Health Research Authority

Generic ionising radiation risk statements

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Guidance notes

About this guidance

This document has been produced to provide generic ionising radiation risk statements to be included in the Integrated Research Application System (IRAS) application form and Participant Information Sheets (PIS) but is not exhaustive. It is recognised that there will be some studies that do not reflect the scenarios set out below and in these instances bespoke statements will be required both in the IRAS form and in the PIS. The statements contained within this document have been designed to meet the requirements of most studies and to ensure that information is provided to research ethics committees (RECs) and trial participants in a consistent manner. They should be used as far as possible.

These statements were developed by the Radiation Assurance Guardians Group of Clinical Radiation Experts (CREs) and Medical Physics Experts (MPEs). Feedback has been sought and incorporated from the Administration of Radioactive Substances Advisory Committee (ARSAC), a Patient and Public Information group and also Health Research Authority (HRA) REC Chairs. A period of consultation in use was held with further feedback received and changes made to incorporate responses where appropriate. This guidance document is maintained by the Four Nations Radiation Assurance Working Party with input from relevant experts outside of this group sought where required.

If you wish to provide feedback on the statements, please email radiation.assurance@hra.nhs.uk.

Additional explanatory notes

The lifetime risk of developing cancer is stated in this document as 50%. This figure was taken from information on the Cancer Research UK (CRUK) website.

Risk descriptors are taken from HPA-CRCE-028 (2011).

This guidance refers to participant cohorts with a poor prognosis as those who are likely to survive for less than 5 years from recruitment. Whilst it is acknowledged that some cancers are variable in their latency, this figure was chosen as the most reasonable number when taking into consideration the variation of different cancers.

How to use this guidance

This guidance should be used in conjunction with the MPE and CRE Review Procedures. These statements are not the only information which the MPE and CRE will provide in their review in the IRAS form.

For Radiation Assurance studies only

The Lead MPE should confirm the scenario which each study matches so that they and the Lead CRE can include the appropriate statement in their assessment in IRAS. The CRE should await the MPE's confirmation of which statement to use before completing their assessment.

The reviewers will also confirm in their review which statement the sponsor should include in the PIS. It is the CRE's responsibility to ensure that the PIS statement in particular is suitable for the participant group and clinical risk.

For studies not using Radiation Assurance

The sponsor should work with the Lead MPE and Lead CRE to ensure that an appropriate risk statement is used in the Participant Information Sheet. The Lead MPE and Lead CRE may choose to use one of the generic IRAS risk statements.

For all studies

Statements in red need to be tailored to the research study. Either a choice of wording is given, or a bespoke statement is required to be provided by the MPE and/or CRE.

Paediatric studies

There are usually multiple Participant Information Sheets for paediatric studies. A radiation risk statement is usually found in the guardian PIS and the young person's PIS. For guardians "you" and "your" in the generic risk statements below should be replaced with "your child" and "your child's". It is expected that these statements may need to be tailored further dependent on the nature of the study and the age of participants.

Mammography

These statements are suitable for use in studies involving mammograms.

Radiological risk

The radiological risk which should be quoted in these statements is the total radiological risk for participants. The total risk was chosen because it was thought that explaining the standard of care risk and additional risk would be more difficult to convey than just explaining overall risk. Due to the variability of routine clinical care across the NHS/HSC it was also felt that it would be inaccurate to quote the additional risk alone.

Suitability of the generic statements

Despite all efforts being made to make the statements suitable for most studies, it is acknowledged that this will not be the case for all studies. The risk statements should be amended to fit the requirements of an individual study or participant population. Society benefits may need to be considered if participants are not likely to derive a benefit from the research.

Deterministic risks (e.g. local skin burns etc.) may need to be considered in addition to stochastic risks if procedures such as X-ray guided interventions or radiotherapy are required.

If, even after amendment, the relevant generic risk statement is not suitable, a revised statement should be produced by the MPE and/or CRE, based closely upon the nearest appropriate generic risk statement.

Generic Risk Statements

1. Studies where all of the exposures are part of routine clinical care

It should be noted that routine clinical care is often variable across the UK. This option should only be used if there will be no additional ionising radiation exposures at any participating site.

If the prognosis of the study cohort is poor, consider using statement 2 instead.

If the protocol specifies the timepoints or other requirements on how exposures should be conducted (e.g. machinery to be used, image slice thickness) consider using an alternative statement.

Dose and risk assessment in the IRAS form (Part B Section 3 Question C1)
This study requires exposures to ionising radiation which would take place as part of routine clinical care. Participants taking part in this study will therefore not be exposed to any additional radiation.

[Insert bespoke statement if required in addition to the above]

Clinical assessment in the IRAS form (Part B Section 3 Question D2)
Not required.

Radiation risk statement in the PIS
[Insert relevant procedure(s)] are part of your routine care. If you take part in this study you will not undergo any additional [insert relevant procedure(s)]. These procedures use ionising radiation to form images of your body and/or provide treatment and/or provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to you are the same whether you take part in this study or not.

2. Studies where all or some of the exposures are additional to routine clinical care, but the life expectancy of the entire study cohort is poor (less than 5 years cohort survival from recruitment)

Dose and risk assessment in the IRAS form (Part B Section 3 Question C1)
This study requires exposures to ionising radiation which are detailed in A1 and B1. Some/all of the exposures required by the study are additional to routine clinical care. The total protocol dose is XX mSv.

Ionising radiation can cause cancer which manifests itself after many years or decades. However, the additional risk of developing cancer as a consequence of taking part in this study is negligible due to the poor prognosis of this study group.

[Insert bespoke statement if required in addition to the above]

Clinical assessment in the IRAS form (Part B Section 3 Question D2)
This study includes adult/paediatric participants with [insert disease details].

The clinical outlook and prognosis of all the participants in this study is poor, less than 5 years. They will receive some additional/significant additional radiation burden, which is above that anticipated in routine clinical care.

The risk of harm from the additional radiation burden is outweighed by the potential benefits the participants and/or wider society may derive from the research study.

Therefore, the additional radiation exposure is justified.

[Insert bespoke statement if required in addition to the above]

Radiation risk statement in the PIS
If you take part in this study you will have [insert relevant procedure(s)]. Some/all of these will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and/or provide treatment and/or provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. In patients with your current clinical condition, the chance of this happening to you is extremely small.

3. Studies where all or some of the exposures are additional to routine clinical care, and where the total radiological risk is less than 0.01%

Dose and risk assessment in the IRAS form (Part B Section 3 Question C1)
This study requires exposures to ionising radiation which are detailed in A1 and B1. Some/all of the exposures required by the study are additional to routine clinical care. The total protocol dose is XX mSv. This is equivalent to XX hours/days/weeks/months of average natural background radiation in the UK.

Ionising radiation can cause cancer which manifests itself after many years or decades. The risk of developing cancer as a consequence of taking part in this study is XX %, which is low. For comparison, the natural lifetime cancer incidence in the general population is about 50%.

[Insert bespoke statement if required in addition to the above]

Clinical assessment in the IRAS form (Part B Section 3 Question D2) for patients
This study includes adult/paediatric participants with [insert disease details].

The clinical outlook and prognosis of all/most of the participants in this study is poor/normal/minimally lowered compared to the general population.

They will receive additional radiation burden, which is above that anticipated in routine clinical care.

Where the exposure is justified, add: The risk of harm from the additional radiation burden is justified as it is essential to provide objective assessment during the trial.

[Insert bespoke statement if required in addition to the above]

Clinical assessment in the IRAS form (Part B Section 3 Question D2) for healthy volunteers
This study includes healthy volunteers who are exposed to radiation that confers a risk to the individual (provided by the MPE). The exposure is justified because [insert bespoke statement describing the benefit to the science/society].

[Insert further bespoke statement if required in addition to the above]

Radiation risk statement in the PIS
If you take part in this study you will have [insert relevant procedure(s)]. Some/all of these will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and/or provide treatment and/or provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure.

For trials not aimed at participants with cancer, add: We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study will add only a very small chance of this happening to you.

For trials in participants who do have cancer, add: The chance of this happening to you as a consequence of taking part in this study is extremely small.

4. Studies where some or most of the total radiation dose is additional to routine clinical care, and where the total radiological risk is greater than 0.01%

Dose and risk assessment in the IRAS form (Part B Section 3 Question C1)
This study requires exposures to ionising radiation which are detailed in A1 and B1. Some/most of the total radiation dose required by the study is additional to routine clinical care. The total protocol dose is XX mSv. This is equivalent to XX years of average natural background radiation in the UK.

Ionising radiation can cause cancer which manifests itself after many years or decades. The risk of developing cancer as a consequence of taking part in this study is estimated as XX %. For comparison, the natural lifetime cancer incidence in the general population is about 50%.

[Insert bespoke statement if required in addition to the above]

Clinical assessment in the IRAS form (Part B Section 3 Question D2)
This study includes adult/paediatric participants with [insert disease details].

The clinical outlook and prognosis of all/most of the participants in this study is poor/normal/minimally lowered compared to the general population.

They will receive some additional/substantial additional radiation burden, some/most of which is above that anticipated in routine clinical care.

The risk of harm from the additional radiation burden is provided by the MPE assessment. The exposure is justified as it is essential to provide objective assessment during the trial.

[Insert bespoke statement if required in addition to the above]

Radiation risk statement in the PIS

If you take part in this study you will have [insert relevant procedure(s)]. Some/most of these will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and/or provide treatment and/or provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure.

For trials not aimed at participants with cancer, add: We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study may increase the chances of this happening to you to about [insert estimated risk] %.

For trials in participants who do have cancer, add: The chances of this happening to you as a consequence of taking part in this study are about [insert estimated risk] %.

5. Studies where all of the total radiation dose is additional to routine clinical care, and where the total radiological risk is greater than 0.01%

Dose and risk assessment in the IRAS form (Part B Section 3 Question C1)

This study requires exposures to ionising radiation which are detailed in A1 and B1. All of the exposures required by the study are additional to routine clinical care. The total protocol dose is XX mSv. This is equivalent to XX years of average natural background radiation in the UK.

Ionising radiation can cause cancer which manifests itself after many years or decades. The risk of developing cancer as a consequence of taking part in this study is estimated as XX %. For comparison, the natural lifetime cancer incidence in the general population is about 50%.

[Insert bespoke statement if required in addition to the above]

Clinical assessment in the IRAS form (Part B Section 3 Question D2) for patients

This study includes adult/paediatric participants with [insert disease details].

The clinical outlook and prognosis of all/most of the participants in this study is poor/normal/minimally lowered compared to the general population.

All radiation delivered to participants in this study is above that anticipated in routine clinical care.

Where the exposure is justified, add: The risk of harm from the additional radiation burden is provided by the MPE evaluation. The exposure is justified because [insert bespoke statement describing the benefit to the patient].

Clinical assessment in the IRAS form (Part B Section 3 Question D2) for healthy volunteers

This study includes healthy volunteers who are exposed to radiation that confers a risk to the individual (provided by the MPE). The exposure is justified because [insert bespoke statement describing the benefit to the science/society].

[Insert further bespoke statement if required in addition to the above]

Radiation risk statement in the PIS

If you take part in this study you will have [insert relevant procedure(s)]. All of these will be extra to those that you would have if you did not take part in the trial. These procedures use ionising radiation to form images of your body and/or provide treatment and/or provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure.

For trials not aimed at participants with cancer, add: We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study will increase the chances of this happening to you to about [insert estimated risk] %.

For trials in participants who do have cancer, add: The chances of this happening to you as a consequence of taking part in this study are about [insert estimated risk] %

6. Studies where the study cohort receive radiotherapy as part of routine care. Some or all of the other exposures are additional to routine care

It should be noted that these statements are suitable for molecular radiotherapy, brachytherapy and external beam radiotherapy.

Dose and risk assessment in the IRAS form (Part B Section 3 Question C1)

This study requires exposures to ionising radiation which are detailed in A1 and B1. Radiotherapy forms part of the study exposures but is being delivered as part of routine clinical care. Some/all of the exposures not associated with the radiotherapy treatment are additional to routine clinical care. The total protocol dose will be substantial due to the contribution from the radiotherapy treatment. The dose from the additional exposures will be a small fraction of this.

Ionising radiation can cause cancer which manifests itself after many years or decades. The risk of developing cancer as a consequence of radiotherapy treatment is an accepted side-effect of the treatment. Participation in the research study will not significantly alter this risk.

[Insert bespoke statement if required in addition to the above]

Clinical assessment in the IRAS form (Part B Section 3 Question D2)
This study includes adult/paediatric participants with [insert disease details].

The participants in this study will receive additional radiation burden, which is above that anticipated in routine clinical care. These additional exposures are required to provide objective radiological disease assessment of treatment response in relation to specific time points.

However, participants in this study will also undergo radiotherapy treatment. The radiation dose incurred from the additional disease assessment exposures will be small compared with the dose incurred from radiotherapy. The highest radiation risk for inducing cancer will be incurred by the radiotherapy treatment (a known potential complication) and this risk will not be significantly altered by the inclusion of the additional exposures.

[Insert bespoke statement if required in addition to the above]

Radiation risk statement in the PIS
You are undergoing Radiotherapy as part of your care and if you take part in this study you will have [insert relevant procedure(s)]. Some/all of these will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and/or provide treatment and/or provide your doctor with other clinical information.

The radiation dose from the [insert relevant procedure(s)] will be very small compared to the dose from the radiotherapy treatment you are receiving.

Ionising radiation may cause cancer many years or decades after the exposure. Taking part in this study will not significantly alter the chances of this happening to you.

7. Studies where the primary research intervention is radiotherapy and there are other exposures, some, or all, of which are additional to routine care. The radiotherapy may be standard, or modified in fractionation regime, target dose, delivery or imaging

MPEs and CREs should work together to provide additional tailoring to the statements provided in this section given that these studies will be very specialised.

It should be noted that these statements are suitable for molecular radiotherapy, brachytherapy and external beam radiotherapy.

Dose and risk assessment in the IRAS form (Part B Section 3 Question C1)
This study requires exposures to ionising radiation which are detailed in A1 and B1. Radiotherapy is the intervention under investigation. Some/all of the exposures not associated with the radiotherapy treatment are additional to routine clinical care.

The MPE should insert a bespoke statement about how novel treatment compares to standard treatment, using the following three options as a guide:

1. The radiotherapy may be modified by altering the radiotherapy fractionation for an improved cancer outcome with a possible risk of worse side effects.
2. The radiotherapy may be modified by increasing the target dose for a potential better cancer outcome with a possible risk of worse side effects.
3. The radiotherapy may be modified by increased imaging during radiotherapy to increase the accuracy of treatment or monitor treatment response for the potential benefits of a reduction in toxicity and a better cancer outcome.

The total protocol dose will be substantial due to the contribution from the radiotherapy treatment. The dose from imaging exposures as part of radiotherapy will be a small fraction of this.

Ionising radiation can cause cancer which manifests itself after many years or decades. The risk of developing cancer as a consequence of radiotherapy treatment is an accepted side-effect of the treatment. Participation in the research study will not significantly alter this risk.

[Insert bespoke statement if required in addition to the above]

Clinical assessment in the IRAS form (Part B Section 3 Question D2)
This study includes adult/paediatric participants with [insert disease details].

The participants in this study will undergo radiotherapy, and other exposures, which result in a radiation burden which is above that anticipated in routine clinical care.

The CRE should insert a bespoke statement about how novel treatment compares to standard treatment, using the following three options as a guide:

1. The radiotherapy may be modified by altering the radiotherapy fractionation for an improved cancer outcome with a possible risk of worse side effects.
2. The radiotherapy may be modified by increasing the target dose for a potential better cancer outcome with a possible risk of worse side effects.
3. The radiotherapy may be modified by increased imaging during radiotherapy to increase the accuracy of treatment or monitor treatment response for the potential benefits of a reduction in toxicity and a better cancer outcome.

The non-radiotherapy additional exposures are required to provide objective radiological disease assessment of treatment response in relation to specific time points or as part of the radiotherapy treatment.

The radiation dose incurred from the additional disease assessment exposures will be small compared with the dose incurred from radiotherapy. The highest radiation risk for inducing cancer will be incurred by the radiotherapy treatment (a known potential complication) and this risk will not be significantly altered by the inclusion of the additional exposures.

[Insert bespoke statement if required in addition to the above]

Radiation risk statement in the PIS
A study-specific statement about short term side effects is required.

Long-term risks: You are undergoing radiotherapy as part of your care. If you take part in this study the radiotherapy you receive may be different to standard radiotherapy.

The MPE and CRE should write a bespoke statement for the study regarding the radiotherapy using the below options as a guide:

1. The radiotherapy will be given over a different number of days. We are investigating if this will improve the effectiveness of the radiotherapy.
2. The radiation dose may be higher. We are investigating if this will increase the effectiveness of the radiotherapy.
3. There may be more imaging during your radiotherapy. We are investigating if this will reduce the side effects and improve the effectiveness of the radiotherapy.

If you take part in this study you will have [insert relevant procedure(s)]. Some/all of these will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and/or provide treatment and/or provide your doctor with other clinical information.

The radiation dose from the [insert relevant procedure(s)] will be very small compared to the dose from the treatment you are receiving.

Ionising radiation may cause cancer many years or decades after the exposure. Taking part in this study will not significantly/may alter the chances of this happening to you.