Queensland Government

Implantable Cardiac Defibrillator (ICD)

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

A. Interpreter / cultural needs

An Interpreter Service is required? ☐ Yes ☐ No

If *Yes*, is a qualified Interpreter present? ☐ Yes ☐ No

A Cultural Support Person is required? ☐ Yes ☐ No

If *Yes*, is a Cultural Support Person present? ☐ Yes ☐ No

B. Condition and treatment

The doctor has explained that you have the following condition: *(Doctor to document in patient's own words)*

.....

.....

This condition requires the following procedure. *(Doctor to document - include site and/or side where relevant to the procedure)*

.....

.....

The following will be performed:

You will have an injection of local anaesthetic into the skin. The implantable cardiac defibrillator is put in below the left or right collarbone, just under the skin. The skin is cut to put the lead(s) into a vein which leads to the heart. The lead(s) is threaded down the vein, into the heart.

The doctors can see the lead by using x ray images. Once positioned in the heart, the leads are tested to make sure they are working properly. They are then connected to the 'pulse generator'. The pulse generator is placed under the skin and the skin is sewn back together.

C. Risks of a implantable cardiac defibrillator (ICD)

In recommending this procedure your doctor has balanced the benefits and risks of the procedure against the benefits and risks of not proceeding. Your doctor believes there is a net benefit to you going ahead. This is a very complicated assessment.

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications (> 5%) include:

- Bruising at the device site.

Uncommon risks and complications (1- 5%) include:

- The ICD lead can move. The lead will need to be put back into place by repeating this procedure.
- Bad bruising if you are taking blood thinning drugs such as Warfarin, Aspirin, Clopidogrel (Plavix or Iscover) or Dipyridamole (Persantin or Asasantin).
- Infection of the ICD site. This will need treatment with antibiotics and/or removal.
- Unexpected device failure. There is a risk of battery (generator) or lead failure. This is uncommon but means the battery or lead will need to be removed and a new one put in.

Rare risks and complications (< 1%) include:

- A punctured lung. This may require a tube to be inserted into the chest to reinflate the lung.
- Blood clot in the subclavian vein.
- A hole is accidentally made in the heart or heart valve. This will need surgery to repair.
- Blood clot in the lung.
- Heart attack.
- A stroke. This can cause long term disability.
- Death due to the procedure or other heart problems.

D. Significant risks and procedure options

(Doctor to document in space provided. Continue in Medical Record if necessary.)

.....

.....

E. Risks of not having this procedure

(Doctor to document in space provided. Continue in Medical Record if necessary.)

.....

.....

F. Anaesthetic

This procedure may require an anaesthetic. *(Doctor to document type of anaesthetic discussed)*

.....

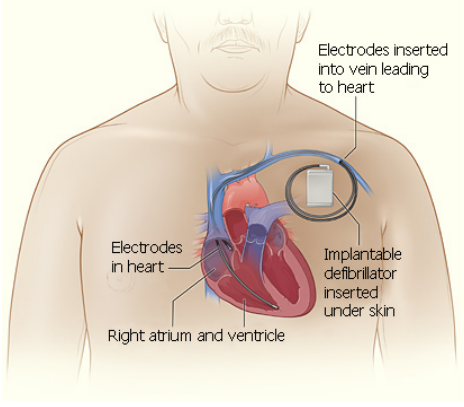

Fig 1. National Heart, Lung and Blood Institute

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PROCEDURAL CONSENT FORM

v6.00 – 02/2011
SW9024

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Queensland Government

Implantable Cardiac Defibrillator (ICD)

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

G. Patient consent

I acknowledge that the doctor has explained;

- my medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- the anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- other relevant procedure options and their associated risks.
- my prognosis and the risks of not having the procedure.
- that no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- the procedure may include a blood transfusion.
- tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- if immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- a doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following Patient Information Sheet/s:

☐ **Local Anaesthetic and Sedation for Your Procedure**

☐ **Implantable Cardiac Defibrillator (ICD)**

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

On the basis of the above statements,

I request to have the procedure

Name of Patient: .....

Signature: .....

Date: .....

Patients who lack capacity to provide consent

Consent must be obtained from a substitute decision maker/s in the order below.

Does the patient have an Advance Health Directive (AHD)?

☐ Yes ▶ Location of the original or certified copy of the AHD: .....

☐ No ▶

Name of Substitute Decision Maker/s: .....

Signature: .....

Relationship to patient: .....

Date: ..... PH No: .....

Source of decision making authority (tick one):

- ☐ Tribunal-appointed Guardian
- ☐ Attorney/s for health matters under Enduring Power of Attorney or AHD
- ☐ Statutory Health Attorney
- ☐ If none of these, the Adult Guardian has provided consent. Ph 1300 QLD OAG (753 624)

H. Doctor/delegate statement

I have explained to the patient all the above points under the Patient Consent section (G) and I am of the opinion that the patient/substitute decision-maker has understood the information.

Name of Doctor/delegate: .....

Designation: .....

Signature: .....

Date: .....

I. Interpreter's statement

I have given a sight translation in

.....

(state the patient's language here) of the consent form and assisted in the provision of any verbal and written information given to the patient/parent or guardian/substitute decision-maker by the doctor.

Name of Interpreter: .....

Signature: .....

Date: .....

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Consent Information - Patient Copy
Implantable Cardiac Defibrillator (ICD)

1. What is an implantable cardiac defibrillator (ICD)?

An ICD will help slow down a fast heartbeat. Sometimes the heart beats too fast. This does not allow the chambers of the heart to fill properly. If enough blood is not pumped around the body and it is untreated, it may lead to dizziness, fainting or loss of consciousness. This is a potentially life threatening condition.

The ICD stops the fast heartbeat. This is done by 'pacing' the heart rapidly or by giving an electrical 'shock' to the heart.

There are three types of ICD. Your doctor will decide which defibrillator suits your condition.

i. Single Chamber: one lead to the lower chamber of the heart.

ii. Dual Chamber: two leads. One to the upper and one to the lower chamber of the heart.

iii. Biventricular: three leads. One to the upper and two to the lower chambers of the heart.

The ICD has two parts, a pulse generator, which senses the heartbeat and delivers impulses to the heart; and a sensing lead, which sends impulses to and from the heart.

The ICD is 'programmed' to your condition by the doctor who puts it in. An external machine is used to check the ICD and to program it. The ICD is battery powered. The ICD 'stands by' and checks the heart rate. If the heart rate is too fast, it will activate. This will give a 'shock' to the heart.

You will have the following procedure:

Before the procedure, you may be given antibiotics. These are given to prevent an infection from occurring.

A needle with a tube connected to it will be put in your arm. This is called an intravenous line or IV.

You will have an injection of local anaesthetic into the skin. The ICD is put in below the left or right collarbone, just under the skin. The skin is cut to put the lead(s) into a vein which leads to the heart. The lead(s) is threaded down the vein, into the heart.

The doctors can see the lead using x-ray images. Once positioned in the heart, the leads are tested to make sure they are working properly. They are then connected to the 'pulse generator'. The pulse generator is placed under the skin and the skin is sewn back together.

After the ICD is implanted

The battery is checked each time you come to your clinic appointment. The battery lasts about 5 years and cannot be recharged. When the battery needs changing, it will require a procedure similar to this procedure.

2. My anaesthetic

This procedure will require an anaesthetic.

See **Local Anaesthetic and Sedation and Your Procedure information sheet** for information about the anaesthetic and the risks involved. If you have any concerns, discuss these with your doctor.

If you have not been given an information sheet, please ask for one.

After an ICD is implanted you are not allowed to drive until the implanting Cardiologist says so and provides written confirmation for Queensland Transport.

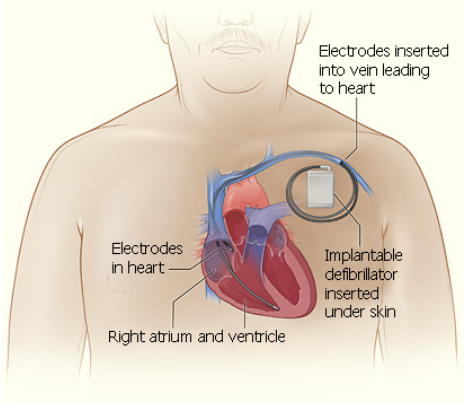

Fig 1. National Heart, Lung and Blood Institute

3. What are the risks of this specific procedure?

In recommending this procedure your doctor has balanced the benefits and risks of the procedure against the benefits and risks of not proceeding. Your doctor believes there is a net benefit to you going ahead. This is a very complicated assessment.

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications (more than 5%) include:

- Bruising at the device site.

Uncommon risks and complications (1- 5%) include:

- The ICD lead can move. The lead will need to be put back into place by repeating this procedure.
- Bad bruising if you are taking blood thinning drugs such as Warfarin, Aspirin, Clopidogrel (Plavix or Iscover) or Dipyridamole (Persantin or Asasantin).
- Infection of the ICD site. This will need treatment with antibiotics and/or removal.
- Unexpected device failure. There is a risk of battery (generator) or lead failure. This is uncommon but means the battery or lead will need to be removed and a new one put in.

Rare risks and complications (less than 1%) include:

- A punctured lung. This may require a tube to be inserted into the chest to reinflate the lung.
- Blood clot in the subclavian vein.
- A hole is accidentally made in the heart or heart valve. This will need surgery to repair.
- Blood clot in the lung.
- Heart attack.
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