Queensland Government

Amniocentesis/Chorionic Villus Sampling Consent

Facility: .....

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

A. Does the patient have capacity?

☐ Yes ➔ ***GO TO** section B* ☐ No ➔ ***COMPLETE** section A*

i. a) Is the patient aged under 18 years?
- ☐ Yes (document parent/guardian name below)
- ☐ No ➔ ***GO TO** ii*

You must adhere to the Advance Health Directive (AHD) or the consent obtained from a substitute decision-maker.

ii. a) Does the patient have an AHD that is applicable to the procedure, treatment or investigation?
- ☐ Yes ☐ No ➔ ***GO TO** iii*

b) If *yes*, has the AHD been sighted and a copy is in the medical record?
- ☐ Yes ☐ No ➔ ***GO TO** iii*

iii. Substitute decision-maker (select one only):
- ☐ Attorney(s) for health matters under an Enduring Power of Attorney or AHD
- ☐ Tribunal-appointed guardian
- ☐ Statutory Health Attorney
- ☐ If none of these, the Office of the Public Guardian must provide consent (ph: 1300 653 187)

Name of substitute decision-maker(s) or parent/guardian:

Signature of substitute decision-maker(s) or parent/guardian:

Relationship to the patient (e.g. substitute decision-maker or parent/guardian)

Date: Phone number:

B. Does the patient need Interpreter/ cultural services?

i. a) Is a language interpretation service required?
- ☐ Yes ☐ No ➔ ***GO TO** ii*

b) If *yes*, is a qualified Interpreter present?
- ☐ Yes (complete section K) ☐ No ☐ N/A

ii. a) Is a cultural support person required?
- ☐ Yes ☐ No ➔ ***GO TO** section C*

b) If *yes*, is a cultural support person present?
- ☐ Yes ☐ No ☐ N/A

C. Condition and treatment

The doctor/clinician has explained that I have the following condition *(doctor/clinician to document in patient's words)*:

This condition requires a procedure *(doctor/clinician to document, include site and/or side where relevant to the procedure)*:

The following treatment will be performed:

Doctor to tick relevant box(es). Cross out any information not applicable to this procedure.

☐ Chorionic Villus Sampling (CVS): A preliminary ultrasound scan is performed, and under ultrasound guidance, a needle is passed through the abdominal wall and the wall of the uterus (womb) into the placenta. A small piece of placenta is removed and the needle is withdrawn. A further scan is done to ensure the welfare of the fetus.

☐ Amniocentesis: A preliminary scan is performed, and under ultrasound guidance, a needle is passed through the abdominal wall and the wall of the uterus (womb) into the sac of fluid (amniotic cavity) around the baby. A small amount (20mls) of fluid is removed and the needle is withdrawn. A further scan is done to ensure the welfare of the fetus.

Rh(D) Immunoglobulin (anti D) Injection is recommended to be given to Rhesus Negative women at the time of CVS or amniocentesis to avoid subsequent antibody formation.

D. Risks and complications of this procedure

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

Common risks and complications include:

- **transient pain** due to passage of the needle through the abdominal wall
- mild **uterine cramping** for 1–2 days after the procedure
- occasional spot bleeding from the vagina after the procedure
- **bleeding** is more common if you have been taking **blood thinning drugs** such as warfarin, aspirin, clopidogrel (Plavix, Iscover, Coplavix), prasugrel (Effient), dipyridamole (Persantin or Asasantin), ticagrelor (Brilinta), ticlopidine (Tilodene), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric.

DO NOT WRITE IN THIS BINDING MARGIN

AMNIOCENTESIS/CHORIONIC VILLUS SAMPLING CONSENT

v6.00 - 12/2018
SW9194

Queensland Government

Amniocentesis/Chorionic Villus Sampling Consent

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

Uncommon risks and complications include:

- **miscarriage** or **fetal loss** due to chorionic villus sampling and amniocentesis is about 1 in 100 women
- infection introduced into the abdominal wall or amniotic fluid, which can cause fetal death and/or miscarriage
- bleeding from the uterine wall or around the fetus (baby), which can cause fetal death and/or miscarriage
- **rupture** of, or leakage from, fluid within the amniotic sac, which can cause fetal death and/or miscarriage or preterm labour
- possible bleeding from fetal (baby's) circulation into your circulation. This could lead to loss of fetus (miscarriage) and/or development of antibodies against the fetus' blood. This can cause problems in subsequent pregnancies
- premature labour and delivery if performed after 20 weeks of pregnancy
- there is an insufficient specimen obtained by chorionic villus sampling/amniocentesis for testing. If this happens, a second procedure (chorionic villus sampling or amniocentesis) may be offered
- there is a 1 or 2 in 100 chance that the result will show that the chromosomes of the placenta are different to that of the fetus. If this happens, a second procedure (amniocentesis) may be offered to clarify the result.

Rare risks and complications include:

- the **test fails** due to unknown reasons, with it failing to give a good enough sample for chromosome and/or DNA analysis.

E. Specific risks for you in having this procedure

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

F. Risks of not having this procedure

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

G. Alternative procedure, treatment or investigation options

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

H. Anaesthetic

This procedure may require an anaesthetic *(doctor/clinician to document type of anaesthetic discussed)*:

I. Anticoagulant/Antiplatelet checklist

Are you/patient on any anticoagulant/ antiplatelet (blood thinning) medication? ☐ Yes ☐ No

If *yes*, please write the name of the medication:

DO NOT WRITE IN THIS BINDING MARGIN

Queensland Government

Amniocentesis/Chorionic Villus Sampling Consent

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

J. Patient/Substitute decision-maker consent

I acknowledge the doctor/clinician has explained:

- my/the patient's medical condition and the proposed procedure/treatment/investigation may require and include additional treatment if the doctor/clinician finds something unexpected. I understand the risks and benefits, including the risks specific to me
- my/the patient's requirement for anaesthetic for this procedure/treatment/investigation. I understand the risks associated with anaesthetic, including the risks specific to me (see Anaesthetic information sheet)
- my/the patient has alternative procedure/treatment/investigation options
- my/the patient's prognosis, and the risks of not having the procedure/treatment/investigation
- no guarantee has been made that the procedure/treatment/investigation will improve my/the patient's condition even though it has been carried out with due professional care
- my/the patient's tissues/blood may be removed and be used for diagnosis/management of my condition, stored and disposed of sensitively by the hospital
- if an immediate life-threatening event happens during my/the patient's procedure/treatment/investigation, I/the patient will be treated based on my discussions with the doctor/clinician or Acute Resuscitation Plan
- a doctor other than the consultant/specialist may conduct/assist with the clinically appropriate procedure/treatment/investigation/examination. I understand this could be a doctor undergoing further training. I understand that all surgical trainees are supervised according to relevant professional guidelines.

I/the patient was able to ask questions and raise concerns with the doctor/clinician about my/the patient's condition, the proposed procedure/treatment and its risks, and my/the patient's treatment options. My questions and concerns have been discussed and answered to my satisfaction.
I/the patient 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 a doctor/clinician.

Student examination/procedure for educational purposes

For the purpose of undertaking professional training, a student(s) may observe the medical examination(s) or procedure(s) and may also, subject to patient consent, perform an examination(s) or assist in performing the procedure(s) on a patient while the patient is under anaesthetic. This is for education purposes only. A student(s) who undertakes an examination(s) or assists in performing the procedure(s) will be under the supervision of the treating doctor, in accordance with the relevant professional guidelines.

For the purposes of education I consent to a student(s) undergoing training to:

- observe examination(s)/procedure(s) ☐ Yes ☐ No
- assist and/or perform examination(s)/procedure(s) ☐ Yes ☐ No

Student - this may include medical, nursing, midwifery, allied health or ambulance students.

I have received the following information sheet(s):

☐ *'Local anaesthetic for your procedure'*
☐ *'Amniocentesis/Chorionic villus sampling'*
☐ *'Blood and blood products transfusion'*

On the basis of the above statements,

I consent to having this procedure.

Name of patient:

Signature: Date:

I consent to:

Name of patient having procedure:

Name of substitute decision-maker:

Signature: Date:

K. Interpreter's statement

I have:

☐ provided a sight translation
☐ translated as per clinician explanation in:

Patient's language:

of this consent form and assisted in the provision of any verbal and written information given to the patient/substitute decision-maker by the doctor/clinician.

Name of patient:

Language of patient:

Name of Interpreter service:

Name of Interpreter:

Interpreter's signature: Date:

L. Doctor/Clinician/Delegate statement

Information for doctor/clinician/delegate:

The information contained within this form is not, and is not intended to be, a substitute for direct communication between the doctor/clinician/delegate and the patient/substitute decision-maker regarding the medical procedure, treatment or investigation described in this form. I have explained to the patient all the content in this patient consent form and I am of the opinion that the patient/substitute decision-maker has understood the information.

Name of doctor/clinician/delegate:

Designation:

Signature: Date:

DO NOT WRITE IN THIS BINDING MARGIN

This page intentionally left blank

Queensland Government

Amniocentesis/Chorionic villus sampling

Informed consent: patient information

Give this patient information sheet to the patient or substitute decision-maker(s) to read carefully and allow time to ask any questions about the procedure.

1. What is this procedure and how will it help me?

Doctor to tick relevant box(es). Cross out any information not applicable to this procedure.

☐ **Chorionic Villus Sampling (CVS):**
A preliminary ultrasound scan is performed, and under ultrasound guidance, a needle is passed through the abdominal wall and the wall of the uterus (womb) into the placenta. A small piece of placenta is removed and the needle is withdrawn. A further scan is done to ensure the welfare of the fetus.

☐ **Amniocentesis:**
A preliminary scan is performed, and under ultrasound guidance, a needle is passed through the abdominal wall and the wall of the uterus (womb) into the sac of fluid (amniotic cavity) around the baby. A small amount (20mls) of fluid is removed and the needle is withdrawn. A further scan is done to ensure the welfare of the fetus.

Rh(D) Immunoglobulin (anti D) Injection is recommended to be given to Rhesus Negative women at the time of CVS or amniocentesis to avoid subsequent antibody formation.

2. My anaesthetic

This procedure will require an anaesthetic. For more information about the anaesthetic and the risks involved, please refer to the anaesthetic information sheet that has been provided to you. Discuss any concerns with your clinician.

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

3. What are the specific risks of this procedure?

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

Common risks and complications include:

- **transient pain** due to passage of the needle through the abdominal wall
- mild **uterine cramping** for 1–2 days after the procedure

3. What are the specific risks of this procedure? *(continued)*

- occasional spot bleeding from the vagina after the procedure
- **bleeding** is more common if you have been taking **blood thinning drugs** such as warfarin, aspirin, clopidogrel (Plavix, Iscover, Coplavix), prasugrel (Effient), dipyridamole (Persantin or Asasantin), ticagrelor (Brilinta), ticlopidine (Tilodene), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric.

Uncommon risks and complications include:

- **miscarriage** or **fetal loss** due to chorionic villus sampling and amniocentesis is about 1 in 100 women
- infection introduced into the abdominal wall or amniotic fluid, which can cause fetal death and/or miscarriage
- bleeding from the uterine wall or around the fetus (baby), which can cause fetal death and/or miscarriage
- **rupture** of, or leakage from, fluid within the amniotic sac, which can cause fetal death and/or miscarriage or preterm labour
- possible bleeding from fetal (baby's) circulation into your circulation. This could lead to loss of fetus (miscarriage) and/or development of antibodies against the fetus' blood. This can cause problems in subsequent pregnancies
- premature labour and delivery if performed after 20 weeks of pregnancy
- there is an insufficient specimen obtained by CVS/amniocentesis for testing. If this happens, a second procedure (CVS or amniocentesis) may be offered
- there is a 1 or 2 in 100 chance that the result will show that the chromosomes of the placenta are different to that of the fetus. If this happens, a second procedure (amniocentesis) may be offered to clarify the result.

3. What are the specific risks of this procedure? *(continued)*

Rare risks and complications include:

- the **test fails** due to unknown reasons, with it failing to give a good enough sample for chromosome and/or DNA analysis.

4. What are the risks specific to me?

There may also be risks specific to your individual condition and circumstances. Please discuss these with your clinician and ensure they are written on the consent form before you sign it.

5. What are the risks of not having this procedure?

There may be consequences if you choose not to have the proposed procedure/treatment/investigation. Please discuss these with your clinician. If you choose not to have the procedure you will not be required to sign a consent form.

6. Who will be performing my procedure?

A doctor other than the consultant/specialist may conduct/assist with the clinically appropriate procedure/treatment/investigation/examination. I understand this could be a doctor undergoing further training, and that all trainees are supervised according to relevant professional guidelines.

If you have any concerns about which doctor/clinician will be performing the procedure, please discuss with the doctor/clinician.

For the purpose of undertaking professional training in this teaching hospital, a student(s) may observe the medical examination(s) or procedure(s).

Subject to your consent, a student(s) may perform an examination(s) or assist in performing the procedure(s) while you are under anaesthetic. This is for education purposes only. A student(s) who undertakes an examination(s) or assists in performing the procedure(s) will be under the supervision of the treating doctor, in accordance with relevant professional guidelines.

If you choose not to consent, it will not adversely affect your access, outcome or rights to medical treatment in any way. You are under no obligation to consent to an examination(s)s or a procedure(s) being undertaken by a student(s) for education purposes.

7. Useful sources of information

Hospital care: before, during and after is available on the Queensland Health website: www.qld.gov.au/health/services/hospital-care/before-after

You can read about:

- Healthcare rights
- Before going to hospital
- Hospital admission
- Going home
- Compliments and concerns

A list of blood thinning medications is available at: www.health.qld.gov.au/consent/bloodthinner

8. Questions to ask my doctor/clinician

Please ask your doctor/clinician if you do not understand any aspect of the information in this patient information sheet or any other information you have been given about your condition, treatment options and proposed procedure.

9. Contact us