, Dr. David Birnie, Co-Investigators, Dr. Dawn Stacey and Krystina Lewis MN, RN, and research assistant Carolynne Brousseau RN. The list will not leave this site.
- The Master List and coded study records will be stored securely. Electronic records will be stored on the Institutional secure server, not on a computer's C drive. Files will be password protected. No portable devices will contain PII.
- For audit purposes only, your original medical records may be reviewed under the supervision of Dr. Dawn Stacey, or Dr. David Birnie by representatives from:
    - the Ottawa Health Science Network Research Ethics Board (OHSN-REB), and the University of Ottawa Heart Institute
- You will not be identified in any publications or presentations resulting from this study.
- Research records will be kept for 10 years, as required by the OHSN-REB.
- At the end of the storage time, all paper records will be shredded and all electronic records will be securely deleted.

Do the investigators have any conflicts of interest?

There are no conflicts of interest to declare related to this study.

What are my responsibilities as a study participant?

It is important to ask Dr. David Birnie, Dr. Dawn Stacey, or any other research team member if you have any questions or concerns.

Will I be informed about any new information that might affect my decision to continue participating?

You will be told in a timely fashion of any new findings during the study that could affect your willingness to continue in the study. You may be asked to sign a new consent form.

Who do I contact if I have any further questions?

If you have any questions about this study, or if you feel that you have experienced a study-related injury or illness, please contact Dr. David Birnie at 1-613-798-5555 ext. 14705, or Dr. Dawn Stacey at 1-613-737-8899 ext. 73817. The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed this protocol. The Board considers the ethical aspects of all research studies involving human participants at the University of Ottawa Heart Institute. If you have any questions about your rights as a study participant, you may contact the Chairperson at 613-798-5555, ext. 16719.

Consent to Participate in Research

- I understand that I or my family member is being asked to participate in a research study about the impact of a decision support strategy for adults faced with the decision to replace or not replace their ICD.
- This study was explained to me by _____.
- I have read, or have had it read to me, each page of this Participant Informed Consent Form.
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this study.
- I will be given a copy of this signed Participant Informed Consent Form.

_____	_____	_____
Participant's Printed Name	Participant's Signature	Date

Investigator or Delegate Statement

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____	_____	_____
Investigator/Delegate's Printed Name	Investigator/Delegate's Signature	Date

Assistance Declaration

Was the participant assisted during the consent process? ❑ Yes ❑ No

❑ The consent form was read to the participant/substitute decision-maker, and the person signing below attests that the study was accurately explained to, and apparently understood by, and consent was freely given by the participant/substitute decision-maker.

❑ The person signing below acted as a translator for the participant/substitute decision-maker during the consent process. He/she attests that they have accurately translated the information for the participant/substitute decision-maker, and believe that the participant/substitute decision-maker has understood the information translated.

_____	_____	_____
Name of Person Assisting (Print)	Signature	Date