

Purpose

To provide researchers with examples of content to be included in Participant Information Consent Forms (PICF) and other material provided to participants where research involves the use of ionising radiation.

PICF example wording

Example 1: If the medical imaging used is the same as standard care

This research study involves exposure to ionising radiation. You will have [number] x-rays, [number] CT scans, [number] MUGA scans of your [bodily location]. These scans will expose you to a medically acceptable dose of radiation.

Example 2: If extra, study-specific medical imaging is undertaken

This research study involves exposure to ionising radiation. Some of these procedures [name them and their number] are additional to those you would have received through everyday living if you were not in this study.

As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 to 3 millisieverts (mSv) each year. The effective dose from this study is about [number] mSv. *[Insert paragraph 1, 2, 3, or 4 from below*].*

***Choose one of the following paragraphs to be inserted above as indicated:**

1. Effective doses less than 2 mSv – At this dose level, no harmful effects of radiation have been demonstrated and the risk is negligible.
2. *Effective doses between 2 and 20 mSv* – At this dose level, no harmful effects of radiation have been demonstrated and the risk is low. The dose from this study is comparable to that received from routine diagnostic medical x-ray and nuclear medicine procedures.
3. *Effective doses between 20 and 50 mSv* – The dose from this study is comparable to that received from several computed tomography (CT) x-ray procedures. The benefits from the study should be weighed against the possible detrimental effects of radiation, including an increased risk of cancer.
In this study, the risk is moderate and the theoretically calculated risk of contracting fatal cancer in the future is considered acceptable.
The possible detrimental effects of radiation should be weighed against the benefits from the study which are (state benefits to the participant or to society).
4. *(If there are no perceived benefits from participating.)*
Effective doses greater than 50 mSv - This research study involves exposure to a significant amount of ionising radiation. The benefits from the study should be weighed against the possible detrimental effects of radiation, including an increased risk of cancer. In this study, the risk is moderate, and the calculated risk of such harm is about 1 in.... (Calculate using the ICRP risk coefficient for fatal cancer in the general population of 5×10^{-2} per Sv).

For studies in children or for persons over the age of 50, the risk of radiogenic cancer should be calculated using age- and sex-specific risk factors. The possible detrimental effects of radiation should be weighed against the benefits from the study which are (state benefits to the participant or to society).

Example 3: If there are no perceived benefits from participating

You will be given a certificate that states the radiation dose you have received from participating in this study. You should keep the certificate for five years and show it if you are recruited for any other research studies in that time.

If you would like to discuss your exposure to radiation with a radiation safety officer, you may contact the radiation regulator in your state. See contact details at: <https://www.arpsa.gov.au/regulation-and-licensing/regulation/state-territory-regulators>.

Standard, plain-language definitions and participant-facing explanations of common imaging procedures for inclusion in PICFs.

Computed Tomography (CT SCAN)

A CT scan uses x-rays to produce a digital cross-sectional image of the body by rotating an x-ray tube around the body. The patient lies flat on a moving table as it passes through a large 'doughnut'.

The procedure takes only a few minutes and is commonly used to assess the stage of progression or follow-up cancer.

For this study, images will be obtained of your *(insert regions to be imaged)*.

Before your appointment, please check with the imaging department to find out if special conditions, such as fasting, will be required.

The imaging specialists will explain the procedure either at your study visit or when you attend the imaging. Please ask questions if you are unsure of the procedure. Before the study, the imaging specialists will ask you to complete a short questionnaire regarding your medical history and allergies. In particular, they will be interested in past kidney disease or reactions to a contrast material such as an injected dye.

During the scan, you may be asked to hold your breath for short periods. The doughnut is open at both ends and there is no discomfort experienced from the scan. If you think you may become anxious during the procedure, let the imaging specialists know.

(Use if contrast will be used) For the study, it will be necessary to inject contrast material (sometimes referred to as "dye") during the scan. This is a common and routine procedure. The contrast when injected through a small cannula inserted in the arm gives a feeling of warmth and sometimes nausea. Severe allergic reactions rarely occur, but if they do, they need urgent treatment. Your imaging specialists have been trained to deal with these. There may be a need to check your kidney function before the scan by referring to blood tests.

(If the imaging procedure has been flagged as routine in the application) Your study doctor has indicated that you would be required to undergo this scan whether or not you were in this study; therefore, having this scan will not change the radiation exposure you would have required routinely. *(Insert: This research study involves exposure to ionising radiation. You will have [number] x-rays, [number] CT scans, [number] MUGA scans of your [bodily location]. These scans will expose you to a medically acceptable dose of radiation.)*

(If not a routine scan, insert: This research study involves exposure to ionising radiation. Some of these procedures [name them and their number] are additional to those you would have received through everyday living if you were not in this study.)

Magnetic Resonance Imaging (MRI)

An MRI is a scanning procedure that uses strong magnets and radio waves to produce signals that are detected by a radio antenna and processed by a computer to create images of the inside of your body. The technique is often used to assess the stage of cancer progression or to follow-up cancers. There is no potentially dangerous ionising radiation as produced in X-ray or nuclear studies in this study.

For this research protocol, *(please state areas of body which will be examined)*.

Before your appointment please check with the imaging department if special conditions such as fasting will be required. This is unusual.

The imaging specialists will explain the procedure either at your study visit or when you attend the imaging. Please ask questions if you are unsure about the procedure. Before the study, the imaging specialists will ask you to complete a short questionnaire regarding your medical history and your allergies. In particular, they will be interested in past kidney disease or reactions to a contrast material such as an injected dye.

Whilst making an appointment for an MRI examination, you will be asked a series of safety questions. If you have any implanted devices, you cannot have an MRI because the very strong magnet may be dangerous. If you answer 'Yes' to any questions, you may be asked to provide details or medical records.

Before entering the MRI scanner room, you will be asked to change into an examination gown.

The scan is performed on a scanning table and a special coil/antenna may be placed over the body part being examined. The scanning table passes into a long tunnel that people with claustrophobia may find challenging. If you become anxious in confined spaces, please let your referring doctor know and sedatives may be prescribed. MRI scanners can be quite loud; for some examinations they make a knocking sound like a jack hammer. Earphones or earplugs may be provided to mask the noise. Constant communication will be maintained during the examination and a buzzer will be provided to alert the technologist.

An MRI examination can last 15 to 60 minutes, depending on the procedure.

There are no known biological side effects/risks to MRI. It is quite common to experience localised warming (region being scanned) during the exam.

(Use if contrast will be used) For your study it will also be necessary to inject contrast material (sometimes referred to as "dye") during the scan. This is a common and routine procedure. The contrast is injected into a small cannula inserted in the arm and when injected often gives a feeling of warmth and sometimes nausea. Severe allergic reactions rarely occur, but if they do, they need urgent treatment. Your imaging specialists have been trained to deal with these. Some severe long-lasting complications may occur in people with very poor kidney function, so there may be a need to check your kidney function before the scan by referring to blood tests.

PET or PET/CT scan

PET (or Positron Emission Tomography) uses special radioactive materials which produce positrons. It is almost universally performed in association with low dose CT (see CT section), to produce three-dimensional images of the body. It is commonly used to assess the stage of cancer progression or to follow-up cancer.

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Ionising Radiation Standard Clauses

It is frequently used to scan “the whole body”, which usually means head to knees. The research study you are participating in will require that you have your {please insert if necessary - area of body to be scanned} scanned.

Please contact the imaging department beforehand to check for any preparation such as fasting from food or drinking water beforehand or avoiding strenuous exercise. It is important also that the department knows if you are diabetic.

The radioactive tracer needed for PET scans is delivered to the hospital or clinic in necessary quantities each day. Due to its short active life, variables in the manufacturing process and possible transport delays, sometimes supplies do not arrive as scheduled. Therefore, we can only confirm an appointment time the day before the shipment is due. If the appointment is missed, your scan may need to be rescheduled.

When you arrive for your scan, you will be asked a series of questions. A plastic cannula will be placed into an arm vein and your blood sugar level measured. In a dedicated uptake room, the radioactive tracer will be injected through the cannula. Unlike x-ray contrast, there are no side effects from this injection.

There will be a wait of up to one hour while the tracer localises. During this time, it is usually possible to listen to music or watch TV, unless your brain is being scanned.

The PET scan involves lying on a moving bed which passes through a short tunnel, which people with claustrophobia may find challenging. If you become anxious in confined spaces, please let your referring doctor know and sedatives may be prescribed. The scanning procedure takes up to 30 minutes. If sedation is required, you will need to arrange for assistance to get home. You must not drive.

A PET scan produces a radiation dose (*incorporate: This research study involves exposure to ionising radiation. Some of these procedures [name them and their number] are additional to those you would have received through everyday living if you were not in this study.*)

References

BA G13 Ionising Radiation Guidance