**Standard wording for Participant Information and Consent Forms (PICFs)**

Standard risk wording has been developed for various imaging procedures and procedures with risks for healthy volunteers. It is recommended to use this wording in the risk section of PICFs.

**Imaging procedures**

### Risks of oral sedation – MRI

Statement for researchers

*Undergoing an MRI requires remaining still in an enclosed space for an extended period. Completing an MRI can be difficult for people who experience anxiety or claustrophobia. Oral sedation is an option in these cases.*

Risk wording

If you find an MRI causes you excessive anxiety or claustrophobia, taking an oral sedative may be an option. Your doctor will let you know if this is suitable for you. Oral sedation is very safe however, there are some risks that occur rarely. The most common risks are feeling dizzy or drowsy, temporary amnesia, unsteadiness and weakness. Most patients do not have these problems. If these problems do happen, they occur soon after the sedation is taken and they usually get better very quickly. If you have any concerns about these risks, you should discuss them with the study team. Following sedation, you will need someone to drive you home.

### Interventional Radiology investigation requiring heavy sedation/anaesthesia

Heavy sedation/anaesthesia is generally very safe however, there are some associated risks. The most common problems are feeling nauseated or vomiting, bruising at the site of injections, sore throat or hoarse voice. Most patients do not have these problems and if they do occur they usually get better very quickly. Damage to teeth may occur, but this is rare and the risk of brain damage or death is exceptionally rare. The risk of problems from anaesthesia increases for patients who are having more major surgery, those with medical problems and those that require difficult anaesthetic procedures. If you have any concerns about these issues, you should discuss them with the study team. Following heavy sedation/anaesthesia, you will need someone to drive you home.

### Risks of iodine based contrast - CT and angiography

The most common reported side effects are a warm feeling, metal taste in the mouth and pain at the injection site. There is also a low risk of side effects such as nausea, tingling and headaches.
The risk of complications associated with the contract dye is rare (less than 1%). Some of these risks are:

- An allergic reaction to the contrast dye. Such reactions usually are mild but may include rash, swelling, tightness in the throat or trouble breathing.
- A possibility for kidney damage if your kidneys are not functioning well. The function of your kidneys will be assessed via the blood testing performed as part of the screening process.

Dye extravasation (fluid flows outside the vessel) can occur which can cause other complications such as damage to tissues that come in contact with the dye.

### Risks of gadolinium-based contrast – MRI

A rare but serious adverse reaction has been observed in patients who received a gadolinium-based contrast material during MRI examinations, a reaction called nephrogenic systemic fibrosis (NSF). Patients with kidney disease are at increased risk of developing NSF which may cause skin thickening, joint pain and/or swelling. In rare cases NSF can lead to lung and heart problems and cause death. To minimize the likelihood that you will be affected, you may be required to have a blood test to measure your kidney function. If your blood test is abnormal, you will not be permitted to receive gadolinium unless specifically approved.

### Genetic Testing Implications

*If the research involves genetic testing which could potentially generate information relevant to the future health of the participant and/or family, please include the following wording in the relevant section of the PICF(s)*

In most research settings limited genomic testing may be undertaken in order to identify subjects most likely to respond to a drug or procedure. (or to identify those most likely to experience side effects). These tests allow recommendations to be made about the safe and effective use of a treatment for future patients.

In other cases, researchers may include a more extensive examination of your genes. You will be alerted about such research in advance to determine whether you wish to be involved. If you agree to participate you should be aware that some genetic findings can have implications for the future health of you and/or your blood relatives. If you decide to find out the results of your genetic test, you may be encouraged to share any risk information with your relatives who might also be affected.

From October 2026, federal legislation bans life insurance companies from using the results of genetic tests taken in any context in underwriting. By law, private health insurance does not use health information (including genetic information) to deny cover or increase premiums. Other types of insurance, such as travel insurance, may still be able to take genetic test results into account when determining cover.

For more information, visit **https://www.genomicsaustralia.gov.au/individuals/genetic-testing-and-life-insurance**

If you have any further concerns, we recommend you seek independent financial advice.

**Procedure risks for healthy volunteers.**

### Liver Biopsy

Liver biopsy is used [routinely*] to evaluate the extent and severity as well as the cause of liver disease. The procedure may require up to a six hour stay in the hospital and involves first localising the liver under ultrasound and to mark the site on the skin where needle biopsy will be performed by a Radiologist. Usually done under light sedation, the skin over the liver is then numbed with a local anaesthetic, followed by the passing a small needle into the liver under direct ultrasound guidance and removing a small sample of liver (1-2 cm long and a few mm in diameter). There is some pain associated with the procedure and usually right shoulder tip pain is experienced. In addition, about 20% of persons having a liver biopsy have some degree of pain over the liver that may last a few minutes to several hours. This occasionally requires pain medication. Other risks include inadvertent perforation of organs adjacent to the liver and bleeding from the biopsy site. Rarely significant internal bleeding may occur such that a blood transfusion, a radiological procedure to block the bleeding vessel, or even an open operation to sew up the hole in the liver is needed. These complications occur in less than 1 in 300 times with the risk of significant haemorrhage being around 1 in 1000 cases. Very rarely (fewer than 1 in 10,000 reported cases) death has occurred from bleeding after a liver biopsy.

* delete if not routine

### Right Heart Catheter

After using local anaesthetic on the skin, a small tube (called a catheter) is placed through a needle in a vein in your arm, neck, or groin. The tube is directed towards the chambers of the right side of the heart, to the main artery feeding your lung or to the veins draining the heart or other organs (eg. the kidney, liver or brain). Moving the tube to different parts of the body is painless and you will generally be unaware of its location.

The risk of death or serious disability resulting from this procedure is extremely small. Amongst thousands of these research procedures performed at The Alfred, we are yet to encounter any serious problem leading to long term disability. There is a slight risk of damaging the vein or wall of the heart with the catheter causing internal bruising or bleeding. Generally this will quickly stop of its own accord and all that would be required is a period of observation. On very rare occasions (so rare that we have not encountered it) it might be necessary to repair the damage with an operation. It is not uncommon to experience some bleeding and bruising where the catheter was inserted in the arm or groin. This can generally be prevented by firm pressure over the area for at least 5 minutes and like other bruises it will resolve over the next week or so. The advancement of the catheter through the heart may cause an abnormal heart rhythm which may cause some thumping in your chest. This

can be alleviated by removal of the catheter or by giving appropriate medication. Occasionally, rhythm disturbances may last a day or two, and require admission to hospital for a controlled shock to restore normal heart rhythm (cardioversion). Rarely, there could be blockage of the vein causing swelling of the relevant limb.

The whole procedure generally lasts 1-2 hours and it may be uncomfortable lying horizontally for this period.

### Venepuncture (Taking Blood Samples)

Having a blood sample taken may cause some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel. Some people may feel faint when having blood taken, and may occasionally faint. Rarely, there could be bleeding or a minor infection. If this happens, it can be easily treated.