Drug Challenge Test (Oral)

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 investigation. (Doctor to document - include site and/or side where relevant to the procedure)

The following will be performed:

Recordings of routine baseline observations (blood pressure -BP, pulse - P and pulse oximetry - SpO2 etc) will be made. A cannula may then be inserted into a vein (intravenous cannula).

Diluted samples of the test drug will be prepared. The most dilute specimen will be swallowed.

Routine monitoring of observations (BP, P, SpO2 etc) will be observed and recorded.

Providing no adverse reaction occurs to the first dose, samples of increasing concentration will be given sequentially.

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

If significant discomfort occurs, treatment with antihistamine, adrenaline or intravenous fluids will be given as required.

I understand that Direct Drug Challenge testing is not without risk. There is a small chance of a severe reaction.

There are real risks involved with Direct Challenge Testing, and it is only undertaken when there is no other test available that can unequivocally determine whether the drug is safe to use.

C. Risks of a drug challenge test (oral)

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 (Angioedema)
  - Cardiac Arrest

- If a serious complication arises during testing this may require admission to hospital as part of the treatment.

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.)
I acknowledge that the doctor has explained:

- my medical condition and the proposed investigation, 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 (Oral)

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed investigation 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 investigation and that these image/s or video/s will assist the doctor to provide appropriate treatment.

On the basis of the above statements,
# Consent Information - Patient Copy

## Drug Challenge Test (Oral)

### 1. What is a drug challenge test (oral)?

| Recordings of routine baseline observations (blood pressure -BP, pulse - P and pulse oximetry - Sp02 etc) will be made. A cannula may then be inserted into a vein (intravenous cannula). |
| Diluted samples of the test drug will be prepared. The most dilute specimen will be swallowed. |
| Routine monitoring of observations (BP, P, Sp02 etc) will be observed and recorded. |
| Providing no adverse reaction occurs to the first dose, samples of increasing concentration will be given sequentially. |
| The development of any signs of allergy or “anaphylaxis” will be regarded as a POSITIVE result. For example low BP (hypotension), wheezy chest (bronchospasm), swelling of the face and/or throat (angioedema), a skin reaction (rash). |
| If significant discomfort occurs, treatment with antihistamine, adrenaline or intravenous fluids will be given as required. |
| I understand that Direct Drug Challenge testing is not without risk. There is a small chance of a severe reaction. |

### 2. What are the risks of this specific procedure?

There are risks and complications with this investigation. 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 (Angioedema)
  - Cardiac Arrest

- If a serious complication arises during testing this may require admission to hospital as part of the treatment.

### 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 tests but this needs to be discussed with the doctor.