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

Standard wording is being developed for various risky procedures and will be added to this location periodically. It is recommended that you use this wording in your (PICFs) when your research involves the following procedures.

**This wording applies to healthy volunteers.  Please consider whether the wording is appropriate for your particular study, and be mindful of any new information when writing the risks section of the PICF.**

**Liver Biopsy** (updated 15 April 2015)

Liver biopsy is used [routinely\*] to evaluate the extent and severity as well as the cause of your 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. Usually done under light sedation, the skin over the liver is then numbed with a local anaesthetic, followed by passing a small needle into the liver 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 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** (updated 25 March 2008)

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./span>

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

**Venepuncture (Taking Blood Samples)** (updated 21 February 2008)

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, or the spot from which tissue is taken could become inflamed. Some people may feel faint when having blood taken, and may occasionally faint. Rarely, there could be a minor infection or bleeding. If this happens, it can be easily treated.

**Genetic Testing Implications** (updated 1 December 2009)

***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 Section 4 What will happen to my test samples?***

"You should be aware that if you decide you want to know the results of your genetic tests, the information we give you could affect your future applications for insurance other than medical insurance. An employer might also ask for the results of your tests.

When you apply for some kinds of insurance, including life insurance, you must reveal all that you know about your health, including the results of any genetic tests. The law allows private insurers to distinguish between their customers on the basis of this information except in the case of medical insurance. For example they might offer a different price for the insurance (higher or lower) or even refuse to offer insurance depending on what you tell them about your health or genetic tests.

But you do not have to tell an insurer that you have participated in a genetic research project unless you have been given your personal results. An insurance company must respect your right not to know the result of a genetic test if that is your wish. For information visit or contact the HGSA ([**www.hgsa.com.au**](http://www.hgsa.com.au)) or the Centre for Genetic Education ([**www.genetics.com.au**](http://www.genetics.com.au))."