Queensland Government

Drug Challenge Test

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)*

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.....

The following will be performed:

Recordings of routine baseline observations (blood pressure -BP, pulse - P and pulse oximetry - Sp02 etc) will be made. A cannula will then be inserted into a vein (intravenous cannula).

Diluted samples of the test drug will be prepared. The most dilute specimen will be injected first via an intravenous infusion into a vein (intravenously). Providing no adverse reaction occurs to the test drug, samples of increasing concentration will be tested.

Routine monitoring of observations (BP, P, Sp02 etc) will be observed and recorded.

Should there be no adverse response after a predetermined time (minimum of 30 minutes) then a less diluted sample of the drug will be infused intravenously.

The development of any signs of 'anaphylaxis' will be regarded as a POSITIVE result. For example low BP (hypotension), wheezy chest (bronchospasm), swelling of the face and /or throat (oedema), a skin reaction (rash).

If signs develop, treatment with adrenaline and intravenous fluids will be given as required.

I understand that Direct Drug Challenge testing is not without risk, there is a chance of a severe reaction and indeed death.

I understand that I must NOT have anything to eat for 6 hours before this test, and I must NOT have anything to drink for 4 hours before this test. Also it is important that I do NOT consume alcohol in the 24 hours before the test.

C. Risks of a drug challenge test

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

Specific risks:

- As with any drug reaction, the most severe risk is Death.
- Other severe risks:
  - Low Blood pressure (Hypotension)
  - Wheeze (Bronchospasm)
  - Swelling of the face and throat (Oedema)
  - Cardiac Arrest

D. Significant risks and procedure options

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

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E. Risks of not having this procedure

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

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DO NOT WRITE IN THIS BINDING MARGIN

PROCEDURAL CONSENT FORM

v4.00 - 03/2011

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Queensland Government

Drug Challenge Test

Facility:

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URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

F. 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.
- other relevant procedure/ treatment 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.
- 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:

☐ **Drug Challenge Test**

- 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)

G. Doctor/delegate statement

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

Name of Doctor/delegate: .....

Designation: .....

Signature: .....

Date: .....

H. 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: .....

DO NOT WRITE IN THIS BINDING MARGIN

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Consent Information - Patient Copy
Drug Challenge Test

1. What is a drug challenge test?

Recordings of routine baseline observations (blood pressure -BP, pulse - P and pulse oximetry - Sp02 etc) will be made. A cannula will then be inserted into a vein (intravenous cannula).

Diluted samples of the test drug will be prepared. The most dilute specimen will be injected first via an intravenous infusion into a vein (intravenously). Providing no adverse reaction occurs to the test drug, samples of increasing concentration will be tested.

Routine monitoring of observations (BP, P, Sp02 etc) will be observed and recorded.

Should there be no adverse response after a predetermined time (minimum of 30 minutes) then a less diluted sample of the drug will be infused intravenously.

The development of any signs of 'anaphylaxis' will be regarded as a POSITIVE result. For example low BP (hypotension), wheezy chest (bronchospasm), swelling of the face and /or throat (oedema), a skin reaction (rash).

If signs develop, treatment with adrenaline and intravenous fluids will be given as required.

No further challenge will be performed if a reaction occurs.

It is important that patients understand that they must NOT eat any food for 6 hours before this test and NOT drink for 4 hours before this test. Also it is important NOT to consume alcohol in the 24 hrs before the test.

2. What are the risks of this specific procedure?

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

Specific risks:

- As with any drug reaction, the most severe risk is Death.
- Other severe risks:
  - Low Blood pressure(Hypotension)
  - Wheeze (Bronchospasm)
  - Swelling of the face and throat (Oedema)
  - Cardiac Arrest

3. What do I need to know about medication?

Some medications can interfere with testing.

It is very important that you discuss any medications you are taking with the doctor beforehand. If it is possible you may need to stop some medications before the skin tests but this needs to be discussed with the doctor.

Notes to talk to my doctor about:

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